



## REPORT

**Study Title:** Effects of AKPharma's Calcium Glycerophosphate  
Nasal Spray wash (AkP 010112A) on Patient-Perceived  
Breathing Comfort

**LSR Protocol Number:** 2749

**Clinical Research Site:** Lovelace Scientific Resources, Inc.  
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## 1.0 EXECUTIVE SUMMARY

AkPharma Inc. has developed a calcium glycerophosphate (CGP) nasal spray wash for perceived rhinitis symptoms. The primary objective of the study is to assess subject nasal allergy symptoms. Also to be examined are changes in morning versus evening symptom scores and onset of the action of calcium glycerophosphate nasal spray, as well as changes observed in nasal eosinophil count and nasal histamine values. On study day 7, 14 and again at study day 21 subjects visit the study center where adherence to symptom diary and weight of the calcium glycerophosphate nasal spray wash is evaluated to confirm adherence. The secondary objective will include the changes observed in the FEV1 (forced expiratory volume in 1 second) and FVC (forced vital capacity) on pulmonary function (spirometry) testing. Spirometry will be repeated on study day 7, 14 and again at study day 21.

In general, the subjects recruited into the study had persistent mild to moderate symptoms at baseline prior to the onset of treatment. Upon treatment with calcium glycerophosphate there was an immediate improvement in all symptom categories after the first week of treatment. Average daily symptoms scores over the three weeks of treatment with AKP010112A were significantly improved from baseline levels (Table 1). There was improvement in Respiratory symptoms. Respiratory function was evaluated (FEV and FVC; reported as % of predicted) at baseline and day 7, 14, and 21. There were no significant differences between baseline measures and anytime during the course of treatment.

In general, the reported adverse events were generally mild to moderate and did not require treatment. The most common adverse effects were stinging/burning immediately following treatment, nasal dryness, and sore throat. These events were most likely associated with the initial delivery of the calcium glycerophosphate. The preponderance of the subjects indicated on a satisfaction questionnaire that they would be willing to use/purchase this product in the future, thus indicating that it was generally well tolerated and provided some noticeable benefit.

## 2.0 REGULATORY COMPLIANCE

This study was conducted in the spirit of U.S. FDA 21 CFR Part 56 (Good Clinical Practice).

## 3.0 KEY STUDY PERSONNEL

**Study Director:** Darlene Harbour, BSN, RN, CCRC

**Principal Investigator:** Jonny Salyer, MD  
Clinical Principal Investigator

**Senior Scientist** Edward G. Barrett, PhD  
Director of Translational Research - Pharmacology

**Study Coordinator:** Leslie Byatt, CCRC



## 4.0 TEST ARTICLE

### 4.1 Identity

Calcium Glycerophosphate (CGP)

### 4.2 Description

CGP is a calcium salt and an approved cosmetic component which has long been used as a food ingredient. CGP is a Dietary Supplement and is generally regarded as safe (GRAS). CGP is a normal cellular constituent, created de novo in the human body as an intermediate metabolite in the Krebs cycle of carbohydrate metabolism. As administered in this nasal rinsing-coating application, essentially all of the molecule that transits the nasal cavity and into the throat will be considered to be ingested, a safe and nutritional pathway for CGP. There are no known contraindications that pertain to ingestion of this molecule other than dietary preclusion of calcium or phosphorus/phosphate. Moreover, there are no known addiction, habituation, or dependency concerns; the molecule is devoid of psychotropic side effects, rebound effects, anti-cholinergic activity, etc.

### 4.3 Supplier

AKPharma, Inc.

### 4.4 Storage Conditions

Ambient temperature (59-86 degrees Fahrenheit)

### 4.5 Dispensing Instructions

Subjects will be instructed to deliver two sprays per nostril twelve hours apart, once in the morning and once in the evening for 21 days. Subjects will be allowed to take two sprays per nostril- four additional times as needed between the morning and evening dose to treat allergy symptoms.

## 5.0 STUDY DESIGN

The overall study design involved four weeks of study participation and recruited twenty (20) subjects. Subjects will be screened for eligibility at Visit 0/day -21 to day -10. Allergic sensitivities will be confirmed using Immunocap testing.

Days minus 7 to minus 1 was a run-in period during in which subjects with perennial allergic rhinitis maintained a rhinitis diary. Subjects returned for evaluation on Visit 2, day 1 (+/- 48 hours). If they qualified after the run in period, they had Pre-Treatment Baseline Assessments performed: spirometry, complete blood count, (CBC), comprehensive metabolic panel (CMP), phosphate level, histamine and eosinophil counts, adverse Event (AE) and concomitant medication review. On Visit 2, Day 1, subjects began to use topical nasal spray wash of calcium glycerophosphate, two sprays per nostril, twelve hours apart, a.m. and p.m. for the balance of the study. Subjects were allowed to take two sprays per nostril- four additional times as needed between the a.m. and p.m. doses. The subject received a demonstration application at enrollment prior to leaving the clinic and self-administered again that night, regardless of time of day demonstration dosage was taken.



The subject returned for study visits on days 7 (+/- 48 hours), 14 (+/- 48 hours) and day 21 (+/- 48 hours) at which time they presented their daily symptom score sheets and had a repeat spirometry performed. A nasal eosinophil test and nasal histamine assay were examined on visit days 1, 7, 14 and 21. On day 21 they had an additional CBC, CMP and phosphate lab test performed.

## 5.1 Subject Eligibility Requirements

The Clinical Research Site recruited and enrolled male and female subjects, ages 18-80 with a history of perennial allergic rhinitis symptoms for at least twelve months prior to entrance to the study. Subjects had to self-report a medical history of known sensitivities to the perennial aeroallergens which included, but was not limited to dust, mold, cat, dog and cockroach. Allergic (IgE) antibodies to perennial aeroallergens were confirmed by an Immunocap lab result.

Subject compliance with the Symptom Diary between visits 1 and 2 had to be 80% or greater in order for subjects to be considered for randomization.

Women of child bearing potential (WOCBP) and men had to agree to use an effective method of birth control during study participation, which may have included surgical sterilization, self-report of being post-menopausal for at least 12 months, double barrier method, or taking birth control pills.

The Clinical Research Site excluded subjects if they did not agree to not wash out of excluded medications such as intranasal or systemic glucocorticosteroids for one month prior to enrollment, intranasal cromolyn for two weeks prior to enrollment, intranasal or systemic decongestants for three days prior to enrollment, and intranasal or systemic antihistamines for three days prior to enrollment, (Loratidine had to be washed out for ten (10) days prior to enrollment). Subjects were excluded if they were taking immunomodulatory or cytotoxic drugs.

General exclusions included a history of rhinitis medicamentosa (overuse of vasoconstrictor nasal sprays, e.g. Afrin®, producing rebound symptoms), planned travel outside the study area that would have precluded adequate follow up and the ability to comply with the visit schedule. Subjects with a diagnosis of asthma with more than two episodes per week or two nocturnal awakenings per month or if they had a known sensitivity to calcium or phosphorus supplements, were taking antihistamine treatment intermittently for atopic dermatitis, urticaria or any indication other than perennials allergic rhinitis, or if they were taking chronic, daily antihistamine treatment and planned to remain on that treatment for the duration of the study.

Subjects with a history of any clinically significant uncontrolled disease were excluded. Significant disease was defined as any disease that in the opinion of the investigator would put the safety of the subject at risk through study participation or would have confounded the interpretation of the study results should the disease/condition exacerbate during the study. Specifically, subjects were excluded if they had a diagnosis of hypercalcemia not limited to malignancy, sarcoidosis or hyperparathyroidism.

Subjects were excluded if they exhibited upon physical exam, nasal obstruction(s) sufficient enough to obstruct air flow that would interfere with study results.

Lastly, subjects were excluded if they were an employee of the clinical research site, an employee of the Sponsor or an immediate family member of the sponsor or the investigator(s). Immediate family was defined as spouse, parent, child and sibling.



Given the frequency of perennial allergic rhinitis in the population, all subjects were recruited from the Lovelace Scientific Resources research database and from the general population in the Albuquerque area.

## **6.0 SAFETY MONITORING**

Adverse Events and/or Unanticipated Problems were monitored for safety, trends, issues that may require stopping the study. All adverse events were documented on an adverse event log in the subjects' individual research record. The Site was also maintained by one continuous running log of all adverse events for all subjects. The Investigator reviewed the adverse event and document severity and causality on the designated signature form. Any serious adverse event was recorded in subjects' research record as well as one continuous running log of serious adverse events at each site. Any serious adverse event were reported to the PI or Sub PI and to AK Pharma. The serious adverse event continuous log will be reviewed at the time of any and all serious adverse event and be documented with initials on the designated signature form. . The PI's and/or sub PI's will call to order meetings if required to discuss any event or patient safety concerns. The protocol will be revised, put on hold or stopped if deemed necessary for patient safety. The PI and or Sub PI will report to regulatory agencies and IRBs in accordance with regulations. The PI will monitor vital signs and patient tolerability at each visit. The PI will make determinations regarding further subject assessment. If the patient cannot tolerate study drug due to side effects they will be withdrawn from the study.

## **7.0 OBSERVATIONS AND MEASUREMENTS**

### **7.1 Blood Collection**

Complete Blood Counts (CBC) and Chemistry Metabolic Panels (CMP) were collected at screening to determine subject safety for eligibility, and was collected at the final visit, again for subject safety. An Immunocap specimen was collected at screening to confirm perennial allergy eligibility. Phosphate levels were collected at screening and at the final visit to ensure subject safety. Nasal washings for eosinophil and histamine counts were collected at Day 1 (baseline), Day 7, 14, and 21 to show any changes while on treatment.

### **7.2 Pulmonary Function Tests (PFT's)**

Basic Spirometry was performed on Day 1 for baseline measurement, and on Day 7, 14, and 21 to show any while on treatment. The specific tests recorded were Forced Vital Capacity (FVC), Forced Expiratory Volume in 1 second (FEV1), and the FVC/FEV1 ratio. Subjects did not undergo bronchodilator evaluation.

### **7.3 Physical Examination**

A screening physical exam was conducted to determine eligibility and final visit physical exam to ensure subject safety.

### **7.4 Results**

Symptom scores were collected over the course of the study on a daily basis in the morning (AM) and in the evening (PM). Six symptoms of twenty patients affected with allergy were recorded during their baseline period (7 days) and following 23-25 days of treatment. Their symptoms included "Runny Nose", "Itchy Nose", "Congestion", "Sneezing", "Hoarse Voice", and "Throat Clearing", with severity ranging from 0-3. We compared symptoms' difference of



the baseline VS 1<sup>st</sup>, 2<sup>nd</sup>, and 3<sup>rd</sup>, week after treatment (Table 1). Comparisons were based on the daily mean for each individual symptom score as well as a total symptom score over the course of the treatment week. Additionally, symptom score differences in the morning and afternoon were compared at baseline and after treatment.

Average daily symptoms scores over the three weeks of treatment with AKP010112A were significantly improved from baseline levels (Table 1). There was improvement in symptoms (“Runny Nose”, “Itchy Nose”, “Congestion”, and “Throat Clearing”) from week 1 to 2 of treatment. By the end of three weeks of treatment only the symptoms of “Itchy Nose” and “Throat Clearing” were further improved from the previous week, however, all symptoms remained significantly improved compared to baseline scores. Total mean daily symptom scores were reduced by 42% by the end of the study following treatment with AKP010112A (Figure 1).

There were differences in some symptom scores in the AM vs PM at baseline and during the treatment phase (Table 2). Total symptoms scores were worse in the AM as characterized by significant differences in “Hoarse Voice”, and “Throat Clearing” at baseline. During the treatment phase while all symptoms improved over baseline they were again worse in the AM (Table 3: “Congestion”, “Hoarse Voice”, and “Throat Clearing”).

Respiratory function was evaluated (FEV and FVC; reported as % of predicted) at baseline and day 7, 14, and 21. There were no significant differences between baseline measures and anytime during the course of treatment (Table 4).

At baseline (day 1 prior to first dose), day 7, day14, and 21 nasal lavages were performed in order to determine if histamine levels were altered by treatment with AKP010112A. Individual histamine levels are reported in figure 3 and there were varied levels even at baseline from individual to individual. Average levels did not change significantly following AKP010112A treatment (Figure 4). Additionally, nasal eosinophils were determined and reported as either not present (0) < rare (1) < few (2) < moderate (3) < many (4). There was no significant treatment effect with AKP010112A on numbers of eosinophils (figure 5 and 6).

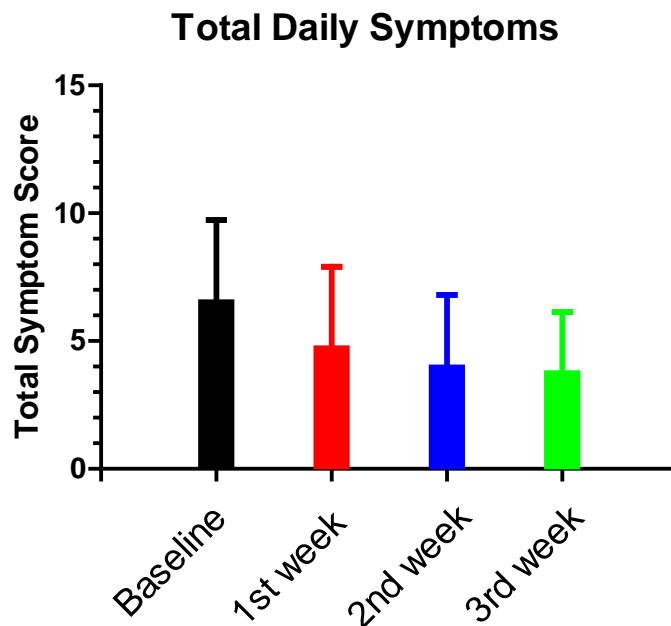
Blood was collected at baseline (day 1 prior to first dose), day 7, day14, and 21 and lab CBC performed. There were no findings that were considered clinically significant. A total of 11 patients reported adverse effects of the treatment compared to 9 that did not. The reported events were generally mild to moderate and did not require treatment. The most common adverse effects were stinging/burning immediately following treatment, nasal dryness, and sore throat. Other less frequently reported adverse events were nose bleeds, bad taste, watery eyes, nasal congestion, and headache. Fifteen of the subjects indicated on a satisfaction questionnaire that they would be willing to use/purchase this product in the future while 4 indicated they would not.

**Table 1 Individual Symptom Scores.**

SYMPTOM	Baseline mean (+/-SD)	1st Week mean (+/-SD)	2nd Week mean (+/-SD)	3rd Week mean (+/-SD)	Baseline VS 1st week after Treatment (p-value)	1st VS 2nd week after Treatment (p-value)	2nd VS 3rd week after Treatment (p-value)	Baseline VS 2nd week after Treatment (p-value)	Baseline VS 3rd week after Treatment (p-value)
Runny Nose	1.601 (+/- 0.957)	1.045 (+/- 0.937)	0.873 (+/- 0.822)	0.836 (+/- 0.726)	<0.0001	0.0063	0.3564	<0.0001	<0.0001
Itchy Nose	0.880 (+/- 0.922)	0.557 (+/- 0.870)	0.447 (+/- 0.803)	0.341 (+/- 0.631)	<0.0001	0.0360	0.0068	<0.0001	<0.0001
Congestion	1.562 (+/- 0.965)	1.207 (+/- 0.852)	0.917 (+/- 0.784)	0.836 (+/- 0.812)	<0.0001	<0.0001	0.2455	<0.0001	<0.0001
Sneezing	0.944 (+/- 1.034)	0.672 (+/- 0.865)	0.579 (+/- 0.806)	0.545 (+/- 0.717)	<0.0001	0.1179	0.3934	<0.0001	<0.0001
Voice Hoarse	0.338 (+/- 0.751)	0.216 (+/- 0.621)	0.288 (+/- 0.704)	0.207 (+/- 0.610)	0.0154	0.1619	0.0906	0.3857	0.0064
Thrt Clearing	1.200 (+/- 0.981)	1.075 (+/- 0.999)	0.856 (+/- 0.992)	1.043 (+/- 1.001)	0.0564	0.0003	0.0148	<0.0001	0.0017
Total symptoms	6.524 (+/- 3.201)	4.723 (+/- 3.184)	3.965 (+/- 2.836)	3.741 (+/- 2.386)	<0.0001	<0.0001	0.1746	<0.0001	<0.0001

The mixed model with repeated measurements was used in analysis. Among the model to test symptoms' changes among different weeks, we consider patients as random effect and include morning / afternoon effect as covariates. Statistical calculations were performed using the SAS<sup>®</sup> software system, Version 9.3 (Cary, NC).

**Figure 2. Average Daily Total Symptom Scores.**



Daily symptom scores were averaged over the baseline period (day -7-0), first week of dosing (day 1-7), second week of dosing (day 8-14), and the third week of dosing (day 15-23(5)). Treatment with AKP010112A significantly improved symptom scores from baseline levels. Symptoms continued to improve over the duration of the study with a 42% improvement by the end of the study. Mean +/- SD.

**Table 2. Average Daily AM vs PM Symptom Scores at Baseline**

SYMPTOM	AM mean (+/-SD)	PM mean (+/-SD)	Test Results (p-value)
Runny Nose	1.603 (+/-0.917)	1.600 (+/- 1.002)	0.6404
Itchy Nose	0.907 (+/- 0.841)	0.850 (+/- 0.905)	0.3457
Congestion	1.556 (+/- 1.011)	1.568 (+/- 0.917)	0.5319
Sneezing	0.960 (+/- 0.999)	0.928 (+/- 1.074)	0.9856
Voice Hoarse	0.464 (+/- 0.847)	0.201 (+/-0.604)	<0.0001
Thrt Clearing	1.351 (+/- 0.939)	1.036 (+/-1.003)	<0.0001
Total symptoms	6.839 (+/- 3.274)	6.187 (+/- 3.096)	0.0315

**Table 3. Average Daily AM vs PM Symptom Scores during Treatment**

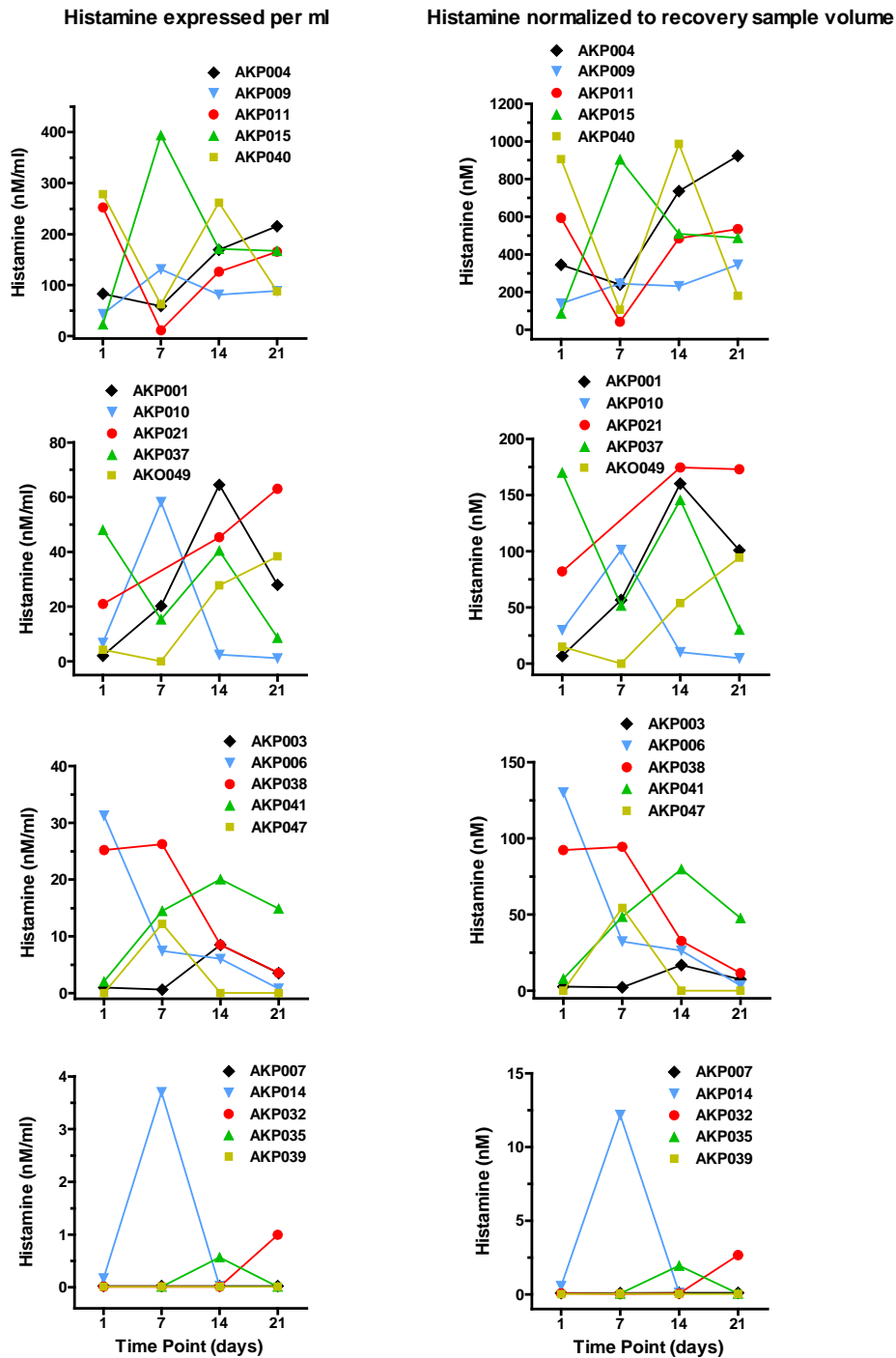
SYMPTOM	AM mean (+/-SD)	PM mean (+/-SD)	Test Results (p-value)
Runny Nose	0.957 (+/- 0.852)	0.888 (+/- 0.825)	0.0737
Itchy Nose	0.587 (+/- 0.868)	0.533 (+/-0.807)	0.0621
Congestion	1.181 (+/- 0.936)	1.098 (+/- 0.871)	0.0104
Sneezing	0.698 (+/- 0.883)	0.679 (+/- 0.873)	0.5796
Voice Hoarse	0.327 (+/-0.740)	0.191 (+/-0.588)	<0.0001
Thrt Clearing	1.100 (+/-0.996)	0.907 (+/- 0.997)	<0.0001
Total symptoms	4.400 (+/- 2.926)	3.925 (+/- 2.760)	0.0001

Scores average over the whole treatment period.

**Table 4. FEV and FVC**

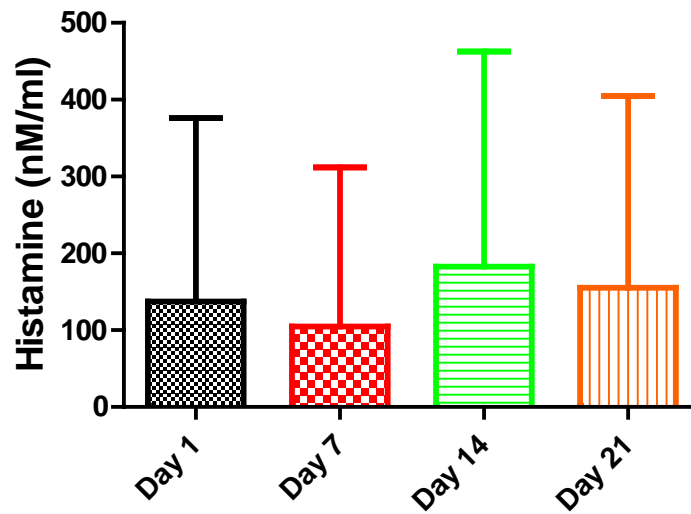
SYMPTOM	Baseline mean (+/-SD)	Day 7 mean (+/-SD)	Day 14 mean (+/-SD)	Day 21 mean (+/-SD)	Baseline VS Day 7 (p-value)	Day 7 VS 14 (p-value)	Day 14 VS 21 (p-value)	Baseline VS Day 14 (p-value)	Baseline VS Day 21 (p-value)
FEV (% Pred)	97.70 (+/- 24.12)	94.95 (+/- 25.26)	95.95 (+/- 25.55)	97.25 (+/- 23.68)	1.5700	0.5709	0.7422	0.9991	0.2569
FVC (% Pred)	107.5 (+/- 23.6)	103.9 (+/- 24.33)	106.2 (+/- 22.86)	108.0 (+/- 22.03)	1.8320	1.1960	0.8905	0.6361	0.2544

2749 AK Pharma - Order of decreased histamine levels



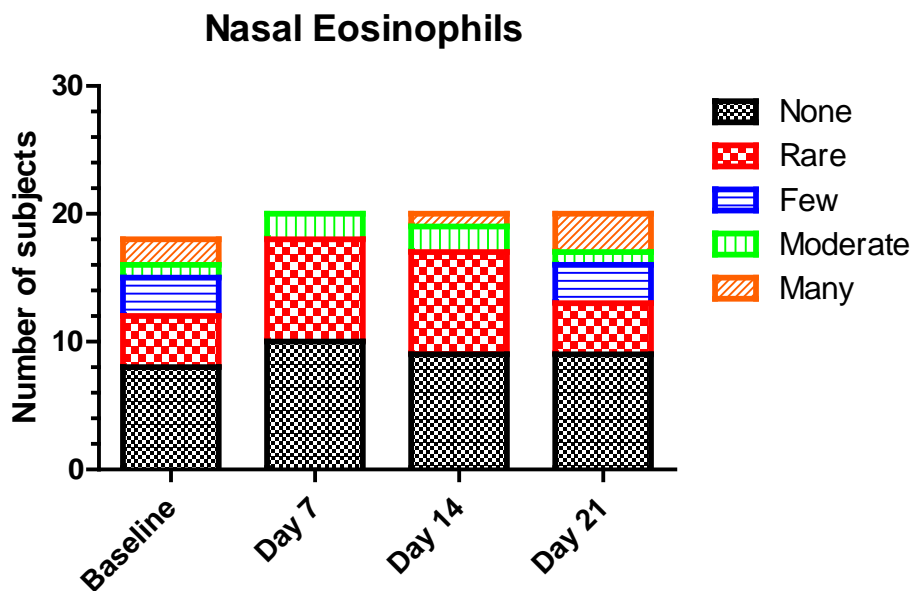
**Figure 3. Individual Histamine levels.**

Histamine levels were determined in nasal lavage fluid at day 1 prior to first dose, day 7, day14, and 21.



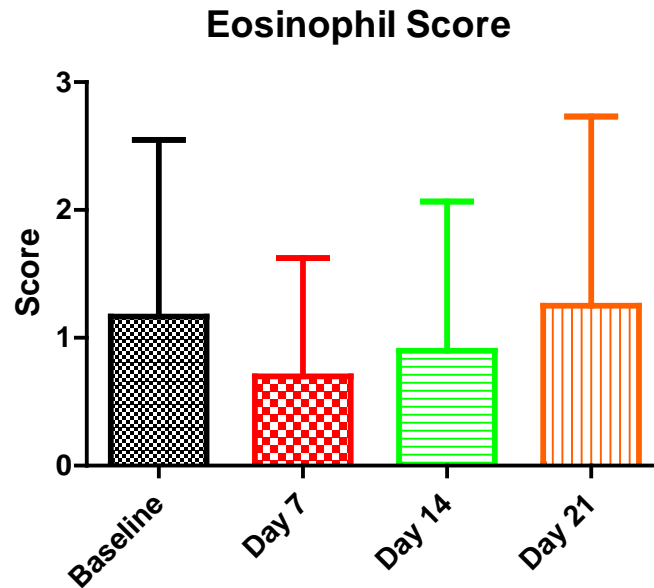
**Figure 4. Average histamine levels.**

Histamine levels were determined in nasal lavage fluid at day 1 prior to first dose, day 7, day 14, and 21. Average levels did not change significantly following AKP010112A treatment. Mean +/- SD.



**Figure 5. Relative numbers of eosinophils in nasal wash.**

There was no apparent effect of treatment on eosinophils in the nasal wash. Graph represents the number of patients identified with a relative level of eosinophils. There was no data for two patients at baseline.



**Figure 6. Relative numbers of eosinophils in nasal wash.**

There was no significant effect of treatment on eosinophils in the nasal wash. Subjective scoring levels of eosinophils were assigned a value: not present (0) < rare (1) < few (2) < moderate (3) < many (4). There was no data for two patients at baseline. Mean +/- SD.

## 8.0 DISCUSSION

The primary objective of the study was to assess subject nasal allergy symptoms following treatment with calcium glycerophosphate. In general, the subjects recruited into the study had persistent mild to moderate symptoms at baseline prior to the onset of treatment. Upon treatment with calcium glycerophosphate there was an immediate improvement in all symptom categories after the first week of treatment. Further, there was improvement in symptoms (“Runny Nose”, “Itchy Nose”, “Congestion”, and “Throat Clearing”) from week 1 to 2 of treatment. By the end of three weeks of treatment only the symptoms of “Itchy Nose” and “Throat Clearing” were further improved from the previous week, however, all symptoms remained significantly improved compared to baseline scores. Interestingly, none of these symptom improvements were associated with changes in nasal histamine or eosinophil levels suggesting that mechanism of action may be independent of mast cell degranulation or the presence of allergic inflammation. Similar results were achieved, in a previous study, in which ragweed sensitized dogs were pretreated with calcium glycerophosphate prior to nasal challenge with allergen. In these preclinical dog studies there was a significant decrease in nasal congestion that was not associated with a decrease mast cell derived mediators or nasal inflammatory cells.

Typically, for individuals with mild to moderate persistent allergic rhinitis the first line of treatment is intranasal corticosteroids or treatment with an antihistamine with or without





decongestant, or cromolyn alone. The early onset of action but achievement of a maximum effect within 2 weeks with calcium glycerophosphate is most similar to the response profile of intranasal steroids (1). However, it appears that the mechanism of actions are likely different as intranasal steroids are typically most effective against late-phase mediators in eosinophilic-dominated inflammation with some effect on the acute phase of the allergic response (2). It is difficult to directly compare calcium glycerophosphate to other treatments as they were not compared head to head in the present study, however, it's interesting to note that the significant reduction in symptoms was achieved in the context of existing symptoms. Antihistamines and cromolyn are not as effective when given after the onset of symptoms (3).

In general, the reported adverse events were generally mild to moderate and did not require treatment. The most common adverse effects were stinging/burning immediately following treatment, nasal dryness, and sore throat. These events were most likely associated with the initial delivery of the calcium glycerophosphate. The preponderance of the subjects indicated on a satisfaction questionnaire that they would be willing to use/purchase this product in the future, thus indicating that it was generally well tolerated and provided some noticeable benefit.


1. Melvin TN and Patel AA. Pharmacotherapy for Allergic Rhinitis *Otolaryngol Clin N Am* 2011; 44; 727–739.
2. Mygind N. Local effect of intranasal beclomethasone dipropionate aerosol in hay fever. *Br Med J* 1973;4:464–6.
3. Krouse JH. Allergic rhinitis—current pharmacotherapy. *Otolaryngol Clin North Am* 2008;41(2):347–58.

## **APPENDIX I PROTOCOL**

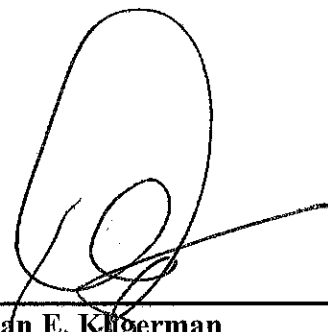
Effects of AkPharma's Calcium Glycerophosphate  
Nasal Spray wash (AkP 010112A) on Patient-Perceived Breathing  
Comfort

Original Protocol Date: 01 May 2013

APPROVED BY:

  
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Principal Investigator  
Lovelace Scientific Resources, Inc.

*3 June 2013*  
\_\_\_\_\_  
Date

  
\_\_\_\_\_  
Alan E. Kligerman  
Chief Executive Officer  
AKPharma, Inc.

*05/22/13*  
\_\_\_\_\_  
Date

## Protocol Summary

Approximately 20-40 million Americans have allergic rhinitis, with direct and indirect costs ranging from \$1.2 billion to \$5.3 billion per year. Perennial allergic rhinitis is a common year round problem that is associated with sneezing, rhinorrhea and nasal congestion. Sneezing is induced by stimulation of nasal sensory nerves while congestion results from vasodilation. Rhinorrhea is associated with increased vascular permeability and granular secretion. A number of chemical mediators contribute to these symptoms including histamine, leukotrienes, interleukins and neuropeptides. A large number of drug interventions sold, including Rx and OTC, both inhaled and orally-taken, address this problem, with greater or lesser success, depending on the individual using them. A common problem with most or all of these drugs is their array of side effects, including addiction, habituation, rebound, dependency, anti-cholinergic effects, drowsiness - or its opposite, hyperactivity -, and psychotropic compromise of demanding activities such as driving or machinery operation.

AkPharma Inc. has developed preliminary data suggesting that calcium glycerophosphate (CGP), used as a nasal spray wash improves perceived rhinitis symptoms, and delivers none of the above named adverse symptoms linked with drugs. AkPharma has commissioned extensive study of this molecule which has a prior history of safe and effective therapeutic applications in other sectors of the body. CGP is a calcium salt and an approved cosmetic component and it has long been used as a food ingredient. CGP is a Dietary Supplement and is generally regarded as safe (GRAS). CGP is a normal cellular constituent, created de novo in the human body as an intermediate metabolite in the Krebs cycle of carbohydrate metabolism. As administered in this nasal rinsing-coating application, essentially all of the molecule that transits the nasal cavity and into the throat will be considered to be ingested, a safe and nutritional pathway for CGP. There is extensive information on its safety, including a recently concluded study conducted on ragweed-sensitized beagle dogs, which demonstrated proof of efficacy, with no untoward physiological or other adverse effects (Barrett, EG, Effects of inhaled calcium glycerophosphate on Rhinitis Responses in Ragweed Sensitized Dogs, Lovelace Respiratory Research Institute, Albuquerque, NM March, 2010). Further, in order to establish the systemic safety of this cosmetic-category product, a further terminal small animal study was conducted on inhalation of

nasally administered doses of CGP at levels proportionally comparable to expected human dosages (Brackee, G, Acoustic Rhinometry and Pathologic Analysis on Ovalbumin-Sensitized Guinea Pigs Treated with Calcium Glycerophosphate, Texas Tech Univ. Laboratory Animal Resources Center, Lubbock, TX). The study results demonstrated no discernable cellular effects in body tissue or in vital organs, including lungs, heart, brain or elsewhere in the study animals and no differences between test and control animals. There are no known contraindications that pertain to ingestion of this molecule other than dietary preclusion of calcium or phosphorus/phosphate. Moreover, there are no known addiction, habituation, or dependency concerns; the molecule is devoid of psychotropic side effects, rebound effects, anti-cholinergic activity, etc. We propose to evaluate subjects with perennial allergic rhinitis with or without lower respiratory tract asthma for potential beneficial effects of intranasal administration of CGP, primarily on their perceived and self-reported changes in respiratory comfort and feelings of breathing “well-being.”

### **Study Design**

The overall study design involves four weeks of study participation and will recruit twenty (20) subjects. Subjects will be screened for eligibility at Visit 0, Day minus 8 (-8). Allergic sensitivities will be confirmed using Immunocap testing.

Days minus 7 to minus 1 will be a run-in period during which subjects with perennial allergic rhinitis will maintain a rhinitis diary (see Diary). Subjects return for evaluation on Visit 2, day 1 (+/- 48 hours). If they qualify after the run in period, they will have Pre-Treatment Baseline Assessments performed: spirometry, complete blood count, (CBC), comprehensive metabolic panel (CMP), phosphate level, histamine and eosinophil counts, adverse Event (AE) and concomitant medication review. On Visit 2, Day 1 subjects will begin to use topical nasal spray wash of calcium glycerophosphate, two sprays per nostril twelve hours apart, a.m. and p.m. for the balance of the study. Subjects will be allowed to take two sprays per nostril- four additional times as needed between the a.m. and p.m. doses. The subject will receive a demonstration application at enrollment prior to leaving the clinic and will self-administer again that night, regardless of time of day demonstration dosage was taken.

The subject will return for study visits on days 7 (+/- 48 hours), 14 (+/- 48 hours) and day 21 (+/- 48 hours) at which time they will present their daily symptom score sheets and have a repeat spirometry performed. A nasal eosinophil test and nasal histamine assay will be examined on visit days 1, 7, 14 and 21. On day 21 they will have an additional CBC, CMP and phosphate lab test performed.

### **Inclusion Criteria**

1. Male or female subjects ages 18-80
2. History of perennial allergic rhinitis symptoms for at least twelve months prior to entrance to the study. Subjects will self-report a medical history of known sensitivities to the perennial aeroallergens which include, but are not limited to dust, mold, cat, dog and cockroach. Allergic (IgE) antibodies to perennial aeroallergens will be confirmed from the Immunocap testing.
3. Compliance with the Respiratory Symptom Diary between visits 1 and 2 of 80% or greater.
4. Women of child Bearing Potential (WOCBP) must be taking an effective method of birth control, surgically sterile, or post-menopausal for at least 12 months. Men must use an effective birth control throughout the course of the study.

### **Exclusion Criteria**

1. Intranasal or systemic glucocorticosteroids within one month of study initiation
  - i. Intranasal cromolyn for two weeks prior to the enrollment
  - ii. Intranasal or systemic decongestants for three days prior to enrollment
  - iii. Intranasal or systemic antihistamines for three days prior to enrollment: oratidine for ten (10) days prior to enrollment
2. A history of rhinitis medicamentosa (overuse of vasoconstrictor nasal sprays, e.g. Afrin®, producing rebound symptoms)
3. Planned travel outside the study area that will preclude adequate follow up and the ability to comply with the visit schedule
4. Subjects with a diagnosis of asthma with more than two episodes per week or two nocturnal awakenings per month.

5. Subjects with known sensitivity to calcium or phosphorus supplements.
6. Subjects who are taking antihistamine treatment intermittently for atopic dermatitis, urticaria or any indication other than perennial allergic rhinitis. Subjects will not be excluded if they are taking chronic, daily antihistamine treatment and plan to remain on that treatment for the duration of the study.
7. Subjects taking immunomodulatory or cytotoxic drugs.
  - a. Subjects who have a history of clinically significant uncontrolled disease, 'Significant' is defined as any disease that in the opinion of the investigator would put the safety of the subject at risk through study participation or would confound the interpretation of the study results if the disease/condition exacerbates during the study.
8. Subjects with a diagnosis of hypercalcemia not limited to malignancy, sarcoidosis or hyperparathyroidism.
9. Subjects with nasal obstruction(s) sufficient enough to obstruct air flow that would interfere with study results and could not be reliably extracted (e.g. polyps).
10. Subject is an investigator, employee of the Sponsor or an immediate family member of the sponsor or the investigator(s). Immediate family is defined as spouse, parent, child and sibling.

### **Subjects Study Protocol**

Beginning on day minus 7 subjects who qualify will begin recording a diary in which they will self evaluate and score their symptoms. Scores will be recorded in both the a.m. and p.m. 12 hours apart at the expected dosing interval. The symptoms to be evaluated are rhinorrhea (runny nose), itching, congestion and sneezing. A 0-3 scale will be used in which 0 = absent symptoms (no sign/symptom evident), 1 = mild symptoms (sign/symptom clearly present, but minimal awareness; easily tolerated), 2 = moderate symptoms (definite awareness of sign/symptoms that is bothersome but tolerable), 3 = severe symptoms (sign/symptom that is hard to tolerate, causes interference with activities of daily living and/or sleep). To qualify, the subject will need to have completed at 80% of the required entries between visits 1 and 2 of the Respiratory Symptom Diary. The information from the diary collected at visit 2 will be considered the baseline nasal symptoms. Throat clearing (post-nasal drip) will also be evaluated. On Visit 2, Day 1, following baseline evaluations, calcium glycerophosphate nasal spray wash will be dispensed. Proper use will be demonstrated to and by the subject, including the appropriate way to squeeze bottle and

get bottle back to its normal ready for re-use dimensions. Subject will take actual dosage at this demonstration. Subject will then commence home usage, using two sprays in each nostril, twelve hours apart, a.m. and p.m. As noted above, subjects will be allowed to take two sprays per nostril- four additional times as needed between the a.m. and p.m. doses. On Day 1, the subject will self-administer again that evening, regardless of time of day that the demonstration dosage was taken. The subjects will record their symptoms scores one hour post-dose and again just prior to the next self-administration. The score recorded an hour after the dose is referred to as the “reflective” symptom score and the score recorded pre-next dose is referred to as “instantaneous” symptom score. A nasal eosinophil test and nasal histamine test is performed at Visit 2 (Day 1), Visit 3 (Day 7), Visit 4 (Day 14), and Visit 5 (Day 21

### **Primary and Secondary End Points**

The primary end point will be the nasal diary score. The secondary end point will include the changes observed in the FEV1 (forced expiratory volume in 1 second) and FVC (forced vital capacity) on pulmonary function (spirometry) testing. Also to be examined as secondary end points are changes in AM versus PM symptom scores and onset of the action of calcium glycerophosphate nasal spray wash as well as changes observed in nasal eosinophil count and nasal histamine values. On study day 7, 14 and again at study day 21 subjects visit the study center where adherence to symptom diary and weight of the calcium glycerophosphate nasal spray wash is evaluated to confirm adherence. As mentioned above, spirometry will be repeated on each of those days. The subjects will also be questioned as to whether symptoms necessitated the use of any additional medications that are excluded above during the prior one-week period. They will also be questioned as to whether there have been any intercurrent infections such as an upper respiratory tract infection (such as the common cold) involving the nose or sinuses. If that proves to be the case, they will be disqualified from continuing in the study. Subjects will also be asked to evaluate quality of life on a 1-10 scale.

### **Statistical Analysis**



## **Subject Recruitment**

Given the frequency of perennial allergic rhinitis in the population, all subjects are expected to be recruited from the Lovelace Scientific Resources research database and the general population in the Albuquerque area. Screening will continue until the study enrolls 20 subjects.

### **Data Safety Monitoring Plan**

Adverse Events/Unanticipated Problems will be monitored for safety, trends, issues that may require stopping the study. All adverse events will be documented on an adverse event record in the subjects' individual research record. The Site will also maintain one continuous running log of all adverse events for all subjects. The PI and/or Sub PI will review the adverse event continuous logs at the time of the event and on a quarterly basis and document severity and causality on the designated signature form. Any serious adverse event will be recorded in subjects' research record as well as one continuous running log of serious adverse events at each site. Any serious adverse event will be reported to the PI or Sub PI and to AK Pharma. The serious adverse event continuous log will be reviewed at the time of any and all serious adverse event and be documented with initials on the designated signature form. . The PI's and/or sub PI's will call to order meetings if required to discuss any event or patient safety concerns. The protocol will be revised, put on hold or stopped if deemed necessary for patient safety. The PI and or Sub PI will report to regulatory agencies and IRBs in accordance with regulations.

The PI will monitor vital signs and patient tolerability at each visit. The PI will make determinations regarding further subject assessment. If the patient cannot tolerate study drug due to side effects they will be withdrawn from the study.

### **Quality Assurance/Monitoring**

Quality reviews will be performed by Lovelace Scientific Resources, Inc., regulatory department personnel on a regular basis determined by the subject enrollment rate. Adherence to the protocol, ICH and GCP guidelines will be monitored.

### Visit Schedule

Assessments/Procedures	VO Day -8	V1 Day-7	V2 Day 1	V3 Day 7	V4 Day 14	V5 Day 21
Informed Consent	X					
Assess Inclusion/Exclusion	X	X	X			
Medical History	X					
Concurrent Medication Review	X	X	X	X	X	X
Assess Adverse Events	X	X	X	X	X	X
Abbreviated Physical Exam	X					X
Lab: Immunocap	X					
Lab: CBC			X			X
Lab: CMP			X			X
Lab: Phosphate			X			X
Lab: Nasal Eosinophil			X	X	X	X
Lab: Nasal Histamine			X	X	X	X
Patient Diary		X				
Symptoms Scores			X	X	X	X
Satisfaction Questionnaire						X
Pulmonary Function Test (PFT)			X	X	X	X
IP Training			X	X	X	X
IP Dosing			X	X	X	X
IP Accountability			X	X	X	X

## **APPENDIX II INFORMED CONSENT FORM**

## INFORMED CONSENT

**TITLE:** Effects of AkPharma's Calcium Glycerophosphate Nasal Spray Wash (AkP010112A) on Patient-Perceived Breathing Comfort

**PROTOCOL NO.:** N/A

**SPONSOR:** AkPharma, Inc

**INVESTIGATOR:** Jonny Salyer, MD

**TELEPHONE:** 505-348-9500

### INTRODUCTION

Before agreeing to participate in this research study, it is important that you read and understand the following explanation of the proposed research study. This consent document describes the purpose, procedures, benefits, risks, discomforts and precautions of the study. It also describes the alternative procedures that are available to you and your right to withdraw from the study at any time. No guarantees or assurances can be made as to the results of the study.

If you are not completely truthful with your study doctor regarding your health history, you may harm yourself by participating in this study.

The study is being conducted for AkPharma Inc. Your study doctor is being paid by AkPharma to conduct this study.

You must think about the information in this consent document for yourself. You must then decide if you want to be in the study.

### BACKGROUND AND PURPOSE

You are being asked to participate in this research study because you have recurring symptoms of nasal allergies and may meet study requirements. Possible causes of these allergy symptoms may include all allergens such as dust, pollen, mold, cat, dog dander or cockroach. Knowing the cause of your allergy symptoms is not required to be a part of the trial.

The study sponsor submitted a preliminary product label and application for approval for its Calcium Glycerophosphate (CGP) Nasal Spray Wash to the FDA in 2008 and in 2011. The FDA raised no objection to the cosmetic CGP nasal wash, its use or to the product label. The ingredients in Calcium Glycerophosphate Nasal Spray Wash are generally recognized as safe (GRAS).

The purpose of this research study is to look at the safety and effectiveness of the Calcium Glycerophosphate Nasal Spray Wash, how it affects your condition, and how well you tolerate Calcium Glycerophosphate Nasal Spray Wash.

## **NUMBER OF SUBJECTS / LENGTH OF PARTICIPATION**

Up to forty (40) persons 18 to 80 years old with allergy symptoms in the past 12 months may take part in the study. The length of your participation in this study will be about 28 days.

## **PROCEDURES**

Before any study-related tests and procedures are performed, you will be asked to read and sign this consent document. The following tests and procedures will be performed to determine if you qualify to take part in this study.

### Screening (Visit 0):

- ◆ Informed Consent
- ◆ Assess Inclusion/Exclusion criteria (study plan requirements)
- ◆ Medical history (including demographic-personal information about yourself, such as date of birth, race, etc.)
- ◆ Record recent and current medications (both over the counter and prescription)
- ◆ Assess for adverse events (any changes in your health you report after signing the informed consent)
- ◆ Limited physical exam
- ◆ Blood (about 2 tablespoons) collection for routine tests.

### Visit 1: (7 days before receiving the nasal wash)

- ◆ Assess Inclusion/Exclusion criteria (study plan requirements)
- ◆ Record recent and current medications (both over the counter and prescription)
- ◆ Assess for adverse events (any changes in your health you report after signing the informed consent)
- ◆ You will be required to keep a diary of symptoms for 28 days (7 days before starting the spray and for 21 days on the spray).

### Visit 2: (Day 1 of Study)

- ◆ Record recent and current medications (both over the counter and prescription)
- ◆ Assess for adverse events (any changes in your health you report after signing the informed consent)
- ◆ Blood (about 2 tablespoons) collection for routine tests.

- ◆ Nasal sample (salt water rinse about 2 tablespoons) collection for routine tests
- ◆ Pulmonary Function Testing (PFT- measurement of breathing patterns measured from breathing through a hand held meter)
- ◆ You will keep a daily diary of symptoms for 28 days (7 days before starting the spray and for 21 days on the spray).
- ◆ You will be trained on the proper use of the nasal wash. Only you can take the study nasal spray wash. It must be kept out of the reach of children and persons who may not be able to read or understand the label.
- ◆ You will be asked to use the nasal wash, 2 sprays each nostril, every 12 hours every day for 21 days. You will be permitted an additional 4 doses per day if needed in-between the 12 hour scheduled doses.
- ◆ You will be given an appropriate amount of the nasal spray wash to take with you.

### Visit 3: (Day 7 of Study)

- ◆ Record recent and current medications (both over the counter and prescription)
- ◆ Assess for adverse events (any changes in your health you report after signing the informed consent)
- ◆ Nasal sample (salt water rinse about 2 tablespoons) collection for routine tests
- ◆ Pulmonary Function Testing (PFT- measurement of breathing patterns measured from breathing through a hand held meter)
- ◆ You will continue to keep a diary of symptoms for 28 days (7 days before starting the spray and for 21 days on the spray). Your diary will be reviewed for completeness.
- ◆ Your ability to use the nasal wash will be assessed. Only you can take the study nasal spray wash. It must be kept out of the reach of children and persons who may not be able to read or understand the label.
- ◆ You will be asked to use the nasal wash, 2 sprays each nostril, every 12 hours every day for 21 days. You will be permitted an additional 4 doses per day if needed in-between the 12 hour scheduled doses.
- ◆ You will return all unused nasal spray wash for weighing and be given new nasal spray wash to take with you.

### Visit 4: (Day 14 of Study)

- ◆ Record recent and current medications (both over the counter and prescription)
- ◆ Assess for adverse events (any changes in your health you report after signing the informed consent)
- ◆ Nasal sample (salt water rinse about 2 tablespoons) collection for routine tests
- ◆ Pulmonary Function Testing (PFT- measurement of breathing patterns measured from breathing through a hand held meter)
- ◆ You will keep a diary of symptoms for 28 days (7 days before starting the spray and for 21 days on the spray). Your diary will be reviewed for completeness.

- ◆ Your ability to use the nasal wash will be assessed. Only you can take the study nasal spray wash. It must be kept out of the reach of children and persons who may not be able to read or understand the label.
- ◆ You will be asked to use the nasal wash, 2 sprays each nostril, every 12 hours every day for 21 days. You will be permitted an additional 4 doses per day if needed in-between the 12 hour scheduled doses.
- ◆ You will return all unused nasal spray wash for weighing and be given new nasal spray wash to take with you.

#### Visit 5: (Day 21 of Study/End of Study)

- ◆ Record recent and current medications (both over the counter and prescription)
- ◆ Assess for adverse events (any changes in your health you report after signing the informed consent)
- ◆ Limited physical exam
- ◆ Blood (about 2 tablespoons) collection for routine tests.
- ◆ Nasal sample (salt water rinse about 2 tablespoons) collection for routine tests
- ◆ Pulmonary Function Testing (PFT- measurement of breathing patterns measured from breathing through a hand held meter)
- ◆ Complete satisfaction questionnaire
- ◆ You will return the symptom diary and unused nasal spray wash for weighing.

### **EXPECTATIONS**

Taking part in a research study can be an inconvenience to your daily life. Please consider the study time commitments and responsibilities as a research participant when you are deciding to take part. If you participate in this study you will be expected to:

- Follow the instructions you are given.
- Come to the study center for all visits that are required.
- Tell the truth to the best of your knowledge about your medical history and current conditions as well as all medications, prescribed or over-the-counter; including vitamins and herbal supplements, you are taking.
- Tell the research staff if you have been in a research study in the last 30 days or if you are currently in another research study.

### **RISKS, SIDE EFFECTS AND/OR DISCOMFORTS**

There are risks of stress, emotional distress, inconvenience and possible loss of privacy and confidentiality associated with participating in a research study.

You may have side effects while participating in the study. Everyone taking part in the study will be followed carefully for any side effects. However, doctors do not know all the side effects that may happen. Side effects may be mild or very serious.

Nasal rinsing may cause nasal/oral discomfort such as dryness, gagging and cough.

Possible side effects from blood drawing include faintness, inflammation of the vein, pain, bruising, or bleeding at the site of puncture. There is also a slight possibility of infection.

No allergic reactions to Calcium Glycerophosphate are known in human experience or in animal studies. Allergic reaction to Calcium Glycerophosphate Nasal Spray Wash is possible. Serious allergic reactions can be life threatening. Persons who have been told not to take either calcium or phosphorus/phosphate should not participate in the study.

The use of Calcium Glycerophosphate Nasal Spray Wash can cause a slight drying of the nasal tissue in some persons.

To date there are no known risks taking Glycerophosphate Nasal Spray Wash.

## **UNFORESEEN RISKS**

Since the study drug Calcium Glycerophosphate (CGP) Nasal Spray Wash is investigational when taken alone or in combination with other medications, there may be other risks that are unknown. All drugs have a potential risk of an allergic reaction, which if not treated promptly, could become life-threatening.

## **PREGNANCY / BIRTH CONTROL**

Women who are pregnant or nursing a child may not participate in this study. If you are a woman of child bearing potential, you must confirm that, to the best of your knowledge, you are not now pregnant, and that you do not intend to become pregnant during the study. We do not know what impact this drug will have on your fertility (your ability to conceive a child or impregnate a female). We also do not know what effects this drug will have on a pregnancy. You must use effective birth control throughout the course of this study. If female, you must avoid getting pregnant. If you become pregnant while in the study, you must tell the study doctor/staff as soon as possible. If male, you should avoid impregnating a female. You must use effective birth control throughout the course of this study. While you are in this study, if your partner becomes pregnant you must tell the study doctor/staff as soon as possible.

## **ALTERNATIVE TREATMENT**

You do not have to be in this study to receive treatment for your nasal allergy symptoms. Other nasal rinses may be available. The study doctor will discuss with you the risks and benefits of the alternative treatments.



## **NEW FINDINGS**

Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be made available to you.

## **BENEFITS**

You may benefit as a result of your participation in this study. There is, however, no guarantee that you will benefit from your participation in this study. Results from this study may benefit others in the future.

## **COMPENSATION FOR PARTICIPATION**

For your time and inconvenience related to your participation in this study, you will be paid for the study visits you complete according to the following schedule: \$50.00 for each of the following visits: Screening, Visit 2, Visit 3, Visit 4 and Visit 5. You will be paid \$20.00 for Visit 1. If you do not complete the study for any reason, you will only be paid for the study visits you do complete. Payment will be mailed at the end of each completed visit.

If you have any questions regarding your compensation for participation, please contact the study staff at the telephone number listed on page one of this consent document.

## **CONFIDENTIALITY**

Records of your participation in this study will be held confidential except as disclosure is required by law or as described in this informed consent document (under "Confidentiality" or "Authorization to Use and Disclose Protected Health Information"). The study doctor, the sponsor or persons working on behalf of the sponsor (such as monitors or auditors), and under certain circumstances, the United States Food and Drug Administration (FDA) and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name. Therefore, absolute confidentiality cannot be guaranteed. If the results of this study are published or presented at meetings, you will not be identified.

## **COMPENSATION FOR INJURY**

If you are injured as a result of taking the study drug(s) or from procedures done for the purpose of this study, the sponsor will pay for those medical expenses necessary to treat your injury that are not covered by your medical insurance or any other third party coverage. There are no plans to provide other compensation beyond that which is

listed in this informed consent document. You will not lose any of your legal rights or release the Sponsor, the study doctor, the study staff, or study site from liability for mistakes or intentional misconduct by signing this consent document.

If you are injured during this study, your study doctor will discuss with you the available medical treatment options.

### **COSTS**

There will be no charge to you for your participation in this study. The study drug, study-related procedures, and study visits will be provided at no charge to you or your insurance company.

### **EMERGENCY CONTACT / IRB CONTACT**

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the study doctor at the telephone number listed on page one of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in a research study being conducted by the study doctor listed on page one of this document.

Liberty IRB, Inc. has approved the information in this consent document and has given approval for the study doctor to do the study. An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. This does not mean the IRB has approved your participation in the study. It also does not mean the study is without risks.

If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, you should write to Liberty IRB at Liberty IRB, 1450 S. Woodland Blvd, Suite 300A, Deland, Florida 32720 or call 386-279-4318 during business hours Monday - Friday 8:00 a.m. to 5:00 p.m. EST.

### **VOLUNTARY PARTICIPATION / WITHDRAWAL**

Your decision to participate in this study is voluntary. You may choose to not participate or you may withdraw from the study for any reason without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care. Investigator or the sponsor can stop your participation at any time without your consent for the following reasons:

- If it appears to be medically harmful to you;
- If you fail to follow directions for participating in the study;
- If it is discovered that you do not meet the study requirements;
- For administrative reasons, including the target number of subjects have entered the treatment phase;

- A change in your medical condition;
- Other reasons, including new information available to the investigator or harmful reactions experienced by you or other subjects in this study;
- If the study is canceled.

If you leave the study before the final regularly scheduled visit, the study doctor may ask you to complete an end-of-study visit for your safety.

### **PRIMARY CARE PHYSICIAN / SPECIALIST NOTIFICATION OPTION**

Please indicate below whether you want us to notify your primary care physician or your specialist of your participation in this study.

\_\_\_\_\_ Yes, I want the study doctor to inform my primary care physician/specialist  
(initials) of my participation in this study.

\_\_\_\_\_ No, I do not want the study doctor to inform my primary care  
(initials) physician/specialist of my participation in this study.

\_\_\_\_\_ I do not have a primary care physician/specialist.  
(initials)

\_\_\_\_\_ The study doctor is my primary care physician/specialist.  
(initials)

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## CONSENT

I have read and understand the information in this informed consent document. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I voluntarily agree to participate in this study until I decide otherwise. I do not give up any of my legal rights by signing this consent document. I will receive a copy of this signed consent document.

\_\_\_\_\_  
Subject's Printed Name

\_\_\_\_\_  
Subject's Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of the Person Conducting the  
Consent Discussion

\_\_\_\_\_  
Signature of the Person Conducting the  
Consent Discussion

\_\_\_\_\_  
Date

## **AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION**

During your participation in this research study, the study doctor, Dr. Jonny Salyer and study staff will collect or create personal health information about you (for example, medical histories and results of any tests, examinations or procedures you undergo while in the study) and record it on study documents. The study doctor will keep this personal health information in your study-related records (that we will refer to as "your study records"). In addition, the study doctor may obtain, and include in your records, information regarding your past, present and/or future physical or mental health and/or condition. Your study doctor may ask you to sign a separate authorization to obtain some or all of your medical records from your doctor. Your study records may include other personal information (such as social security number, medical record numbers, date of birth, etc.), which could be used to identify you. Health information that could identify you is called "Protected Health Information" (or "PHI").

Under federal law (the "Privacy Rule"), your PHI that is created or obtained during this research study cannot be "used" to conduct the research or "disclosed" (given to anyone) for research purposes without your permission. This permission is called an "Authorization." Therefore, you may not participate in this study unless you give your permission to use and disclose your PHI by signing this Authorization. By signing, you are agreeing to allow the study doctor and staff to use your PHI to conduct this study.

By signing this Authorization, you also are agreeing to allow the study doctor to disclose PHI as described below:

- The sponsor of this study and anyone working on behalf of the sponsor to conduct this study (referred to as "the sponsor"). The sponsor will analyze and evaluate the PHI and may use it to develop new tests, procedures and commercial products. The study staff will assign a code number and/or letters to your records, which means that you will not ordinarily be identified in the records sent to the sponsor. The sponsor may, however, look at your complete study records that identify you. In addition, the sponsor may visit the study site to oversee the way the study is being conducted and may review your PHI during these visits to

make sure the information is correct.

- The Institutional Review Board ("IRB") may have access to your PHI in relation to its responsibilities as an Institutional Review Board.

The study doctor or sponsor may disclose your PHI to the United States Food and Drug Administration ("FDA") or similar regulatory agencies in the United States and/or foreign countries.

These disclosures also help ensure that the information related to the research is available to all parties who may need it for research purposes.

Except for the disclosures described above, your PHI will not be shared with others unless required by law. If your PHI is given to the parties listed above and/or to others who are not required to comply with the federal law, your PHI will no longer be protected by this law and could possibly be used or disclosed in ways other than those listed here.

You have a right to see and make copies of your PHI. You are agreeing, however, by signing this document, not to see or copy some or all of your PHI until the sponsor has completed all work related to this study. At that time, you may ask to see your records.

This Authorization will expire 50 years from the date you sign it unless you revoke (cancel or withdraw) it sooner.

You have a right to revoke your Authorization at any time. If you revoke it, your PHI will no longer be used for this study, except to the extent the parties to the research have already taken action based upon your Authorization or need the information to complete analysis and reports for this research. To revoke your Authorization, you must write to the study doctor, stating that you are revoking your Authorization to Use and Disclose Protected Health Information. If you revoke this Authorization, you will not be allowed to continue to be in this study.

You will receive a copy of this Authorization after you have signed it.

\_\_\_\_\_  
Signature of Subject

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of Subject

\_\_\_\_\_  
Signature of the Person Obtaining the  
Authorization

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of the Person Obtaining the  
Authorization

## **APPENDIX III INSTRUCTIONS FOR SUBJECTS**



## **Instructions for Subjects - Nasal Spray Wash Study**

### **CGP Nasal Spray Wash Self-Administration**

1. Blow your nose gently before using CGP Nasal Spray Wash.
2. Shake bottle slightly before using spray.
3. Gently insert the bottle tip into your left nostril while using your thumb or finger of your right hand to close off the right nostril. Keep your head upright.
4. Squeeze the bottle fully while at the same time inhaling all the spray through your left nostril. (Quickly remove bottle after spraying to minimize drawback into bottle.)
5. Repeat steps 3 and 4 with bottle nozzle in your right nostril, closing your left nostril with your left hand.
6. Do this procedure twice - so you have taken two sprays in each nostril, alternately.
7. Avoid blowing your nose for at least 10 minutes after application.
8. Excess moisture may be sniffed upwards and either swallowed or spit out.

Minimum required dosage, 2 sprays per nostril in the morning and 2 sprays per nostril in the evening, approximately 12 hours apart.

Note: You may take additional sprays besides the morning and evening double sprays. You can take these any time of day or night, as needed or desired. Single sprays per nostril may suffice at such times, although 2 sprays are permitted. Do not take spray more than four additional times per 24-hour period. Record all doses you take, including when and how many sprays are taken.

Jonny Salyer, MD, Lovelace Scientific Resources, Inc. Emergency Phone: (505) 348-9500

## **APPENDIX IV SUBJECT DATA**

**AKP-001**

2,49 AKPharma PERENNIAL ALLERGIES  
SCREENING/VISIT 1 SOURCE DOCUMENTS

Initials: BLS Site #:      Subject #: AKP 001

**PATIENT DEMOGRAPHICS**

**Patient Demographics**

Date of Birth: 25 / Jun / 1948 (dd/mmm/yyyy)

Gender:  Male  Female

If female, Indicate Childbearing Potential

Childbearing  Surgically sterilized  Post-Menopausal

Ethnicity:  Hispanic  Non Hispanic

Race:  Asian  Black  Caucasian  American Indian

Pacific Islander  Other, Specify \_\_\_\_\_

**Smoking History**

Smoking Status:  None (smoked less than 100 cigarettes in lifetime)

Former (previously smoked more than 100 cigarettes in lifetime)

Current (smokes now)

If subject is a former or current smoker, please indicate:

Years smoked: \_\_\_\_\_

Cigarettes per day: \_\_\_\_\_

CRC Signature: Walter Byatt

Date: 18, Oct, 13 (dd/mmm/yy)



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Scientific Resources  
 Clin Trials Leslie Byatt  
 2441 Ridgecrest Dr SE  
 Albuquerque, NM 87108

Client Nbr  
 24664

PATIENT NAME: **BLS, BLS** PATIENT ID: **AAGG3648** DOB: **06/25/1948** SEX: **M** REPORT STATUS: **Final** PAGE: **1**  
 PHYSICIAN: **Unlisted Physician,** COLLECT DATE & TIME: **10/18/2013 15:00 (a)** RECEIVE DATE & TIME: **10/18/2013 19:47** PRINT DATE & TIME: **10/24/2013 06:05**  
 REQUISITION NO.: **30920906** PT. PHONE NO.: **0** PATIENT NO.: **AKP001**  
 COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
---Footnotes---					
(a) Duplicate tests are printed on this report					
Allerg, Panel 18 Collected on: 10/18/2013 15:00					
Allerg, Juniper		<b>9.80</b> H	kU/L	<0.35	
Allerg, Cottonwood	<0.10		kU/L	<0.35	
Allerg, West. Ragweed	0.20		kU/L	<0.35	
Allerg, Russian Thistle	<0.10		kU/L	<0.35	
Allerg, Bermuda Grass	<0.10		kU/L	<0.35	
Allerg, Alternaria	<0.10		kU/L	<0.35	
Allerg, Mesquite	<0.10		kU/L	<0.35	
Allerg, Cockroach	<0.10		kU/L	<0.35	
Allerg, Derm. pter.			kU/L	<0.35	

Quantity not sufficient  
 Unable to assay, test credited, please resubmit.

Allerg, Derm. farinae kU/L <0.35  
 quantity not sufficient  
 Unable to assay, test credited, please resubmit.

Allerg, Clad. herb. <0.10 kU/L <0.35  
 Allerg, Firebush <0.10 kU/L <0.35  
 Allerg, Cat Dander Ep kU/L <0.35

Quantity not sufficient  
 Unable to assay, test credited, please resubmit.

Allerg, Dog Dander **10.70** H kU/L <0.35

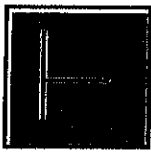
The standard classification system utilizes the following class cutoffs.

Class	ku/L	Interpretation
0	<0.35	Negative for Allergen
I	0.35-0.69	Positive for Allergen
II	0.70-3.49	Strongly Positive
III	3.5-17.49	Strongly Positive
IV	17.5-52.49	Strongly Positive
V	52.5-99.99	Strongly Positive
VI	>100	Strongly Positive

Results with allergens scoring in Class 1 should be considered weakly positive or equivocal. Class 2 and higher should be considered positive. Although increasing class ranges (0-VI) are reflective of increasing concentrations of allergen-specific IgE, this may not correlate with the degree of clinical response when challenged with the specific allergen. The correlation of allergy laboratory results with clinical history is essential. A negative test may not rule out clinical allergy.

Allerg, Bluegrass <0.10 kU/L <0.35  
 Allerg, Pigweed <0.10 kU/L <0.35  
 Allerg, Mulberry kU/L <0.35  
 quantity not sufficient

*Handwritten:* Sub-I  
 24 Oct 2013



Name: BLS,  
 Gender: Male  
 Age: 65 Race: Caucasian  
 Height(in): 74.0 Weight(lb): 270  
 Any Info:

Id: AKP-001  
 Date: 11/06/13  
 Temp: 19 PBar: 637  
 Physician:  
 Technician: dg

Spirometry		(BTPS)	PRE-RX		POST-RX		Post
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	% Chg
FVC	Liters	5.15	5.16	100			
FEV1	Liters	4.09	3.60	88			
FEV1/FVC	%	78	70	89			
FEF25-75%	L/sec	4.01	2.08	52			
FEF50%	L/sec	4.94	3.86	78			
FEF75%	L/sec	1.85	0.50	27			
IC	Liters						
VC	Liters	5.15					
PEF	L/sec	9.40	7.01	75			
MVV	L/min	148					
PIF	L/sec		2.80				
FEV1/FEV6%			77				

**Lung Volumes/Plethysmography**

Vtg	Liters	
VC	Liters	5.15
TLC	Liters	7.54
RV	Liters	2.73
RV/TLC	%	39
FRC PL	Liters	3.71
ERV	Liters	
IC	Liters	

**Diffusion**

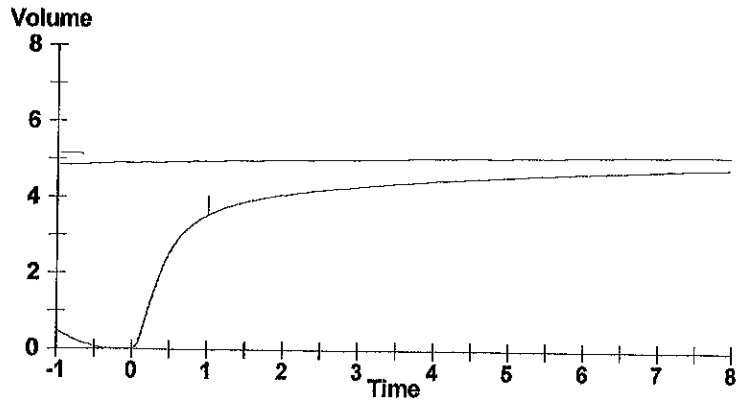
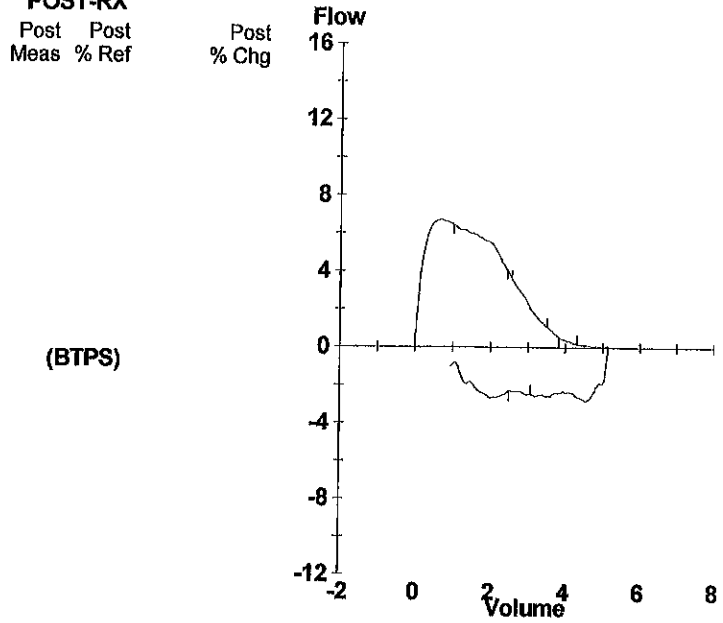
DLCO	mL/mmHg/min	29.6
DL Adj	mL/mmHg/min	29.6
DLCO/VA	mL/mHg/min/L	3.11
VA	Liters	
BHT	Sec	

**Resistance**

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.20
Gaw	L/sec/cmH2O	0.890
sRaw	cmH2O/L/s/L	4.44
sGaw	L/s/cmH2O/L	0.225
Vtg (Raw)	Liters	

Comments:

Interpretation:





Name: BLS,  
 Gender: Male  
 Age: 65 Race: Caucasian  
 Height(in): 74.0 Weight(lb): 270  
 Any Info:

Id: AKP-001  
 Date: 11/13/13  
 Temp: 19 PBar: 640  
 Physician:  
 Technician: VL

Spirometry		(BTPS)	PRE-RX		POST-RX		Post	Flow
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	% Chg	
FVC	Liters	5.15	4.75	92				
FEV1	Liters	4.09	3.42	84				
FEV1/FVC	%	78	72	92				
FEF25-75%	L/sec	4.01	2.69	67				
FEF50%	L/sec	4.94	3.83	78				
FEF75%	L/sec	1.85	1.01	54				
IC	Liters							
VC	Liters	5.15						
PEF	L/sec	9.40	8.71	93				
MVV	L/min	148						
PIF	L/sec		2.28					
FEV1/FEV6%			75					

Lung Volumes/Plethysmography

Vtg	Liters	
VC	Liters	5.15
TLC	Liters	7.54
RV	Liters	2.73
RV/TLC	%	39
FRC PL	Liters	3.71
ERV	Liters	
IC	Liters	

Diffusion

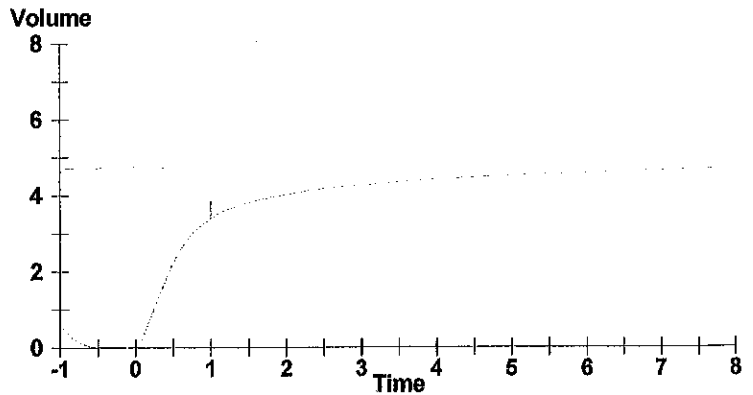
DLCO	mL/mmHg/min	29.6
DL Adj	mL/mmHg/min	29.6
DLCO/VA	mL/mHg/min/L	3.13
VA	Liters	
BHT	Sec	

Resistance

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.20
Gaw	L/sec/cmH2O	0.890
sRaw	cmH2O/L/s/L	4.44
sGaw	L/s/cmH2O/L	0.225
Vtg (Raw)	Liters	

Comments:

Interpretation:





Name: BLS,  
 Gender: Male  
 Age: 65 Race: Caucasian  
 Height(in): 74.0 Weight(lb): 278  
 Any Info:

Id: akp-001  
 Date: 11/20/13  
 Temp: 20 PBar: 628  
 Physician:  
 Technician: VL

Spirometry		(BTPS)	PRE-RX		POST-RX		Post
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	% Chg
FVC	Liters	5.15	4.51	88			
FEV1	Liters	4.09	3.31	81			
FEV1/FVC	%	78	73	94			
FEF25-75%	L/sec	4.01	2.44	61			
FEF50%	L/sec	4.94	3.31	67			
FEF75%	L/sec	1.85	1.01	55			
IC	Liters						
VC	Liters	5.15					
PEF	L/sec	9.40	8.85	94			
MVV	L/min	148					
PIF	L/sec		4.82				
FEV1/FEV6%			75				

Lung Volumes/Plethysmography

Vtg	Liters	
VC	Liters	5.15
TLC	Liters	7.54
RV	Liters	2.73
RV/TLC	%	39
FRC PL	Liters	3.65
ERV	Liters	
IC	Liters	

Diffusion

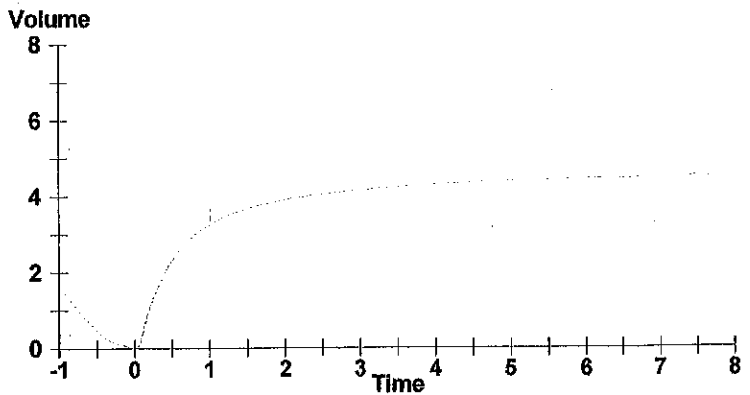
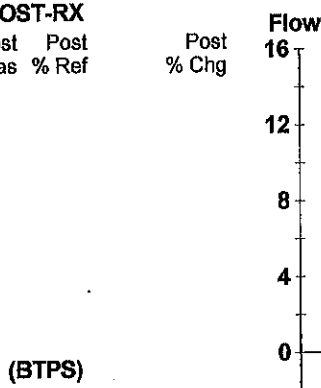
DLCO	mL/mmHg/min	30.1
DL Adj	mL/mmHg/min	30.1
DLCO/VA	mL/mHg/min/L	3.07
VA	Liters	
BHT	Sec	

Resistance

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.22
Gaw	L/sec/cmH2O	0.877
sRaw	cmH2O/L/s/L	4.46
sGaw	L/s/cmH2O/L	0.224
Vtg (Raw)	Liters	

Comments:

Interpretation:







Name: BLS,  
 Gender: Male  
 Age: 65 Race: Caucasian  
 Height(in): 74.0 Weight(lb): 278  
 Any Info:

Id: AKP-001  
 Date: 11/27/13  
 Temp: 19 PBar: 637  
 Physician:  
 Technician: VL

Spirometry		(BTPS)	PRE-RX		POST-RX		Post
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	% Chg
FVC	Liters	5.15	4.89	95			
FEV1	Liters	4.09	3.66	89			
FEV1/FVC	%	78	75	96			
FEF25-75%	L/sec	4.01	2.80	70			
FEF50%	L/sec	4.94	3.89	79			
FEF75%	L/sec	1.85	0.98	53			
IC	Liters						
VC	Liters	5.15					
PEF	L/sec	9.40	11.41	121			
MVV	L/min	148					
PIF	L/sec		4.00				
FEV1/FEV6%			77				

Lung Volumes/Plethysmography

Vtg	Liters	
VC	Liters	5.15
TLC	Liters	7.54
RV	Liters	2.73
RV/TLC	%	39
FRC PL	Liters	3.65
ERV	Liters	
IC	Liters	

Diffusion

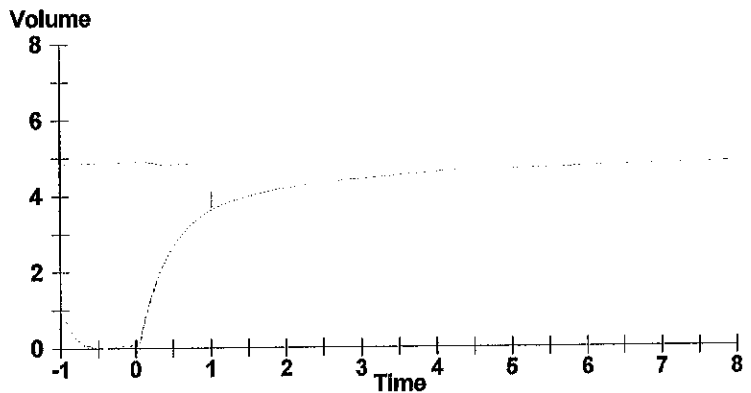
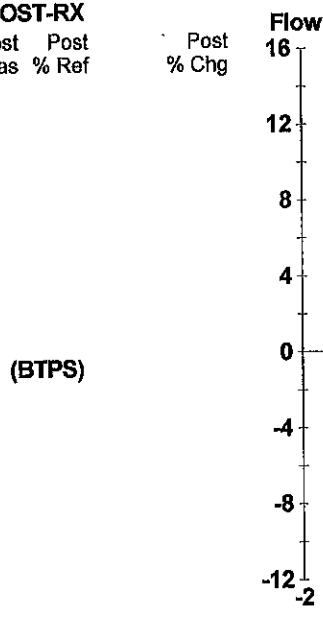
DLCO	mL/mmHg/min	30.1
DL Adj	mL/mmHg/min	30.1
DLCO/VA	mL/mHg/min/L	3.11
VA	Liters	
BHT	Sec	

Resistance

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.22
Gaw	L/sec/cmH2O	0.877
sRaw	cmH2O/L/s/L	4.46
sGaw	L/s/cmH2O/L	0.224
Vtg (Raw)	Liters	

Comments:

Interpretation:



EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT

Next day  
↙

DAILY SYMPTOMS SCORE SHEET (SCREEN DIARY)  
CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

DAY	7	8	9	10	11	12	13	14	15	16	17
AM	10/30	10/31	11/1	11/2	11/3	11/4	11/5	11/6	11/7		
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
DAY PM	11/7	11/8	11/9	11/10	11/11	11/12	11/13	11/14	11/15	11/16	11/17
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N=No

SUBJECT NUMBER: AKP001

DATE COMPLETED: 11/6/13

SUBJECT INITIALS AND DATE: BD 11/6/13



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Scientific Resources  
 Leslie Byatt, MD  
 2441 Ridgecrest Dr SE  
 Albuquerque, NM 87108-5129

Client Nbr  
 24684

PATIENT NAME: **X, BLS** PATIENT ID: **AAGH2825** DOB: **06/25/1948** SEX: **M** REPORT STATUS: **Final** PAGE: **1**  
 PHYSICIAN: **Unlisted Physician,** COLLECT DATE & TIME: **11/06/2013 16:32 (a)** RECEIVE DATE & TIME: **11/07/2013 00:06** PRINT DATE & TIME: **11/08/2013 15:32**  
 REQUISITION NO.: **30920949** PT. PHONE NO.: **0** PATIENT NO.: **AKP001**  
 COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			

---Footnotes---

(a) Duplicate tests are printed on this report

Comp Metabolic Panel Collected on: 11/06/2013 16:32  
 Sodium **142**  
 Potassium **4.5**  
 Chloride **107**  
 CO2 **25**  
 Anion Gap **10**  
 Glucose **88**  
 BUN **20**  
 Creatinine **1.13**

mmol/L 134-144  
 mmol/L 3.5-5.1  
 mmol/L 98-111  
 mmol/L 20-30  
 6-14  
 mg/dL 60-100  
 mg/dL 7-31  
 mg/dL 0.62-1.68

Creatinine method is IDMS traceable. EstGFR Calculation has been adjusted.  
 Please note new reference range effective 5/23/2013.

eGFR non-African Am **>60** mL/min/1.73m2 **>60**  
 GFR Comment

Estimated GFR values are not accurate in acute kidney failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, the very old or very young, races other than Caucasian or African American, people with acute illnesses, or amputations.

Calcium **10.1** mg/dL 8.4-10.4  
 Total Protein **7.3** gm/dL 6.1-8.2  
 Albumin **4.6** gm/dL 3.4-4.7  
 Globulin **2.7** gm/dL 2.4-4.2  
 Bilirubin, total **0.9** mg/dL 0.3-1.2  
 Alk Phos **79** U/L 38-150  
 AST(SGOT) **20** U/L 6-58  
 ALT(SGPT) **35** U/L 14-67

Collected on: 11/06/2013 16:32  
 Fasting **NO**

CBC Collected on: 11/06/2013 16:32  
 WBC **6.8**  
 RBC **5.79**  
 Hgb **18.5**  
 Hct **55**  
 MCV **95**  
 MCHC **33.8**  
 RDW **12.7**  
 Platelets **168**

x10E3 4.0-10.6  
 x10E6 4.64-6.00  
 gm/dL 14.5-17.7  
 % 42-53  
 fL 81-98  
 gm/dL 31.2-35.2  
 % 11.0-14.5  
 x10E3 150-400

*12 Nov 13  
 NCS MDM  
 NCS MDM  
 12 Nov 13*

Collected on: 11/06/2013 16:32  
 Phys, Addr, Phone

NO PHYSICIAN LISTED

Collected on: 11/06/2013 16:32  
 Phys, Addr, Phone

NOT GIVEN

Collected on: 11/06/2013 16:32  
 Important Info

Client notified that no specimen(s) were received for the following tests:  
 A specimen for CMP was received and per client the slides were sent for Eosinophil Count.

End of Report

*MDM MDM  
 12 Nov 13*

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS	1	2	3	4	5	6	7	8	9
DAY AM	11/06/13	11/07/13	11/08/13	11/09/13	11/10/13	11/11/13	11/12/13	11/13/13	11/14/13
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
DAY PM	1 4	2 8	3 4	4 4	4 5 4	4 6	4 7	8	9
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N=No

SUBJECT NUMBER: BLS

DATE COMPLETED: 11/13/13

SUBJECT INITIALS AND DATE: BS 11-13-13



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505 ) 938-8922

Lovelace Scientific Resources  
Leslie Byatt, Clin Trials  
2441 Ridgecrest Dr SE  
Albuquerque, NM 87108-5129

Client Nbr  
24664

PATIENT NAME <b>BLS, BLS</b>	PATIENT ID <b>AAGH6054</b>	DOB <b>06/25/1948</b>	SEX <b>M</b>	REPORT STATUS <b>Final</b>	PAGE <b>1</b>
PHYSICIAN <b>Unlisted Physician,</b>	COLLECT DATE & TIME <b>11/13/2013 15:10</b>	RECEIVE DATE & TIME <b>11/13/2013 20:27</b>	PRINT DATE & TIME <b>11/14/2013 06:10</b>		
REQUISITION NO. <b>30920935</b>	PT. PHONE NO. <b>0</b>	PATIENT NO. <b>AKP001</b>			
COMMENTS :					

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Eos, Respiratory Phys, Addr, Phone	None seen			NS	
	NO PHYSICIAN INDICATED				

*NCS*

*Jalyn PI 18 Nov 2013*

End of Report

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)

ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

DAY AM	4 <sup>1</sup> 11/13/13	4 <sup>2</sup> 11/14/13	4 <sup>3</sup> 11/15/13	4 <sup>4</sup> 11/16/13	4 <sup>5</sup> 11/17/13	4 <sup>6</sup> 11/18/13	4 <sup>7</sup> 11/19/13	4 <sup>8</sup> 11/20/13	4 <sup>9</sup> 11/21/13
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
<b>DAY PM</b>	<b>4 1</b>	<b>4 2</b>	<b>4 3</b>	<b>4 4</b>	<b>4 5 4</b>	<b>4 6 4</b>	<b>4 7</b>	<b>8</b>	<b>9</b>
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N= No

SUBJECT NUMBER: AKP01 DATE COMPLETED: 11/13/13 - 11/21/13

SUBJECT INITIALS AND DATE: BD 11-20-13



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505 ) 938-8922

Lovelace Scientific Resources  
Leslie Byatt, MD  
2441 Ridgecrest Dr SE  
Albuquerque, NM 87108-5129

Client Nbr  
24864

PATIENT NAME <b>BLS, BLS</b>	PATIENT ID <b>AAGG3648</b>	DOB <b>06/25/1948</b>	SEX <b>M</b>	REPORT STATUS <b>Final</b>	PAGE <b>1</b>
PHYSICIAN <b>Unlisted Physician,</b>	COLLECT DATE & TIME <b>11/20/2013 15:30</b>	RECEIVE DATE & TIME <b>11/20/2013 20:12</b>	PRINT DATE & TIME <b>11/21/2013 06:06</b>		
REQUISITION NO. <b>30920939</b>	PT. PHONE NO. <b>0</b>	PATIENT NO. <b>AKP001</b>			
COMMENTS :					

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Eos, Respiratory Phys, Addr, Phone		Rare		NS	
	NO PHYSICIAN GIVEN				

*NCS  
11/21 Nov 2013*

*Salzer - PI  
21 Nov 2013*

End of Report

Study Identification: AKP has me Sheet 2/10/14  
AKI 2002/14  
 Subject Number: 020 001 LSR Study #: 2744 2749  
 Subject Initials: BLS

**ADVERSE EVENT LOG**

Adverse Event	** Start Date (DD/MMM/YYYY)	SEVERITY	Relationship to Study Drug (Suspected/Not Suspected)	** End Date (DD/MMM/YYYY)	Action Taken	Investigator Initials/Date
<i>None</i>						
						/
						/
						/
						/
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						/
						/
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						/
						/
						/
						/
						/

\*\* If day is unknown, write UNK in space provided, but every effort should be made to be as specific as possible \*\*

Investigator Signature (at end of study): [Signature] Date: 27 Nov 2013  
 SC Signature (at end of study): [Signature] Date: 11/27/13



2749 AKPharma PERENNIAL ALLERGIES  
V6/DAY 21 SOURCE DOCUMENTS

Initials: BLS Site #: — Subject #: 001 AKP

**CONCURRENT MEDICATION (See LSR Worksheet)**

LSR Concurrent Medication Worksheet Completed:  YES  NO  
If, no please comment: NO new meds reported

**Note: Review Medications regarding Disallowed Medications and for Specific Washout Windows.**

**Adverse Events (Update Worksheet)**

Did the patient experience a new adverse event:  YES  NO  
If, yes please comment: NO changes in health

Did the patient experience have a change to an existing AE:  YES  NO  N/A  
If, yes please comment: \_\_\_\_\_

**URINE PREGNANCY TEST (Please attach results)**

Date Collected: \_\_\_\_\_ (dd/mmm/yy)

N/A  
male

Panel	Please circle one	Sample Time (24:00 hr)	Result
Pregnancy Test β-HCG	Serum      Urine	____:____	<input type="checkbox"/> Positive* <input type="checkbox"/> Negative <input type="checkbox"/> N/A

\*If test returns a Positive result, the patient can not be enrolled.

CRC Signature: Ericka Maldonado Date: 27, Nov, 13 (dd/mmm/yy)

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)

ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY) S M T W

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

DAY	4 <sup>14</sup> 11/20	4 <sup>15</sup> 11/21	4 <sup>16</sup> 11/22	4 <sup>17</sup> 11/23	4 <sup>18</sup> 11/24	4 <sup>19</sup> 11/25	4 <sup>20</sup> 11/26	4 <sup>21</sup> 11/27	22
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
DAY PM	4 <sup>14</sup>	4 <sup>15</sup>	4 <sup>16</sup>	4 <sup>17</sup>	4 <sup>18</sup>	4 <sup>19</sup>	4 <sup>20</sup>	4 <sup>21</sup>	22
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N=No

SUBJECT NUMBER: AP001 DATE COMPLETED: 11/20/13

SUBJECT INITIALS AND DATE: AS 11-27-13

Start -> here.



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Scientific Resources  
 Leslie Byatt, Urin Trials  
 2441 Ridgecrest Dr SE  
 Albuquerque, NM 87108-5129

Client Nbr  
 24664

PATIENT NAME: **X, BLS**  
 PATIENT ID: **AAGH2825**    DOB: **06/25/1948**    SEX: **M**    REPORT STATUS: **Final**    PAGE: **1**  
 PHYSICIAN: **Unlisted Physician,**    COLLECT DATE & TIME: **11/27/2013 15:03**    RECEIVE DATE & TIME: **11/27/2013 18:42**    PRINT DATE & TIME: **11/28/2013 06:11**  
 REQUISITION NO.: **30920955**    PT. PHONE NO.: **0**    PATIENT NO.: **AKP001**  
 COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
<b>Comp Metabolic Panel</b>					
Sodium	140		mmol/L	134-144	
Potassium	3.8		mmol/L	3.5-5.1	
Chloride	105		mmol/L	98-111	
CO2	28		mmol/L	20-30	
Anion Gap	7			6-14	
Glucose		109	mg/dL	60-100	
Impaired fasting glucose (IFG) is defined as a fasting glucose level of 100-126 mg/dL. (ADA Guidelines Diabetes Care 26: (3160-3167)2003)					
BUN	13		mg/dL	7-31	
Creatinine	1.05		mg/dL	0.62-1.66	
Creatinine method is IDMS traceable. EstGFR Calculation has been adjusted.					
Please note new reference range effective 5/23/2013.					
eGFR non-African Am	>60		mL/min/1.73m2	>60	
GFR Comment	Estimated GFR values are not accurate in acute kidney failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, the very old or very young, races other than Caucasian or African American, people with acute illnesses, or amputations.				
Calcium	9.2		mg/dL	8.4-10.4	
Total Protein	6.9		gm/dL	6.1-8.2	
Albumin	4.3		gm/dL	3.4-4.7	
Globulin	2.6		gm/dL	2.4-4.2	
Bilirubin, total	0.9		mg/dL	0.3-1.2	
Alk Phos	68		U/L	38-150	
AST(SGOT)	21		U/L	6-58	
ALT(SGPT)	38		U/L	14-67	
Fasting Phosphorus	NO				
Phosphorus	2.7		mg/dL	2.3-5.6	
<b>CBC</b>					
WBC	6.2		x10E3	4.0-10.6	
RBC	5.64		x10E6	4.64-6.00	
Hgb	17.5		gm/dL	14.5-17.7	
Hct	53		%	42-53	
MCV	94		fL	81-98	
MCHC	33.1		gm/dL	31.2-35.2	
RDW	12.6		%	11.0-14.5	
Platelets	158		x10E3	150-400	
Eos, Respiratory Phys, Addr, Phone	Not given			NS	

*NCS JS 2 Dec 2013*

*Rare*  
*NCS JS 2 Dec 2013*

*Salzer PI 2 Dec 2013*

BLS / AKP  
001

11/27/13

**Effects of AkPharma's Calcium Glycerophosphate  
Nasal Spray wash (AkP 010112A) on Patient-Perceived Breathing Comfort**

**SATISFACTION QUESTIONNAIRE:**

Would you use / purchase this nasal wash product in the future?"  YES  NO

You are also encouraged to make any free comments regarding your experience in the use of this product regarding your opinion of any of its effects not covered specifically in the Daily Diary:

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[Type text]  
Subject initials and Date B 11-27-13

Study Staff Initials and Date Em 11/27/13

**AKP-003**

4749 AKPharma PERENNIAL ALLERGIES  
SCREENING/VISIT 1 SOURCE DOCUMENTS

Initials: MJC Site #: \_\_\_\_\_ Subject #: AKP003

PATIENT DEMOGRAPHICS

**Patient Demographics**

Date of Birth: 23, Aug, 1944 (dd/mmm/yyyy)

Gender:  Male  Female

If female, Indicate Childbearing Potential NA

Childbearing  Surgically sterilized  Post-Menopausal

Ethnicity:  Hispanic  Non Hispanic

Race:  Asian  Black  Caucasian  American Indian

Pacific Islander  Other, Specify \_\_\_\_\_

**Smoking History**

Smoking Status:  None (smoked less than 100 cigarettes in lifetime)

Former (previously smoked more than 100 cigarettes in lifetime)

Current (smokes now)

If subject is a former or current smoker, please indicate:

Years smoked: 28 Cigarettes per day: 10

CRC Signature: Erica Maldonado Date: 23 Sep 2013 (dd/mmm/yyyy)



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Scientific Resources  
Clin Trials/ Leslie Byatt  
2441 Ridgecrest Dr SE  
Albuquerque, NM 87108

Client Nbr  
24864

PATIENT NAME: **X, MJC** PATIENT ID: **AAGF0188** DOB: **08/23/1944** SEX: **M** REPORT STATUS: **Final** PAGE: **1**

PHYSICIAN: **Unlisted Physician,** COLLECT DATE & TIME: **09/23/2013 08:20** RECEIVE DATE & TIME: **09/23/2013 19:01** PRINT DATE & TIME: **09/25/2013 06:07**

REQUISITION NO.: **30920879** PT. PHONE NO.: **0** PATIENT NO.: **AKP003**

COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Allerg, Panel 18					
Allerg, Juniper		23.10 H	KU/L	<0.35	
Allerg, Cottonwood		15.20 H	KU/L	<0.35	
Allerg, West. Ragweed		1.40 H	KU/L	<0.35	
Allerg, Russian Thistle		16.60 H	KU/L	<0.35	
Allerg, Bermuda Grass		9.20 H	KU/L	<0.35	
Allerg, Alternaria	<0.10		KU/L	<0.35	
Allerg, Mesquite		14.20 H	KU/L	<0.35	
Allerg, Cockroach		0.60 H	KU/L	<0.35	
Allerg, Derm. pter.	0.30		KU/L	<0.35	

The standard classification system utilizes the following class cutoffs.

Class	ku/L	Interpretation
0	<0.35	Negative for Allergen
I	0.35-0.69	Positive for Allergen
II	0.70-3.49	Strongly Positive
III	3.5-17.49	Strongly Positive
IV	17.5-52.49	Strongly Positive
V	52.5-99.99	Strongly Positive
VI	>100	Strongly Positive

Results with allergens scoring in Class 1 should be considered weakly positive or equivocal. Class 2 and higher should be considered positive. Although increasing class ranges (0-vi) are reflective of increasing concentrations of allergen-specific IgE, this may not correlate with the degree of clinical response when challenged with the specific allergen. The correlation of allergy laboratory results with clinical history is essential. A negative test may not rule out clinical allergy.

Allerg, Derm. farinae	0.30		KU/L	<0.35
Allerg, Clad. herb.		0.40 H	KU/L	<0.35
Allerg, Firebush		8.70 H	KU/L	<0.35
Allerg, Cat Dander Ep	<0.10		KU/L	<0.35
Allerg, Dog Dander		0.40 H	KU/L	<0.35
Allerg, Bluegrass		7.80 H	KU/L	<0.35
Allerg, Pigweed		15.70 H	KU/L	<0.35
Allerg, Mulberry		9.20 H	KU/L	<0.35
Allerg, Helminth	<0.10		KU/L	<0.35
Phys, Addr, Phone	NOT GIVEN			

End of Report

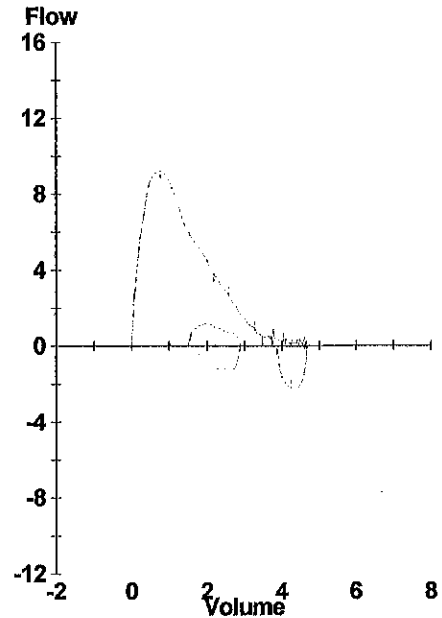
*Meets inclusion criteria  
 for Russian Thistle, Western Ragweed,  
 Cockroach and dog dander*  
*Walter  
 9/25/13*



Name: MJC,  
 Gender: Male  
 Age: 69 Race: Caucasian  
 Height(in): 72.0 Weight(lb): 187  
 Any Info:

Id: AKP-003  
 Date: 10/09/13  
 Temp: 20 PBar: 628  
 Physician:  
 Technician:

Spirometry		(BTPS)	PRE-RX		POST-RX		Post
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	% Chg
FVC	Liters	4.61	4.89	102			
FEV1	Liters	3.64	3.35	92			
FEV1/FVC	%	78	71	91			
FEF25-75%	L/sec	3.57	1.94	54			
FEF50%	L/sec	4.45	3.50	79			
FEF75%	L/sec	1.60	0.49	31			
IC	Liters						
VC	Liters	4.61					
PEF	L/sec	8.78	9.23	105			
MVV	L/min	136					
PIF	L/sec		2.32				
FEV1/FEV6%			75				



Lung Volumes/Plethysmography

Vtg	Liters	
VC	Liters	4.61
TLC	Liters	7.00
RV	Liters	2.66
RV/TLC	%	40
FRC PL	Liters	4.01
ERV	Liters	
IC	Liters	

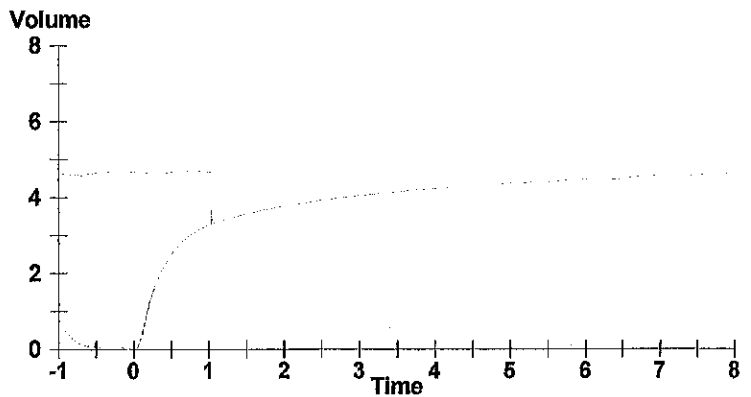
Diffusion

DLCO	mL/mmHg/min	22.5
DL Adj	mL/mmHg/min	22.5
DLCO/VA	mL/mHg/min/L	2.98
VA	Liters	
BHT	Sec	

Resistance

Raw Total	cmH2O/L/sec	
Raw insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.09
Gaw	L/sec/cmH2O	0.963
sRaw	cmH2O/L/s/L	4.36
sGaw	L/s/cmH2O/L	0.229
Vtg (Raw)	Liters	

Comments:



Interpretation:





Name: MJC,  
 Gender: Male  
 Age: 69 Race: Caucasian  
 Height(in): 72.0 Weight(lb): 180  
 Any Info:

Id: AKP-003  
 Date: 10/16/13  
 Temp: 19 PBar: 631  
 Physician:  
 Technician: VL

Spirometry		(BTPS)	PRE-RX		POST-RX		Post
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	% Chg
FVC	Liters	4.61	4.77	103			
FEV1	Liters	3.64	3.45	95			
FEV1/FVC %		78	72	93			
FEF25-75%L/sec		3.57	2.50	70			
FEF50%	L/sec	4.45	4.10	92			
FEF75%	L/sec	1.60	0.77	48			
IC	Liters						
VC	Liters	4.61					
PEF	L/sec	8.78	9.22	105			
MVV	L/min	136					
PIF	L/sec		3.78				
FEV1/FEV6%			75				

Lung Volumes/Plethysmography

Vtg	Liters	
VC	Liters	4.61
TLC	Liters	7.00
RV	Liters	2.66
RV/TLC	%	40
FRC PL	Liters	4.07
ERV	Liters	
IC	Liters	

Diffusion

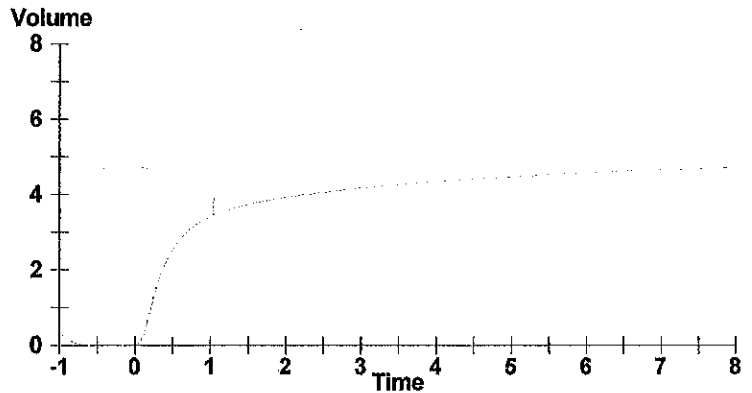
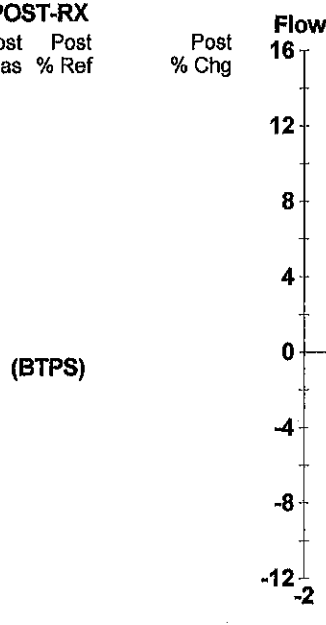
DLCO	mL/mmHg/min	22.0
DL Adj	mL/mmHg/min	22.0
DLCO/VA	mL/mHg/min/L	3.00
VA	Liters	
BHT	Sec	

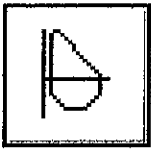
Resistance

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.07
Gaw	L/sec/cmH2O	0.977
sRaw	cmH2O/L/s/L	4.35
sGaw	L/s/cmH2O/L	0.230
Vtg (Raw)	Liters	

Comments:

Interpretation:





Name: MJC,  
 Gender: Male  
 Age: 69 Race: Caucasian  
 Height(in): 72.0 Weight(lb): 187  
 Any Info:

Id: AKP-003  
 Date: 10/23/13  
 Temp: 20 PBar: 634  
 Physician:  
 Technician: VL

Spirometry		(BTPS)	PRE-RX		POST-RX		Post % Chg
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	
FVC	Liters	4.61	4.85	105			
FEV1	Liters	3.64	3.42	94			
FEV1/FVC	%	78	70	90			
FEF25-75%	L/sec	3.57	2.11	59			
FEF50%	L/sec	4.45	3.63	82			
FEF75%	L/sec	1.60	0.58	36			
IC	Liters						
VC	Liters	4.61					
PEF	L/sec	8.78	10.33	118			
MVV	L/min	136					
PIF	L/sec						
FEV1/FEV6%			74				

Lung Volumes/Plethysmography

Vtg	Liters	
VC	Liters	4.61
TLC	Liters	7.00
RV	Liters	2.66
RV/TLC	%	40
FRC PL	Liters	4.01
ERV	Liters	
IC	Liters	

Diffusion

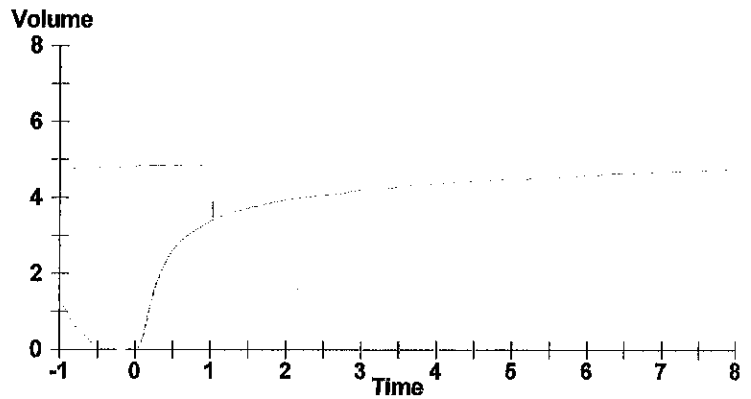
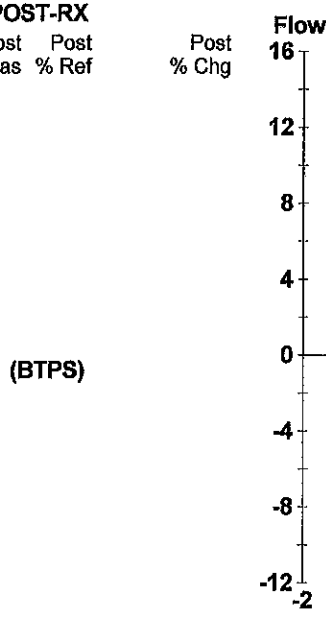
DLCO	mL/mmHg/min	22.5
DL Adj	mL/mmHg/min	22.5
DLCO/VA	mL/mHg/min/L	3.02
VA	Liters	
BHT	Sec	

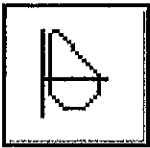
Resistance

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.09
Gaw	L/sec/cmH2O	0.963
sRaw	cmH2O/L/s/L	4.36
sGaw	L/s/cmH2O/L	0.229
Vtg (Raw)	Liters	

Comments:

Interpretation:





Name: MJC,  
 Gender: Male  
 Age: 69 Race: Caucasian  
 Height(in): 72.0 Weight(lb): 183  
 Any Info:

Id: AKP-003  
 Date: 10/30/13  
 Temp: 21 PBar: 629  
 Physician:  
 Technician: VL

Spirometry		(BTPS)	PRE-RX		POST-RX		Post
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	% Chg
FVC	Liters	4.61	4.76	103			
FEV1	Liters	3.64	3.48	95			
FEV1/FVC	%	78	73	94			
FEF25-75%	L/sec	3.57	2.40	67			
FEF50%	L/sec	4.45	3.64	82			
FEF75%	L/sec	1.60	0.66	41			
IC	Liters						
VC	Liters	4.61					
PEF	L/sec	8.78	9.85	112			
MVV	L/min	136					
PIF	L/sec		1.09				
FEV1/FEV6%			76				

Lung Volumes/Plethysmography

		(BTPS)
Vtg	Liters	
VC	Liters	4.61
TLC	Liters	7.00
RV	Liters	2.66
RV/TLC	%	40
FRC PL	Liters	4.04
ERV	Liters	
IC	Liters	

Diffusion

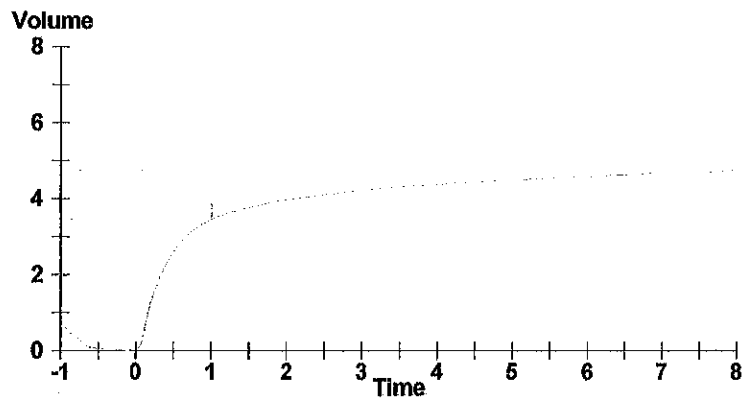
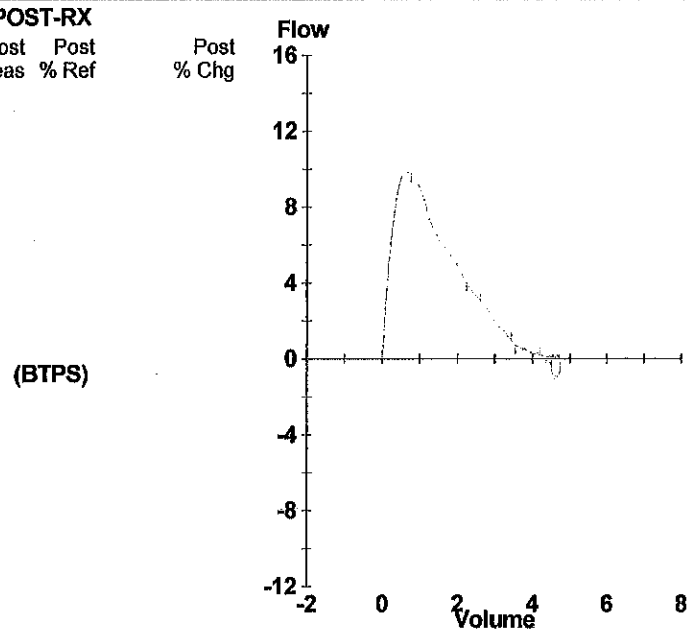
DLCO	mL/mmHg/min	22.2
DL Adj	mL/mmHg/min	22.2
DLCO/VA	mL/mHg/min/L	2.99
VA	Liters	
BHT	Sec	

Resistance

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.08
Gaw	L/sec/cmH2O	0.971
sRaw	cmH2O/L/s/L	4.36
sGaw	L/s/cmH2O/L	0.230
Vtg (Raw)	Liters	

Comments:

Interpretation:



EFFECTS OF AIKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AIKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (SCREEN DIARY)  
CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

Next visit 10:15am

DAY AM	-7	-6	-5	-4	-3	-2	-1	0	0
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
DAY PM	-7	-6	-5	-4	-3	-2	-1	0	0
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

SCALE 0 to 3

- 0= No symptoms (no symptoms detected)
  - 1= Mild symptoms (symptoms present but easily tolerated)
  - 2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)
  - 3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)
- Y=Yes N=No

SUBJECT NUMBER: AKP-003 DATE COMPLETED: 10-2-13 SUBJECT INITIALS AND DATE: Am J 10-2-13



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Scientific Resources  
 Clin Trials-Leslie Byatt  
 2441 Ridgecrest Dr SE  
 Albuquerque, NM 87108

Client Nbr  
 24664

PATIENT NAME: **MJC, MJC** PATIENT ID: **AAGF8916** DOB: **08/23/1944** SEX: **M** REPORT STATUS: **Final** PAGE: **1**  
 PHYSICIAN: **Unlisted Physician,** COLLECT DATE & TIME: **10/09/2013 10:26** RECEIVE DATE & TIME: **10/09/2013 20:52** PRINT DATE & TIME: **10/11/2013 06:10**  
 REQUISITION NO.: **30920909** PT. PHONE NO.: **0** PATIENT NO.: **AKP003**  
 COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Eos, Respiratory		Rare *		NS	
Comp Metabolic Panel					
Sodium	137		mmol/L	134-144	
Potassium	4.2		mmol/L	3.5-5.1	
Chloride	104		mmol/L	98-111	
CO2	23		mmol/L	20-30	
Anion Gap	10			6-14	
Glucose		116 H	mg/dL	80-100	<i>Nes Order 11 Oct 13</i>
Impaired fasting glucose (IFG) is defined as a fasting glucose level of 100-126 mg/dL. (ADA Guidelines Diabetes Care 26: (3160-3167)2003)					
BUN	20		mg/dL	7-31	
Creatinine	1.10		mg/dL	0.62-1.66	
Creatinine method is IDMS traceable. EstGFR calculation has been adjusted. Please note new reference range effective 5/23/2013.					
eGFR non-African Am	>60		mL/min/1.73m2	>60	
GFR Comment	Estimated GFR values are not accurate in acute kidney failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, the very old or very young, races other than Caucasian or African American, people with acute illnesses, or amputations.				
Calcium	8.9		mg/dL	8.4-10.4	
Total Protein	6.9		gm/dL	6.1-8.2	
Albumin	4.4		gm/dL	3.4-4.7	
Globulin	2.5		gm/dL	2.4-4.2	
Bilirubin, total		1.3 H	mg/dL	0.3-1.2	<i>Nes Order 11 Oct 13</i>
Alk Phos	94		U/L	38-150	
AST(SGOT)	23		U/L	6-58	
ALT(SGPT)	41		U/L	14-67	
Fasting	NO				
CBC					
WBC	4.1		x10E3	4.0-10.6	
RBC	4.83		x10E6	4.64-6.00	
Hgb	16.0		gm/dL	14.5-17.7	
Hct	47		%	42-53	
MCV	96		fL	81-98	
MCHC	34.4		gm/dL	31.2-35.2	
RDW	12.3		%	11.0-14.5	
Platelets	179		x10E3	150-400	
Phys, Addr, Phone	Not given				
Important Info	Client contacted for clarification of test orders. Per client's request, the following test(s) will be performed: Eosinophils, Respiratory				

End of Report



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Cln Trials Lesire Byatt  
2441 Ridgecrest Dr SE  
Albuquerque, NM 87108

Client Nbr  
24664

PATIENT NAME **TGC, TGC** PATIENT ID **AAGF9554** DOB **04/30/1946** SEX **M** REPORT STATUS **Final** PAGE **1**

PHYSICIAN **Unlisted Physician,** COLLECT DATE & TIME **10/10/2013 08:00** RECEIVE DATE & TIME **10/10/2013 19:16** PRINT DATE & TIME **10/11/2013 06:10**

REQUISITION NO. **30920910** PT. PHONE NO. **0** PATIENT NO. **AKP006**

COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Eos, Respiratory Phys, Addr, Phone		Moderate *		NS	<i>NS</i> <i>11 Oct 13</i>

NO ORDERING PHYSICIAN

End of Report

**EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT**

**DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)**

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

DAY AM	1	2	3	4	5	6	7	8	9
Runny Nose 0 to 3	10/9/13 0 1 2 3	10/10/13 0 1 2 3	10/11/13 0 1 2 3	10/12/13 0 1 2 3	10/13/13 0 1 2 3	10/14/13 0 1 2 3	10/15/13 0 1 2 3	10/16/13 0 1 2 3	10/17/13 0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
<b>DAY PM</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>	<b>9</b>
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

AM  
3:30  
3rd  
Dose

**SCALE 0 to 3**

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N=No

SUBJECT NUMBER: AKP003 DATE COMPLETED: 10/9/13 - 10/16/13 SUBJECT INITIALS AND DATE: AKP 10-14-13



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2441 Ridgecrest Dr SE  
Albuquerque, NM 87108

Client Nbr  
24664

PATIENT NAME: **MJC, MJC**      PATIENT ID: **AAGF8916**      DOB: **08/23/1944**      SEX: **M**      REPORT STATUS: **Final**      PAGE: **1**

PHYSICIAN: **Unlisted Physician,**      COLLECT DATE & TIME: **10/16/2013 10:15**      RECEIVE DATE & TIME: **10/16/2013 20:38**      PRINT DATE & TIME: **10/17/2013 06:08**

REQUISITION NO.: **30920908**      PT. PHONE NO.: **0**      PATIENT NO.: **AKP003**

COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Eos, Respiratory Phys, Addr, Phone	None seen Not given	<i>NCS</i> <i>JS 10/18/13</i>		NS	
End of Report					

*NCS*      *Salzer PI 18 Oct 2013*

*Day 7*



EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

DAY AM	7	8	9	10	11	12	13	14	15
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
DAY PM	7	8	9	10	11	12	13	14	15
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

SCALE 0 to 3

- 0= No symptoms (no symptoms detected)
  - 1= Mild symptoms (symptoms present but easily tolerated)
  - 2= Moderate symptoms (awareness of symptoms; bothersome but tolerable)
  - 3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)
- Y=Yes N=No

SUBJECT NUMBER: AKP013 DATE COMPLETED: 10/23/13

SUBJECT INITIALS AND DATE:

AKP 10-23-13

Start  
Stop



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Leslie Byatt, Clin Trials  
2441 Ridgecrest Dr SE  
Albuquerque, NM 87108-5129

Client Nbr  
24664

PATIENT NAME **MJC, MJC** PATIENT ID **AAGF8916** DOB **08/23/1944** SEX **M** REPORT STATUS **Final** PAGE **1**

PHYSICIAN **Unlisted Physician,** COLLECT DATE & TIME **10/23/2013 10:30** RECEIVE DATE & TIME **10/24/2013 17:48** PRINT DATE & TIME **10/25/2013 06:09**

REQUISITION NO. **30920972** PT. PHONE NO. **0** PATIENT NO. **AKP003**

COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Eos, Respiratory Phys, Addr, Phone	None seen	Not given		NS	

End of Report

*From SubI  
29 Oct 2013*

Study Identification: 0749

Subject Number: AKP003

LSR Study #: \_\_\_\_\_

Subject Initials: MJC

### ADVERSE EVENT LOG

Adverse Event	** Start Date (DD/MMM/YYYY)	SEVERITY	Relationship to Study Drug (Suspected/Not Suspected)	** End Date (DD/MMM/YYYY)	Action Taken	Investigator Initials/Date
<del>NONE REPORTED Em 10/30/13</del>						

\*\* If day is unknown, write UNK in space provided, but every effort should be made to be as specific as possible \*\*

Investigator Signature (at end of study): [Signature] Date: 30 Oct 2013

SC Signature (at end of study): [Signature] Date: 10/30/13



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 Leslie Byatt, MD  
 2441 Ridgecrest Dr SE  
 Albuquerque, NM 87108-5129

Client Nbr  
 24664

PATIENT NAME: **MJC, MJC** PATIENT ID: **AAGF8916** DOB: **08/23/1944** SEX: **M** REPORT STATUS: **Final** PAGE: **1**  
 PHYSICIAN: **Unlisted Physician,** COLLECT DATE & TIME: **10/30/2013 10:23** RECEIVE DATE & TIME: **10/30/2013 19:48** PRINT DATE & TIME: **10/31/2013 06:06**  
 REQUISITION NO.: **30920966** PT. PHONE NO.: **0** PATIENT NO.: **AKP003**  
 COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
<b>Comp Metabolic Panel</b>					
Sodium	138		mmol/L	134-144	
Potassium	4.5		mmol/L	3.5-5.1	
Chloride	106		mmol/L	98-111	
CO2	28		mmol/L	20-30	
Anion Gap	6			6-14	
Glucose	92		mg/dL	60-100	
BUN	14		mg/dL	7-31	
Creatinine	1.16		mg/dL	0.62-1.66	
Creatinine method is IDMS traceable. EstGFR Calculation has been adjusted. Please note new reference range effective 5/23/2013.					
eGFR non-African Am	>60		mL/min/1.73m2	>60	
GFR Comment	Estimated GFR values are not accurate in acute kidney failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, the very old or very young, races other than Caucasian or African American, people with acute illnesses, or amputations.				
Calcium	8.8		mg/dL	8.4-10.4	
Total Protein	7.0		gm/dL	6.1-8.2	
Albumin	4.4		gm/dL	3.4-4.7	
Globulin	2.6		gm/dL	2.4-4.2	
Bilirubin, total		1.6 H	mg/dL	0.3-1.2	
Alk Phos	107		U/L	38-150	
AST(SGOT)	21		U/L	6-58	
ALT(SGPT)	34		U/L	14-67	
Fasting	Not given				
<b>CBC</b>					
WBC	5.3		x10E3	4.0-10.6	
RBC	4.74		x10E6	4.64-6.00	
Hgb	15.9		gm/dL	14.5-17.7	
Hct	46		%	42-53	
MCV	97		fL	81-98	
MCHC	34.6		gm/dL	31.2-35.2	
RDW	12.6		%	11.0-14.5	
Platelets	164		x10E3	150-400	
Eos, Respiratory	None seen				
Phys, Addr, Phone	Not given				

*NCS  
 Baber PT  
 1 Nov 2013*

End of Report

Study Identification: AKP003 2749 EM 9/23/13

LSR #: 2749

Subject Number: AKP003

Subject Initials: MJC

**CONCOMITANT MEDICATION LOG**

List all prescription medications you are taking. Also include over-the-counter medications, vitamins and supplements.

Name of Medication	Indication (What you take it for)	Dose	Unit	Frequency	Route	* Start Date (Day/Month/Year)	Stop Date	Ongoing at EOS (for Clinic use)
EXAMPLE	Diabetes	500	MG	2 Tabs per day	Oral	UNK/AUG/1999		<input type="checkbox"/>
Finasteride	BPH	5	mg	QD	oral	--/--/1997		<input checked="" type="checkbox"/>
Fluticasone	Seasonal allergies	50	mcg	<del>QD</del> PRN IH	PRN IH	--/--/1997	June 2013	<input type="checkbox"/>
Lisinopril	Hypertension	10	mg	QD	oral	--/--/2000		<input checked="" type="checkbox"/>
Loratadine	Seasonal allergies	10	mg	QD	oral	--/--/1998	9/24/13	<input checked="" type="checkbox"/>
Tamulosin	BPH	0.4	mg	QD	oral	--/--/1997		<input checked="" type="checkbox"/>
Cold (AlkaSeltzer) PLUS	Seasonal allergies	pkgs	pkgs	PRN	oral	--/--/2000	EM 9/23/13	<input type="checkbox"/>
Ibuprofen	osteoarthritis	800	mg	PRN	oral	--/--/2005	EM 9/23/13	<input checked="" type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>

\* If day or month of medication date is unknown, write UNK in space provided

Investigator Signature (at end of study): [Signature]

Date: 26 Feb 2014

SC Signature (at end of study): [Signature]

Date: 2/21/14

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

DAY	14	15	16	17	18	19	20	21	22
AM	10/23/13	10/24/13	10/25/13	10/26/13	10/27/13	10/28/13	10/29/13	10/30/13	
Runny Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Itchy Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Congestion 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Sneezing 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Voice Hoarse Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO
Throat Clearing Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO
DAY PM	14	15	16	17	18	19	20	21	22
Runny Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Itchy Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Congestion 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Sneezing 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Voice Hoarse Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO
Throat Clearing Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N=No

SUBJECT NUMBER: AKP003 DATE COMPLETED: 10/30/13

SUBJECT INITIALS AND DATE: AKP 10/30/13

Effects of AkPharma's Calcium Glycerophosphate  
Nasal Spray wash (AkP 010112A) on Patient-Perceived Breathing Comfort

MJC / AKP-003

SATISFACTION QUESTIONNAIRE:

Would you use / purchase this nasal wash product in the future?"  YES  NO

You are also encouraged to make any free comments regarding your experience in the use of this product regarding your opinion of any of its effects not covered specifically in the Daily Diary:

Trouble Free Experience

[Type text]

Subject initials and Date

MJC 10/30/13

Study Staff Initials and Date

EM 10/30/13

**AKP-004**



2,49 AKPharma PERENNIAL ALLERGIES  
SCREENING/VISIT 1 SOURCE DOCUMENTS

Initials: RJE Site #: \_\_\_\_\_ Subject #: AKP004

**PATIENT DEMOGRAPHICS**

**Patient Demographics**

Date of Birth: 10 Jun 1942 (dd/mmm/yyyy)

Gender:  Male  Female

If female, Indicate Childbearing Potential N/A

Childbearing  Surgically sterilized  Post-Menopausal

Ethnicity:  Hispanic  Non Hispanic

Race:  Asian  Black  Caucasian  American Indian

Pacific Islander  Other, Specify \_\_\_\_\_

**Smoking History**

Smoking Status:  None (smoked less than 100 cigarettes in lifetime)

Former (previously smoked more than 100 cigarettes in lifetime)

Current (smokes now)

If subject is a former or current smoker, please indicate:

Years smoked: 10 years

Cigarettes per day: 1 ppa

CRC Signature: Erica Maldonado

Date: 9/23/2013 (dd/mmm/yy)



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Science Resources  
 Clin Trials-Leslie Byatt  
 2441 Ridgecrest Dr SE  
 Albuquerque, NM 87108

Client Nbr  
 24664

PATIENT NAME: **X, RJE** PATIENT ID: **AAGF0190** DOB: **06/10/1942** SEX: **M** REPORT STATUS: **Final** PAGE: **1**

PHYSICIAN: **Unlisted Physician,** COLLECT DATE & TIME: **09/23/2013 11:00** RECEIVE DATE & TIME: **09/23/2013 19:02** PRINT DATE & TIME: **09/26/2013 06:06**

REQUISITION NO.: **30920880** PT. PHONE NO.: **0** PATIENT NO.: **AKP004**

COMMENTS :

Test	Result			Units	Reference Range	Site Code
	In Range	Out of Range				
Allerg,Panel 18						
Allerg,Juniper		9.20	H	KU/L	<0.35	
Allerg,Cottonwood		0.40	H	KU/L	<0.35	
Allerg,West.Ragweed	<0.10			KU/L	<0.35	
Allerg,Russian Thistle		7.30	H	KU/L	<0.35	
Allerg,Bermuda Grass	0.20			KU/L	<0.35	
Allerg,Alternaria	<0.10			KU/L	<0.35	
Allerg,Mesquite		0.70	H	KU/L	<0.35	
Allerg,Cockroach	<0.10			KU/L	<0.35	
Allerg,Derm. pter.	<0.10			KU/L	<0.35	
Allerg,Derm. farinae	<0.10			KU/L	<0.35	
Allerg,Clad. herb.	<0.10			KU/L	<0.35	
Allerg,Firebush		1.10	H	KU/L	<0.35	
Allerg,Cat Dander Ep		1.20	H	KU/L	<0.35	

The standard classification system utilizes the following class cutoffs.

Class	ku/L	Interpretation
0	<0.35	Negative for Allergen
I	0.35-0.69	Positive for Allergen
II	0.70-3.49	Strongly Positive
III	3.5-17.49	Strongly Positive
IV	17.5-52.49	Strongly Positive
V	52.5-99.99	Strongly Positive
VI	>100	Strongly Positive

Results with allergens scoring in Class 1 should be considered weakly positive or equivocal. Class 2 and higher should be considered positive. Although increasing class ranges (0-VI) are reflective of increasing concentrations of allergen-specific IgE, this may not correlate with the degree of clinical response when challenged with the specific allergen. The correlation of allergy laboratory results with clinical history is essential. A negative test may not rule out clinical allergy.

Allerg,Dog Dander	0.20			KU/L	<0.35
Allerg,Bluegrass		1.80	H	KU/L	<0.35
Allerg,Pigweed		1.90	H	KU/L	<0.35
Allerg,Mulberry		2.70	H	KU/L	<0.35
Allerg,Helminth	<0.10			KU/L	<0.35
Phys, Addr, Phone	NOT GIVEN				

End of Report

*Volunteer demonstrates reactivity to perennial allergens Cat Dander & epithelium and Russian Thistle. Meets inclusion criteria.*

X, RJE

09/26/2013 06:06

*Salvador  
 26 Sept 2013*

FAX24664



Name: RJE,  
 Gender: Male  
 Age: 71 Race: Caucasian  
 Height(in): 67.0 Weight(lb): 208  
 Any Info:

Id: AKP-004  
 Date: 10/08/13  
 Temp: 21 PBar: 632  
 Physician:  
 Technician: VL

Spirometry		(BTPS)	PRE-RX		POST-RX		Post % Chg
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	
FVC	Liters	3.45	3.51	102			
FEV1	Liters	2.72	2.48	91			
FEV1/FVC	%	79	70	89			
FEF25-75%	L/sec	2.75	1.58	57			
FEF50%	L/sec	3.49	2.16	62			
FEF75%	L/sec	1.15	0.52	45			
IC	Liters						
VC	Liters	3.45					
PEF	L/sec	7.51	6.96	93			
MVV	L/min	116					
PIF	L/sec						
FEV1/FEV6%			73				

Lung Volumes/Plethysmography

Vtg	Liters	
VC	Liters	3.45
TLC	Liters	5.78
RV	Liters	2.35
RV/TLC	%	41
FRC PL	Liters	3.01
ERV	Liters	
IC	Liters	

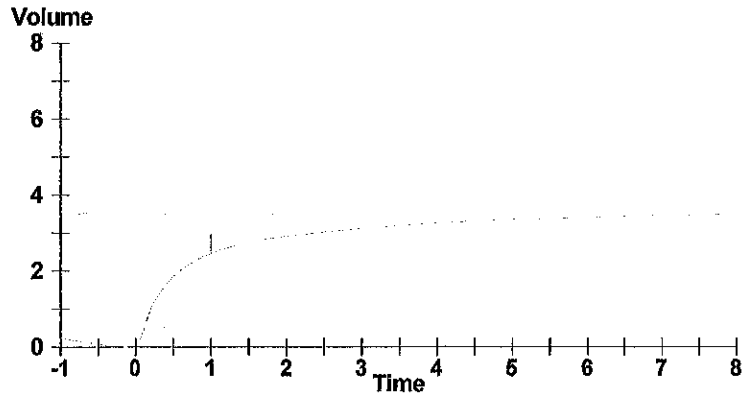
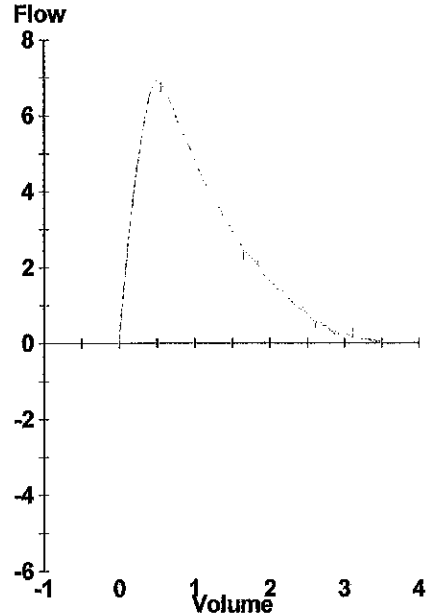
Diffusion

DLCO	mL/mmHg/min	21.7
DL Adj	mL/mmHg/min	21.7
DLCO/VA	mL/mHg/min/L	2.97
VA	Liters	
BHT	Sec	

Resistance

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.56
Gaw	L/sec/cmH2O	0.723
sRaw	cmH2O/L/s/L	4.71
sGaw	L/s/cmH2O/L	0.212
Vtg (Raw)	Liters	

Comments:



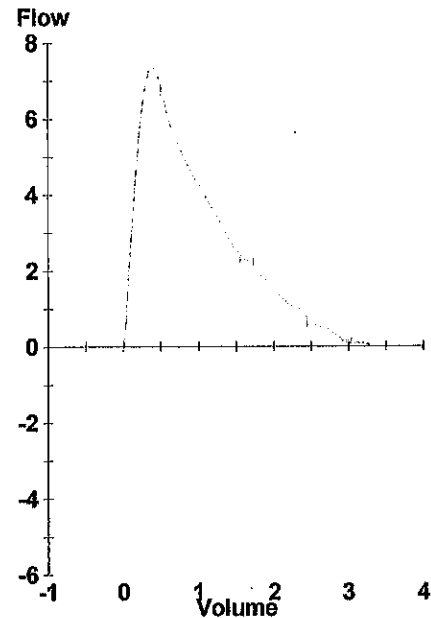
Interpretation:



Name: RJE,  
 Gender: Male  
 Age: 71 Race: Caucasian  
 Height(in): 67.0 Weight(lb): 206  
 Any Info:

Id: AKP-004  
 Date: 10/15/13  
 Temp: 20 PBar: 631  
 Physician:  
 Technician: VL

Spirometry		(BTPS)	PRE-RX		POST-RX		Post % Chg
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	
FVC	Liters	3.45	3.29	95			
FEV1	Liters	2.72	2.38	88			
FEV1/FVC %		79	72	92			
FEF25-75%L/sec		2.75	1.68	61			
FEF50%	L/sec	3.49	2.13	61			
FEF75%	L/sec	1.15	0.67	58			
IC	Liters						
VC	Liters	3.45					
PEF	L/sec	7.51	7.37	98			
MVV	L/min	116					
PIF	L/sec						
FEV1/FEV6%			73				



Lung Volumes/Plethysmography (BTPS)

Vt	Liters	
VC	Liters	3.45
TLC	Liters	5.78
RV	Liters	2.35
RV/TLC	%	41
FRC PL	Liters	3.03
ERV	Liters	
IC	Liters	

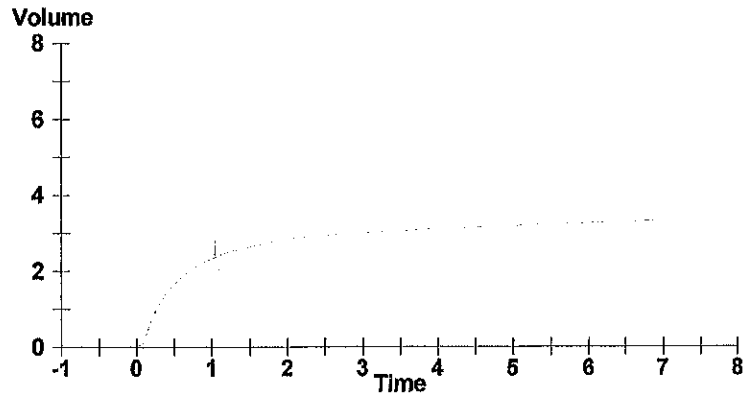
Diffusion

DLCO	mL/mmHg/min	21.6
DL Adj	mL/mmHg/min	21.6
DLCO/VA	mL/mHg/min/L	2.96
VA	Liters	
BHT	Sec	

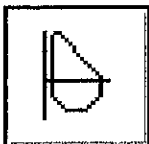
Resistance

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.55
Gaw	L/sec/cmH2O	0.727
sRaw	cmH2O/L/s/L	4.70
sGaw	L/s/cmH2O/L	0.213
Vtg (Raw)	Liters	

Comments:



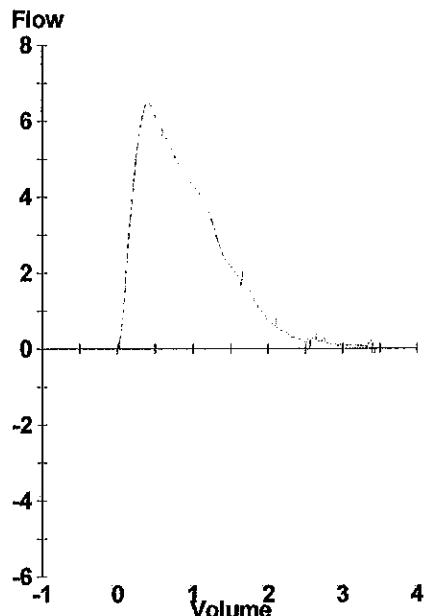
Integration:



Name: RJE,  
 Gender: Male  
 Age: 71 Race: Caucasian  
 Height(in): 67.0 Weight(lb): 205  
 Any Info:

Id: AKP-004  
 Date: 10/22/13  
 Temp: 21 PBar: 635  
 Physician:  
 Technician:

Spirometry		(BTPS)	PRE-RX		POST-RX		Post
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	% Chg
FVC	Liters	3.45	3.44	100			
FEV1	Liters	2.72	2.13	78			
FEV1/FVC %		79	62	79			
FEF25-75%/sec		2.75	0.69	25			
FEF50%	L/sec	3.49	1.59	45			
FEF75%	L/sec	1.15	0.08	7			
IC	Liters						
VC	Liters	3.45					
PEF	L/sec	7.51	6.98	93			
MVV	L/min	116					
PIF	L/sec						
FEV1/FEV6%			70				



Lung Volumes/Plethysmography

Parameter	Units	Value
Vtg	Liters	
VC	Liters	3.45
TLC	Liters	5.78
RV	Liters	2.35
RV/TLC	%	41
FRC PL	Liters	3.03
ERV	Liters	
IC	Liters	

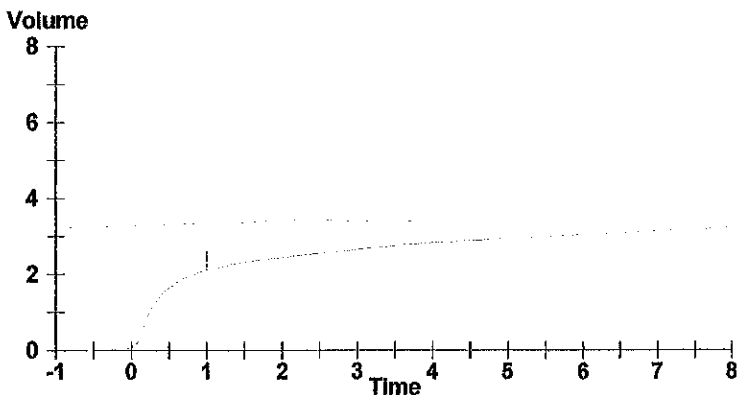
Diffusion

DLCO	mL/mmHg/min	21.6
DL Adj	mL/mmHg/min	21.6
DLCO/VA	mL/mHg/min/L	2.98
VA	Liters	
BHT	Sec	

Resistance

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.55
Gaw	L/sec/cmH2O	0.728
sRaw	cmH2O/L/s/L	4.70
sGaw	L/s/cmH2O/L	0.213
Vtg (Raw)	Liters	

Comments:



Interpretation:



Name: RJE,  
 Gender: Male  
 Age: 71 Race: Caucasian  
 Height(in): 67.0 Weight(lb): 201  
 Any Info:

Id: AKP-004  
 Date: 10/29/13  
 Temp: 20 PBar: 630  
 Physician:  
 Technician: VL

Spirometry		(BTPS)	PRE-RX		POST-RX		Post
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	% Chg
FVC	Liters	3.45	3.53	102			
FEV1	Liters	2.72	2.25	83			
FEV1/FVC %		79	64	81			
FEF25-75%/sec		2.75	0.89	32			
FEF50%	L/sec	3.49	1.53	44			
FEF75%	L/sec	1.15	0.30	26			
IC	Liters						
VC	Liters	3.45					
PEF	L/sec	7.51	7.02	93			
MVV	L/min	116					
PIF	L/sec		1.58				
FEV1/FEV6%			70				

Lung Volumes/Plethysmography

Vtg	Liters	
VC	Liters	3.45
TLC	Liters	5.78
RV	Liters	2.35
RV/TLC	%	41
FRC PL	Liters	3.06
ERV	Liters	
IC	Liters	

Diffusion

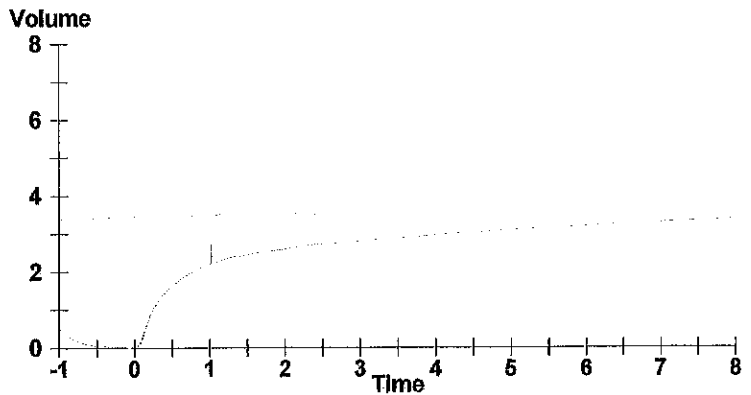
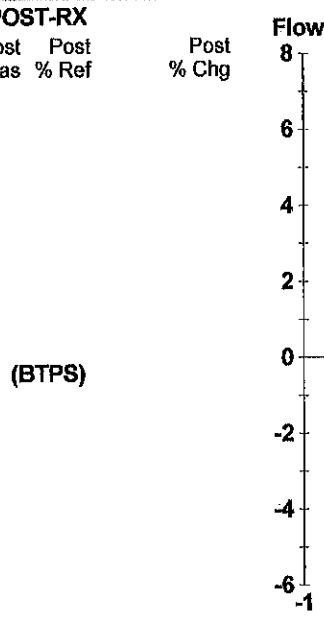
DLCO	mL/mmHg/min	21.3
DL Adj	mL/mmHg/min	21.3
DLCO/VA	mL/mHg/min/L	2.95
VA	Liters	
BHT	Sec	

Resistance

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.53
Gaw	L/sec/cmH2O	0.735
sRaw	cmH2O/L/s/L	4.69
sGaw	L/s/cmH2O/L	0.213
Vtg (Raw)	Liters	

Comments:

Interpretation:





1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Sci. Resources  
 Clin Trials-Leslie Byatt  
 2441 Ridgecrest Dr SE  
 Albuquerque, NM 87108

Client Nbr  
 24664

PATIENT NAME: RJE, RJE  
 PHYSICIAN: Unlisted Physician,  
 REQUISITION NO.: 30920926  
 COMMENTS :  
 PATIENT ID: AAGF8237  
 COLLECT DATE & TIME: 10/08/2013 10:05  
 PATIENT NO.: AKP-004  
 DOB: 06/10/1942  
 RECEIVE DATE & TIME: 10/08/2013 20:16  
 SEX: M  
 REPORT STATUS: Final  
 PRINT DATE & TIME: 10/09/2013 06:05  
 PAGE 1

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Comp Metabolic Panel					
Sodium	135		mmol/L	134-144	
Potassium		3.1 L	mmol/L	3.5-5.1	
Chloride	101		mmol/L	98-111	
CO2	26		mmol/L	20-30	
Anion Gap	8			6-14	
Glucose		121 H	mg/dL	60-100	
Impaired fasting glucose (IFG) is defined as a fasting glucose level of 100-126 mg/dL. (ADA Guidelines Diabetes Care 26: (3160-3167)2003)					
BUN	24		mg/dL	7-31	
Creatinine	0.88		mg/dL	0.62-1.66	
Creatinine method is IDMS traceable. EstGFR Calculation has been adjusted. Please note new reference range effective 5/23/2013.					
eGFR non-African Am	>60		mL/min/1.73m2	>60	
GFR Comment	Estimated GFR values are not accurate in acute kidney failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, the very old or very young, races other than Caucasian or African American, people with acute illnesses, or amputations.				
Calcium	9.5		mg/dL	8.4-10.4	
Total Protein	7.3		gm/dL	6.1-8.2	
Albumin	3.9		gm/dL	3.4-4.7	
Globulin	3.4		gm/dL	2.4-4.2	
Bilirubin, total	0.9		mg/dL	0.3-1.2	
Alk Phos	66		U/L	38-150	
AST(SGOT)	25		U/L	6-58	
ALT(SGPT)	51		U/L	14-87	
Fasting Phosphorus	NO				
Phosphorus	2.8		mg/dL	2.3-5.6	
CBC					
WBC	4.6		x10E3	4.0-10.6	
RBC		4.35 L	x10E6	4.64-6.00	
Hgb	15.5		gm/dL	14.5-17.7	
Hct	44		%	42-53	
MCV		102 H	fL	81-98	
MCHC	35.1		gm/dL	31.2-35.2	
RDW	11.8		%	11.0-14.5	
Platelets	203		x10E3	150-400	
Eos, Respiratory Phys, Addr, Phone	Not given		Rare *	NS	

End of Report

*DM Sub I*  
 09 Oct 2013

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT

*Newt Mast*

DAILY SYMPTOMS SCORE SHEET (SCREEN DIARY)  
CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

DAY AM	10/1/13	10/2	10/3	10/4	10/5	10/6	10/7	10/8	10/9
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES (NO)	YES (NO)	YES (NO)	YES (NO)	YES (NO)	YES (NO)	YES (NO)	YES (NO)	YES (NO)
Throat Clearing Y/N	YES (NO)	YES (NO)	YES (NO)	YES (NO)	YES (NO)	YES (NO)	YES (NO)	YES (NO)	YES (NO)
DAY PM	-7	-6	-5	-4	-3	-2	-1	0	0
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES (NO)	YES (NO)	YES (NO)	YES (NO)	YES (NO)	YES (NO)	YES (NO)	YES (NO)	YES (NO)
Throat Clearing Y/N	YES (NO)	YES (NO)	YES (NO)	YES (NO)	YES (NO)	YES (NO)	YES (NO)	YES (NO)	YES (NO)

SCALE 0 to 3

- 0= No symptoms (no symptoms detected)
- 1= Mild symptoms (symptoms present but easily tolerated)
- 2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)
- 3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)
- Y=Yes N=No

*Itchy Eyes*

SUBJECT NUMBER: *AKP-004* DATE COMPLETED: *10/1/13 - 10/8/13*

SUBJECT INITIALS AND DATE: *RJE 10/8/13*

*RJE*



**EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT**

**DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)**

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

DAY	1	2	3	4	5	6	7	8	9
AM	10/8	10/9	10/10	10/11	10/12	10/13	10/14	10/15	
Runny Nose 0 to 3	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0
Itchy Nose 0 to 3	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0
Congestion 0 to 3	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0
Sneezing 0 to 3	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0
Voice Hoarse Y/N	YES NO NO	YES NO NO	YES NO NO	YES NO NO	YES NO NO	YES NO NO	YES NO NO	YES NO NO	YES NO NO
Throat Clearing Y/N	YES NO NO	YES NO NO	YES NO NO	YES NO NO	YES NO NO	YES NO NO	YES NO NO	YES NO NO	YES NO NO
DAY PM	1	2	3	4	5	6	7	8	9
Runny Nose 0 to 3	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0
Itchy Nose 0 to 3	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0
Congestion 0 to 3	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0
Sneezing 0 to 3	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0
Voice Hoarse Y/N	YES NO NO	YES NO NO	YES NO NO	YES NO NO	YES NO NO	YES NO NO	YES NO NO	YES NO NO	YES NO NO
Throat Clearing Y/N	YES NO NO	YES NO NO	YES NO NO	YES NO NO	YES NO NO	YES NO NO	YES NO NO	YES NO NO	YES NO NO

SCALE 0 to 3, 5-9-1

- 0= No symptoms (no symptoms detected)
- 1= Mild symptoms (symptoms present but easily tolerated)
- 2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)
- 3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)
- Y=Yes N= NO

SUBJECT NUMBER: AKP 004      DATE COMPLETED: 10/8/13 - 10/17/13      SUBJECT INITIALS AND DATE: SPG 10/15/13

→ show



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505 ) 938-8922

Lovelace Scientific Resources  
Clin Trials-Leslie Byatt  
2441 Ridgecrest Dr SE  
Albuquerque, NM 87108

Client Nbr  
24864

PATIENT NAME **RJE, RJE** PATIENT ID **AAGF8237** DOB **06/10/1942** SEX **M** REPORT STATUS **Final** PAGE **1**  
 PHYSICIAN **Unlisted Physician,** COLLECT DATE & TIME **10/15/2013 10:00** RECEIVE DATE & TIME **10/15/2013 20:47** PRINT DATE & TIME **10/16/2013 06:08**  
 REQUISITION NO. **30920914** PT. PHONE NO. **0** PATIENT NO. **AKP-004**  
 COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Eos, Respiratory Phys, Addr, Phone	None seen			NS	
NO PHYSICIAN GIVEN					

Callback Accession Comments:  
 T3392344  
 EOSR, UNKPHY  
 0/15/2013 10:32 pm FAXED TO 3488546 NCCS1685  
**End of Report**

*Handwritten:*  
 Sub I  
 16 Oct 2013

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT

Next Visit  
10/22/13 @ 10:00 am  
w/ ERICKA

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)  
CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

DAY AM	1 <sup>10/15</sup>	2 <sup>10/16</sup>	3 <sup>10/17</sup>	4 <sup>10/18</sup>	5 <sup>10/19</sup>	6 <sup>10/20</sup>	7 <sup>10/21</sup>	8 <sup>10/22</sup>	9
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
<b>DAY PM</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>	<b>9</b>
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

→  
starts there

SCALE 0 to 3  
10-8 4-8-1 10-8-1 11-2-1 3-8-2

- 0= No symptoms (no symptoms detected)
- 1= Mild symptoms (symptoms present but easily tolerated)
- 2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)
- 3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)
- Y=Yes N=No

SUBJECT NUMBER: AKP004 DATE COMPLETED: 10/15/13

SUBJECT INITIALS AND DATE: AK 10/22/13



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505 ) 938-8922

Lovelace Scientific Resources  
Clin Trials-Leslie Byatt  
2441 Ridgecrest Dr SE  
Albuquerque, NM 87108

Client Nbr  
24664

PATIENT NAME <b>RJE, RJE</b>	PATIENT ID <b>AAGF8237</b>	DOB <b>06/10/1942</b>	SEX <b>M</b>	REPORT STATUS <b>Final</b>	PAGE <b>1</b>
PHYSICIAN <b>Unlisted Physician,</b>	COLLECT DATE & TIME <b>10/22/2013 10:32</b>	RECEIVE DATE & TIME <b>10/22/2013 19:42</b>	PRINT DATE & TIME <b>10/23/2013 06:06</b>		
REQUISITION NO. <b>30920973</b>	PT. PHONE NO. <b>0</b>	PATIENT NO. <b>AKP-004</b>			
COMMENTS :					

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Eos, Respiratory Phys, Addr, Phone	None seen			NS	
	NO PHYSICIAN GIVEN				

End of Report

*AKP*  
23 Oct 2013

Study Identification: Alpharma Allergo LSR Study #: 2749

Subject Number: AKP 004 Subject Initials: RJE

ADVERSE EVENT LOG

Adverse Event	** Start Date (DD/MMM/YYYY)	SEVERITY	Relationship to Study Drug (Suspected/Not Suspected)	** End Date (DD/MMM/YYYY)	Action Taken	Investigator Initials/Date
<del>None</del>						
						/
						/
						/
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						/
						/
						/
						/

\*\* If day is unknown, write UNK in space provided, but every effort should be made to be as specific as possible\*\*

Investigator Signature (at end of study): [Signature] Date: 26 Feb 2014  
SC Signature (at end of study): [Signature] Date: 26 Feb 14

Study Identification: 2749

LSR #: \_\_\_\_\_

Subject Number: AKP 004

Subject Initials: RJE

**CONCOMITANT MEDICATION LOG**

List all prescription medications you are taking. Also include over-the-counter medications, vitamins and supplements.

Name of Medication	Indication (What you take it for)	Dose	Unit	Frequency	Route	* Start Date (Day/Month/Year)	Stop Date	Ongoing at EOS (for Clinic Use)
EXAMPLE	Diabetes	500	MG	2 Tabs per day	Oral	UNK/AUG/1999		<input type="checkbox"/>
Aspirin	cardiac prophylaxis	81	mg	QD	oral	--/--/1990	Cont	<input checked="" type="checkbox"/>
CO-Q10	Dietary Supplement	300	mg	QD	oral	--/--/2011	Cont	<input checked="" type="checkbox"/>
Amlodipine	Hypertension	10	mg	QD	oral	--/--/2008	Cont	<input checked="" type="checkbox"/>
Losartan	Hypertension	5	mg	BID	oral	--/--/2012	Cont	<input checked="" type="checkbox"/>
Fexofenadine	seasonal allergies	180	mg		oral	--/--/2006	Cont 9/12/2013	<input type="checkbox"/>
Hydralazine	Hypertension	150	mg	BID	oral	--/--/2008	Cont	<input checked="" type="checkbox"/>
Chlorothiazide	Hypertension	25	mg	QD	oral	--/--/2012	Cont	<input checked="" type="checkbox"/>
Simvastatin	Hypercholesterolemia	20	mg	QD	oral	--/--/1992	7/Jul/2013	<input type="checkbox"/>
cortisone	OA knee	1	mg	QD	IM	10/24/13	10/24/13	<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>

\* If day or month of medication date is unknown, write UNK in space provided

Investigator Signature (at end of study): [Signature] Date: 76 Feb-2014

SC Signature (at end of study): [Signature] Date: 10/29/13

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

DAY AM	14	15	16	17	18	19	20	21	22
Runny Nose 0 to 3	10/22/13 0 1 2 3	10/23/13 0 1 2 3	10/24/13 0 1 2 3	10/25/13 0 1 2 3	10/26/13 0 1 2 3	10/27/13 0 1 2 3	10/28/13 0 1 2 3	10/29/13 0 1 2 3	10/30/13 0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
DAY PM	14	15	16	17	18	19	20	21	22
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

SCALE 0 to 3

- 0= No symptoms (no symptoms detected)
- 1= Mild symptoms (symptoms present but easily tolerated)
- 2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)
- 3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)
- Y=Yes N=No

4-p-1  
11-a-2 10-a-1 3-p-1  
4-p-1 3-p-1

AKP004  
10/22/13  
DATE COMPLETED: 10/22/13

SUBJECT NUMBER: RJE  
SUBJECT INITIALS AND DATE: RJE 10/24/13

RJE 10/29/13



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Scientific Resources  
 Leslie Byatt, CLIA  
 2441 Ridgcrest Dr SE  
 Albuquerque, NM 87108-5129

Client Nbr  
 24664

PATIENT NAME: **X, RJE** PATIENT ID: **AAGF0190** DOB: **06/10/1942** SEX: **M** REPORT STATUS: **Final** PAGE: **1**  
 PHYSICIAN: **Unlisted Physician,** COLLECT DATE & TIME: **10/29/2013 10:05** RECEIVE DATE & TIME: **10/29/2013 19:10** PRINT DATE & TIME: **10/30/2013 06:09**  
 REQUISITION NO.: **30920919** PT. PHONE NO.: **0** PATIENT NO.: **AKP004**  
 COMMENTS :

Test	Result			Units	Reference Range	Site Code
	In Range	Out of Range				
Comp Metabolic Panel						
Sodium	134			mmol/L	134-144	
Potassium		3.2	L	mmol/L	3.5-5.1	NCS <i>WJ</i>
Chloride		97	L	mmol/L	98-111	NCS <i>WJ</i>
CO2	27			mmol/L	20-30	
Anion Gap	10				6-14	NCS <i>WJ</i>
Glucose		112	H	mg/dL	60-100	
Impaired fasting glucose (IFG) is defined as a fasting glucose level of 100-126 mg/dL. (ADA Guidelines Diabetes Care 26: (3160-3167)2003)						
BUN	25			mg/dL	7-31	
Creatinine	0.83			mg/dL	0.62-1.66	
Creatinine method is IDMS traceable. EstGFR calculation has been adjusted. Please note new reference range effective 5/23/2013.						
eGFR non-African Am	>60			mL/min/1.73m2	>60	
GFR Comment	Estimated GFR values are not accurate in acute kidney failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, the very old or very young, races other than Caucasian or African American, people with acute illnesses, or amputations.					
Calcium	9.5			mg/dL	8.4-10.4	
Total Protein	6.9			gm/dL	6.1-8.2	
Albumin	3.8			gm/dL	3.4-4.7	
Globulin	3.1			gm/dL	2.4-4.2	
Bilirubin, total	0.8			mg/dL	0.3-1.2	
Alk Phos	65			U/L	38-150	
AST(SGOT)	23			U/L	6-58	
ALT(SGPT)	40			U/L	14-67	
Fasting Phosphorus	NO					
	3.0			mg/dL	2.3-5.6	
CBC						
WBC	5.9			x10E3	4.0-10.6	
RBC		4.37	L	x10E6	4.64-6.00	NCS <i>WJ</i>
Hgb	15.3			gm/dL	14.5-17.7	
Hct	43			%	42-53	
MCV		99	H	fL	81-98	NCS <i>WJ</i>
MCHC		35.3	H	gm/dL	31.2-35.2	NCS <i>WJ</i>
RDW	11.5			%	11.0-14.5	
Platelets	185			x10E3	150-400	
Eos, Respiratory	None seen				NS	
Phys, Addr, Phone	Unknown					

Callback Accession Comments:

T3427418

AGAP, ALB, ALKP, ALT, AST, BUN, CA, CL, CO2, CREA, EOSR, FAST, GFRCOM, GFRW, GLOB, GLU, HCT, HGB, K, MCHC, MCV, NA, PLT, PO4, RBC, RDW, TBIL, TP, UNKPHY, WBC

10/29/2013 09:28 pm FAXED TO 3488546 NC CS1685

End of Report

*WJ Sub I  
 30 Oct 2013*



**Effects of AkPharma's Calcium Glycerophosphate  
Nasal Spray wash (AkP 010112A) on Patient-Perceived Breathing Comfort**

**SATISFACTION QUESTIONNAIRE:**

Would you use / purchase this nasal wash product in the future?"  YES  NO

You are also encouraged to make any free comments regarding your experience in the use of this product regarding your opinion of any of its effects not covered specifically in the Daily Diary:

*For a person with trouble breathing out of both nostrils consistently, this product has been wonderful. During the trial period I have been breathing through my nose better than I can remember during my adult life.*

[Type text]

Subject initials and Date

*AF 10/29/13*

Study Staff Initials and Date

*CB 10/29/13*

**AKP-006**

2/49 AKPharma PERENNIAL ALLERGIES  
SCREENING/VISIT 1 SOURCE DOCUMENTS

Initials: TBC Site #: \_\_\_\_\_ Subject #: 006

**PATIENT DEMOGRAPHICS**

**Patient Demographics**

Date of Birth: 30 Apr 1946 (dd/mmm/yyyy)

Gender:  Male  Female

If female, Indicate Childbearing Potential

Childbearing  Surgically sterilized  Post-Menopausal

Ethnicity:  Hispanic  Non Hispanic

Race:  Asian  Black  Caucasian  American Indian

Pacific Islander  Other, Specify \_\_\_\_\_

**Smoking History**

Smoking Status:  None (smoked less than 100 cigarettes in lifetime)

Former (previously smoked more than 100 cigarettes in lifetime)

Current (smokes now)

If subject is a former or current smoker, please indicate:

Years smoked: \_\_\_\_\_

Cigarettes per day: \_\_\_\_\_

CRC Signature: \_\_\_\_\_

Date: 25 Sep 2003 (dd/mmm/yy)



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Sci Resources  
Clin Trials-Leslie Byatt  
2441 Ridgcrest Dr SE  
Albuquerque, NM 87108

Client Nbr  
24664

PATIENT NAME: TGC, TGC      PATIENT ID: AAGF0173      DOB: 04/30/1946      SEX: M      REPORT STATUS: Final      PAGE: 1

PHYSICIAN: Unlisted Physician,      COLLECT DATE & TIME: 09/23/2013 15:10      RECEIVE DATE & TIME: 09/23/2013 18:39      PRINT DATE & TIME: 09/25/2013 06:07

REQUISITION NO.: 30920882      PT. PHONE NO.: 0      PATIENT NO.: 006

COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Allerg, Panel 18					
Allerg, Juniper		3.40 H	KU/L	<0.35	
Allerg, Cottonwood	<0.10		KU/L	<0.35	
Allerg, West. Ragweed	<0.10		KU/L	<0.35	
Allerg, Russian Thistle	<0.10		KU/L	<0.35	
Allerg, Bermuda Grass		5.70 H	KU/L	<0.35	
Allerg, Alternaria		0.40 H	KU/L	<0.35	
Allerg, Mesquite	<0.10		KU/L	<0.35	
Allerg, Cockroach	<0.10		KU/L	<0.35	
Allerg, Derm. pter.	<0.10		KU/L	<0.35	

The standard classification system utilizes the following class cutoffs.

Class	ku/L	Interpretation
0	<0.35	Negative for Allergen
I	0.35-0.69	Positive for Allergen
II	0.70-3.49	Strongly Positive
III	3.5-17.49	Strongly Positive
IV	17.5-52.49	Strongly Positive
V	52.5-99.99	Strongly Positive
VI	>100	Strongly Positive

Results with allergens scoring in Class 1 should be considered weakly positive or equivocal. Class 2 and higher should be considered positive. Although increasing class ranges (0-VI) are reflective of increasing concentrations of allergen-specific IgE, this may not correlate with the degree of clinical response when challenged with the specific allergen. The correlation of allergy laboratory results with clinical history is essential. A negative test may not rule out clinical allergy.

Allerg, Derm. farinae	<0.10		KU/L	<0.35
Allerg, Clad. herb.	<0.10		KU/L	<0.35
Allerg, Firebush	<0.10		KU/L	<0.35
Allerg, Cat Dander Ep		0.50 H	KU/L	<0.35
Allerg, Dog Dander	0.10		KU/L	<0.35
Allerg, Bluegrass		1.80 H	KU/L	<0.35
Allerg, Pigweed	<0.10		KU/L	<0.35
Allerg, Mulberry	<0.10		KU/L	<0.35
Allerg, Helminth	<0.10		KU/L	<0.35
Phys, Addr, Phone	NOT GIVEN			

End of Report

*Inclusion Criteria*  
*9/25/13*  
 positive for Alternaria Alternaria  
 positive for cat dander + epithelium  
 Halyer 9/25/13



Name: TGC,  
 Gender: Male  
 Age: 67 Race: Caucasian  
 Height(in): 74.0 Weight(lb): 196  
 Any Info:

Id: AKP-006  
 Date: 10/03/13  
 Temp: 22 PBar: 630  
 Physician:  
 Technician: VL

Spirometry		(BTPS)	PRE-RX		POST-RX		
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	Post % Chg
FVC	Liters	5.09	4.62	91			
FEV1	Liters	4.03	2.82	70			
FEV1/FVC	%	78	61	78			
FEF25-75%	L/sec	3.94	1.24	32			
FEF50%	L/sec	4.87	** 1.82	** 37			
FEF75%	L/sec	1.80	0.36	20			
IC	Liters						
VC	Liters	5.09					
PEF	L/sec	9.33	8.99	96			
MVV	L/min	145					
PIF	L/sec		0.95				
FEV1/FEV6%			68				

Lung Volumes/Plethysmography

Vt	Liters	
VC	Liters	5.09
TLC	Liters	7.51
RV	Liters	2.77
RV/TLC	%	40
FRC PL	Liters	4.27
ERV	Liters	
IC	Liters	

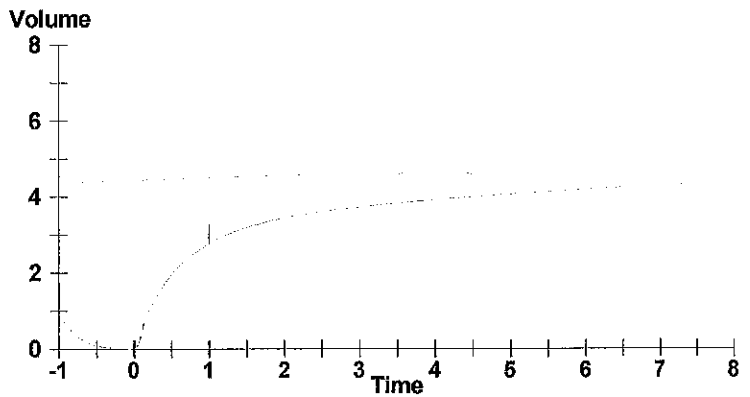
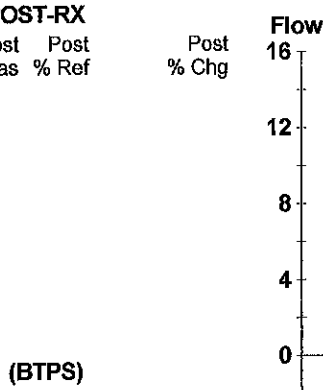
Diffusion

DLCO	mL/mmHg/min	24.3
DL Adj	mL/mmHg/min	24.3
DLCO/VA	mL/mHg/min/L	3.04
VA	Liters	
BHT	Sec	

Resistance

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.01
Gaw	L/sec/cmH2O	1.025
sRaw	cmH2O/L/s/L	4.31
sGaw	L/s/cmH2O/L	0.232
Vt (Raw)	Liters	

Comments:



Integrating...



Name: TGC,  
 Gender: Male  
 Age: 67 Race: Caucasian  
 Height(in): 74.0 Weight(lb): 196  
 Any Info:

Id: AKP-006  
 Date: 10/10/13  
 Temp: 21 PBar: 627  
 Physician:  
 Technician: vl

		(BTPS)	PRE-RX		POST-RX		
Spirometry		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	Post % Chg
FVC	Liters	5.09	4.72	93			
FEV1	Liters	4.03	2.92	72			
FEV1/FVC %		78	62	79			
FEF25-75%L/sec		3.94	1.17	30			
FEF50%	L/sec	4.87	** 1.87	** 38			
FEF75%	L/sec	1.80	** 0.32	** 18			
IC	Liters						
VC	Liters	5.09					
PEF	L/sec	9.33	8.78	94			
MVV	L/min	145					
PIF	L/sec		4.11				
FEV1/FEV6%			70				

Lung Volumes/Plethysmography

Vtg	Liters	
VC	Liters	5.09
TLC	Liters	7.51
RV	Liters	2.77
RV/TLC	%	40
FRC PL	Liters	4.27
ERV	Liters	
IC	Liters	

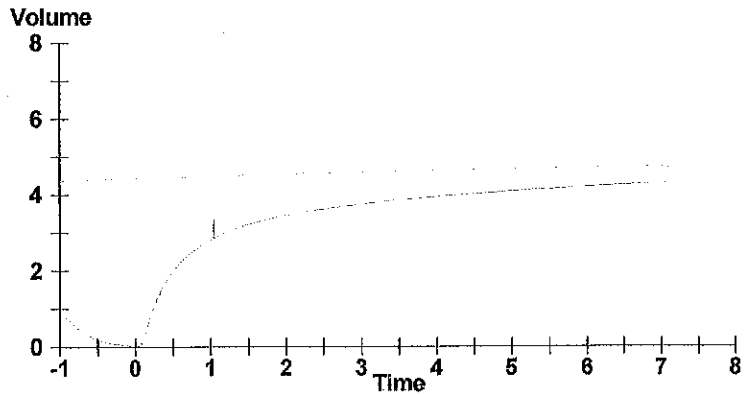
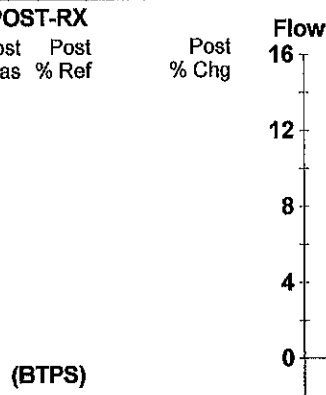
Diffusion

DLCO	mL/mmHg/min	24.3
DL Adj	mL/mmHg/min	24.3
DLCOVA	mL/mmHg/min/L	3.02
VA	Liters	
BHT	Sec	

Resistance

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.01
Gaw	L/sec/cmH2O	1.025
sRaw	cmH2O/L/s/L	4.31
sGaw	L/s/cmH2O/L	0.232
Vtg (Raw)	Liters	

Comments:



Info: 0000000000



Name: TGC,  
 Gender: Male  
 Age: 67 Race: Caucasian  
 Height(in): 74.0 Weight(lb): 196  
 Any Info:

Id: AKP-006  
 Date: 10/17/13  
 Temp: 19 PBar: 631  
 Physician:  
 Technician: VL

Spirometry		(BTPS)	PRE-RX		POST-RX		Post	Flow
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	% Chg	
FVC	Liters	5.09	4.63	91				
FEV1	Liters	4.03	2.89	72				
FEV1/FVC %		78	62	80				
FEF25-75%	L/sec	3.94	1.19	30				
FEF50%	L/sec	4.87	** 1.76	** 36				
FEF75%	L/sec	1.80	** 0.34	** 19				
IC	Liters							
VC	Liters	5.09						
PEF	L/sec	9.33	8.59	92				
MVV	L/min	145						
PIF	L/sec		4.38					
FEV1/FEV6%			70					

Lung Volumes/Plethysmography

Vt	Liters	
VC	Liters	5.09
TLC	Liters	7.51
RV	Liters	2.77
RV/TLC	%	40
FRC PL	Liters	4.27
ERV	Liters	
IC	Liters	

Diffusion

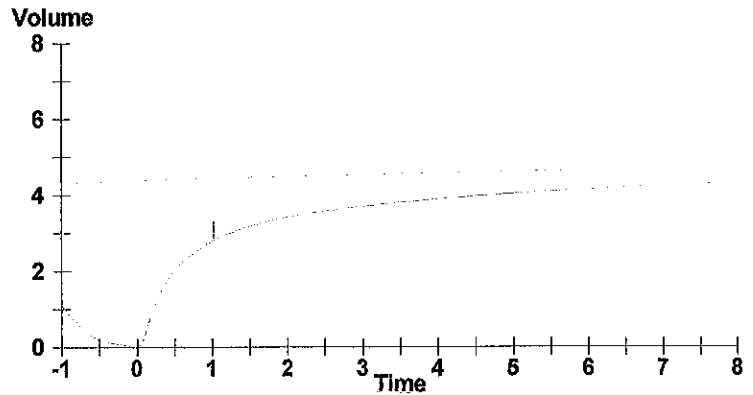
DLCO	mL/mmHg/min	24.3
DL Adj	mL/mmHg/min	24.3
DLCO/VA	mL/mHg/min/L	3.04
VA	Liters	
BHT	Sec	

Resistance

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.01
Gaw	L/sec/cmH2O	1.025
sRaw	cmH2O/L/s/L	4.31
sGaw	L/s/cmH2O/L	0.232
Vt (Raw)	Liters	

Comments:

Interpretation:





Name: TGC,  
 Gender: Male  
 Age: 67 Race: Caucasian  
 Height(in): 74.0 Weight(lb): 196  
 Any Info:

Id: AKP-006  
 Date: 10/24/13  
 Temp: 20 PBar: 634  
 Physician:  
 Technician: VL

Spirometry		(BTPS)	PRE-RX		POST-RX		Post	Flow
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	% Chg	16
FVC	Liters	5.09	4.61	91				12
FEV1	Liters	4.03	2.96	73				8
FEV1/FVC	%	78	64	82				4
FEF25-75%	L/sec	3.94	1.49	38				0
FEF50%	L/sec	4.87	** 2.15	** 44				-4
FEF75%	L/sec	1.80	0.46	26				-8
IC	Liters							-12
VC	Liters	5.09						-2
PEF	L/sec	9.33	8.72	94				0
MVV	L/min	145						2
PIF	L/sec		4.66					4
FEV1/FEV6%			69					6

Lung Volumes/Plethysmography

Vtg	Liters	
VC	Liters	5.09
TLC	Liters	7.51
RV	Liters	2.77
RV/TLC	%	40
FRC PL	Liters	4.27
ERV	Liters	
IC	Liters	

Diffusion

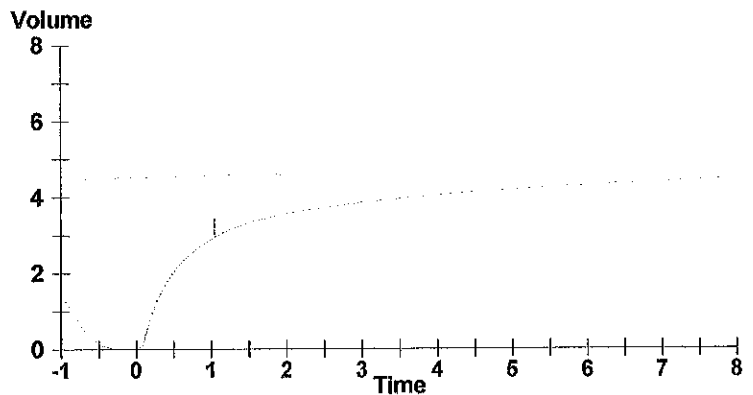
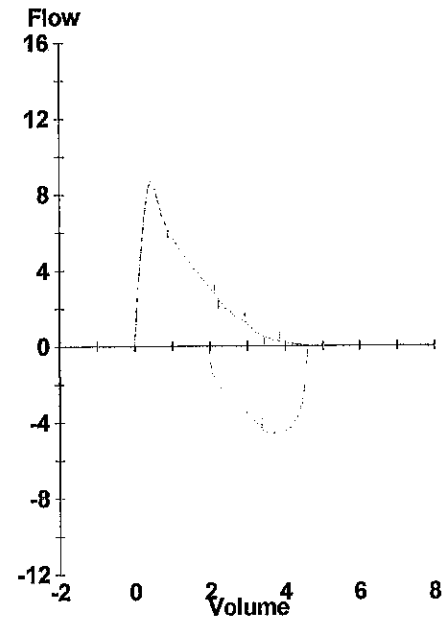
DLCO	mL/mmHg/min	24.3
DL Adj	mL/mmHg/min	24.3
DLCOVA	mL/mmHg/min/L	3.06
VA	Liters	
BHT	Sec	

Respiration

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.01
Gaw	L/sec/cmH2O	1.025
sRaw	cmH2O/L/s/L	4.31
sGaw	L/s/cmH2O/L	0.232
Vtg (Raw)	Liters	

Comments:

(BTPS)



Reference Values



TriCore Reference Laboratories  
 1001 Woodward Pl NE  
 Albuquerque, NM 87102  
 (505) 938-8922

Patient Name: TGC, TGC  
 Medical Record: AAGF0173  
 DOB: 04/30/1946 Age: 67Y Sex: M  
 Account Number: 30920928  
 Attending MD: Unlisted Physician  
 Patient ID: 006  
 Patient Phone: 0

H3250423 COLL: 10/03/2013 08:45 REC: 10/04/2013 19:41 PHYS: Unlisted Physician  
 Req# : 30920928

10/04/2013 11:23 pm FAXED TO 5053458546 NC CS10030

Comp Metabolic Panel

Sodium	143	[134-144]	mmol/L
Potassium	4.4	[3.5-5.1]	mmol/L
Chloride	109	[98-111]	mmol/L
CO2	26	[20-30]	mmol/L
Anion Gap	8	[6-14]	
Glucose	90	[60-100]	mg/dL
BUN	18	[7-31]	mg/dL
Creatinine	1.13	[0.62-1.66]	mg/dL

Creatinine method is IDMS traceable. EstGFR Calculation has been adjusted.

eGFR non-African Am  
 GFR Comment

Please note new reference range effective 5/23/2013.  
 >60 [ >60 ] mL/min/1.73m2  
 Estimated GFR values are not accurate in acute kidney failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, the very old or very young, races other than Caucasian or African American, people with acute illnesses, or amputations.

Calcium	9.1	[8.4-10.4]	mg/dL
Total Protein	6.9	[6.1-8.2]	gm/dL
Albumin	3.9	[3.4-4.7]	gm/dL
Globulin	3.0	[2.4-4.2]	gm/dL
Bilirubin, total	0.5	[0.3-1.2]	mg/dL
Alk Phos	138	[38-150]	U/L
AST (SGOT)	17	[6-58]	U/L
ALT (SGPT)	24	[14-67]	U/L

Fasting NO

Phosphorus 2.7 [2.3-5.6] mg/dL

CBC

WBC	4.7	[4.0-10.6]	x10E3
RBC	5.11	[4.64-6.00]	x10E6
Hgb	L 12.9	[14.5-17.7]	gm/dL
Hct	42	[42-53]	%
MCV	83	[81-98]	fL
MCHC	L 30.4	[31.2-35.2]	gm/dL
RDW	H 15.3	[11.0-14.5]	%
Platelets	211	[150-400]	x10E3

*NCS [Signature] 11 Oct 13*  
*NCS [Signature] 11 Oct 13*  
*NCS [Signature] 11 Oct 13*

CONTINUED

Printed: 10/09/2013 15:57

Patient Name: TGC, TGC  
 Medical Record #: AAGF0173  
 Location: CORE

Page: 1

INTERIM REPORT

TriCore Reference Laboratories  
1001 Woodward Pl NE  
Albuquerque, NM 87102  
(505) 938-8922

Patient Name: TGC, TGC  
Medical Record: AAGF0173  
DOB: 04/30/1946 Age: 67Y Sex: M  
Account Number: 30920928  
Attending MD: Unlisted Physician  
Patient ID: 006  
Patient Phone: 0

H3250423 COLL: 10/03/2013 08:45 REC: 10/04/2013 19:41 PHYS: Unlisted Physician  
Req# : 30920928

10/04/2013 11:23 pm FAXED TO 5053458546 NC CS10030

Eos, Respiratory \* Rare [NS]

Phys, Addr, Phone NOT GIVEN

*NTM  
11 Oct 2013*

END OF REPORT

Printed: 10/09/2013 15:57

INTERIM REPORT

Patient Name: TGC, TGC  
Medical Record #: AAGF0173  
Location: CORE

Page: 2

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (SCREEN DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

DAY AM	9 <sup>-7</sup>	9 <sup>-6</sup>	9 <sup>-5</sup>	9 <sup>-4</sup>	9 <sup>-3</sup>	10 <sup>1</sup>	10 <sup>2</sup>	10 <sup>1</sup>	10 <sup>0</sup>	10 <sup>1</sup>	10 <sup>0</sup>	10 <sup>1</sup>
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
-Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
DAY PM	-7	-6	-5	-4	-3	-2	-1	0	0			
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

SCALE 0 to 3

- 0= No symptoms (no symptoms detected)
- 1= Mild symptoms (symptoms present but easily tolerated)
- 2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)
- 3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

SUBJECT NUMBER: AKP 006 DATE COMPLETED: 02/3/2013 SUBJECT INITIALS AND DATE: AKP 10/3/13

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT

6:52 AM 6:35 AM

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

DAY	1	2	3	4	5	6	7	8	9
AM	15/03/13	10/04/13	10/05/13	10/06/13	10/07/13	10/08/13	10/09/13	10/10/13	10/11/13
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
DAY PM	1	2	3	4	5	6	7	8	9
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

SCALE 0 to 3

- 0= No symptoms (no symptoms detected)
- 1= Mild symptoms (symptoms present but easily tolerated)
- 2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)
- 3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N=No

SUBJECT NUMBER: AKP004  
DATE COMPLETED: 10/3/13

SUBJECT INITIALS AND DATE: 10/10/13

AKP004 10/10/13

TriCore Reference Laboratories  
1001 Woodward Pl NE  
Albuquerque, NM 87102  
(505)938-8922

Patient Name: TGC,TGC  
Medical Record: AAGF9554  
DOB:04/30/1946 Age:67Y Sex:M  
Account Number: 30920910  
Attending MD: Unlisted Physician  
Patient ID:AKP006  
Patient Phone:0

H3265159 COLL: 10/10/2013 08:00 REC: 10/10/2013 19:16 PHYS: Unlisted Physician  
Req# : 30920910

10/11/2013 09:24 am FAXED TO 3488546 NC CS11533

Eos, Respiratory \* Moderate [NS]

Phys, Addr, Phone NO ORDERING PHYSICIAN

*Dr. Gaine MD*  
*15 Oct 2013*

Printed: 10/11/2013 09:24

INTERIM REPORT

END OF REPORT

Patient Name: TGC,TGC  
Medical Record #: AAGF9554  
Location: CORE

Page: 1

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT

Next effects

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

DAY AM	7	8	9	10	11	12	13	14	15
Runny Nose 0 to 3	10/10 0 1 2 3	10/11 0 1 2 3	10/12 0 1 2 3	10/13 0 1 2 3	10/14 0 1 2 3	10/15 0 1 2 3	10/16 0 1 2 3	10/17 0 1 2 3	10/18 0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
DAY PM	7	8	9	10	11	12	13	14	15
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

SCALE 0 to 3

- 0= No symptoms (no symptoms detected)
- 1= Mild symptoms (symptoms present but easily tolerated)
- 2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)
- 3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)
- Y=Yes N= No

\*

OVER-

start here

SUBJECT NUMBER: AKP 000 DATE COMPLETED: 10/10/13 - 10/17/13 SUBJECT INITIALS AND DATE: \_\_\_\_\_



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505 ) 938-8922

Lovelace Scie. Resources  
Cln Trials-Leslie Byatt  
2441 Ridgcrest Dr SE  
Albuquerque, NM 87108

Client Nbr  
24664

PATIENT NAME <b>TGC, TGC</b>	PATIENT ID <b>AAGF0173</b>	DOB <b>04/30/1946</b>	SEX <b>M</b>	REPORT STATUS <b>Final</b>	PAGE <b>1</b>
PHYSICIAN <b>Unlisted Physician,</b>	COLLECT DATE & TIME <b>10/17/2013 08:05</b>	RECEIVE DATE & TIME <b>10/17/2013 19:35</b>	PRINT DATE & TIME <b>10/18/2013 06:07</b>		
REQUISITION NO. <b>30920916</b>	PT. PHONE NO. <b>0</b>	PATIENT NO. <b>006</b>			
COMMENTS :					

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Eos, Respiratory Phys, Addr, Phone	Not given	Rare *		NS	

End of Report

*NCS  
Salzer 18 Oct 2013*

Study Identification: AK Pharma LSR Study #: 2749

Subject Number: AKP 006 Subject Initials: TGC

ADVERSE EVENT LOG

Adverse Event	** Start Date (DD/MMM/YYYY)	SEVERITY	Relationship to Study Drug (Suspected/Not Suspected)	** End Date (DD/MMM/YYYY)	Action Taken	Investigator Initials/Date
Nose bleed	12/Oct/13	mild	Suspected	12/Oct/13	None Related to mtd. Lister Smo	TGC 26 Feb 14
Difficulty passing Nasal passage	13/Oct/13	mod	Suspected	01/Nov/13	NONE	TGC 26 Feb 14
Nose bleed	19/Oct/13	mild	Suspected	05/Nov/13	NONE	TGC 26 Feb 14
						/
						/
						/
						/
						/
						/
						/
						/
						/

\*\* If day is unknown, write UNK in space provided, but every effort should be made to be as specific as possible

Investigator Signature (at end of study): [Signature] Date: 26 Feb 2014  
 SC Signature (at end of study): [Signature] Date: 2/26/14





1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505 ) 938-8922

Lovelace Scientific Resources  
Leslie Byatt, Clin Trials  
2441 Ridgecrest Dr SE  
Albuquerque, NM 87108-5129

Client Nbr  
24664

PATIENT NAME: **TGC, TGC** PATIENT ID: **AAGF0173** DOB: **04/30/1946** SEX: **M** REPORT STATUS: **Final** PAGE: **1**  
 PHYSICIAN: **Unlisted Physician,** COLLECT DATE & TIME: **10/24/2013 08:37** RECEIVE DATE & TIME: **10/24/2013 21:13** PRINT DATE & TIME: **10/29/2013 06:03**  
 REQUISITION NO.: **30920970** PT. PHONE NO.: **0** PATIENT NO.: **006**  
 COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Comp Metabolic Panel					
Sodium	139		mmol/L	134-144	
Potassium	4.1		mmol/L	3.5-5.1	
Chloride	107		mmol/L	98-111	
CO2	26		mmol/L	20-30	
Anion Gap	6			6-14	
Glucose	85		mg/dL	60-100	
BUN	16		mg/dL	7-31	
Creatinine	1.23		mg/dL	0.62-1.66	
Creatinine method is IDMS traceable. EstGFR Calculation has been adjusted. Please note new reference range effective 5/23/2013.					
eGFR non-African Am		59	L mL/min/1.73m2	>60	
GFR Comment	Estimated GFR values are not accurate in acute kidney failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, the very old or very young, races other than Caucasian or African American, people with acute illnesses, or amputations.				
Calcium	9.8		mg/dL	8.4-10.4	
Total Protein	7.2		gm/dL	6.1-8.2	
Albumin	4.2		gm/dL	3.4-4.7	
Globulin	3.0		gm/dL	2.4-4.2	
Bilirubin, total	0.5		mg/dL	0.3-1.2	
Alk Phos	147		U/L	38-150	
AST(SGOT)	18		U/L	6-58	
ALT(SGPT)	26		U/L	14-67	
Fasting	NO				
CBC					
WBC	5.1		x10E3	4.0-10.6	
RBC	5.28		x10E6	4.64-6.00	
Hgb		13.4	L gm/dL	14.5-17.7	
Hct	44		%	42-53	
MCV	84		fL	81-98	
MCHC		30.4	L gm/dL	31.2-35.2	
RDW		14.9	H %	11.0-14.5	
Platelets	206		x10E3	150-400	
Eos, Respiratory		Few	*	NS	
Phys, Addr, Phone	Not given				
Allerg,Panel 18					
Allerg,Juniper		3.60	H KU/L	<0.35	
Allerg,Cottonwood	<0.10		KU/L	<0.35	
Allerg,West Ragweed	<0.10		KU/L	<0.35	
Allerg,Russian Thistle	<0.10		KU/L	<0.35	
Allerg,Bermuda Grass		9.30	H KU/L	<0.35	
Allerg,Alternaria		0.40	H KU/L	<0.35	
Allerg,Mesquite	<0.10		KU/L	<0.35	
Allerg,Cockroach	<0.10		KU/L	<0.35	
Allerg,Derm. pter.	<0.10		KU/L	<0.35	

*NCS MDM  
29 Oct 2013*

*29 Oct 2013  
NCS MDM  
Sub-I*

*NCS MDM  
NCS MDM  
NCS MDM*

*NCS MDM*

*NCS MDM  
NCS MDM  
29 Oct 2013*

The standard classification system utilizes the following class cutoffs.

Class	ku/L	Interpretation
0	<0.35	Negative for Allergen
I	0.35-0.69	Positive for Allergen

Study Identification: 2749

LSR #: \_\_\_\_\_

Subject Number: AKP 006

Subject Initials: TEL

### CONCOMITANT MEDICATION LOG

List all prescription medications you are taking. Also include over-the-counter medications, vitamins and supplements.

Name of Medication	Indication (What you take it for)	Dose	Unit	Frequency # of Tabs per day	Route	* Start Date (Day/Month/Year)	Stop Date	Ongoing at EOS (for Clinic use)
EXAMPLE	Diabetes	500	MG	2	Oral	UNK/AUG/1999		<input type="checkbox"/>
Paracetamol	Aspirin	85	mg	QOD	P.O.	unk/unk/988		<input checked="" type="checkbox"/>
Multivitamins	Albendazole	?	76	QD	P.O.	unk/unk/2005		<input checked="" type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>

\* If day or month of medication date is unknown, write UNK in space provided

Investigator Signature (at end of study): [Signature] Date: 26 Feb 2014

SC Signature (at end of study): [Signature] Date: 2/20/14

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

DAY	14	15	16	17	18	19	20	21	22
AM	10/17	10/18	10/19	10/20	10/21	10/22	10/23	10/24	
Runny Nose	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
0 to 3									
Itchy Nose	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
0 to 3									
Congestion	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
0 to 3									
Sneezing	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
0 to 3									
Voice Hoarse	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Y/N									
Throat Clearing	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Y/N									
DAY PM	14	15	16	17	18	19	20	21	22
Runny Nose	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
0 to 3									
Itchy Nose	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
0 to 3									
Congestion	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
0 to 3									
Sneezing	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
0 to 3									
Voice Hoarse	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Y/N									
Throat Clearing	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Y/N									

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N=No

*Over*

SUBJECT NUMBER: AKP006 DATE COMPLETED: 10/24/13

SUBJECT INITIALS AND DATE: TGC 10/24/13

TGC/2749

Effects of AkPharma's Calcium Glycerophosphate  
Nasal Spray wash (AkP 010112A) on Patient-Perceived Breathing Comfort

SATISFACTION QUESTIONNAIRE:

Would you use / purchase this nasal wash product in the future?"  YES  NO

You are also encouraged to make any free comments regarding your experience in the use of this product regarding your opinion of any of its effects not covered specifically in the Daily Diary:

*It worked about the same as other  
nose spray's.*

*It would depend upon per price.*

*I'm not sure if it ~~is~~ is the weather  
or the product but ~~I~~ I have ~~an~~ an  
exceptionally dry nose now.*

[Type text]

Subject initials and Date

*Alb. 10/24/13*

Study Staff Initials and Date

*EM 10/24/13*

**AKP-007**

4749 AKPharma PERENNIAL ALLERGIES  
SCREENING/VISIT 1 SOURCE DOCUMENTS

Initials: JLJ Site #: \_\_\_\_\_ Subject #: AKP 007

PATIENT DEMOGRAPHICS

**Patient Demographics**

Date of Birth: 13 / OCT / 1966 (dd/mmm/yyyy)

Gender:  Male  Female

If female, Indicate Childbearing Potential

Childbearing  Surgically sterilized  Post-Menopausal  
IUD since 12005

Ethnicity:  Hispanic  Non Hispanic

Race:  Asian  Black  Caucasian  American Indian

Pacific Islander  Other, Specify \_\_\_\_\_

**Smoking History**

Smoking Status:  None (smoked less than 100 cigarettes in lifetime)

Former (previously smoked more than 100 cigarettes in lifetime)

Current (smokes now)

If subject is a former or current smoker, please indicate:

Years smoked: 30 Cigarettes per day: 10 per day

CRC Signature: Erica Maldonado Date: 24 / sep 2013 (dd/mmm/yy)



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Sci. Resources  
Clin Trials Leslie Byatt  
2441 Ridgecrest Dr SE  
Albuquerque, NM 87108

Client Nbr  
24664

PATIENT NAME: JLJ, JLJ      PATIENT ID: AAGF0870      DOB: 10/13/1966      SEX: F      REPORT STATUS: Final      PAGE: 1

PHYSICIAN: Unlisted Physician,      COLLECT DATE & TIME: 09/24/2013 10:30      RECEIVE DATE & TIME: 09/24/2013 19:42      PRINT DATE & TIME: 09/26/2013 06:06

REQUISITION NO.: 30920881      PT. PHONE NO.: 0

COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Allerg, Panel 18					
Allerg, Juniper		7.20 H	kU/L	<0.35	
Allerg, Cottonwood		3.90 H	kU/L	<0.35	
Allerg, West. Ragweed		0.80 H	kU/L	<0.35	
Allerg, Russian Thistle - NCS of 10/18/13		20.50 H	kU/L	<0.35	
Allerg, Bermuda Grass		5.20 H	kU/L	<0.35	
Allerg, Alternaria	<0.10		kU/L	<0.35	
Allerg, Mesquite		5.70 H	kU/L	<0.35	
Allerg, Cockroach	0.30		kU/L	<0.35	
Allerg, Derm. pter.		0.40 H	kU/L	<0.35	

The standard classification system utilizes the following class cutoffs.

Class	ku/L	Interpretation
0	<0.35	Negative for Allergen
I	0.35-0.69	Positive for Allergen
II	0.70-3.49	Strongly Positive
III	3.5-17.49	Strongly Positive
IV	17.5-52.49	Strongly Positive
V	52.5-99.99	Strongly Positive
VI	>100	Strongly Positive

Results with allergens scoring in Class 1 should be considered weakly positive or equivocal. Class 2 and higher should be considered positive. Although increasing class ranges (0-VI) are reflective of increasing concentrations of allergen-specific IgE, this may not correlate with the degree of clinical response when challenged with the specific allergen. The correlation of allergy laboratory results with clinical history is essential. A negative test may not rule out clinical allergy.

Allerg, Derm. farinae		0.50 H	kU/L	<0.35
Allerg, Clad. herb.	<0.10		kU/L	<0.35
Allerg, Firebush		3.40 H	kU/L	<0.35
Allerg, Cat Dander Ep	<0.10		kU/L	<0.35
Allerg, Dog Dander	<0.10		kU/L	<0.35
Allerg, Bluegrass		2.50 H	kU/L	<0.35
Allerg, Pigweed		6.60 H	kU/L	<0.35
Allerg, Mulberry		1.20 H	kU/L	<0.35
Allerg, Helminth	<0.10		kU/L	<0.35
Phys, Addr, Phone	UNKNOWN			

End of Report

*Subject shows reactivity to known perennial allergens Russian Thistle, Derm. pter and Derm. farinae (dust mites)*

JLJ, JLJ

09/26/2013 06:06

FAX24664

*Meets inclusion criteria - Salzer 26 Sept 2013*



Name: JLJ,  
 Gender: Female  
 Age: 46 Race: Caucasian  
 Height(in): 63.0 Weight(lb): 154  
 Any Info:

Id: AKP-007  
 Date: 10/02/13  
 Temp: 22 PBar: 632  
 Physician:  
 Technician: VL

		(BTPS)	PRE-RX		POST-RX		Post
Spirometry		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	% Chg
FVC	Liters	3.13	4.16	133			
FEV1	Liters	2.62	3.42	131			
FEV1/FVC	%	85	82	97			
FEF25-75%	L/sec	2.97	4.01	135			
FEF50%	L/sec	3.59	** 5.54	** 154			
FEF75%	L/sec	1.43	1.61	112			
IC	Liters						
VC	Liters	3.13					
PEF	L/sec	5.95	7.79	131			
MVV	L/min	103					
PIF	L/sec		3.52				
FEV1/FEV6%			85				

Lung Volumes/Plethysmography

Vtg	Liters			
VC	Liters	3.13		
TLC	Liters	4.80		
RV	Liters	1.64		
RV/TLC	%	34		
FRC PL	Liters	2.58		
ERV	Liters			
IC	Liters			

Diffusion

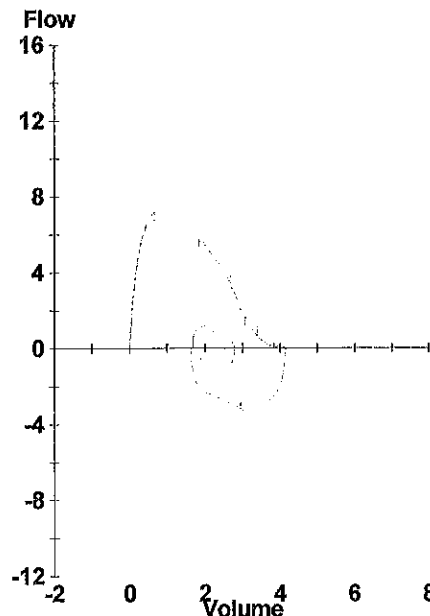
DLCO	mL/mmHg/min	21.9
DL Adj	mL/mmHg/min	21.9
DLCO/VA	mL/mHg/min/L	3.47
VA	Liters	
BHT	Sec	

Resistance

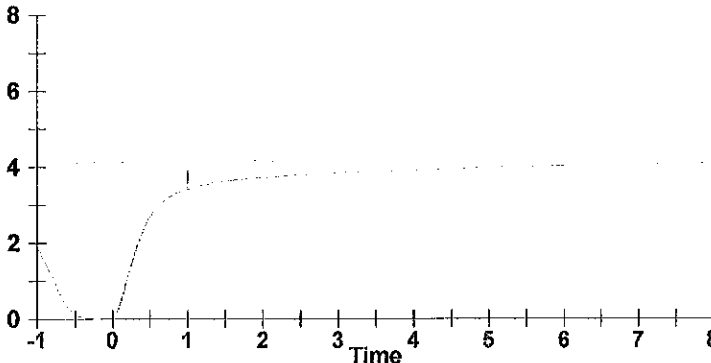
Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.49
Gaw	L/sec/cmH2O	0.619
sRaw	cmH2O/L/s/L	3.85
sGaw	L/s/cmH2O/L	0.260
Vtg (Raw)	Liters	

Comments:

(BTPS)



Volume



Interpretation:

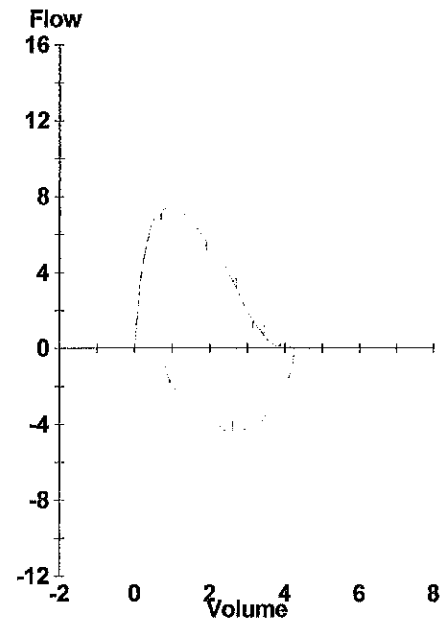




Name: JLJ,  
 Gender: Female  
 Age: 46 Race: Caucasian  
 Height(in): 63.0 Weight(lb): 154  
 Any Info:

Id: AKP-007  
 Date: 10/09/13  
 Temp: 20 PBar: 628  
 Physician:  
 Technician: VL

Spirometry		(BTPS)	PRE-RX		POST-RX		Post % Chg
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	
FVC	Liters	3.13	4.31	138			
FEV1	Liters	2.62	3.46	132			
FEV1/FVC	%	85	80	95			
FEF25-75%	L/sec	2.97	3.79	127			
FEF50%	L/sec	3.59	5.34	148			
FEF75%	L/sec	1.43	1.42	99			
IC	Liters						
VC	Liters	3.13					
PEF	L/sec	5.95	8.17	137			
PIF	L/sec		4.37				



Plethysmograph  
 Lung Volumes (BTPS)

Vtg	Liters	
VC	Liters	3.13
TLC	Liters	4.80
RV	Liters	1.64
RV/TLC	%	34
FRC PL	Liters	2.58
ERV	Liters	
IC	Liters	

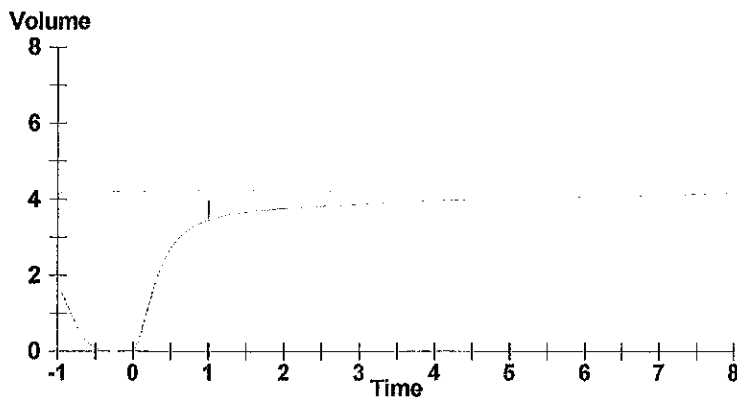
Diffusion

DLCO	mL/mmHg/min	21.9
DL Adj	mL/mmHg/min	21.9
DLCO/VA	mL/mHg/min/L	3.45
VA	Liters	
BHT	Sec	

Resistance

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.49
Gaw	L/sec/cmH2O	0.619
sRaw	cmH2O/L/s/L	3.85
sGaw	L/s/cmH2O/L	0.260
Vtg (Raw)	Liters	

Comments:



Information



Name: JLJ,  
 Gender: Female  
 Age: 47 Race: Caucasian  
 Height(in): 63.0 Weight(lb): 159  
 Any Info:

Id: AKP-007  
 Date: 10/16/13  
 Temp: 19 PBar: 631  
 Physician:  
 Technician: VL

Spirometry		(BTPS)	PRE-RX		POST-RX		Post % Chg
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	
FVC	Liters	3.12	4.15	133			
FEV1	Liters	2.60	3.50	135			
FEV1/FVC	%	84	84	100			
FEF25-75%	L/sec	2.94	4.24	144			
FEF50%	L/sec	3.57	** 5.89	** 165			
FEF75%	L/sec	1.41	1.72	122			
IC	Liters						
VC	Liters	3.12					
PEF	L/sec	5.93	** 8.78	** 148			
MVV	L/min	102					
PIF	L/sec		2.34				
FEV1/FEV6%			87				

Lung Volumes/Plethysmography

Vtg	Liters	
VC	Liters	3.12
TLC	Liters	4.80
RV	Liters	1.64
RV/TLC	%	34
FRC PL	Liters	2.54
ERV	Liters	
IC	Liters	

Diffusion

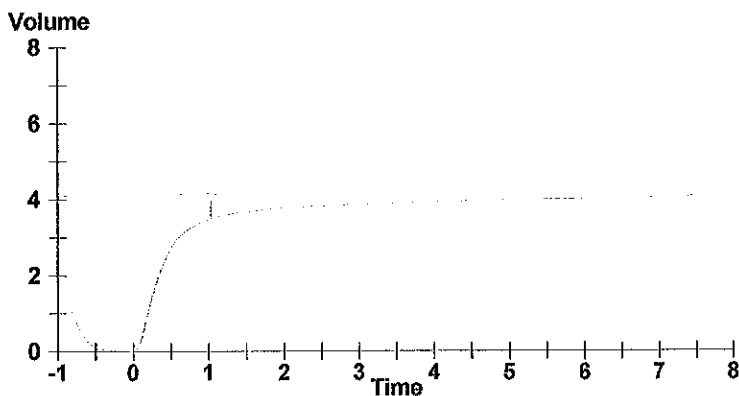
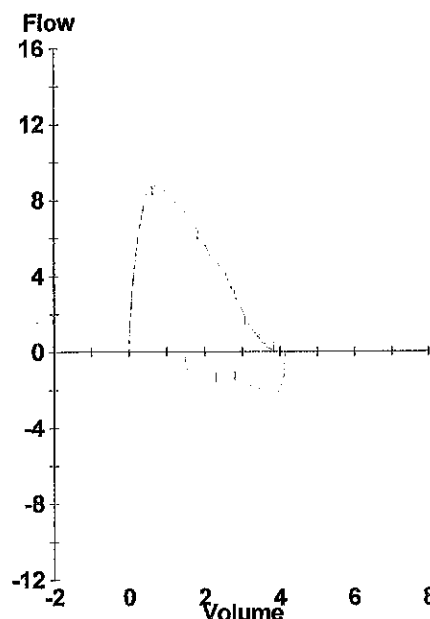
DLCO	mL/mmHg/min	22.2
DL Adj	mL/mmHg/min	22.2
DLCO/VA	mL/mHg/min/L	3.44
VA	Liters	
BHT	Sec	

Resistance

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.52
Gaw	L/sec/cmH2O	0.609
sRaw	cmH2O/L/s/L	3.86
sGaw	L/s/cmH2O/L	0.259
Vtg (Raw)	Liters	

Comments:

(BTPS)



Interpretation:



Name: JLJ,  
 Gender: Female  
 Age: 47 Race: Caucasian  
 Height(in): 63.0 Weight(lb): 156  
 Any Info:

Id: AKP007  
 Date: 10/22/13  
 Temp: 21 PBar: 635  
 Physician:  
 Technician: VL

Spirometry		(BTPS)	PRE-RX		POST-RX		Post
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	% Chg
FVC	Liters	3.12	4.01	129			
FEV1	Liters	2.60	3.30	127			
FEV1/FVC	%	84	82	97			
FEF25-75%	L/sec	2.94	3.95	134			
FEF50%	L/sec	3.57	** 5.52	** 154			
FEF75%	L/sec	1.41	1.52	108			
IC	Liters						
VC	Liters	3.12					
PEF	L/sec	5.93	8.35	141			
MVV	L/min	102					
PIF	L/sec		3.18				
FEV1/FEV6%			85				

Lung Volumes/Plethysmography

Vtg	Liters	
VC	Liters	3.12
TLC	Liters	4.80
RV	Liters	1.64
RV/TLC	%	34
FRC PL	Liters	2.56
ERV	Liters	
IC	Liters	

Diffusion

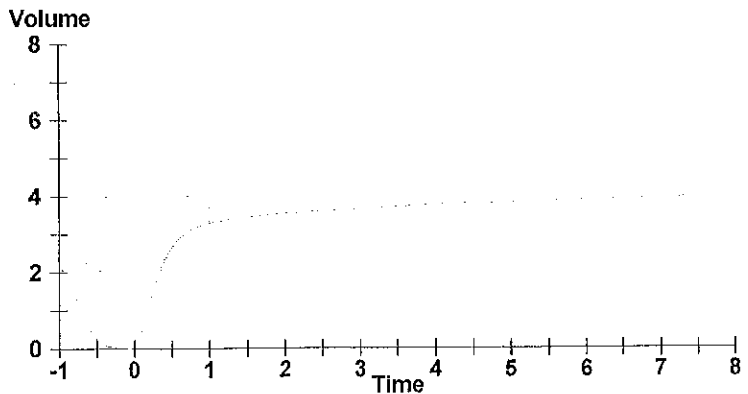
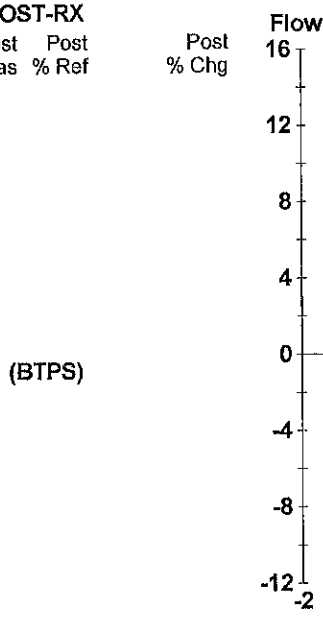
DLCO	mL/mmHg/min	22.0
DL Adj	mL/mmHg/min	22.0
DLCO/VA	mL/mHg/min/L	3.47
VA	Liters	
BHT	Sec	

Resistance

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.50
Gaw	L/sec/cmH2O	0.615
sRaw	cmH2O/L/s/L	3.86
sGaw	L/s/cmH2O/L	0.259
Vtg (Raw)	Liters	

Comments:

Interpretation:



EFFECTS OF AKPharma's-CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (SCREEN DIARY)  
CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

DAY AM	-7	-6	-5	-4	-3	-2	-1	0	0
Runny Nose 0 to 3	9/25/13 0 1 2 3	9/26/13 0 1 2 3	9/27/13 0 1 2 3	9/28/13 0 1 2 3	9/29/13 0 1 2 3	9/30/13 0 1 2 3	10/01/13 0 1 2 3	10/02/13 0 1 2 3	10/03/13 0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
DAY PM	-7	-6	-5	-4	-3	-2	-1	0	0
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N= No

SUBJECT NUMBER: AKP 007 / JLS DATE COMPLETED: 9/25/13 - 10/2/13

SUBJECT INITIALS AND DATE: JS 10/2/13

JS  
10/2/13



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Scientific Resources  
 Clin Trials-Leslie Byatt  
 2441 Ridgecrest Dr SE  
 Albuquerque, NM 87108

Client Nbr  
 24664

PATIENT NAME: JLJ, JLJ      PATIENT ID: AAGF0870      DOB: 10/13/1966      SEX: F      REPORT STATUS: Final      PAGE: 1

PHYSICIAN: Unlisted Physician,      COLLECT DATE & TIME: 10/02/2013 13:15      RECEIVE DATE & TIME: 10/02/2013 20:37      PRINT DATE & TIME: 10/03/2013 06:06

REQUISITION NO.: 30920875      PT. PHONE NO.: 0      PATIENT NO.: 007

COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
<b>Comp Metabolic Panel</b>					
Sodium	136		mmol/L	134-144	
Potassium	4.3		mmol/L	3.5-5.1	
Chloride	107		mmol/L	98-111	
CO2	20		mmol/L	20-30	
Anion Gap	9			6-14	
Glucose		112 H	mg/dL	60-100	NCS NUPM 03 Oct 2013
Impaired fasting glucose (IFG) is defined as a fasting glucose level of 100-126 mg/dL. (ADA Guidelines Diabetes Care 26: (3160-3167)2003)					
BUN	11		mg/dL	7-31	
Creatinine	1.02		mg/dL	0.50-1.40	
Creatinine method is IDMS traceable. EstGFR Calculation has been adjusted. Please note new reference range effective 5/23/2013.					
eGFR non-African Am		58 L	mL/min/1.73m2	>60	NCS NUPM 03 Oct 2013
GFR Comment	Estimated GFR values are not accurate in acute kidney failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, the very old or very young, races other than Caucasian or African American, people with acute illnesses, or amputations.				
Calcium	8.6		mg/dL	8.4-10.4	
Total Protein	6.7		gm/dL	6.1-8.2	
Albumin	4.1		gm/dL	3.4-4.7	
Globulin	2.6		gm/dL	2.4-4.2	
Bilirubin, total	0.3		mg/dL	0.3-1.2	
Alk Phos	74		U/L	38-150	
AST(SGOT)	13		U/L	6-58	
ALT(SGPT)	26		U/L	14-67	
Fasting Phosphorus	NO				
Phosphorus	2.7		mg/dL	2.3-5.6	
<b>CBC</b>					
WBC	4.7		x10E3	4.0-10.6	
RBC	4.44		x10E6	4.00-5.36	
Hgb	13.2		gm/dL	12.0-16.0	
Hct	40		%	36-48	
MCV	90		fL	81-98	
MCHC	33.1		gm/dL	31.2-35.2	
RDW	13.1		%	11.0-14.5	
Platelets	304		x10E3	150-400	
Eos, Respiratory		Rare	*	NS	NCS NUPM 03 Oct 2013
Phys, Addr, Phone	NOT GIVEN				

End of Report

*Handwritten signature and date: 03 Oct 2013*

**EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT**

**DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)**

*CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS*

DAY AM	1	2	3	4	5	6	7	8	9
Runny Nose 0 to 3	0 1 2 3 10/2	0 1 2 3 10/3	0 1 2 3 10/4	0 1 2 3 10/5	0 1 2 3 10/6	0 1 2 3 10/7	0 1 2 3 10/8	0 1 2 3 10/9	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3
Congestion 0 to 3	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3
Sneezing 0 to 3	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3
Voice Hoarse Y/N	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES
Throat Clearing Y/N	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES
<b>DAY PM</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>	<b>9</b>
Runny Nose 0 to 3	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3
Congestion 0 to 3	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3
Sneezing 0 to 3	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3
Voice Hoarse Y/N	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES
Throat Clearing Y/N	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES

**SCALE 0 to 3**

- 0= No symptoms (no symptoms detected)
  - 1= Mild symptoms (symptoms present but easily tolerated)
  - 2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)
  - 3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)
- Y=Yes N=No

SUBJECT NUMBER: AKP-007 DATE COMPLETED: 10/2/13 10:13 AM SUBJECT INITIALS AND DATE: AS 10/9/13

*Start 10/2/13*



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505 ) 938-8922

Lovelace Scient Resources  
Clin Trials-Leslie Byatt  
2441 Ridgecrest Dr SE  
Albuquerque, NM 87108

Client Nbr  
24864

PATIENT NAME **JLJ, JLJ** PATIENT ID **AAGF8933** DOB **10/13/1966** SEX **F** REPORT STATUS **Final** PAGE **1**  
 PHYSICIAN **Unlisted Physician,** COLLECT DATE & TIME **10/09/2013 13:10** RECEIVE DATE & TIME **10/09/2013 21:04** PRINT DATE & TIME **10/10/2013 08:35**  
 REQUISITION NO. **30920927** PT. PHONE NO. **0** PATIENT NO. **AKP007**  
 COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Eos, Respiratory Phys, Addr, Phone	Not given	Rare *		NS	

End of Report

*Handwritten signature and date: 10 OCT 2013*

**EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT**

**DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)**

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

DAY AM	7	8	9	10	11	12	13	14	15
Runny Nose 0 to 3	10/9 0 1 2 3 0 1 2 3	10/10 0 1 2 3 0 1 2 3	10/11 0 1 2 3 0 1 2 3	10/12 0 1 2 3 0 1 2 3	10/13 0 1 2 3 0 1 2 3	10/14 0 1 2 3 0 1 2 3	11/15 0 1 2 3 0 1 2 3	10/16 0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Itchy Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Congestion 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Sneezing 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Voice Hoarse Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO
Throat Clearing Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO
<b>DAY PM</b>	<b>7</b>	<b>8</b>	<b>9</b>	<b>10</b>	<b>11</b>	<b>12</b>	<b>13</b>	<b>14</b>	<b>15</b>
Runny Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Itchy Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Congestion 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Sneezing 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Voice Hoarse Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO
Throat Clearing Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO

**SCALE 0 to 3**

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N=NO

*9:00 AM  
5:00 PM*

SUBJECT NUMBER: AKP-007 DATE COMPLETED: 10/16/13

SUBJECT INITIALS AND DATE: JLJ 10/16/13

*Diary off on waking up in the middle of the night weight gain*

*stop now*





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Lovelace Sci. Resources  
Clin Trials Leslie Wyatt  
2441 Ridgecrest Dr SE  
Albuquerque, NM 87108

Client Nbr  
24664

PATIENT NAME <b>JLJ, JLJ</b>	PATIENT ID <b>AAGG2360</b>	DOB <b>10/13/1966</b>	SEX <b>F</b>	REPORT STATUS <b>Final</b>	PAGE <b>1</b>
PHYSICIAN <b>Unlisted Physician,</b>	COLLECT DATE & TIME <b>10/16/2013 13:30</b>	RECEIVE DATE & TIME <b>10/16/2013 20:15</b>	PRINT DATE & TIME <b>10/17/2013 06:08</b>		
REQUISITION NO. <b>30920920</b>	PT. PHONE NO. <b>0</b>	PATIENT NO. <b>AKP007</b>	COMMENTS :		

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Eos, Respiratory Phys, Addr, Phone	Not given	Rare *		NS	

*NCS  
JS 10/18/13*

End of Report

*NCS Jalyer PI 18 Oct 2013*

*Day 14*

Study Identification: 2749

LSR Study #: \_\_\_\_\_

Subject Number: AKP007

Subject Initials: JLS

ADVERSE EVENT LOG

Adverse Event	** Start Date (DD/MMM/YYYY)	SEVERITY	Relationship to Study Drug (Suspected/Not Suspected)	** End Date (DD/MMM/YYYY)	Action Taken	Investigator Initials/Date
stinging w/ itching	02/Oct/2013	mild	Suspected	23/Oct/2013	NONE	JLS 2/21/14
spots bleed intermittent	04/Oct/2013	mild	Suspected	06/Oct/2013	NONE	JLS 2/21/14
clizziness	07/Oct/2013	mild	Not Suspected	08 Oct 14/21/13	NONE	JLS 2/21/14
Sleeplessness	07/Oct/2013	mild	Not Suspected	23/Oct/2013	NONE	JLS 2/21/14
Weight gain	19/Oct/2013	mild	Not Suspected	16/Oct/2013	NONE	JLS 2/21/14

\*\* If day is unknown, write UNK in space provided, but every effort should be made to be as specific as possible\*\*

Investigator Signature (at end of study): [Signature] Date: 26 Feb 2014

SC Signature (at end of study): [Signature] Date: 2/21/14

Study Identification: 2749

LSR #: \_\_\_\_\_

Subject Number: AKP1007

Subject Initials: OLJ

**CONCOMITANT MEDICATION LOG**

List all prescription medications you are taking. Also include over-the-counter medications, vitamins and supplements.

Name of Medication	Indication (What you take it for)	Dose	Unit	Frequency	Route	* Start Date (Day/Month/Year)	Stop Date	Ongoing at EOS (for Clinic use)
EXAMPLE	Diabetes	500	MG	2 Tabs per day	Oral	UNK/AUG/1999		<input type="checkbox"/>
Levothyroxine	Hyperthyroidism	68.5	mg	QD	oral	---/--/2005		<input checked="" type="checkbox"/>
Benadryl	Seasonal allergies	25	mg	PRN	oral	---/--/1983	10/5/13 <sup>st</sup>	<input type="checkbox"/>
Sulfamethoxazole	S/P cyst excised	800/160	mg	QD	oral	26/Sep/2013	26/Oct/13	<input type="checkbox"/>
Cephalexin	S/P cyst excised	500	mg	TID	oral	26/Sep/2013	10/Oct/13	<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>

\* If day or month of medication date is unknown, write UNK in space provided

Investigator Signature (at end of study): \_\_\_\_\_ Date: 20 Feb 2014

SC Signature (at end of study): Calvin Bygott Date: 2/21/14

**EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT**

**DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)**

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

23

DAY AM	1 10/16/13	2 10/17/13	3 10/18/13	4 10/19/13	5 10/20/13	6 10/21/13	7 10/22/13	8 10/24/13	9 10/25/13
Runny Nose 0 to 3	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0
Itchy Nose 0 to 3	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0
Congestion 0 to 3	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0
Sneezing 0 to 3	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0
Voice Hoarse Y/N	YES NO NO	YES NO NO	YES NO NO	YES NO NO	YES NO NO	YES NO NO	YES NO NO	YES NO NO	YES NO NO
Throat Clearing Y/N	YES NO NO	YES NO NO	YES NO NO	YES NO NO	YES NO NO	YES NO NO	YES NO NO	YES NO NO	YES NO NO
<b>DAY PM</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>	<b>9</b>
Runny Nose 0 to 3	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0
Itchy Nose 0 to 3	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0
Congestion 0 to 3	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0
Sneezing 0 to 3	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0
Voice Hoarse Y/N	YES NO NO	YES NO NO	YES NO NO	YES NO NO	YES NO NO	YES NO NO	YES NO NO	YES NO NO	YES NO NO
Throat Clearing Y/N	YES NO NO	YES NO NO	YES NO NO	YES NO NO	YES NO NO	YES NO NO	YES NO NO	YES NO NO	YES NO NO

**SCALE 0 to 3**

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N= No

SUBJECT NUMBER: AKP 007  
JLJ

DATE COMPLETED: 10/16/13

SUBJECT INITIALS AND DATE: JLJ 10/22/13



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Lovelace Scientific Resources  
 Clin Trials-Leslie Byatt  
 2441 Ridgcrest Dr SE  
 Albuquerque, NM 87108

Client Nbr  
 24664

PATIENT NAME **JLJ, JLJ** PATIENT ID **AAGF0870** DOB **10/13/1966** SEX **F** REPORT STATUS **Final** PAGE **1**

PHYSICIAN **Unlisted Physician,** COLLECT DATE & TIME **10/22/2013 13:47** RECEIVE DATE & TIME **10/22/2013 19:25** PRINT DATE & TIME **10/24/2013 06:05**

REQUISITION NO. **30920917** PT. PHONE NO. **0** PATIENT NO. **007**

COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Eos, Respiratory Phys, Addr, Phone	None seen			NS	
NO PHYSICIAN GIVEN					
Allerg, Panel 18					
Allerg, Juniper		7.10 H	KU/L	<0.35	
Allerg, Cottonwood		4.60 H	KU/L	<0.35	
Allerg, West. Ragweed		0.80 H	KU/L	<0.35	
Allerg, Russian Thistle		21.20 H	KU/L	<0.35	
Allerg, Bermuda Grass		6.00 H	KU/L	<0.35	
Allerg, Alternaria	<0.10		KU/L	<0.35	
Allerg, Mesquite		7.40 H	KU/L	<0.35	
Allerg, Cockroach	0.20		KU/L	<0.35	
Allerg, Derm. pter.		0.40 H	KU/L	<0.35	

The standard classification system utilizes the following class cutoffs.

Class	ku/L	Interpretation
0	<0.35	Negative for Allergen
I	0.35-0.69	Positive for Allergen
II	0.70-3.49	Strongly Positive
III	3.5-17.49	Strongly Positive
IV	17.5-52.49	Strongly Positive
V	52.5-99.99	Strongly Positive
VI	>100	Strongly Positive

*Handwritten signature and date: 24 Oct 2013*

Results with allergens scoring in class 1 should be considered weakly positive or equivocal. Class 2 and higher should be considered positive. Although increasing class ranges (0-VI) are reflective of increasing concentrations of allergen-specific IgE, this may not correlate with the degree of clinical response when challenged with the specific allergen. The correlation of allergy laboratory results with clinical history is essential. A negative test may not rule out clinical allergy.

Allerg, Derm. farinae		0.50 H	KU/L	<0.35
Allerg, Clad. herb.	<0.10		KU/L	<0.35
Allerg, Firebush		3.30 H	KU/L	<0.35
Allerg, Cat Dander Ep	<0.10		KU/L	<0.35
Allerg, Dog Dander	<0.10		KU/L	<0.35
Allerg, Bluegrass		2.80 H	KU/L	<0.35
Allerg, Pigweed		7.40 H	KU/L	<0.35
Allerg, Mulberry		1.50 H	KU/L	<0.35
Allerg, Helminth	<0.10		KU/L	<0.35
CBC				
WBC	5.4		x10E3	4.0-10.6
RBC	4.60		x10E6	4.00-5.36
Hgb	14.0		gm/dL	12.0-16.0
Hct	41		%	36-48
MCV	90		fL	81-98

Continued on next page

JLJ, JLJ

10/24/2013 06:05

FAX24664



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Lovelace Scientific Resources  
 Clin Trials Leslie Byatt  
 2441 Ridgecrest Dr SE  
 Albuquerque, NM 87108

Client Nbr  
 24664

PATIENT NAME: **JLJ, JLJ**      PATIENT ID: **AAGF0870**      DOB: **10/13/1966**      SEX: **F**      REPORT STATUS: **Final**      PAGE: **2**

PHYSICIAN: **Unlisted Physician,**      COLLECT DATE & TIME: **10/22/2013 13:47**      RECEIVE DATE & TIME: **10/22/2013 19:25**      PRINT DATE & TIME: **10/24/2013 06:05**

REQUISITION NO. **30920917**      PT. PHONE NO. **0**      PATIENT NO. **007**

COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
MCHC	33.9		gm/dL	31.2-35.2	
RDW	13.1		%	11.0-14.5	
Platelets	290		x10E3	150-400	
Differential	Auto Diff				
Diff Type	48		%	40-76	
Neutrophils	40		%	16-47	
Lymphocytes	5		%	3-13	
Monocytes		6	%	0-5	H
Eosinophils	1		%	0-2	
Basophils	2.5		x10E3	1.8-7.0	
Abs. Neutrophil	2.1		x10E3	1.0-3.4	
Abs. Lymphocyte	0.3		x10E3	0.2-0.8	
Abs. Monocyte	0.3		x10E3	0.0-0.3	
Abs. Eosinophil	0.1		x10E3	0.0-0.1	
Abs. Basophil					

Deferred Test

Your requisition did not indicate a test for the EDTA tube received. Due to the instability of the specimen, a CBC with differential was performed. If you have any questions, please call Client Services at (505) 938-8922. Federal regulation requires written authorization for any test order modification to be submitted within 30 days. Please fax this report with your authorization signature to (505)938 8034 TriCore Reference Laboratories ATTN: Medical Records Imaging Department.

SIGNATURE \_\_\_\_\_ DATE \_\_\_\_\_

End of Report

*[Handwritten Signature]*      24 Oct 2013

**Effects of AkPharma's Calcium Glycerophosphate  
Nasal Spray wash (AkP 010112A) on Patient-Perceived Breathing Comfort**

**SATISFACTION QUESTIONNAIRE:**

Would you use / purchase this nasal wash product in the future?"  YES  NO

You are also encouraged to make any free comments regarding your experience in the use of this product regarding your opinion of any of its effects not covered specifically in the Daily Diary:

It didn't seem to help much, but allergies cause different symptoms every day for me depending on whether I'm outside or dusting the house etc. so it was hard to tell for sure.

[Type text]

Subject initials and Date JS 10/22/13

Study Staff Initials and Date Em 10/22/13

**AKP-009**



4749 AKPharma PERENNIAL ALLERGIES  
SCREENING/VISIT 1 SOURCE DOCUMENTS

Initials: R-A Site #: \_\_\_\_\_ Subject #: AKP009

**PATIENT DEMOGRAPHICS**

**Patient Demographics**

Date of Birth: 14 Feb 1910 <sup>Em</sup> (dd/mmm/yyyy)  
9/25/13

Gender:  Male  Female

If female, Indicate Childbearing Potential N/A

Childbearing  Surgically sterilized  Post-Menopausal

Ethnicity:  Hispanic  Non Hispanic

Race:  Asian  Black  Caucasian  American Indian

Pacific Islander  Other, Specify \_\_\_\_\_

**Smoking History**

Smoking Status:  None (smoked less than 100 cigarettes in lifetime)

Former (previously smoked more than 100 cigarettes in lifetime)

Current (smokes now)

If subject is a former or current smoker, please indicate:

Years smoked: \_\_\_\_\_ Cigarettes per day: \_\_\_\_\_

CRC Signature: Giicka Maldonado Date: 25 Sep 2013 (dd/mmm/yyyy)



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Scientific Resources  
 Clin Trials-Leslie Byatt  
 2441 Ridgecrest Dr SE  
 Albuquerque, NM 87108

Client Nbr  
 24664

PATIENT NAME: RA, RA  
 PATIENT ID: AAGF1615  
 DOB: 02/14/1960  
 SEX: M  
 REPORT STATUS: Final  
 PAGE: 1  
 PHYSICIAN: Unlisted Physician,  
 COLLECT DATE & TIME: 09/25/2013 08:57  
 RECEIVE DATE & TIME: 09/25/2013 19:47  
 PRINT DATE & TIME: 09/27/2013 06:08  
 REQUISITION NO.: 30920897  
 PT. PHONE NO.: 0  
 PATIENT NO.: AKP009  
 COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Allerg, Panel 18					
Allerg, Juniper		9.50 H	KU/L	<0.35	
Allerg, Cottonwood	<0.10		KU/L	<0.35	
Allerg, West. Ragweed	<0.10		KU/L	<0.35	
Allerg, Russian Thistle		5.30 H	KU/L	<0.35	
Allerg, Bermuda Grass		29.20 H	KU/L	<0.35	
Allerg, Alternaria	<0.10		KU/L	<0.35	
Allerg, Mesquite	0.10		KU/L	<0.35	
Allerg, Cockroach	<0.10		KU/L	<0.35	
Allerg, Derm. pter.	0.30		KU/L	<0.35	

The standard classification system utilizes the following class cutoffs.

Class	ku/L	Interpretation
0	<0.35	Negative for Allergen
I	0.35-0.69	Positive for Allergen
II	0.70-3.49	Strongly Positive
III	3.5-17.49	Strongly Positive
IV	17.5-52.49	Strongly Positive
V	52.5-99.99	Strongly Positive
VI	>100	Strongly Positive

Results with allergens scoring in class 1 should be considered weakly positive or equivocal. Class 2 and higher should be considered positive. Although increasing class ranges (0-VI) are reflective of increasing concentrations of allergen-specific IgE, this may not correlate with the degree of clinical response when challenged with the specific allergen. The correlation of allergy laboratory results with clinical history is essential. A negative test may not rule out clinical allergy.

Allerg, Derm. farinae	0.50	H	KU/L	<0.35
Allerg, Clad. herb.	<0.10		KU/L	<0.35
Allerg, Firebush		0.80 H	KU/L	<0.35
Allerg, Cat Dander Ep	0.20		KU/L	<0.35
Allerg, Dog Dander	0.10		KU/L	<0.35
Allerg, Bluegrass		12.00 H	KU/L	<0.35
Allerg, Pigweed		1.80 H	KU/L	<0.35
Allerg, Mulberry	0.20		KU/L	<0.35
Allerg, Helminth	<0.10		KU/L	<0.35
Phys, Addr, Phone	Unknown			

End of Report

*Subject shows reactivity to Dust mite (D. farinae) Perennial allergen, confirmed by ImmunoCAP testing. Meets inclusion criteria*

RA, RA

09/27/2013 06:08

*Salger*  
 27 Sept 2013

FAX24664



Name: R-A,  
 Gender: Male  
 Age: 53 Race: Hispanic  
 Height(in): 67.0 Weight(lb): 173  
 Any Info:

Id: AKP-009  
 Date: 10/11/13  
 Temp: 19 PBar: 630  
 Physician:  
 Technician: VL

Spirometry		(BTPS)	PRE-RX		POST-RX		Post	Flow
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	% Chg	
FVC	Liters	3.99	5.26	132				
FEV1	Liters	3.24	3.94	121				
FEV1/FVC	%	81	75	92				
FEF25-75%	L/sec	3.40	3.19	94				
FEF50%	L/sec	4.15	4.27	103				
FEF75%	L/sec	1.57	1.24	79				
IC	Liters							
VC	Liters	3.99						
PEF	L/sec	8.14	9.56	117				
MVV	L/min	139						
PIF	L/sec		1.42					
FEV1/FEV6%			78					

Lung Volumes/Plethysmography

Vtg	Liters			
VC	Liters	3.99		
TLC	Liters	6.05		
RV	Liters	2.05		
RV/TLC	%	35		
FRC PL	Liters	3.29		
ERV	Liters			
IC	Liters			

Diffusion

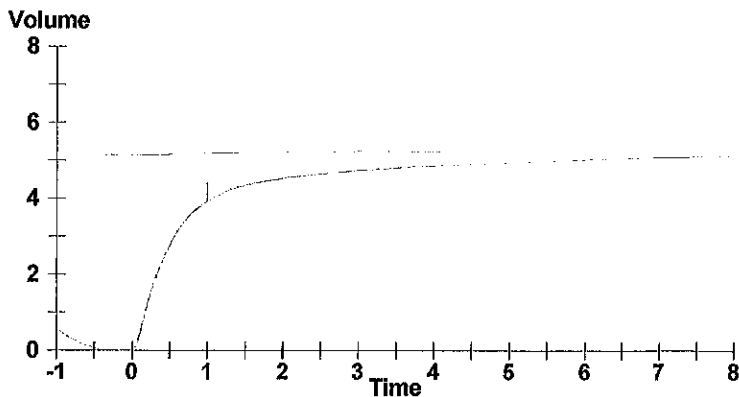
DLCO	mL/mmHg/min	23.6
DL Adj	mL/mmHg/min	23.6
DLCO/VA	mL/mHg/min/L	3.32
VA	Liters	
BHT	Sec	

Resistance

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.40
Gaw	L/sec/cmH2O	0.789
sRaw	cmH2O/L/s/L	4.59
sGaw	L/s/cmH2O/L	0.218
Vtg (Raw)	Liters	

Comments:

Interpretation:





Name: R-A,  
Gender: Male  
Age: 53 Race: Hispanic  
Height(in): 67.0 Weight(lb): 173  
Any Info:

Id: AKP-009  
Date: 10/17/13  
Temp: 19 PBar: 631  
Physician:  
Technician:

Spirometry		(BTPS)	PRE-RX		POST-RX		Post	Flow
		Ref	Pre	Pre	Post	Post	% Chg	
			Meas	% Ref	Meas	% Ref		
FVC	Liters	3.99	5.17	130				
FEV1	Liters	3.24	3.92	121				
FEV1/FVC	%	81	76	93				
FEF25-75%	L/sec	3.40	3.26	96				
FEF50%	L/sec	4.15	3.90	94				
FEF75%	L/sec	1.57	1.51	96				
IC	Liters							
VC	Liters	3.99						
PEF	L/sec	8.14	8.89	109				
MVV	L/min	139						
PIF	L/sec		1.16					
FEV1/FEV6%			78					

Lung Volumes/Plethysmography

Vtg	Liters	
VC	Liters	3.99
TLC	Liters	6.05
RV	Liters	2.05
RV/TLC	%	35
FRC PL	Liters	3.29
ERV	Liters	
IC	Liters	

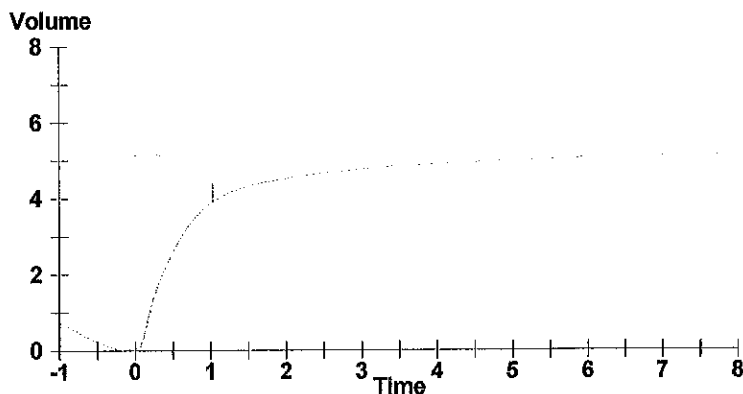
Diffusion

DLCO	mL/mmHg/min	23.6
DL Adj	mL/mmHg/min	23.6
DLCO/VA	mL/mHg/min/L	3.32
VA	Liters	
BHT	Sec	

Resistance

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.40
Gaw	L/sec/cmH2O	0.789
sRaw	cmH2O/L/s/L	4.59
sGaw	L/s/cmH2O/L	0.218
Vtg (Raw)	Liters	

Comments:



Interpretation:

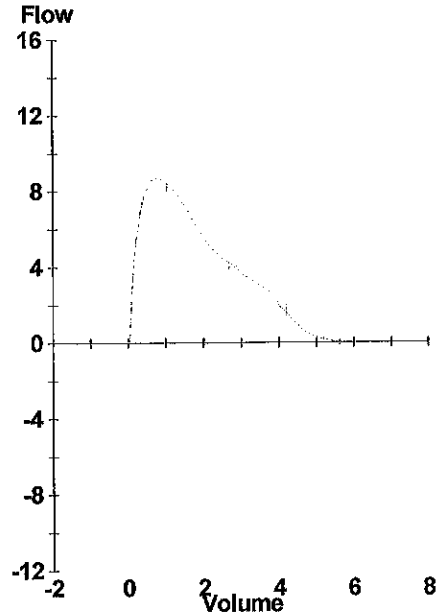


Name: R-A,  
 Gender: Male  
 Age: 53 Race: Hispanic  
 Height(in): 67.0 Weight(lb): 173  
 Any Info:

Id: AKP-009  
 Date: 10/24/13  
 Temp: 20 PBar: 634  
 Physician:  
 Technician: VL

Spirometry		(BTPS)	PRE-RX		POST-RX		Post
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	% Chg
FVC	Liters	3.99	5.64	142			
FEV1	Liters	3.24	4.23	130			
FEV1/FVC	%	81	75	92			
FEF25-75%	L/sec	3.40	3.39	100			
FEF50%	L/sec	4.15	4.04	98			
FEF75%	L/sec	1.57	1.56	99			
IC	Liters						
VC	Liters	3.99					
PEF	L/sec	8.14	8.71	107			
MVV	L/min	139					
PIF	L/sec						
FEV1/FEV6%			77				

(BTPS)



Lung Volumes/Plethysmography

Vtg	Liters	
VC	Liters	3.99
TLC	Liters	6.05
RV	Liters	2.05
RV/TLC	%	35
FRC PL	Liters	3.29
ERV	Liters	
IC	Liters	

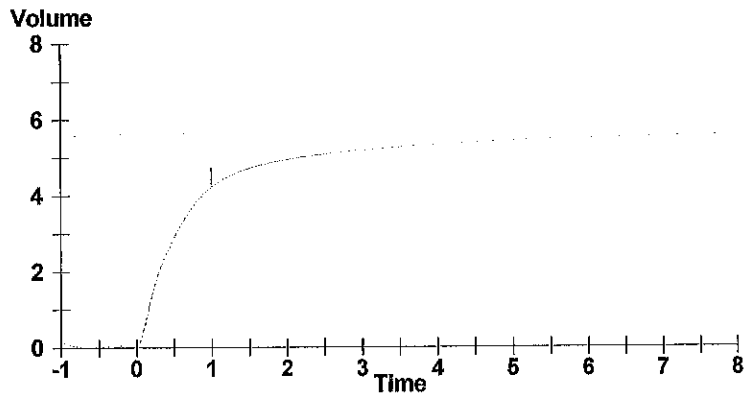
Diffusion

DLCO	mL/mmHg/min	23.6
DL Adj	mL/mmHg/min	23.6
DLCO/VA	mL/mHg/min/L	3.34
VA	Liters	
BHT	Sec	

Resistance

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.40
Gaw	L/sec/cmH2O	0.789
sRaw	cmH2O/Ls/L	4.59
sGaw	L/s/cmH2O/L	0.218
Vtg (Raw)	Liters	

Comments:



Interpretation:



Name: R-A,

Id: AKP-009

Gender: Male

Date: 11/01/13

Age: 53 Race:

Temp: 19

PBar: 633

Height(in): 67.0 Weight(lb): 172

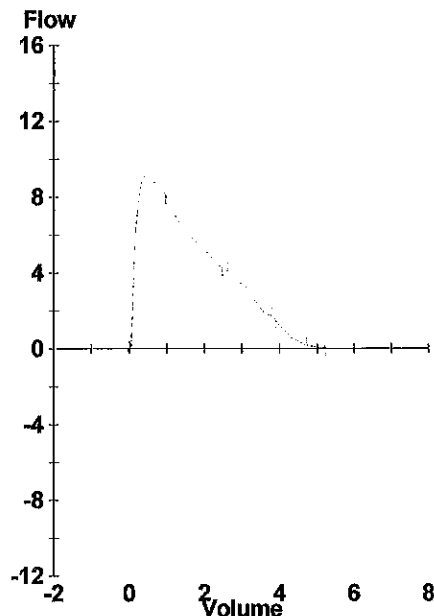
Physician:

Any Info:

Technician: VL

Spirometry		(BTPS)	PRE-RX		POST-RX		Post
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	% Chg
FVC	Liters	3.99	5.26	132			
FEV1	Liters	3.24	3.82	118			
FEV1/FVC	%	81	73	89			
FEF25-75%	L/sec	3.40	2.87	84			
FEF50%	L/sec	4.15	3.71	89			
FEF75%	L/sec	1.57	1.29	82			
IC	Liters						
VC	Liters	3.99					
PEF	L/sec	8.14	9.08	112			
MVV	L/min	139					
PIF	L/sec						
FEV1/FEV6%			76				

(BTPS)



Lung Volumes/Plethysmography

Vtg	Liters	
VC	Liters	3.99
TLC	Liters	6.05
RV	Liters	2.05
RV/TLC	%	35
FRC PL	Liters	3.30
ERV	Liters	
IC	Liters	

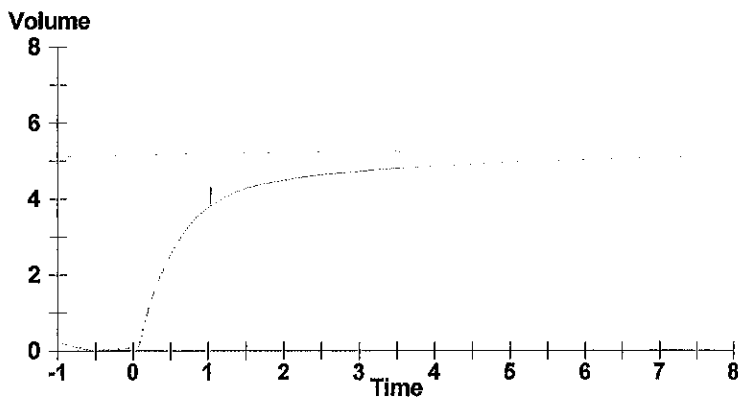
Diffusion

DLCO	mL/mmHg/min	23.6
DL Adj	mL/mmHg/min	23.6
DLCO/VA	mL/mHg/min/L	3.33
VA	Liters	
BHT	Sec	

Resistance

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.39
Gaw	L/sec/cmH2O	0.791
sRaw	cmH2O/Ls/L	4.59
sGaw	L/s/cmH2O/L	0.218
Vtg (Raw)	Liters	

Comments:



Interpretation:



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Scientific Resources  
Clin Trials Leslie Byatt  
2441 Ridgcrest Dr SE  
Albuquerque, NM 87108

Client Nbr  
24864

PATIENT NAME: RA, X  
PATIENT ID: AAGG0250  
DOB: 02/14/1966  
SEX: M  
REPORT STATUS: Final  
PAGE: 1  
PHYSICIAN: Unlisted Physician,  
COLLECT DATE & TIME: 10/11/2013 13:15  
RECEIVE DATE & TIME: 10/11/2013 19:01  
PRINT DATE & TIME: 10/14/2013 06:10  
REQUISITION NO.: 30920911  
PT. PHONE NO.: 0  
PATIENT NO.: AKP 009  
COMMENTS:

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Comp Metabolic Panel					
Sodium	137		mmol/L	134-144	
Potassium	4.3		mmol/L	3.5-5.1	
Chloride	103		mmol/L	98-111	
CO2	25		mmol/L	20-30	
Anion Gap	9			6-14	
Glucose	94		mg/dL	60-100	
BUN	12		mg/dL	7-31	
Creatinine	0.77		mg/dL	0.62-1.66	
Creatinine method is IDMS traceable. EstGFR Calculation has been adjusted. Please note new reference range effective 5/23/2013.					
eGFR non-African Am	>60		mL/min/1.73m <sup>2</sup>	>60	
GFR Comment	Estimated GFR values are not accurate in acute kidney failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, the very old or very young, races other than Caucasian or African American, people with acute illnesses, or amputations.				
Calcium	9.7		mg/dL	8.4-10.4	
Total Protein	6.9		gm/dL	6.1-8.2	
Albumin	4.1		gm/dL	3.4-4.7	
Globulin	2.8		gm/dL	2.4-4.2	
Bilirubin, total	1.0		mg/dL	0.3-1.2	
Alk Phos	60		U/L	38-150	
AST(SGOT)	14		U/L	6-58	
ALT(SGPT)	22		U/L	14-67	
Fasting Phosphorus	NO				
Phosphorus	3.5		mg/dL	2.3-5.6	
CBC					
WBC	7.0		x10E3	4.0-10.6	
RBC	5.20		x10E6	4.64-6.00	
Hgb	15.7		gm/dL	14.5-17.7	
Hct	46		%	42-53	
MCV	88		fL	81-98	
MCHC	34.5		gm/dL	31.2-35.2	
RDW	12.5		%	11.0-14.5	
Platelets	247		x10E3	150-400	
Eos, Respiratory		Few	*	NS	
Phys, Addr, Phone	Not given				

Callback Accession Comments:

F3200806

AGAP, ALB, ALKP, ALT, AST, BUN, CA, CL, CO2, CREA, EOSR, FAST, GFRCOM, GFRW, GLOB, GLU, HCT, HGB, K, MCHC, MCV, NA, PLT, PO4, RBC, RDW, TBIL, TP, UNKPHY, WBC

10/12/2013 06:28 am FAXED TO 33488546 NC CS111533

End of Report

*M. M. [Signature]*  
15 Oct 2013

EFFECTS OF AKPharma's-CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (SCREEN DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

DAY	-7	-6	-5	-4	-3	-2	-1	0	19/12/13
AM	10/04/13	10/05/13	10/06/13	10/07/13	10/08/13	10/09/13	10/10/13	10/11/13	10/12/13
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
DAY PM	-7	-6	-5	-4	-3	-2	-1	0	0
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N= No

SUBJECT NUMBER: AKP009 DATE COMPLETED: 10/4/13 - 10/11/13

SUBJECT INITIALS AND DATE: RA 10-11-13

R-A



EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)

ON PATIENT-PERCEIVED BREATHING COMFORT

Day 1-9. **Next Visit**

DAILY SYMPTOMS SCORE SHEET (SCREEN-DIARY)  
CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

DAY	-7	-6	-5	-4	-3	-2	-1	0	0
AM	10/11	10/12	10/13	10/14	10/15	10/16	10/17	10/18	10/18
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 2 3	0 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 2 3	0 2 3	0 1 2 3	0 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 2 3	0 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 2 3	0 2 3	0 2 3	0 1 2 3	0 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES <input checked="" type="radio"/>	YES <input checked="" type="radio"/>	YES <input checked="" type="radio"/>	YES <input checked="" type="radio"/>	YES <input checked="" type="radio"/>	YES <input checked="" type="radio"/>	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES <input checked="" type="radio"/>	YES <input checked="" type="radio"/>	YES <input checked="" type="radio"/>	YES <input checked="" type="radio"/>	YES <input checked="" type="radio"/>	YES <input checked="" type="radio"/>	YES NO	YES NO
DAY PM	-7	-6	-5	-4	-3	-2	-1	0	0
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 2 3	0 2 3	0 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 2 3	0 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 2 3	0 1 2 3	0 1 2 3	0 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES <input checked="" type="radio"/>	YES <input checked="" type="radio"/>	YES <input checked="" type="radio"/>	YES <input checked="" type="radio"/>	YES <input checked="" type="radio"/>	YES <input checked="" type="radio"/>	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES <input checked="" type="radio"/>	YES <input checked="" type="radio"/>	YES <input checked="" type="radio"/>	YES <input checked="" type="radio"/>	YES <input checked="" type="radio"/>	YES <input checked="" type="radio"/>	YES NO	YES NO	YES NO

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N= No

SUBJECT NUMBER: AK-P009

DATE COMPLETED: 10/11/13 - 10/17/13

SUBJECT INITIALS AND DATE: RA 10-17-13

Start new



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505 ) 938-8922

Lovelace Scientific Resources  
Clin Trials/ Leslie Wyatt  
2441 Ridgcrest Dr SE  
Albuquerque, NM 87108

Client Nbr  
24864

PATIENT NAME <b>R-A, R-A</b>	PATIENT ID <b>AAGG2990</b>	DOB <b>02/14/1960</b>	SEX <b>M</b>	REPORT STATUS <b>Final</b>	PAGE <b>1</b>
PHYSICIAN <b>Unlisted Physician,</b>	COLLECT DATE & TIME <b>10/17/2013 14:00</b>	RECEIVE DATE & TIME <b>10/17/2013 19:46</b>	PRINT DATE & TIME <b>10/18/2013 06:07</b>		
REQUISITION NO. <b>30920899</b>	PT. PHONE NO. <b>0</b>	PATIENT NO. <b>ACP009</b>			
COMMENTS :					

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Eos, Respiratory Phys, Addr, Phone	Not given	Rare *		NS	

End of Report

*NCS  
Salzer 18 Oct 2013*

**EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT**

**DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)**

**CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS**

DAY	7	8	9	10	11	12	13	14	15
AM	10/17	10/18	10/19	10/20	10/21	10/22	10/23	10/24	15
Runny Nose 0 to 3	<del>1</del> 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	<del>1</del> 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	<del>1</del> 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES <del>NO</del>	YES <del>NO</del>	YES <del>NO</del>	YES <del>NO</del>	YES <del>NO</del>	YES <del>NO</del>	YES <del>NO</del>	YES <del>NO</del>	YES <del>NO</del>
Throat Clearing Y/N	YES <del>NO</del>	YES <del>NO</del>	YES <del>NO</del>	YES <del>NO</del>	YES <del>NO</del>	YES <del>NO</del>	YES <del>NO</del>	YES <del>NO</del>	YES <del>NO</del>
<b>DAY PM</b>	<b>7</b>	<b>8</b>	<b>9</b>	<b>10</b>	<b>11</b>	<b>12</b>	<b>13</b>	<b>14</b>	<b>15</b>
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES <del>NO</del>	YES <del>NO</del>	YES <del>NO</del>	YES <del>NO</del>	YES <del>NO</del>	YES <del>NO</del>	YES <del>NO</del>	YES <del>NO</del>	YES <del>NO</del>
Throat Clearing Y/N	YES <del>NO</del>	YES <del>NO</del>	YES <del>NO</del>	YES <del>NO</del>	YES <del>NO</del>	YES <del>NO</del>	YES <del>NO</del>	YES <del>NO</del>	YES <del>NO</del>

**SCALE 0 to 3**

- 0= No symptoms (no symptoms detected)
  - 1= Mild symptoms (symptoms present but easily tolerated)
  - 2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)
  - 3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)
- Y=Yes N= No

SUBJECT NUMBER: AKP 009 DATE COMPLETED: 10/24/13 SUBJECT INITIALS AND DATE: PA 10/24/13

*measured*



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505 ) 938-8922

Lovelace Science Resources  
Leslie Byatt, Clin Trials  
2441 Ridgecrest Dr SE  
Albuquerque, NM 87108-5129

Client Nbr  
24664

PATIENT NAME <b>RA, RA</b>	PATIENT ID <b>AAGF1615</b>	DOB <b>02/14/1960</b>	SEX <b>M</b>	REPORT STATUS <b>Final</b>	PAGE <b>1</b>
PHYSICIAN <b>Unlisted Physician,</b>	COLLECT DATE & TIME <b>10/24/2013 13:36</b>	RECEIVE DATE & TIME <b>10/24/2013 18:13</b>	PRINT DATE & TIME <b>10/25/2013 06:09</b>		
REQUISITION NO.      PT. PHONE NO.	PATIENT NO.				
<b>30920969              0</b>	<b>AKP009</b>				
COMMENTS :					

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Eos, Respiratory Phys, Addr, Phone	Not given	Rare *		NS	

End of Report

*Handwritten:* Sub I  
29 Oct 2013

Study Identification: 2749

Subject Number: AKP009

LSR Study #: \_\_\_\_\_

Subject Initials: R-A

ADVERSE EVENT LOG

Adverse Event	** Start Date (DD/MMM/YYYY)	SEVERITY	Relationship to Study Drug (Suspected/Not Suspected)	** End Date (DD/MMM/YYYY)	Action Taken	Investigator Initials/Date
Sore throat	27 Oct / 2013	mild	Suspected	25 / OCT / 2013	none	MMM / 27 Feb 14
dryness at application site	27 Oct / 2013	mild	Suspected	04 / NOV / 2013	none	MMM / 27 Feb 14
Burning at application site	27 Oct / 2013	mild	Suspected	04 / NOV / 2013	none	MMM / 27 Feb 14
itching at application site	11 Oct / 2013	mild	Suspected	04 / NOV / 2013	none	MMM / 27 Feb 14
itching on site	13 Oct / 2013	mild	Suspected	04 / NOV / 2013	Blew his nose	MMM / 27 Feb 14
itching on site	11 Oct / 2013	mild	Suspected	04 / NOV / 2013	none	MMM / 27 Feb 14

\*\* If day is unknown, write UNK in space provided, but every effort should be made to be as specific as possible\*\*

Investigator Signature (at end of study): [Signature] Date: 27 Feb 2014

SC Signature (at end of study): [Signature] Date: 2/21/14



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Scientific Resources  
 Leslie Byatt, Clinical Trials  
 2441 Ridgecrest Dr SE  
 Albuquerque, NM 87108-5129

Client Nbr  
 24664

PATIENT NAME: R-A, R-A  
 PATIENT ID: AAGG2990  
 DOB: 02/14/1960  
 SEX: M  
 REPORT STATUS: Final  
 PAGE: 1  
 PHYSICIAN: Unlisted Physician,  
 COLLECT DATE & TIME: 11/01/2013 09:50  
 RECEIVE DATE & TIME: 11/01/2013 19:02  
 PRINT DATE & TIME: 11/04/2013 06:13  
 REQUISITION NO.: 30920886  
 PT. PHONE NO.: 0  
 PATIENT NO.: ACP009  
 COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Comp Metabolic Panel					
Sodium	138		mmol/L	134-144	
Potassium	4.1		mmol/L	3.5-5.1	
Chloride	105		mmol/L	98-111	
CO2	26		mmol/L	20-30	
Anion Gap	7			6-14	
Glucose		(104) H	mg/dL	60-100	
Impaired fasting glucose (IFG) is defined as a fasting glucose level of 100-126 mg/dL. (ADA Guidelines Diabetes Care 26: (3160-3167)2003)					
BUN	12		mg/dL	7-31	
Creatinine	0.78		mg/dL	0.62-1.66	
Creatinine method is IDMS traceable. EstGFR calculation has been adjusted. Please note new reference range effective 5/23/2013.					
eGFR non-African Am	>60		mL/min/1.73m2	>60	
GFR Comment	Estimated GFR values are not accurate in acute kidney failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, the very old or very young, races other than Caucasian or African American, people with acute illnesses, or amputations.				
Calcium	9.2		mg/dL	8.4-10.4	
Total Protein	7.0		gm/dL	6.1-8.2	
Albumin	4.3		gm/dL	3.4-4.7	
Globulin	2.7		gm/dL	2.4-4.2	
Bilirubin, total		(1.3) H	mg/dL	0.3-1.2	
Alk Phos	59		U/L	38-150	
AST(SGOT)	12		U/L	6-58	
ALT(SGPT)	23		U/L	14-67	
Fasting	NO				
CBC					
WBC	6.2		x10E3	4.0-10.6	
RBC	5.50		x10E6	4.84-6.00	
Hgb	16.0		gm/dL	14.5-17.7	
Hct	48		%	42-53	
MCV	87		fL	81-98	
MCHC	33.6		gm/dL	31.2-35.2	
RDW	12.2		%	11.0-14.5	
Platelets	248		x10E3	150-400	
Eos, Respiratory		Few		NS	
Phys, Addr, Phone	NO PHYSICIAN GIVEN				

NCS JS 11/8/13

NCS JS 11/8/13

Few  
 NCS JS 11/8/13

End of Report

*Galvan - PI NCS 8 Nov 2013*

Study Identification: 2749

LSR #: \_\_\_\_\_

Subject Number: AKP 009

Subject Initials: R-VA

**CONCOMITANT MEDICATION LOG**

List all prescription medications you are taking. Also include over-the-counter medications, vitamins and supplements.

Name of Medication	Indication (What you take it for)	Dose	Unit	Frequency	Route	* Start Date (Day/Month/Year)	Stop Date	Ongoing at EOS (for Clinic use)
EXAMPLE	Diabetes	500	M/G	2 Tabs per day	Oral	UNK/AUG/1999		<input type="checkbox"/>
Multivitamin	Dietary Supplement	1	TAB	QD	oral	--/--/1995		<input checked="" type="checkbox"/>
ASA	sinus headaches	650	mg	PRN	PO	1993		<input checked="" type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>

\* If day or month of medication date is unknown, write UNK in space provided

Investigator Signature (at end of study): [Signature] Date: 27 Feb 2014

SC Signature (at end of study): [Signature] Date: 2/21/14

**EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP0101122A)  
ON PATIENT-PERCEIVED BREATHING COMFORT**

**DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)**

*CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS*

DAY AM	14	15	16	17	18	19	20	21	22
Runny Nose 0 to 3	<del>0 1 2 3</del>	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	<del>0 1 2 3</del>	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	<del>0 1 2 3</del>	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	<del>0 1 2 3</del>	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	<del>YES NO</del>	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	<del>YES NO</del>	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
<b>DAY PM</b>	<b>14</b>	<b>15</b>	<b>16</b>	<b>17</b>	<b>18</b>	<b>19</b>	<b>20</b>	<b>21</b>	<b>22</b>
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

**SCALE 0 to 3**

- 0= No symptoms (no symptoms detected)
  - 1= Mild symptoms (symptoms present but easily tolerated)
  - 2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)
  - 3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)
- Y=Yes N=No

R-14

11/01/13

SUBJECT NUMBER: AKP009

DATE COMPLETED: 10/14/13

SUBJECT INITIALS AND DATE: RA 11-1-13



R-A / AKP009

11/01/13

**Effects of AkPharma's Calcium Glycerophosphate  
Nasal Spray wash (AkP 010112A) on Patient-Perceived Breathing Comfort**

**SATISFACTION QUESTIONNAIRE:**

Would you use / purchase this nasal wash product in the future?"  YES  NO

You are also encouraged to make any free comments regarding your experience in the use of this product regarding your opinion of any of its effects not covered specifically in the Daily Diary:

Dry nose 2 hrs after application

Crusty nose every morning

Sinus irritation after using spray

[Type text]

Subject initials and Date RA 11-1-13

Study Staff Initials and Date Em 11/01/13

**AKP-010**

4749 AKPharma PERENNIAL ALLERGIES  
SCREENING/VISIT 1 SOURCE DOCUMENTS

Initials: CHA Site #: \_\_\_\_\_ Subject #: AKP 010

PATIENT DEMOGRAPHICS

**Patient Demographics**

Date of Birth: 06, Jul, 1956 (dd/mmm/yyyy)

Gender:  Male  Female

If female, Indicate Childbearing Potential NIA

Childbearing  Surgically sterilized  Post-Menopausal

Ethnicity:  Hispanic  Non Hispanic

Race:  Asian  Black  Caucasian  American Indian

Pacific Islander  Other, Specify \_\_\_\_\_

**Smoking History**

Smoking Status:  None (smoked less than 100 cigarettes in lifetime)

Former (previously smoked more than 100 cigarettes in lifetime)

Current (smokes now)

If subject is a former or current smoker, please indicate:

Years smoked: 10 Cigarettes per day: 1pk per day

CRC Signature: Erica macdonado Date: 25 Sep 2013 (dd/mmm/yy)



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Scientific Resources  
 Clin Trials Lestive Wyatt  
 2441 Ridgecrest Dr SE  
 Albuquerque, NM 87108

Client Nbr  
 24864

PATIENT NAME: **CHA, X** PATIENT ID: **AAGF1636** DOB: **07/06/1956** SEX: **M** REPORT STATUS: **Final** PAGE: **1**  
 PHYSICIAN: **Unlisted Physician,** COLLECT DATE & TIME: **09/25/2013 11:40** RECEIVE DATE & TIME: **09/25/2013 20:13** PRINT DATE & TIME: **09/27/2013 06:08**  
 REQUISITION NO.: **30920891** PT. PHONE NO.: **0** PATIENT NO.: **AKP010**  
 COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Allerg, Panel 18					
Allerg, Juniper		5.80 H	KU/L	<0.35	
Allerg, Cottonwood	0.30		KU/L	<0.35	
Allerg, West. Ragweed	<0.10		KU/L	<0.35	
Allerg, Russian Thistle		1.00 H	KU/L	<0.35	
Allerg, Bermuda Grass		5.60 H	KU/L	<0.35	
Allerg, Alternaria		1.40 H	KU/L	<0.35	
Allerg, Mesquite	0.30		KU/L	<0.35	
Allerg, Cockroach	<0.10		KU/L	<0.35	
Allerg, Derm. pter.	<0.10		KU/L	<0.35	

The standard classification system utilizes the following class cutoffs.

Class	ku/L	Interpretation
0	<0.35	Negative for Allergen
I	0.35-0.69	Positive for Allergen
II	0.70-3.49	Strongly Positive
III	3.5-17.49	Strongly Positive
IV	17.5-52.49	Strongly Positive
V	52.5-99.99	Strongly Positive
VI	>100	Strongly Positive

Results with allergens scoring in Class 1 should be considered weakly positive or equivocal. Class 2 and higher should be considered positive. Although increasing class ranges (0-VI) are reflective of increasing concentrations of allergen-specific IgE, this may not correlate with the degree of clinical response when challenged with the specific allergen. The correlation of allergy laboratory results with clinical history is essential. A negative test may not rule out clinical allergy.

Allerg, Derm. farinae	0.10		KU/L	<0.35
Allerg, Clad. herb.	<0.10		KU/L	<0.35
Allerg, Firebush		0.70 H	KU/L	<0.35
Allerg, Cat Dander Ep		0.60 H	KU/L	<0.35
Allerg, Dog Dander		17.80 H	KU/L	<0.35
Allerg, Bluegrass		2.00 H	KU/L	<0.35
Allerg, Pigweed	0.10		KU/L	<0.35
Allerg, Mulberry	<0.10		KU/L	<0.35
Allerg, Helminth	<0.10		KU/L	<0.35
Phys, Addr, Phone	Not given			

End of Report

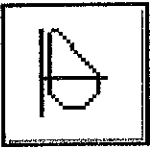
*ImmunoCAP testing confirms reactivity to perennial aero allergens, mold (Alternaria), Cat dander & epithelium and dog dander. Meets laboratory inclusion criteria*

CHA, X

09/27/2013 06:08

*Galley*  
 27 Sept 2013

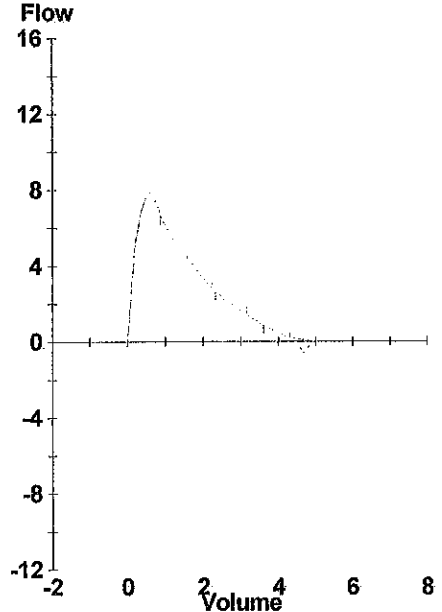
FAX24864



Name: CHA,  
 Gender: Male  
 Age: 57 Race: Caucasian  
 Height(in): 72.0 Weight(lb): 246  
 Any Info:

Id: AKP-010  
 Date: 10/31/13  
 Temp: 21 PBar: 631  
 Physician:  
 Technician: VL

Spirometry		(BTPS) Ref	PRE-RX		POST-RX		Post % Chg
			Pre Meas	Pre % Ref	Post Meas	Post % Ref	
FVC	Liters	4.96	4.85	98			
FEV1	Liters	3.99	3.21	81			
FEV1/FVC %		80	66	83			
FEF25-75%L/sec		4.01	1.98	49			
FEF50%	L/sec	4.89	2.42	50			
FEF75%	L/sec	1.88	0.83	44			
IC	Liters						
VC	Liters	4.96					
PEF	L/sec	9.20	7.87	86			
MVV	L/min	151					
PIF	L/sec		0.62				
FEV1/FEV6%			69				



Lung Volumes/Plethysmography

Vtg	Liters	
VC	Liters	4.96
TLC	Liters	7.18
RV	Liters	2.46
RV/TLC	%	36
FRC.PL	Liters	3.55
ERV	Liters	
IC	Liters	

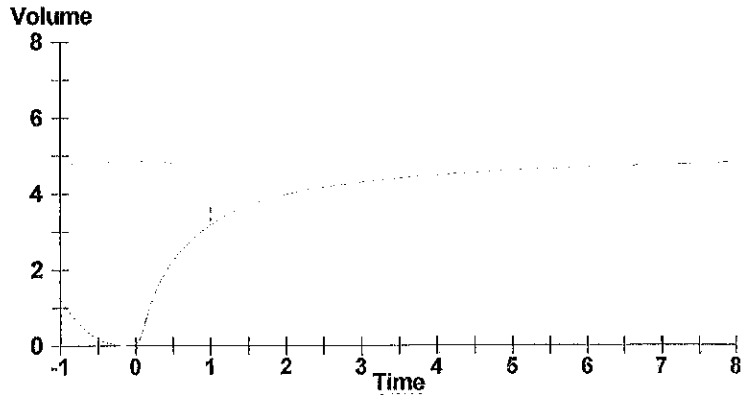
Diffusion

DLCO	mL/mmHg/min	29.3
DL Adj	mL/mmHg/min	29.3
DLCOVA	mL/mmHg/min/L	3.24
VA	Liters	
BHT	Sec	

Resistance

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.27
Gaw	L/sec/cmH2O	0.852
sRaw	cmH2O/L/s/L	4.49
sGaw	L/s/cmH2O/L	0.223
Vtg (Raw)	Liters	

Compliance



Interpretability



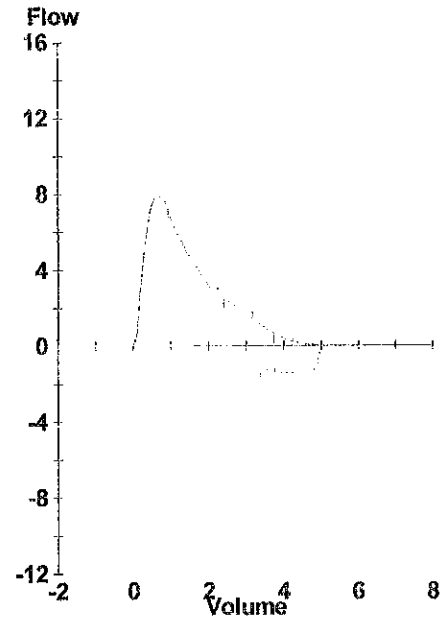
Lawrence Scientific Resources  
 1041 Ridgewood Dr SE  
 Albuquerque, NM 87102

Name: CHA,  
 Gender: Male  
 Age: 57 Race: Caucasian  
 Height(in): 72.0 Weight(lb): 246  
 Any Info:

Id: AKP-010  
 Date: 11/07/13  
 Temp: 19 PBar: 639  
 Physician:  
 Technician: VL

		(BTPS)	PRE-RX		POST-RX		Post
		Ref	Pre	Pre	Post	Post	% Chg
			Mean	% Ref	Mean	% Ref	
FVC	Liters	4.96	4.99	100			
FEV1	Liters	3.59	3.21	80			
FEV1/FVC	%	30	34	81			
FEF25-75%	L/sec	4.01	1.70	44			
FEF50%	L/sec	4.89	2.28	47			
FEF75%	L/sec	1.85	0.63	33			
IC	Liters						
VC	Liters	4.96					
PEF	L/sec	9.20	8.69	94			
MVV	L/min	151					
PIF	L/sec		1.57				
FEV1/FEV6%			69				

(BTPS)



Flow-Volume graph (BTPS)

Vtg	Liters	
VC	Liters	4.96
TLC	Liters	7.18
RV	Liters	2.46
RV/TLC	%	36
FRC PL	Liters	3.55
ERV	Liters	
IC	Liters	

Diffusion

DLCO	mL/min/lg/min	29.3
DL Adj	mL/mmHg/min	29.3
VA	L/min	3.29
BHT	Sec	

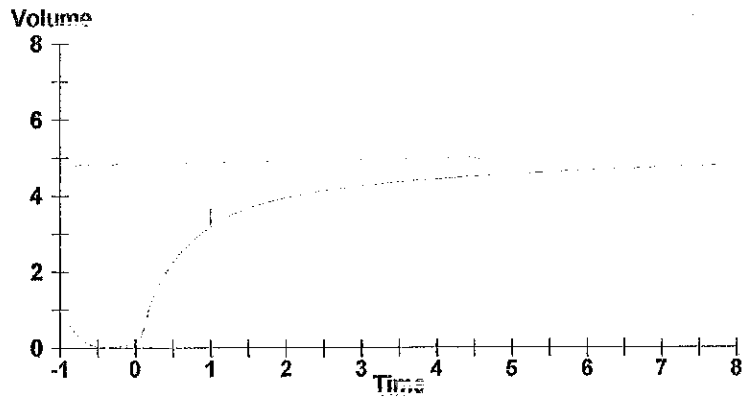
Respiration

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw PEEP	cmH2O	1.07
Raw	L/second/cmH2O	0.955
sRaw	cmH2O/L/sec	1.07

Flow

Volume

Computer print



Interpretation

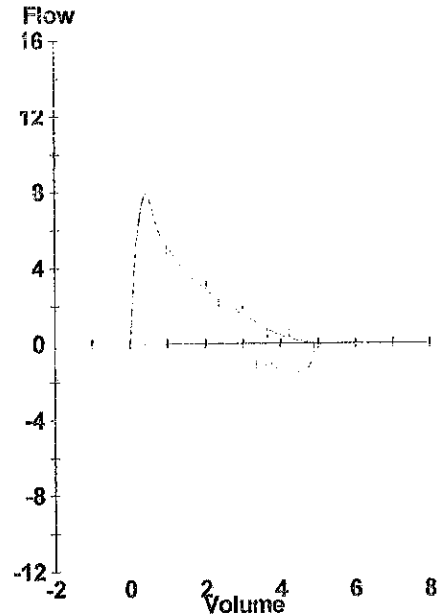


Name: CHA,  
 Gender: Male  
 Age: 57 Race: Caucasian  
 Height(in): 72.0 Weight(lb): 246  
 Any Info:

Id: AKP-010  
 Date: 11/14/13  
 Temp: 20 PBar: 632  
 Physician:  
 Technician:

		(BTPS)	PRE-RX		POST-RX		Post
		Ref	Pre	Pre	Post	Post	% Chg
			Meas	% Ref	Meas	% Ref	
FVC	Liters	4.90	4.91	99			
FEV1	Liters	2.67	2.68	99			
FEV1/FVC %		50	52	77			
FEF25-75% /sec		4.01	1.70	42			
FEF50% /sec		4.89	** 2.10	** 43			
FEF75% /sec		1.55	0.69	37			
IC	Liters						
VC	Liters	4.96					
PEF	L/sec	9.20	7.94	86			
MVV	L/min	151					
PIF	L/sec		1.58				
FEV1/FEV6%			65				

(BTPS)



Large Airway/Calypso Analysis

Vtg	Liters	
VC	Liters	4.96
TLC	Liters	7.18
RV	Liters	2.46
RV/TLC	%	36
FRC PL	Liters	3.55
ERV	Liters	
IC	Liters	

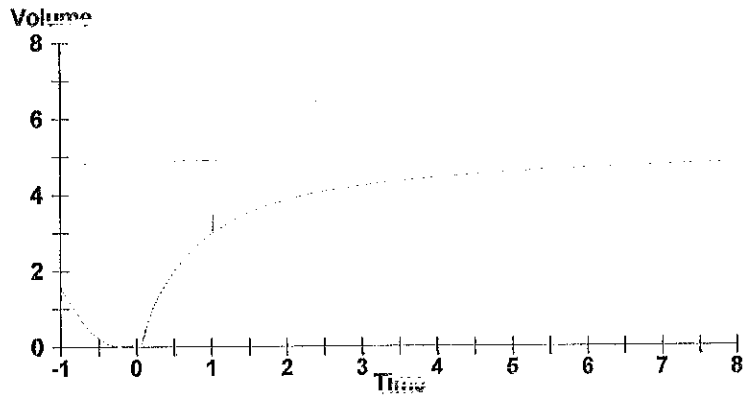
Diffusion

DLCO	mL/min/mmHg	29.3
DL Adj	mL/mmHg/min	29.3
VA	L/min	3.25
BHT	Sec	

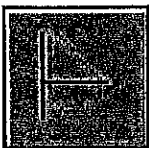
Resistance

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Gaw	L/sec/cmH2O	1.27
sRaw	cmH2O/L/sec	

Compliance



Interpretation:



Name: CHA,  
 Gender: Male  
 Age: 57 Race: Caucasian  
 Height(in): 72.0 Weight(lb): 246  
 Any Info:

Id: AKP-010  
 Date: 11/21/13  
 Temp: 21 PBar: 630  
 Physician:  
 Technician: VL

Spirometry		(BTPS)	PRE-RX		POST-RX		Post
		Ref	Pre	Pre	Post	Post	% Chg
			Meas	% Ref	Meas	% Ref	
FVC	Liters	4.96	4.96	100			
FEV1	Liters	3.99	3.16	79			
FEV1/FVC	%	80	64	80			
FEF25-75%	L/sec	4.01	1.84	46			
FEF50%	L/sec	4.89	2.45	50			
FEF75%	L/sec	1.88	0.67	36			
IC	Liters						
VC	Liters	4.96					
PEF	L/sec	9.20	8.73	95			
MVV	L/min	151					
PIF	L/sec		2.07				
FEV1/FEV6%			68				

**Lung Volumes/Plethysmography**

Vtg	Liters	
VC	Liters	4.96
TLC	Liters	7.18
RV	Liters	2.46
RV/TLC	%	36
FRC PL	Liters	3.55
ERV	Liters	
IC	Liters	

**Diffusion**

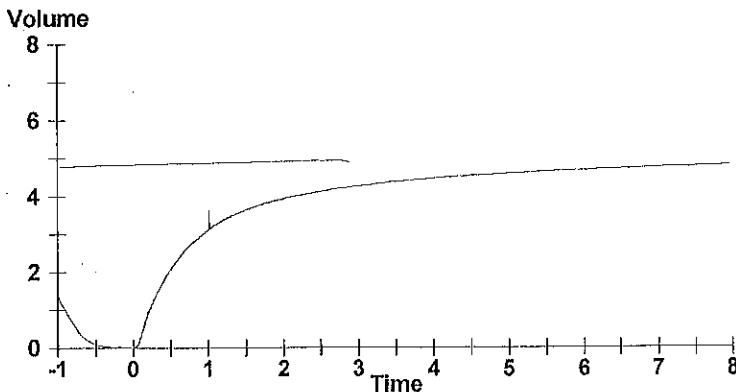
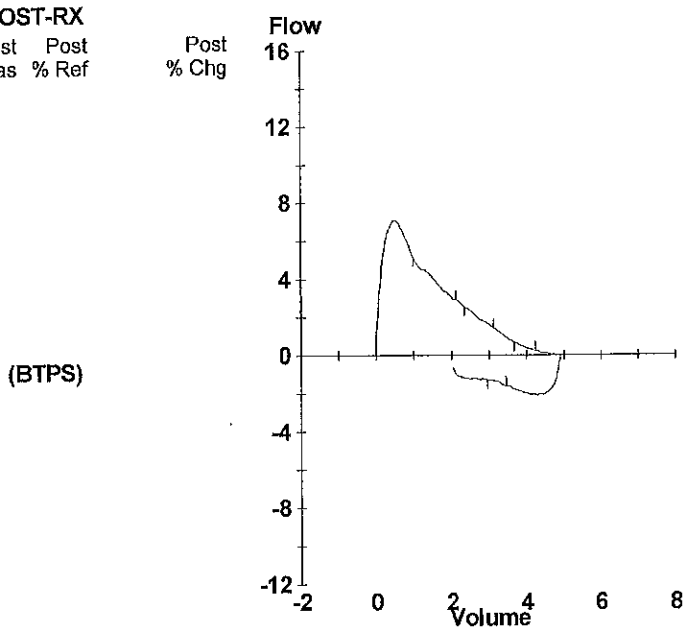
DLCO	mL/mmHg/min	29.3
DL Adj	mL/mmHg/min	29.3
DLCO/VA	mL/mHg/min/L	3.24
VA	Liters	
BHT	Sec	

**Resistance**

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.27
Gaw	L/sec/cmH2O	0.852
sRaw	cmH2O/L/s/L	4.49
sGaw	L/s/cmH2O/L	0.223
Vtg (Raw)	Liters	

Comments:

Interpretation:







1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505 ) 938-8922

Lovelace Scientific Resources  
 Leslie Byatt, Clin Trials  
 2441 Ridgecrest Dr SE  
 Albuquerque, NM 87108-5129

Client Nbr  
 24864

PATIENT NAME: **CHA, CHA** PATIENT ID: **AAGH0028** DOB: **07/06/1956** SEX: **M** REPORT STATUS: **Final** PAGE: **1**  
 PHYSICIAN: **Unlisted Physician,** COLLECT DATE & TIME: **10/31/2013 14:38** RECEIVE DATE & TIME: **10/31/2013 20:48** PRINT DATE & TIME: **11/01/2013 06:06**  
 REQUISITION NO.: **30920901** PT. PHONE NO.: **0** PATIENT NO.: **AKP010**  
 COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Comp Metabolic Panel					
Sodium	140		mmol/L	134-144	
Potassium	3.8		mmol/L	3.5-5.1	
Chloride	105		mmol/L	98-111	
CO2	25		mmol/L	20-30	
Anion Gap	10			6-14	
Glucose		107 (H)	mg/dL	60-100	
Impaired fasting glucose (IFG) is defined as a fasting glucose level of 100-126 mg/dL. (ADA Guidelines Diabetes Care 26: (3160-3167)2003)					
BUN	14		mg/dL	7-31	
Creatinine	1.10		mg/dL	0.62-1.66	
Creatinine method is IDMS traceable. EstGFR calculation has been adjusted. Please note new reference range effective 5/23/2013.					
eGFR non-African Am	>60		mL/min/1.73m2	>60	
GFR Comment	Estimated GFR values are not accurate in acute kidney failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, the very old or very young, races other than Caucasian or African American, people with acute illnesses, or amputations.				
Calcium	9.2		mg/dL	8.4-10.4	
Total Protein	6.9		gm/dL	6.1-8.2	
Albumin	3.9		gm/dL	3.4-4.7	
Globulin	3.0		gm/dL	2.4-4.2	
Bilirubin, total	0.4		mg/dL	0.3-1.2	
Alk Phos	67		U/L	38-150	
AST(SGOT)	18		U/L	6-58	
ALT(SGPT)	34		U/L	14-67	
Fasting	NOT GIVEN				
CBC					
WBC	9.0		x10E3	4.0-10.6	
RBC	5.36		x10E6	4.64-6.00	
Hgb	15.8		gm/dL	14.5-17.7	
Hct	48		%	42-53	
MCV	89		fL	81-98	
MCHC	33.0		gm/dL	31.2-35.2	
RDW	13.0		%	11.0-14.5	
Platelets	236		x10E3	150-400	
Eos, Respiratory	None seen				
Phys, Addr, Phone	NOT GIVEN				

*NCS  
 JS 11/1/13*

*Salzer - PI  
 14 Nov 2013*

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (SCREEN DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

DAY AM	-7	-6	-5	-4	-3	-2	-1	0	0
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
DAY PM	-7	-6	-5	-4	-3	-2	-1	0	0
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

SCALE 0 to 3

- 0= No symptoms (no symptoms detected)
  - 1= Mild symptoms (symptoms present but easily tolerated)
  - 2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)
  - 3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)
- Y=Yes N=No

SUBJECT NUMBER: AKP DATE COMPLETED: 10/31/13 SUBJECT INITIALS AND DATE: CHA 10/31/13

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

DAY AM	1	2	3	4	5	6	7	8	9
Runny Nose 0 to 3	10/31/13 0 1 2 3	11/01/13 0 1 2 3	11/02/13 0 1 2 3	11/03/13 0 1 2 3	11/04/13 0 1 2 3	11/05/13 0 1 2 3	11/06/13 0 1 2 3	11/07/13 0 1 2 3	11/08/13 0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
DAY PM	1	2	3	4	5	6	7	8	9
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

SCALE 0 to 3

- 0= No symptoms (no symptoms detected)
  - 1= Mild symptoms (symptoms present but easily tolerated)
  - 2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)
  - 3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)
- Y=Yes N=No

SUBJECT NUMBER: AKP010 DATE COMPLETED: 11/7/13

SUBJECT INITIALS AND DATE: [Signature] 11/07/13



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Scientific Resources  
 Leslie Byatt, MD  
 2441 Ridgecrest Dr SE  
 Albuquerque, NM 87108-6129

Client Nbr  
 24864

PATIENT NAME: **X, CHA** PATIENT ID: **AAGH3323** DOB: **07/06/1956** SEX: **M** REPORT STATUS: **Final** PAGE: **1**  
 PHYSICIAN: **Unlisted Physician,** COLLECT DATE & TIME: **11/07/2013 14:30** RECEIVE DATE & TIME: **11/07/2013 20:29** PRINT DATE & TIME: **11/08/2013 06:06**  
 REQUISITION NO.: **30920956** PT. PHONE NO.: **0** PATIENT NO.: **AKP010**  
 COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
<b>Comp Metabolic Panel</b>					
Sodium	139		mmol/L	134-144	
Potassium	4.0		mmol/L	3.5-5.1	
Chloride	107		mmol/L	98-111	
CO2	21		mmol/L	20-30	
Anion Gap	11			6-14	
Glucose	84		mg/dL	60-100	
BUN	13		mg/dL	7-31	
Creatinine	1.02		mg/dL	0.62-1.66	
Creatinine method is IDMS traceable. EstGFR Calculation has been adjusted. Please note new reference range effective 5/23/2013.					
eGFR non-African Am	>60		mL/min/1.73m2	>60	
GFR Comment	Estimated GFR values are not accurate in acute kidney failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, the very old or very young, races other than Caucasian or African American, people with acute illnesses, or amputations.				
Calcium	8.5		mg/dL	8.4-10.4	
Total Protein	6.8		gm/dL	6.1-8.2	
Albumin	3.9		gm/dL	3.4-4.7	
Globulin	2.9		gm/dL	2.4-4.2	
Bilirubin, total	0.4		mg/dL	0.3-1.2	
Alk Phos	69		U/L	38-150	
AST(SGOT)	19		U/L	6-58	
ALT(SGPT)	30		U/L	14-67	
Fasting Phosphorus	NO				
Phosphorus	2.8		mg/dL	2.3-5.6	
<b>CBC</b>					
WBC	7.7		x10E3	4.0-10.6	
RBC	5.16		x10E6	4.64-6.00	
Hgb	15.7		gm/dL	14.5-17.7	
Hct	46		%	42-53	
MCV	90		fL	81-98	
MCHC	33.9		gm/dL	31.2-35.2	
RDW	13.1		%	11.0-14.5	
Platelets	219		x10E3	150-400	
Eos, Respiratory				NS	
Phys, Addr, Phone					

*NCS of 11/8/13*

**Rare**

FAX RESULTS 348  
 8546

End of Report

*Walter - PI  
 NCS 8 Nov 2013*

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

DAY AM	7	8	9	10	11	12	13	14	15
Runny Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Itchy Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Congestion 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Sneezing 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Voice Hoarse Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO
Throat Clearing Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO
DAY PM	7	8	9	10	11	12	13	14	15
Runny Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Itchy Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Congestion 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Sneezing 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Voice Hoarse Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO
Throat Clearing Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO

SCALE 0 to 3

- 0= No symptoms (no symptoms detected)
- 1= Mild symptoms (symptoms present but easily tolerated)
- 2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)
- 3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)
- Y=Yes N=No

SUBJECT NUMBER: AKP010 DATE COMPLETED: 11/14/13

SUBJECT INITIALS AND DATE: AKP 11/14/13

score



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505 ) 938-8922

Lovelace Scientific Resources  
Leslie Byatt, Clin Trials  
2441 Ridgcrest Dr SE  
Albuquerque, NM 87108-5129

Client Nbr  
24864

PATIENT NAME <b>X, CHA</b>	PATIENT ID <b>AAGH3323</b>	DOB <b>07/06/1956</b>	SEX <b>M</b>	REPORT STATUS <b>Final</b>	PAGE <b>1</b>
PHYSICIAN <b>Unlisted Physician,</b>	COLLECT DATE & TIME <b>11/14/2013 09:50</b>	RECEIVE DATE & TIME <b>11/14/2013 19:24</b>	PRINT DATE & TIME <b>11/15/2013 06:10</b>		
REQUISITION NO. <b>30920938</b>	PT. PHONE NO. <b>0</b>	PATIENT NO. <b>AKP010</b>			
COMMENTS :					

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Eos, Respiratory Phys, Addr, Phone	NOT GIVEN	Rare *		NS	

End of Report

*M. M. Guinn MD*  
19 Nov 2013



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Scientific Resources  
 Leslie Byatt, Clin Trials  
 2441 Ridgecrest Dr SE  
 Albuquerque, NM 87108-5129

Client Nbr  
 24684

PATIENT NAME: **CHA, CHA** PATIENT ID: **AAGH0028** DOB: **07/06/1956** SEX: **M** REPORT STATUS: **Final** PAGE: **1**  
 PHYSICIAN: **Unlisted Physician,** COLLECT DATE & TIME: **11/21/2013 10:52** RECEIVE DATE & TIME: **11/21/2013 19:02** PRINT DATE & TIME: **11/22/2013 06:08**  
 REQUISITION NO. **30920937** PT. PHONE NO. **0** PATIENT NO. **AKP010**  
 COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
<b>Comp Metabolic Panel</b>					
Sodium	140		mmol/L	134-144	
Potassium	4.0		mmol/L	3.5-5.1	
Chloride	105		mmol/L	98-111	
CO2	27		mmol/L	20-30	
Anion Gap	8			6-14	
Glucose	87		mg/dL	60-100	
BUN	13		mg/dL	7-31	
Creatinine	0.91		mg/dL	0.62-1.66	
Creatinine method is IDMS traceable. EstGFR Calculation has been adjusted. Please note new reference range effective 5/23/2013.					
eGFR non-African Am	>60		mL/min/1.73m2	>60	
GFR Comment	Estimated GFR values are not accurate in acute kidney failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, the very old or very young, races other than Caucasian or African American, people with acute illnesses, or amputations.				
Calcium	8.9		mg/dL	8.4-10.4	
Total Protein	7.0		gm/dL	6.1-8.2	
Albumin	3.8		gm/dL	3.4-4.7	
Globulin	3.2		gm/dL	2.4-4.2	
Bilirubin, total	0.4		mg/dL	0.3-1.2	
Alk Phos	66		U/L	38-150	
AST(SGOT)	15		U/L	6-58	
ALT(SGPT)	28		U/L	14-67	
Fasting	NO				
<b>CBC</b>					
WBC	7.5		x10E3	4.0-10.6	
RBC	5.38		x10E6	4.64-6.00	
Hgb	16.3		gm/dL	14.5-17.7	
Hct	48		%	42-53	
MCV	89		fL	81-98	
MCHC	33.9		gm/dL	31.2-35.2	
RDW	13.1		%	11.0-14.5	
Platelets	209		x10E3	150-400	
<b>Differential</b>					
Diff Type	Auto Diff				
Neutrophils	54		%	40-76	
Lymphocytes	32		%	16-47	
Monocytes	10		%	3-13	
Eosinophils	3		%	0-5	
Basophils	1		%	0-2	
Abs. Neutrophil	4.1		x10E3	1.8-7.0	
Abs. Lymphocyte	2.4		x10E3	1.0-3.4	
Abs. Monocyte	0.7		x10E3	0.2-0.8	
Abs. Eosinophil	0.2		x10E3	0.0-0.3	
Abs. Basophil	0.1		x10E3	0.0-0.1	
Eos, Respiratory		Many	*	NS	
Phys, Addr, Phone	NO PHYSICIAN GIVEN				

**Deferred Test**

Your requisition did not indicate a test for the EDTA tube received. Due to the instability of the specimen, a CBC with differential was performed. If you have any questions, please call Client Services at (505) 938-8922.



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Leslie Byatt, Clin Trials  
2441 Ridgecrest Dr SE  
Albuquerque, NM 87108-5129

Client Nbr  
24664

PATIENT NAME <b>CHA, CHA</b>	PATIENT ID <b>AAGH0028</b>	DOB <b>07/06/1956</b>	SEX <b>M</b>	REPORT STATUS <b>Final</b>	PAGE <b>2</b>
PHYSICIAN <b>Unlisted Physician,</b>	COLLECT DATE & TIME <b>11/21/2013 10:52</b>	RECEIVE DATE & TIME <b>11/21/2013 19:02</b>	PRINT DATE & TIME <b>11/22/2013 06:08</b>		
REQUISITION NO. <b>30920937</b>	PT. PHONE NO. <b>0</b>	PATIENT NO. <b>AKP010</b>			

COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			

Federal regulation requires written authorization for any test order modification to be submitted within 30 days. Please fax this report with your authorization signature to (505)938 8034 TriCore Reference Laboratories ATTN: Medical Records Imaging Department.

*[Handwritten Signature]* 27 Nov 2013  
SIGNATURE DATE

End of Report



**EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT**

**DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)**

**CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS**

DAY	14	15	16	17	18	19	20	21	22
AM	11/14	11/15	11/16	11/17	11/18	11/19	11/20	11/21	11/22
Runny Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Itchy Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Congestion 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Sneezing 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Voice Hoarse Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO
Throat Clearing Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO
DAY PM	14	15	16	17	18	19	20	21	22
Runny Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Itchy Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Congestion 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Sneezing 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Voice Hoarse Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO
Throat Clearing Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO

**SCALE 0 to 3**

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N= No

SUBJECT NUMBER: AKP010 DATE COMPLETED: 11/14/13

SUBJECT INITIALS AND DATE: AA 11/21/13

AKP  
CAH 1010  
11/21/13

Effects of AkPharma's Calcium Glycerophosphate  
Nasal Spray wash (AkP 010112A) on Patient-Perceived Breathing Comfort

SATISFACTION QUESTIONNAIRE:

Would you use / purchase this nasal wash product in the future?"  YES  NO

You are also encouraged to make any free comments regarding your experience in the use of this product regarding your opinion of any of its effects not covered specifically in the Daily Diary:

IT HELPED CLEAR MY HEAD FOR 1/2 HOURS  
AFTER TAKING IT. WAS GOOD TO USE JUST BEFORE  
GOING TO BED.

AT TIMES I FEEL A LITTLE BURNING WHEN  
TAKING THE SPRAY

Subject completed this questionnaire,  
but inadvertently did not initial  
and date the bottom. *em late entry*  
2/27/14

[Type text]

Subject initials and Date \_\_\_\_\_

Study Staff Initials and Date *VB* 11/21/13

Study Identification: 2749 LSR Study #: 2749  
 Subject Number: AKP 010 Subject Initials: CTHA

ADVERSE EVENT LOG

Adverse Event (intermittent)	** Start Date (DD/MMM/YYYY)	SEVERITY	Relationship to Study Drug (Suspected/Not Suspected)	** End Date (DD/MMM/YYYY)	Action Taken	Investigator Initials/Date
Burning at app. site	31/OCT/2013	Mild	Suspected	20/NOV/2013	NONE	AKP 21 Nov 13

\*\* If day is unknown, write UNK in space provided, but every effort should be made to be as specific as possible\*\*

Investigator Signature (at end of study): [Signature] Date: 21 Nov 2013  
 SC Signature (at end of study): [Signature] Date: 11/21/13

Study Identification: 2749

Subject Number: AKP009 Em 9126113

10

Subject Initials: CHA

**CONCOMITANT MEDICATION LOG**

List all prescription medications you are taking. Also include over-the-counter medications, vitamins and supplements.

Name of Medication	Indication (What you take it for)	Dose	Unit	Frequency	Route	* Start Date (Day/Month/Year)	Stop Date	Ongoing at EOS (for Clinic use)
EXAMPLE	Diabetes	500	MG	2 Tabs per day	Oral	UNK/AUG/1999		<input type="checkbox"/>
Flonase	Seasonal allergies	1	spray (each nostril)	QD	INH	--/--/2009	29 SEP 2013	<input type="checkbox"/>
Multi vitamin	Dietary Supplement	1	TAB	QD	oral	--/--/1998		<input checked="" type="checkbox"/>
Fish Oil	Dietary Supplement	200 mg	mg	QD	oral	--/--/2011		<input checked="" type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>

\* If day or month of medication date is unknown, write UNK in space provided

Investigator Signature (at end of study): [Signature] Date: 21 Nov 2013

SC Signature (at end of study): Brecha macedonada Date: 10/21/13

LoveLace Scientific Resources, Inc - ConMeds 04/2013

PAGE: 1 of 1

**AKP-011**

2749 AKPharma PERENNIAL ALLERGIES  
SCREENING/VISIT 1 SOURCE DOCUMENTS

Initials: RCD Site #: — Subject #: AKP 011

**PATIENT DEMOGRAPHICS**

**Patient Demographics**

Date of Birth: 09, April 1940 (dd/mmm/yyyy)

Gender:  Male  Female

If female, Indicate Childbearing Potential N/A

Childbearing  Surgically sterilized  Post-Menopausal

Ethnicity:  Hispanic  Non Hispanic

Race:  Asian  Black  Caucasian  American Indian

Pacific Islander  Other, Specify \_\_\_\_\_

**Smoking History**

Smoking Status:  None (smoked less than 100 cigarettes in lifetime)

Former (previously smoked more than 100 cigarettes in lifetime)

Current (smokes now)

If subject is a former or current smoker, please indicate:

Years smoked: 13 Cigarettes per day: 40

CRC Signature: [Signature] Date: 9, 25, 13 (dd/mmm/yy)



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505 ) 938-8922

Lovelace Scient Resources  
 Clin Trials-Leslie Wyatt  
 2441 Ridgecrest Dr SE  
 Albuquerque, NM 87108

Client Nbr  
 24664

PATIENT NAME: **RCD, RCD** PATIENT ID: **AAGF6660** DOB: **04/09/1940** SEX: **M** REPORT STATUS: **Final** PAGE: **1**  
 PHYSICIAN: **Unlisted Physician,** COLLECT DATE & TIME: **10/04/2013 11:33** RECEIVE DATE & TIME: **10/04/2013 19:52** PRINT DATE & TIME: **10/08/2013 06:06**  
 REQUISITION NO.: **30920921** PT. PHONE NO.: **0** PATIENT NO.: **AKP011**  
 COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Allerg,Panel 18					
Allerg,Juniper		6.60 H	KU/L	<0.35	
Allerg,Cottonwood	0.20		KU/L	<0.35	
Allerg,West.Ragweed	<0.10		KU/L	<0.35	
Allerg,Russian Thist	0.20		KU/L	<0.35	
Allerg,Bermuda Grass	0.10		KU/L	<0.35	
Allerg,Alternaria		2.70 H	KU/L	<0.35	
Allerg,Mesquite		0.50 H	KU/L	<0.35	
Allerg,Cockroach	<0.10		KU/L	<0.35	
Allerg,Derm. pter.	<0.10		KU/L	<0.35	

The standard classification system utilizes the following class cutoffs.

Class	ku/L	Interpretation
0	<0.35	Negative for Allergen
I	0.35-0.69	Positive for Allergen
II	0.70-3.49	Strongly Positive
III	3.5-17.49	Strongly Positive
IV	17.5-52.49	Strongly Positive
V	52.5-99.99	Strongly Positive
VI	>100	Strongly Positive

Results with allergens scoring in Class 1 should be considered weakly positive or equivocal. Class 2 and higher should be considered positive. Although increasing class ranges (0-VI) are reflective of increasing concentrations of allergen-specific IgE, this may not correlate with the degree of clinical response when challenged with the specific allergen. The correlation of allergy laboratory results with clinical history is essential. A negative test may not rule out clinical allergy.

Allerg,Derm. farinae	<0.10		KU/L	<0.35
Allerg,Clad. herb.	<0.10		KU/L	<0.35
Allerg,Firebush	<0.10		KU/L	<0.35
Allerg,Cat Dander Ep	0.30		KU/L	<0.35
Allerg,Dog Dander	<0.10		KU/L	<0.35
Allerg,Bluegrass	0.20		KU/L	<0.35
Allerg,Pigweed		0.50 H	KU/L	<0.35
Allerg,Mulberry	<0.10		KU/L	<0.35
Allerg,Helminth	0.20		KU/L	<0.35
Phys, Addr, Phone	NOT GIVEN			

End of Report

*Positive result.  
 Sub-I 08 Oct 2013*

Name: RCD,  
 Gender: Male  
 Age: 73 Race: Caucasian  
 Height(in): 75.0 Weight(lb): 221  
 Any Info:

Id: AKP-011  
 Date: 10/16/13  
 Temp: 19 PBar: 631  
 Physician:  
 Technician:

Spirometry		(BTPS)	PRE-RX		POST-RX		Post
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	% Chg
FVC	Liters	5.16	3.80	74			
FEV1	Liters	4.06	2.90	72			
FEV1/FVC	%	77	76	99			
FEF25-75%	L/sec	3.89	2.42	62			
FEF50%	L/sec	4.85	4.95	102			
FEF75%	L/sec	1.76	1.18	67			
IC	Liters						
VC	Liters	5.16					
PEF	L/sec	9.35	11.71	125			
MVV	L/min	141					
PIF	L/sec						
FEV1/FEV6%				77			

**Lung Volumes/Plethysmography**

Vtg	Liters	
VC	Liters	5.16
TLC	Liters	7.66
RV	Liters	2.94
RV/TLC	%	42
FRC PL	Liters	4.23
ERV	Liters	
IC	Liters	

**Diffusion**

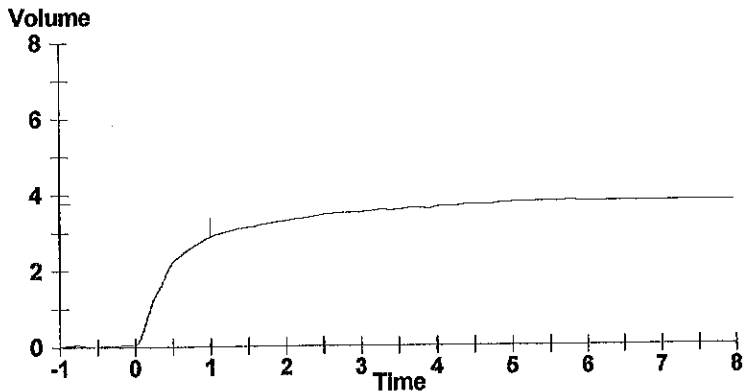
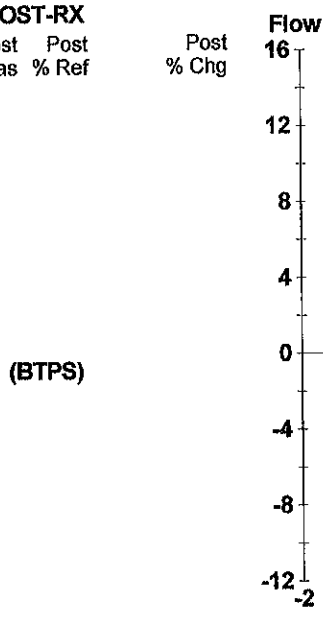
DLCO	mL/mmHg/min	25.0
DL Adj	mL/mmHg/min	25.0
DLCO/VA	mL/mHg/min/L	2.92
VA	Liters	
BHT	Sec	

**Resistance**

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.02
Gaw	L/sec/cmH2O	1.015
sRaw	cmH2O/L/s/L	4.31
sGaw	L/s/cmH2O/L	0.232
Vtg (Raw)	Liters	

Comments:

Interpretation:





Name: RCD,  
 Gender: Male  
 Age: 73 Race: Caucasian  
 Height(in): 75.0 Weight(lb): 221  
 Any Info:

Id: AKP-011  
 Date: 10/23/13  
 Temp: 20 PBar: 634  
 Physician:  
 Technician: VL

Spirometry		(BTPS)	PRE-RX		POST-RX		Post
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	% Chg
FVC	Liters	5.16	3.89	75			
FEV1	Liters	4.06	2.93	72			
FEV1/FVC	%	77	75	98			
FEF25-75%	L/sec	3.89	2.32	60			
FEF50%	L/sec	4.85	5.43	112			
FEF75%	L/sec	1.76	0.57	32			
IC	Liters						
VC	Liters	5.16					
PEF	L/sec	9.35	9.84	105			
MVV	L/min	141					
PIF	L/sec						
FEV1/FEV6%			75				

**Lung Volumes/Plethysmography**

Vtg	Liters	
VC	Liters	5.16
TLC	Liters	7.66
RV	Liters	2.94
RV/TLC	%	42
FRC PL	Liters	4.23
ERV	Liters	
IC	Liters	

**Diffusion**

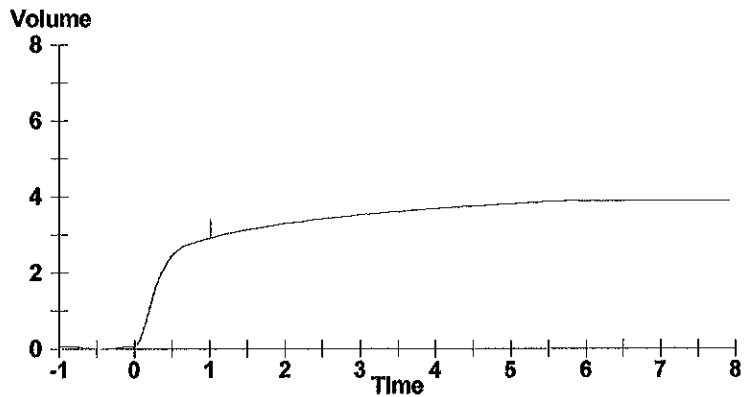
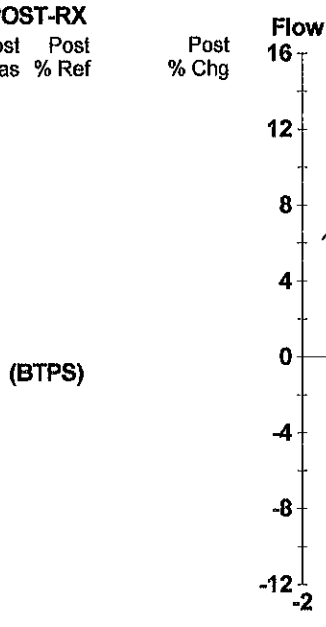
DLCO	mL/mmHg/min	25.0
DL Adj	mL/mmHg/min	25.0
DLCO/VA	mL/mHg/min/L	2.93
VA	Liters	
BHT	Sec	

**Resistance**

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.02
Gaw	L/sec/cmH2O	1.015
sRaw	cmH2O/L/s/L	4.31
sGaw	L/s/cmH2O/L	0.232
Vtg (Raw)	Liters	

Comments:

Interpretation:



Name: RCD,  
 Gender: Male  
 Age: 73 Race: Caucasian  
 Height(in): 75.0 Weight(lb): 221  
 Any Info:

Id: AKP-011  
 Date: 10/29/13  
 Temp: 20 PBar: 630  
 Physician:  
 Technician: VL

Spirometry		(BTPS)	PRE-RX		POST-RX		Post % Chg
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	
FVC	Liters	5.16	4.02	78			
FEV1	Liters	4.06	2.83	70			
FEV1/FVC	%	77	70	92			
FEF25-75%	L/sec	3.89	1.65	42			
FEF50%	L/sec	4.85	3.88	80			
FEF75%	L/sec	1.76	0.43	24			
IC	Liters						
VC	Liters	5.16					
PEF	L/sec	9.35	12.30	132			
MVV	L/min	141					
PIF	L/sec						
FEV1/FEV6%				72			

**Lung Volumes/Plethysmography**

Vtg	Liters	
VC	Liters	5.16
TLC	Liters	7.66
RV	Liters	2.94
RV/TLC	%	42
FRC PL	Liters	4.23
ERV	Liters	
IC	Liters	

**Diffusion**

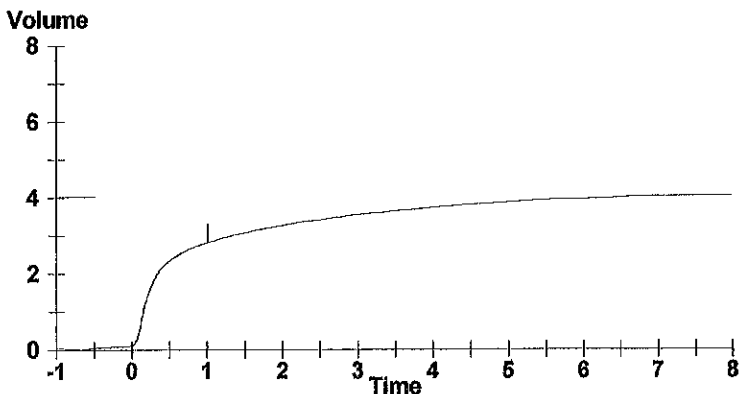
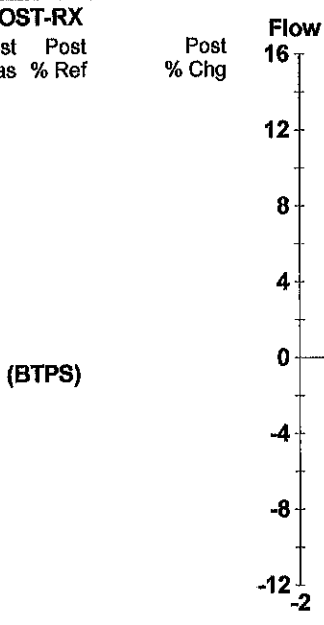
DLCO	mL/mmHg/min	25.0
DL Adj	mL/mmHg/min	25.0
DLCO/VA	mL/mHg/min/L	2.91
VA	Liters	
BHT	Sec	

**Resistance**

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.02
Gaw	L/sec/cmH2O	1.015
sRaw	cmH2O/L/s/L	4.31
sGaw	L/s/cmH2O/L	0.232
Vtg (Raw)	Liters	

Comments:

Interpretation:

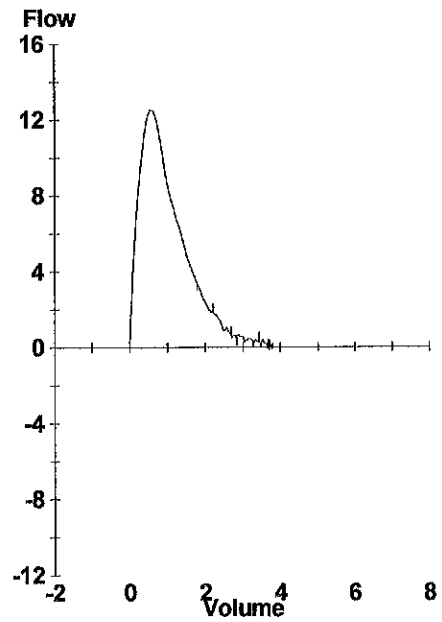


Name: RCD,  
 Gender: Male  
 Age: 73 Race: Caucasian  
 Height(in): 75.0 Weight(lb): 221  
 Any Info:

Id: AKP-011  
 Date: 11/08/13  
 Temp: 19 PBar: 634  
 Physician:  
 Technician: VL

Spirometry		(BTPS)	PRE-RX		POST-RX		Post
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	% Chg
FVC	Liters	5.16	3.82	74			
FEV1	Liters	4.06	2.73	67			
FEV1/FVC	%	77	71	93			
FEF25-75%	L/sec	3.89	1.69	43			
FEF50%	L/sec	4.85	2.95	61			
FEF75%	L/sec	1.76	0.58	33			
IC	Liters						
VC	Liters	5.16					
PEF	L/sec	9.35	12.53	134			
MVV	L/min	141					
PIF	L/sec						
FEV1/FEV6%			71				

(BTPS)



**Lung Volumes/Plethysmography**

Vtg	Liters	
VC	Liters	5.16
TLC	Liters	7.66
RV	Liters	2.94
RV/TLC	%	42
FRC PL	Liters	4.23
ERV	Liters	
IC	Liters	

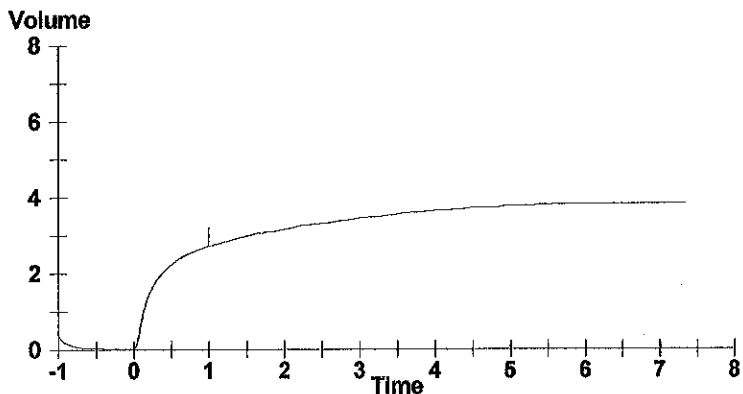
**Diffusion**

DLCO	mL/mmHg/min	25.0
DL Adj	mL/mmHg/min	25.0
DLCO/VA	mL/mHg/min/L	2.93
VA	Liters	
BHT	Sec	

**Resistance**

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.02
Gaw	L/sec/cmH2O	1.015
sRaw	cmH2O/L/s/L	4.31
sGaw	L/s/cmH2O/L	0.232
Vtg (Raw)	Liters	

Comments:



Interpretation:

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (SCREEN DIARY)  
CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

DAY AM	-7	-6	-5	-4	-3	-2	-1	0	0
Runny Nose 0 to 3	10/10 0 1 2 3	10/11 0 1 2 3	10/12 0 1 2 3	10/13 0 1 2 3	10/14 0 1 2 3	10/15 0 1 2 3	10/16 0 1 2 3	10/17 0 1 2 3	0 0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	<del>YES</del> NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	<del>YES</del> NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
DAY PM	-7	-6	-5	-4	-3	-2	-1	0	0
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N=No

SUBJECT NUMBER: AKP 011

DATE COMPLETED: 10/10/13 - 10/16/13

SUBJECT INITIALS AND DATE: AKP 10/16/13

start here →



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Scientific Resources  
 Clin Trials Leslie Byatt  
 2441 Ridgecrest Dr SE  
 Albuquerque, NM 87108

Client Nbr  
 24664

PATIENT NAME: **RCD, RCD** PATIENT ID: **AAGF6660** DOB: **04/09/1940** SEX: **M** REPORT STATUS: **Final** PAGE: **1**  
 PHYSICIAN: **Unlisted Physician,** COLLECT DATE & TIME: **10/16/2013 14:30** RECEIVE DATE & TIME: **10/16/2013 20:20** PRINT DATE & TIME: **10/17/2013 06:08**  
 REQUISITION NO.: **30920913** PT. PHONE NO.: **0** PATIENT NO.: **AKP011**  
 COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
<b>Comp Metabolic Panel</b>					
Sodium	139		mmol/L	134-144	
Potassium	4.3		mmol/L	3.5-5.1	
Chloride	103		mmol/L	98-111	
CO2	26		mmol/L	20-30	
Anion Gap	10			6-14	
Glucose	96		mg/dL	60-100	
BUN	20		mg/dL	7-31	
Creatinine	1.27		mg/dL	0.62-1.66	
Creatinine method is IDMS traceable. EstGFR Calculation has been adjusted. Please note new reference range effective 5/23/2013.					
eGFR non-African Am	56	L	mL/min/1.73m2	>60	<i>NCS gs 10/18/13</i>
GFR Comment	Estimated GFR values are not accurate in acute kidney failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, the very old or very young, races other than Caucasian or African American, people with acute illnesses, or amputations.				
Calcium	10.0		mg/dL	8.4-10.4	
Total Protein	7.0		gm/dL	6.1-8.2	
Albumin	4.4		gm/dL	3.4-4.7	
Globulin	2.6		gm/dL	2.4-4.2	
Bilirubin, total	0.8		mg/dL	0.3-1.2	
Alk Phos	111		U/L	38-150	
AST(SGOT)	20		U/L	6-58	
ALT(SGPT)	36		U/L	14-67	
Fasting Phosphorus	NO				
Phosphorus	3.6		mg/dL	2.3-5.6	
<b>CBC</b>					
WBC	10.0		x10E3	4.0-10.6	
RBC	5.35		x10E6	4.64-6.00	
Hgb	17.2		gm/dL	14.6-17.7	
Hct	49		%	42-53	
MCV	91		fL	81-98	
MCHC	35.2		gm/dL	31.2-35.2	
RDW	12.9		%	11.0-14.5	
Platelets	228		x10E3	150-400	
Eos, Respiratory	None seen			NS	
Phys, Addr, Phone	Not given				

End of Report

*NCS  
 Salzer PI 18 Oct 2013*

*Randomization*

**EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT**

**DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)**

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

DAY	1	2	3	4	5	6	7	8	9
AM	10/16	10/17	10/18	10/19	10/20	10/21	10/22	10/23	
Runny Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Itchy Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Congestion 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Sneezing 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Voice Hoarse Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO
Throat Clearing Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO
DAY PM	1	2	3	4	5	6	7	8	9
Runny Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Itchy Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Congestion 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Sneezing 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Voice Hoarse Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO
Throat Clearing Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO

**SCALE 0 to 3**

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N= No

SUBJECT NUMBER: AKP 011 DATE COMPLETED: 10/16/13 - 10/23/13 am

SUBJECT INITIALS AND DATE: RCB 10/23/13

*all new  
start here*



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505 ) 938-8922

Lovelace Scientific Resources  
Leslie Byatt, MD  
2441 Ridgecrest Dr SE  
Albuquerque, NM 87108-5129

Client Nbr  
24664

PATIENT NAME **RCD, RCD** PATIENT ID **AAGF6660** DOB **04/09/1940** SEX **M** REPORT STATUS **Final** PAGE **1**

PHYSICIAN **Unlisted Physician,** COLLECT DATE & TIME **10/23/2013 14:36** RECEIVE DATE & TIME **10/24/2013 17:52** PRINT DATE & TIME **10/25/2013 06:09**

REQUISITION NO. **30920900** PT. PHONE NO. **0** PATIENT NO. **AKP011**

COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Eos, Respiratory Phys, Addr, Phone	None seen	Not given		NS	

*Wm Sub I  
29 Oct 2013*

End of Report

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT

Next visit 2:00 pm

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)  
CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

DAY AM	7	8	9	10	11	12	13	14	15
Runny Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Itchy Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Congestion 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Sneezing 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Voice Hoarse Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO
Throat Clearing Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO
DAY PM	7	8	9	10	11	12	13	14	15
Runny Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Itchy Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Congestion 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Sneezing 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Voice Hoarse Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO
Throat Clearing Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO

SCALE 0 to 3

- 0= No symptoms (no symptoms detected)
- 1= Mild symptoms (symptoms present but easily tolerated)
- 2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)
- 3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)
- Y=Yes N=No

SUBJECT NUMBER: AKP011 DATE COMPLETED: 10/23/13

SUBJECT INITIALS AND DATE: [Signature] 10/29/2013





1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505 ) 938-8922

Lovelace Scientific Resources  
Leslie Byatt, MD  
2441 Ridgecrest Dr SE  
Albuquerque, NM 87108-5129

Client Nbr  
24664

PATIENT NAME <b>X, RCD</b>	PATIENT ID <b>AAGG8637</b>	DOB <b>09/04/1940</b>	SEX <b>M</b>	REPORT STATUS <b>Final</b>	PAGE <b>1</b>
PHYSICIAN <b>Unlisted Physician,</b>	COLLECT DATE & TIME <b>10/29/2013 14:30</b>	RECEIVE DATE & TIME <b>10/29/2013 19:11</b>	PRINT DATE & TIME <b>10/30/2013 06:09</b>		
REQUISITION NO. <b>30920918</b>	PT. PHONE NO. <b>0</b>	PATIENT NO. <b>AKP011</b>			

COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Eos, Respiratory Phys, Addr, Phone	<b>None seen Unknown</b>			<b>NS</b>	

Callback Accession Comments:  
T3427433  
EOSR, UNKPHY  
10/29/2013 09:29 pm FAXED TO 3488546 NCCS1685  
**End of Report**

*MDM Sub-I  
30 OCT 2013*

Study Identification: AKPharms LSR Study #: 2749  
 Subject Number: AKP011 Subject Initials: RCD

ADVERSE EVENT LOG

Adverse Event	** Start Date (DD/MMM/YYYY)	SEVERITY	Relationship to Study Drug (Suspected/Not Suspected)	** End Date (DD/MMM/YYYY)	Action Taken	Investigator Initials/Date
<del> </del>	<del> </del>	<del> </del>	<del> </del>	<del> </del>	<del> </del>	<del> </del>
<del> </del>	<del> </del>	<del> </del>	<del> </del>	<del> </del>	<del> </del>	<del> </del>
<del> </del>	<del> </del>	<del> </del>	<del> </del>	<del> </del>	<del> </del>	<del> </del>
<del> </del>	<del> </del>	<del> </del>	<del> </del>	<del> </del>	<del> </del>	<del> </del>
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<del> </del>	<del> </del>	<del> </del>	<del> </del>	<del> </del>	<del> </del>	<del> </del>
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<del> </del>	<del> </del>	<del> </del>	<del> </del>	<del> </del>	<del> </del>	<del> </del>

\*\* If day is unknown, write UNK in space provided, but every effort should be made to be as specific as possible\*\*

Investigator Signature (at end of study): AK Pharmaceut Date: 13 Nov 2013  
 SC Signature (at end of study): Walter Byrd Date: 11/12/13

**EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT**

**DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)**

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

DAY AM	14	15	16	17	18	19	20	21	22
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
<b>DAY PM</b>	<b>14</b>	<b>15</b>	<b>16</b>	<b>17</b>	<b>18</b>	<b>19</b>	<b>20</b>	<b>21</b>	<b>22</b>
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

**SCALE 0 to 3**

- 0= No symptoms (no symptoms detected)
  - 1= Mild symptoms (symptoms present but easily tolerated)
  - 2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)
  - 3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)
- Y=Yes N=No

SUBJECT NUMBER: AKP011

DATE COMPLETED: 11/8/13

SUBJECT INITIALS AND DATE: RCB

11/8/2013

11/7 11/8  
0 0  
0 0  
0 1  
0 0  
NO NO  
YES YES  
PM  
YES  
YES



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Scientific Resources  
 Leslie Byatt, Clin Trials  
 2441 Ridgecrest Dr SE  
 Albuquerque, NM 87108-5129

Client Nbr  
 24664

PATIENT NAME: RCD, RCD      PATIENT ID: AAGH3924      DOB: 04/09/1949      SEX: M      REPORT STATUS: Final      PAGE: 1

PHYSICIAN: Unlisted Physician,      COLLECT DATE & TIME: 11/08/2013 11:11      RECEIVE DATE & TIME: 11/08/2013 18:52      PRINT DATE & TIME: 11/11/2013 06:08

REQUISITION NO.: 30920951      PT. PHONE NO.: 0      PATIENT NO.: AKP011

COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
<b>Comp Metabolic Panel</b>					
Sodium	138		mmol/L	134-144	
Potassium	4.0		mmol/L	3.5-5.1	
Chloride	103		mmol/L	98-111	
CO2	23		mmol/L	20-30	
Anion Gap	12			6-14	
Glucose		106 H	mg/dL	60-100	<i>nes w/dm 12 Nov 13</i>
Impaired fasting glucose (IFG) is defined as a fasting glucose level of 100-126 mg/dL. (ADA Guidelines Diabetes Care 26: (3160-3167)2003)					
BUN	14		mg/dL	7-31	
Creatinine	1.20		mg/dL	0.62-1.66	
Creatinine method is IDMS traceable. EstGFR Calculation has been adjusted. Please note new reference range effective 5/23/2013.					
eGFR non-African Am	>60		mL/min/1.73m2	>60	
GFR Comment	Estimated GFR values are not accurate in acute kidney failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, the very old or very young, races other than Caucasian or African American, people with acute illnesses, or amputations.				
Calcium	9.3		mg/dL	8.4-10.4	
Total Protein	6.9		gm/dL	6.1-8.2	
Albumin	4.4		gm/dL	3.4-4.7	
Globulin	2.5		gm/dL	2.4-4.2	
Bilirubin, total	0.9		mg/dL	0.3-1.2	
Alk Phos	110		U/L	38-150	
AST(SGOT)	21		U/L	6-58	
ALT(SGPT)	38		U/L	14-67	
Fasting	Not given				
<b>CBC</b>					
WBC	8.2		x10E3	4.0-10.6	
RBC	5.35		x10E6	4.64-6.00	
Hgb	17.3		gm/dL	14.5-17.7	
Hct	49		%	42-53	
MCV	92		fL	81-98	
MCHC	35.2		gm/dL	31.2-36.2	
RDW	13.2		%	11.0-14.5	
Platelets	197		x10E3	150-400	
Eos, Respiratory	None seen				
Phys, Addr, Phone	Unknown				

End of Report

*nes w/dm  
12 Nov 13*

TGC / AKP  
1006

**Effects of AkPharma's Calcium Glycerophosphate  
Nasal Spray wash (AkP 010112A) on Patient-Perceived Breathing Comfort**

**SATISFACTION QUESTIONNAIRE:**

Would you use / purchase this nasal wash product in the future?"  YES  NO

NGB  
11/4/13

You are also encouraged to make any free comments regarding your experience in the use of this product regarding your opinion of any of its effects not covered specifically in the Daily Diary:

BURNING SENSATION, BAD TASTE

[Type text]

Subject initials and Date

NGB 11/4/13

Study Staff Initials and Date

EM 11/04/13

**AKP-014**

12/49 AKPharma PERENNIAL ALLERGIES  
SCREENING/VISIT 1 SOURCE DOCUMENTS

Initials: N6B  
DNE Site #:      Subject #: AKP-014

10/01/13

**PATIENT DEMOGRAPHICS**

**Patient Demographics**

Date of Birth: 09 April 1955 (dd/mmm/yyyy)

Gender:  Male  Female

If female, Indicate Childbearing Potential

Childbearing  Surgically sterilized  Post-Menopausal

Ethnicity:  Hispanic  Non Hispanic

Race:  Asian  Black  Caucasian  American Indian

Pacific Islander  Other, Specify \_\_\_\_\_

**Smoking History**

Smoking Status:  None (smoked less than 100 cigarettes in lifetime)

Former (previously smoked more than 100 cigarettes in lifetime)

Current (smokes now)

If subject is a former or current smoker, please indicate:

Years smoked: 30 Cigarettes per day: 15

CRC Signature: Usher Byatt Date: 10 / 01 / 13 (dd/mmm/yy)



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Scientific Resources  
 Clin Trials Leslie Byatt  
 2441 Ridgecrest Dr SE  
 Albuquerque, NM 87108

Client Nbr  
 24664

PATIENT NAME: **DNG, DNG** PATIENT ID: **AAGF4531** DOB: **04/09/1955** SEX: **F** REPORT STATUS: **Final** PAGE: **1**  
 PHYSICIAN: **Unlisted Physician,** COLLECT DATE & TIME: **10/01/2013 13:40** RECEIVE DATE & TIME: **10/01/2013 20:30** PRINT DATE & TIME: **10/03/2013 06:06**  
 REQUISITION NO.: **30920877** PT. PHONE NO.: **0** PATIENT NO.: **AKP-014**  
 COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Allerg, Panel 18					
Allerg, Juniper		45.40 H	KU/L	<0.35	
Allerg, Cottonwood	<0.10		KU/L	<0.35	
Allerg, West. Ragweed	<0.10		KU/L	<0.35	
Allerg, Russian Thistle	<0.10		KU/L	<0.35	
Allerg, Bermuda Grass	0.20		KU/L	<0.35	
Allerg, Alternaria	<0.10		KU/L	<0.35	
Allerg, Mesquite	<0.10		KU/L	<0.35	
Allerg, Cockroach	<0.10		KU/L	<0.35	
Allerg, Derm. pter.	<0.10		KU/L	<0.35	

The standard classification system utilizes the following class cutoffs.

Class	ku/L	Interpretation
0	<0.35	Negative for Allergen
I	0.35-0.69	Positive for Allergen
II	0.70-3.49	Strongly Positive
III	3.5-17.49	Strongly Positive
IV	17.5-52.49	Strongly Positive
V	52.5-99.99	Strongly Positive
VI	>100	Strongly Positive

Results with allergens scoring in Class 1 should be considered weakly positive or equivocal. Class 2 and higher should be considered positive. Although increasing class ranges (0-VI) are reflective of increasing concentrations of allergen-specific IgE, this may not correlate with the degree of clinical response when challenged with the specific allergen. The correlation of allergy laboratory results with clinical history is essential. A negative test may not rule out clinical allergy.

Allerg, Derm. farinae	<0.10		KU/L	<0.35
Allerg, Clad. herb.	<0.10		KU/L	<0.35
Allerg, Firebush	<0.10		KU/L	<0.35
Allerg, Cat Dander Ep		12.50 H	KU/L	<0.35
Allerg, Dog Dander		0.60 H	KU/L	<0.35
Allerg, Bluegrass		24.50 H	KU/L	<0.35
Allerg, Pigweed	<0.10		KU/L	<0.35
Allerg, Mulberry	<0.10		KU/L	<0.35
Allerg, Helminth	<0.10		KU/L	<0.35

Phys, Addr, Phone

NO PHYSICIAN GIVEN

Important Info

CLARIFICATION OF PATIENTS NAME PER CLIENT THEY ONLY USE LETTERS

End of Report

*Meets inclusion criteria  
 [Signature]  
 03 Oct 2013*

DNG, DNG

10/03/2013 06:06

FAX24664



Name: NGB,  
 Gender: Female  
 Age: 58 Race: Caucasian  
 Height(in): 63.0 Weight(lb): 126  
 Any Info:

Id: AKP-014  
 Date: 10/14/13  
 Temp: 18 PBar: 627  
 Physician:  
 Technician:

Spirometry		(BTPS)	PRE-RX		POST-RX		Post
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	% Chg
FVC	Liters	2.93	3.41	116			
FEV1	Liters	2.39	2.34	98			
FEV1/FVC	%	83	69	83			
FEF25-75%	L/sec	2.60	1.35	52			
FEF50%	L/sec	3.31	1.98	60			
FEF75%	L/sec	1.13	0.40	35			
IC	Liters						
VC	Liters	2.93					
PEF	L/sec	5.65	6.85	121			
MVV	L/min	93					
PIF	L/sec		2.23				
FEV1/FEV6%			73				

**Lung Volumes/Plethysmography**

Vtg	Liters	
VC	Liters	2.93
TLC	Liters	4.71
RV	Liters	1.74
RV/TLC	%	37
FRC PL	Liters	2.79
ERV	Liters	
IC	Liters	

**Diffusion**

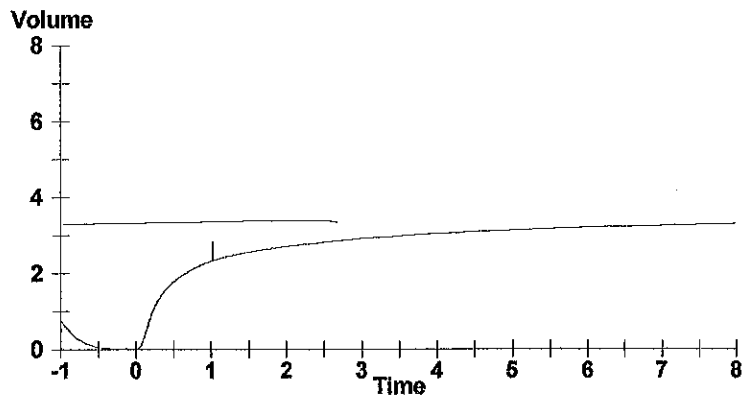
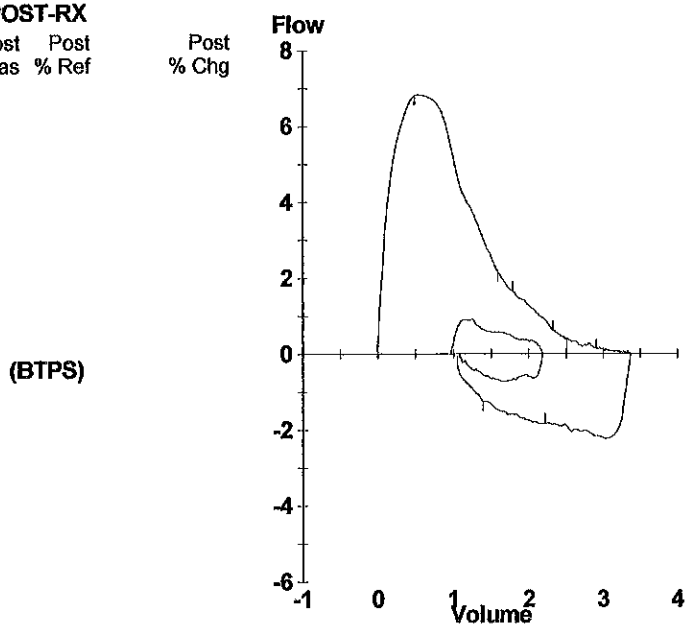
DLCO	mL/mmHg/min	18.3
DL Adj	mL/mmHg/min	18.3
DLCO/VA	mL/mHg/min/L	3.20
VA	Liters	
BHT	Sec	

**Resistance**

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.37
Gaw	L/sec/cmH2O	0.670
sRaw	cmH2O/L/s/L	3.82
sGaw	L/s/cmH2O/L	0.262
Vtg (Raw)	Liters	

Comments:

Interpretation:



Name: NGB,  
 Gender: Female  
 Age: 58 Race: Caucasian  
 Height(in): 64.0 Weight(lb): 126  
 Any Info:

Id: AKP-014  
 Date: 10/21/13  
 Temp: 22 PBar: 633  
 Physician:  
 Technician: VL

Spirometry		(BTPS)	PRE-RX		POST-RX		Post
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	% Chg
FVC	Liters	3.06	3.46	113			
FEV1	Liters	2.49	2.44	98			
FEV1/FVC	%	83	71	85			
FEF25-75%	L/sec	2.69	1.49	55			
FEF50%	L/sec	3.40	2.28	67			
FEF75%	L/sec	1.18	0.38	32			
IC	Liters						
VC	Liters	3.06					
PEF	L/sec	5.78	6.92	120			
MVV	L/min	93					
PIF	L/sec		1.84				
FEV1/FEV6%			75				

Lung Volumes/Plethysmography

Vtg	Liters	
VC	Liters	3.06
TLC	Liters	4.91
RV	Liters	1.83
RV/TLC	%	37
FRC PL	Liters	2.93
ERV	Liters	
IC	Liters	

Diffusion

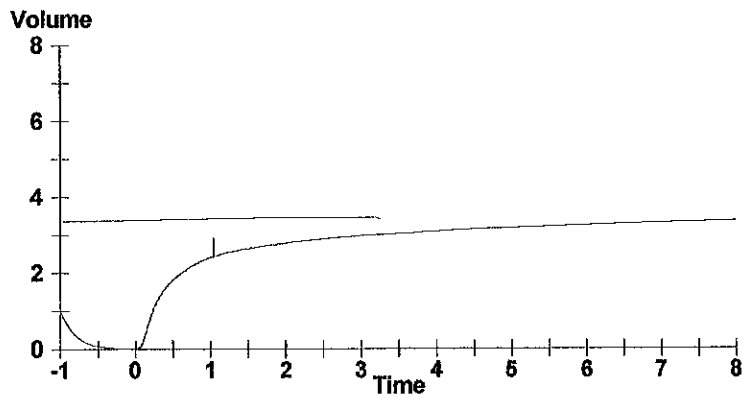
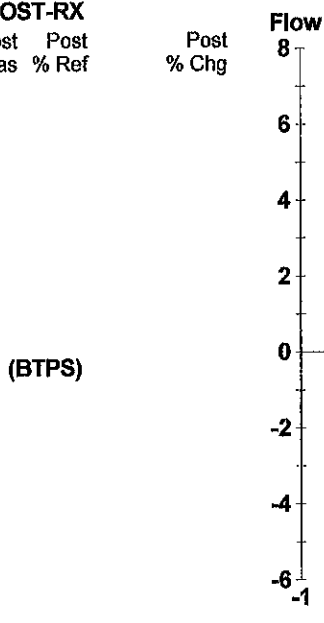
DLCO	mL/mmHg/min	18.7
DL Adj	mL/mmHg/min	18.7
DLCO/VA	mL/mHg/min/L	3.23
VA	Liters	
BHT	Sec	

Resistance

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.30
Gaw	L/sec/cmH2O	0.703
sRaw	cmH2O/L/s/L	3.80
sGaw	L/s/cmH2O/L	0.263
Vtg (Raw)	Liters	

Comments:

Interpretation:



Name: NGB,  
 Gender: Female  
 Age: 58 Race: Caucasian  
 Height(in): 64.0 Weight(lb): 124  
 Any Info:

Id: AKP-014  
 Date: 10/28/13  
 Temp: 19 PBar: 628  
 Physician:  
 Technician: VL

Spirometry		(BTPS)	PRE-RX		POST-RX		Post
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	% Chg
FVC	Liters	3.06	3.35	109			
FEV1	Liters	2.49	2.28	92			
FEV1/FVC	%	83	68	82			
FEF25-75%	L/sec	2.69	1.18	44			
FEF50%	L/sec	3.40	1.84	54			
FEF75%	L/sec	1.18	0.32	27			
IC	Liters						
VC	Liters	3.06					
PEF	L/sec	5.78	6.95	120			
MVV	L/min	93					
PIF	L/sec		1.32				
FEV1/FEV6%			72				

**Lung Volumes/Plethysmography**

Vtg	Liters	
VC	Liters	3.06
TLC	Liters	4.91
RV	Liters	1.83
RV/TLC	%	37
FRC PL	Liters	2.95
ERV	Liters	
IC	Liters	

**Diffusion**

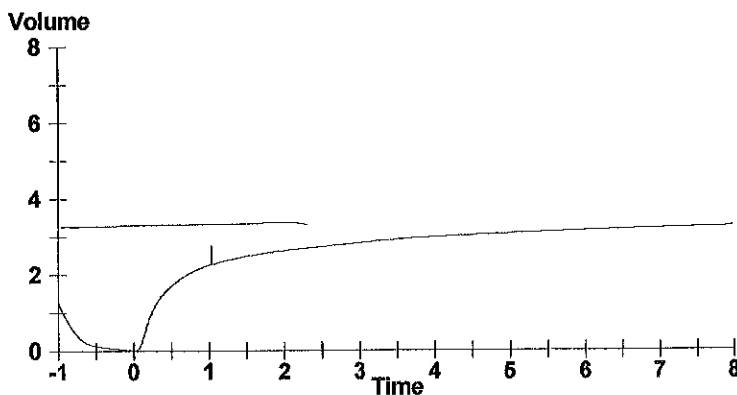
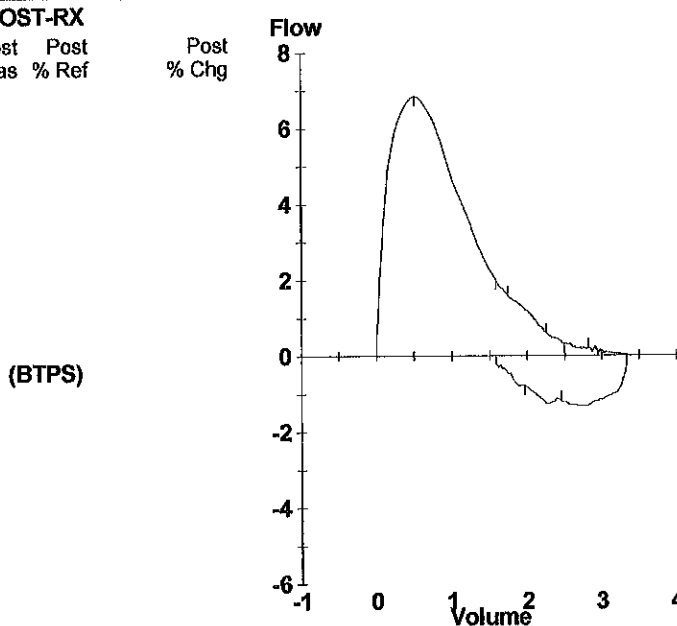
DLCO	mL/mmHg/min	18.5
DL Adj	mL/mmHg/min	18.5
DLCO/VA	mL/mHg/min/L	3.21
VA	Liters	
BHT	Sec	

**Resistance**

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.29
Gaw	L/sec/cmH2O	0.707
sRaw	cmH2O/L/s/L	3.80
sGaw	L/s/cmH2O/L	0.263
Vtg (Raw)	Liters	

Comments:

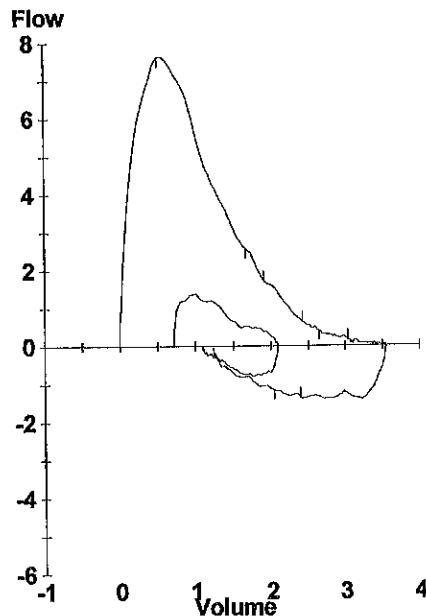
Interpretation:



Name: NGB,  
 Gender: Female  
 Age: 58 Race: Caucasian  
 Height(in): 63.8 Weight(lb): 124  
 Any Info:

Id: AKP-014  
 Date: 11/04/13  
 Temp: 20 PBar: 628  
 Physician:  
 Technician: VL

Spirometry		(BTPS)	PRE-RX		POST-RX		Post
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	% Chg
FVC	Liters	3.02	3.56	118			
FEV1	Liters	2.46	2.45	100			
FEV1/FVC	%	83	69	83			
FEF25-75%	L/sec	2.66	1.35	51			
FEF50%	L/sec	3.37	2.36	70			
FEF75%	L/sec	1.16	0.39	33			
IC	Liters						
VC	Liters	3.02					
PEF	L/sec	5.75	7.64	133			
MVV	L/min	93					
PIF	L/sec		1.40				
FEV1/FEV6%			74				



**Lung Volumes/Plethysmography**

Vtg	Liters	
VC	Liters	3.02
TLC	Liters	4.87
RV	Liters	1.81
RV/TLC	%	37
FRC PL	Liters	2.92
ERV	Liters	
IC	Liters	

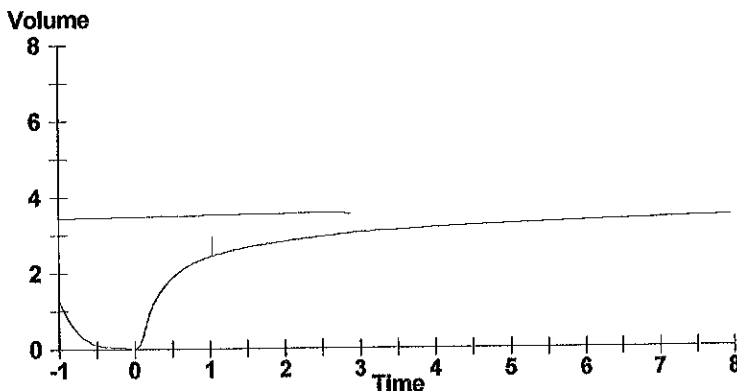
**Diffusion**

DLCO	mL/mmHg/min	18.4
DL Adj	mL/mmHg/min	18.4
DLCO/VA	mL/mHg/min/L	3.21
VA	Liters	
BHT	Sec	

**Resistance**

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.30
Gaw	L/sec/cmH2O	0.700
sRaw	cmH2O/L/s/L	3.80
sGaw	L/s/cmH2O/L	0.263
Vtg (Raw)	Liters	

Comments:



Interpretation:

EFFECTS OF AKPharma's-CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (SCREEN DIARY)  
CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

DAY AM	10/07/13	10/06/13	10/09/13	10/10/13	10/11/13	10/12/13	10/13/13	10/14/13	10/15/13
Runny Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Itchy Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Congestion 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Sneezing 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Voice Hoarse Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO
Throat Clearing Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO
DAY PM	-7	-6	-5	-4	-3	-2	-1	0	0
Runny Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Itchy Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Congestion 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Sneezing 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Voice Hoarse Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO
Throat Clearing Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N= No

SUBJECT NUMBER: AKP014

DATE COMPLETED: 10/7/13 - 10/14/13

SUBJECT INITIALS AND DATE

NGB 10/14/13



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Scientific Resources  
 Clin Trials-Leslie Byatt  
 2441 Ridgecrest Dr SE  
 Albuquerque, NM 87108

Client Nbr  
 24664

PATIENT NAME: **ATNGB, ATNGB** PATIENT ID: **AAGG1070** DOB: **04/09/1955** SEX: **F** REPORT STATUS: **Final** PAGE: **1**  
 PHYSICIAN: **Unlisted Physician,** COLLECT DATE & TIME: **10/14/2013 10:30** RECEIVE DATE & TIME: **10/14/2013 19:41** PRINT DATE & TIME: **10/15/2013 13:31**  
 REQUISITION NO.: **30920912** PT. PHONE NO.: **0** PATIENT NO.: **AKP014**  
 COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
<b>Comp Metabolic Panel</b>					
Sodium	141		mmol/L	134-144	
Potassium	4.2		mmol/L	3.5-5.1	
Chloride	103		mmol/L	98-111	
CO2	30		mmol/L	20-30	
Anion Gap	8			6-14	
Glucose		104 H	mg/dL	60-100	
Impaired fasting glucose (IFG) is defined as a fasting glucose level of 100-126 mg/dL. (ADA Guidelines Diabetes Care 26: (3160-3167)2003)					
BUN	18		mg/dL	7-31	
Creatinine	0.86		mg/dL	0.50-1.40	
Creatinine method is IDMS traceable. EstGFR Calculation has been adjusted. Please note new reference range effective 5/23/2013.					
eGFR non-African Am	>60		mL/min/1.73m2	>60	
GFR Comment	Estimated GFR values are not accurate in acute kidney failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, the very old or very young, races other than Caucasian or African American, people with acute illnesses, or amputations.				
Calcium	9.2		mg/dL	8.4-10.4	
Total Protein	7.1		gm/dL	6.1-8.2	
Albumin	4.0		gm/dL	3.4-4.7	
Globulin	3.1		gm/dL	2.4-4.2	
Bilirubin, total	0.6		mg/dL	0.3-1.2	
Alk Phos	55		U/L	38-150	
AST(SGOT)	26		U/L	6-58	
ALT(SGPT)	29		U/L	14-67	
Fasting Phosphorus	NO				
Phosphorus	4.0		mg/dL	2.3-5.6	
<b>CBC</b>					
WBC	7.5		x10E3	4.0-10.6	
RBC	4.38		x10E6	4.00-5.36	
Hgb	14.2		gm/dL	12.0-16.0	
Hct	42		%	36-48	
MCV	96		fL	81-98	
MCHC	33.6		gm/dL	31.2-35.2	
RDW	13.2		%	11.0-14.5	
Platelets	350		x10E3	150-400	
Eos, Respiratory Phys, Addr, Phone	None seen				

*NCS MDD  
 16 Oct 2013*

*NCS MDD  
 16 Oct 2013*

NO PHYSICIAN GIVEN  
 CLARIFICATION OF NAME PER CLIENT THEY USE LETTERS AS THE NAME

End of Report

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

DAY AM	1	2	3	4	5	6	7	8	9
Runny Nose 0 to 3	19/14 0 1 2 3	10/15 0 1 2 3	10/16 0 1 2 3	10/17 0 1 2 3	10/18 0 1 2 3	10/19 0 1 2 3	10/20 0 1 2 3	10/21 0 1 2 3	10/22 0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
<b>DAY PM</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>	<b>9</b>
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

Start here

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N= No

XTRA DOSE 7 PM

SUBJECT NUMBER AKP 014 DATE COMPLETED: 10/21/13

SUBJECT INITIALS AND DATE: AKP 10/21/13



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505 ) 938-8922

Lovelace Scientific Resources  
Clin Trials-Leslie Byatt  
2441 Ridgecrest Dr SE  
Albuquerque, NM 87108

Client Nbr  
24664

PATIENT NAME <b>NGB, NGB</b>	PATIENT ID <b>AAGG4464</b>	DOB <b>04/09/1955</b>	SEX <b>F</b>	REPORT STATUS <b>Final</b>	PAGE <b>1</b>
PHYSICIAN <b>Unlisted Physician,</b>	COLLECT DATE & TIME <b>10/21/2013 10:45</b>	RECEIVE DATE & TIME <b>10/21/2013 18:29</b>	PRINT DATE & TIME <b>10/22/2013 06:06</b>		
REQUISITION NO. <b>30920915</b>	PT. PHONE NO. <b>0</b>	PATIENT NO. <b>AKP014</b>			
COMMENTS :					

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Eos, Respiratory Phys, Addr, Phone	None seen Not given			NS	

End of Report

*M. McGuire MD*  
22 Oct 2013



EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

DAY AM	7	8	9	10	11	12	13	14	15
Runny Nose 0 to 3	10/21/13 0 1 2 3	10/22/13 0 1 2 3	10/23/13 0 1 2 3	10/24/13 0 1 2 3	10/25/13 0 1 2 3	10/26/13 0 1 2 3	10/27/13 0 1 2 3	10/28/13 0 1 2 3	10/29/13 0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
DAY PM	7	8	9	10	11	12	13	14	15
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

SCALE 0 to 3

- 0= No symptoms (no symptoms detected)
- 1= Mild symptoms (symptoms present but easily tolerated)
- 2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)
- 3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)
- Y=Yes N=No

XTRA  
DOSE  
7 PM

SUBJECT NUMBER: AKP DATE COMPLETED: 10/28/13

SUBJECT INITIALS AND DATE: AKP 10/28/13

NGB



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505 ) 938-8922

Lovelace Scientific Resources  
Leslie Byatt, MD  
2441 Ridgecrest Dr SE  
Albuquerque, NM 87108-5129

Client Nbr  
24664

PATIENT NAME <b>NGB, NGB</b>	PATIENT ID <b>AAGG4464</b>	DOB <b>04/09/1955</b>	SEX <b>F</b>	REPORT STATUS <b>Final</b>	PAGE <b>1</b>
PHYSICIAN <b>Unlisted Physician,</b>	COLLECT DATE & TIME <b>10/28/2013 10:40</b>	RECEIVE DATE & TIME <b>10/28/2013 19:01</b>	PRINT DATE & TIME <b>10/29/2013 06:03</b>		
REQUISITION NO. <b>30920968</b>	PT. PHONE NO. <b>0</b>	PATIENT NO. <b>AKP014</b>			
COMMENTS :					

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Eos, Respiratory Phys, Addr, Phone	None seen	Not given		NS	

End of Report

*AKP014 Sub I*  
~~28~~ 29 Oct 2013  
 error  
 non  
 29 Oct 13

Study Identification: 2749 LSR Study #: 2749  
 Subject Number: AKP014 Subject Initials: NGB

ADVERSE EVENT LOG

Adverse Event	** Start Date (DD/MMM/YYYY)	SEVERITY	Relationship to Study Drug (Suspected/Not Suspected)	** End Date (DD/MMM/YYYY)	Action Taken	Investigator Initials/Date
Stinging Craze (top, r)	19/OCT/2013	mild	Suspected	04/NOV/2013	NONE	NGB/14 Dec 13
Bad Taste	14/OCT/2013	mild	Suspected	04/NOV/2013	NONE	NGB/14 Dec 13
Nose Bleed	09/Oct/2013	mild	Suspected	09/Oct/2013	NONE	NGB/14 Dec 13
Swelling LEFT FOREARM	03/NOV/2013	mild	Not suspected	ongoing	GOING TO ALL HEW PCP RE: THIS	NGB/27 Feb 14
Swollen RE INDEX FINGER	03/NOV/2013	mild	Not suspected	ongoing	GOING TO ALL HEW PCP RE: THIS	NGB/27 Feb 14

\*\* If day is unknown, write UNK in space provided, but every effort should be made to be as specific as possible\*\*

Investigator Signature (at end of study): AKP Date: 27 Feb 2014  
 SC Signature (at end of study): Calvin Boyd Date: 2/24/14  
 Lovelace Scientific Resources, Inc - AdverseEvents 04/2013 PAGE: 1 of 1

Study Identification: AK Pharma Allergy

LSR #: 2749

Subject Number: AKP014

Subject Initials: NBB

**CONCOMITANT MEDICATION LOG**

List all prescription medications you are taking. Also include over-the-counter medications, vitamins and supplements.

Name of Medication	Indication (What you take it for)	Dose	Unit	Frequency	Route	* Start Date (Day/Month/Year)	Stop Date	Ongoing at EOS (for Clinic use)
EXAMPLE	Diabetes	500	MG	2 Tabs per day	Oral	UNK/AUG/1999		<input type="checkbox"/>
Calcium + D3	supplement	600	mg	QD	PO	2013		<input checked="" type="checkbox"/>
Fish Oil	supplement	1200	mg	QD	PO	2013		<input checked="" type="checkbox"/>
MVI	supplement	1	tab	QD	PO	2010		<input checked="" type="checkbox"/>
Premarin	HRT	0.3	mg	QD	PO	1994		<input checked="" type="checkbox"/>
glucosamine	OA	3000	mg	QD	PO	2011		<input checked="" type="checkbox"/>
Chondroitin	OA	1000	mg	QD	PO	2011		<input checked="" type="checkbox"/>
MSSM	supplement	750	mg	QD	PO	2011		<input checked="" type="checkbox"/>
HRTZ	water retention	12.5	mg	prn	PO	2006		<input checked="" type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>

\* If day or month of medication date is unknown, write UNK in space provided

Investigator Signature (at end of study): Walter Byatt Date: 2/21/14

SC Signature (at end of study): Walter Byatt Date: 2/21/14

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (SCREEN DIARY)  
CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

DAY AM.	-7	-6	-5	-4	-3	-2	-1	0
Runny Nose 0 to 3	10/28/13 0 1 2 3	10/29/13 0 1 2 3	10/30/13 0 1 2 3	10/30/13 0 1 2 3	11/01/13 0 1 2 3	11/02/13 0 1 2 3	11/03/13 0 1 2 3	11/04/13 0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
DAY PM	-7	-6	-5	-4	-3	-2	-1	0
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N= No

SUBJECT NUMBER: AKP014 DATE COMPLETED: 11/04/13 SUBJECT INITIALS AND DATE: WLB 11/04/13



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505 ) 938-8922

Lovelace Scientific Resources  
 Leslie Byatt, MD  
 2441 Ridgecrest Dr SE  
 Albuquerque, NM 87108-5129

Client Nbr  
 24664

PATIENT NAME **NOB, NOB** PATIENT ID **AAGH1349** DOB **04/09/1955** SEX **F** REPORT STATUS **Final** PAGE **1**  
 PHYSICIAN **Unlisted Physician,** COLLECT DATE & TIME **11/04/2013 10:32** RECEIVE DATE & TIME **11/04/2013 20:19** PRINT DATE & TIME **11/05/2013 06:10**  
 REQUISITION NO. **30920950** PT. PHONE NO. **0** PATIENT NO. **AKP014**  
 COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
<b>Comp Metabolic Panel</b>					
Sodium	137		mmol/L	134-144	
Potassium	4.0		mmol/L	3.5-5.1	
Chloride	103		mmol/L	98-111	
CO2	28		mmol/L	20-30	
Anion Gap	6			6-14	
Glucose	100		mg/dL	60-100	
Impaired fasting glucose (IFG) is defined as a fasting glucose level of 100-126 mg/dL. (ADA Guidelines Diabetes Care 26: (3160-3167)2003)					
BUN	16		mg/dL	7-31	
Creatinine	0.82		mg/dL	0.50-1.40	
Creatinine method is IDMS traceable. EstGFR Calculation has been adjusted. Please note new reference range effective 5/23/2013.					
eGFR non-African Am	>60		mL/min/1.73m2	>60	
GFR Comment	Estimated GFR values are not accurate in acute kidney failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, the very old or very young, races other than Caucasian or African American, people with acute illnesses, or amputations.				
Calcium	8.9		mg/dL	8.4-10.4	
Total Protein	7.1		gm/dL	6.1-8.2	
Albumin	3.9		gm/dL	3.4-4.7	
Globulin	3.2		gm/dL	2.4-4.2	
Bilirubin, total	0.5		mg/dL	0.3-1.2	
Alk Phos	55		U/L	38-150	
AST(SGOT)	25		U/L	6-58	
ALT(SGPT)	28		U/L	14-67	
Fasting	<b>NOT GIVEN</b>				
<b>CBC</b>					
WBC	7.7		x10E3	4.0-10.6	
RBC	4.12		x10E6	4.00-5.36	
Hgb	13.1		gm/dL	12.0-16.0	
Hct	41		%	36-48	
MCV		99	fL	81-98	
MCHC	32.1		gm/dL	31.2-35.2	
RDW	13.2		%	11.0-14.5	
Platelets	278		x10E3	150-400	
Eos, Respiratory	None seen				
Phys, Addr, Phone	PHYS UNKN				

*NCS [Signature]*  
 07 Nov 13

End of Report

TGC / AKP  
1006

**Effects of AkPharma's Calcium Glycerophosphate  
Nasal Spray wash (AkP 010112A) on Patient-Perceived Breathing Comfort**

**SATISFACTION QUESTIONNAIRE:**

Would you use / purchase this nasal wash product in the future?"  YES  NO

NGB  
11/4/13

You are also encouraged to make any free comments regarding your experience in the use of this product regarding your opinion of any of its effects not covered specifically in the Daily Diary:

BURNING SENSATION, BAD TASTE

[Type text]

Subject initials and Date

NGB 11/4/13

Study Staff Initials and Date

EM 11/04/13

**AKP-015**



749 AKPharma PERENNIAL ALLERGIES  
SCREENING/VISIT 1 SOURCE DOCUMENTS

Initials: BJK Site #: \_\_\_\_\_ Subject #: AKP013<sup>5</sup>  
SM  
10/03/13

3

PATIENT DEMOGRAPHICS

**Patient Demographics**

Date of Birth: 08 / Jun / 1955 (dd/mm/yyyy)

Gender:  Male  Female

If female, Indicate Childbearing Potential

Childbearing  Surgically sterilized  Post-Menopausal

Ethnicity:  Hispanic  Non Hispanic

Race:  Asian  Black  Caucasian  American Indian

Pacific Islander  Other, Specify \_\_\_\_\_

**Smoking History**

Smoking Status:  None (smoked less than 100 cigarettes in lifetime)

Former (previously smoked more than 100 cigarettes in lifetime)

Current (smokes now)

If subject is a former or current smoker, please indicate:

Years smoked: \_\_\_\_\_ Cigarettes per day: \_\_\_\_\_

CRC Signature: Erica Maldonado Date: 03 / OCT / 2013 (dd/mm/yy)



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Scientific Resources  
 Clin Trials Lesne Byatt  
 2441 Ridgecrest Dr SE  
 Albuquerque, NM 87108

Client Nbr  
 24664

PATIENT NAME: **BJK, BJK** PATIENT ID: **AAGF5252** DOB: **06/08/1955** SEX: **F** REPORT STATUS: **Final** PAGE: **1**  
 PHYSICIAN: **Unlisted Physician,** COLLECT DATE & TIME: **10/02/2013 10:38** RECEIVE DATE & TIME: **10/02/2013 20:39** PRINT DATE & TIME: **10/03/2013 06:06**  
 REQUISITION NO.: **30920894** PT. PHONE NO.: **0** PATIENT NO.: **AKP015**  
 COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Allerg, Panel 18					
Allerg, Juniper	0.20		KU/L	<0.35	
Allerg, Cottonwood		1.40 H	KU/L	<0.35	
Allerg, West. Ragweed		2.20 H	KU/L	<0.35	
Allerg, Russian Thistle		27.80 H	KU/L	<0.35	
Allerg, Bermuda Grass		35.80 H	KU/L	<0.35	
Allerg, Alternaria	0.30		KU/L	<0.35	
Allerg, Mesquite		4.50 H	KU/L	<0.35	
Allerg, Cockroach		0.40 H	KU/L	<0.35	
Allerg, Derm. pter.	0.20		KU/L	<0.35	

The standard classification system utilizes the following class cutoffs.

Class	ku/L	Interpretation
0	<0.35	Negative for Allergen
I	0.35-0.69	Positive for Allergen
II	0.70-3.49	Strongly Positive
III	3.5-17.49	Strongly Positive
IV	17.5-52.49	Strongly Positive
V	52.5-99.99	Strongly Positive
VI	>100	Strongly Positive

Results with allergens scoring in class 1 should be considered weakly positive or equivocal. Class 2 and higher should be considered positive. Although increasing class ranges (0-VI) are reflective of increasing concentrations of allergen-specific IgE, this may not correlate with the degree of clinical response when challenged with the specific allergen. The correlation of allergy laboratory results with clinical history is essential. A negative test may not rule out clinical allergy.

Allerg, Derm. farinae	0.40	H	KU/L	<0.35
Allerg, Clad. herb.	<0.10		KU/L	<0.35
Allerg, Firebush	3.80	H	KU/L	<0.35
Allerg, Cat Dander Ep	<0.10		KU/L	<0.35
Allerg, Dog Dander	<0.10		KU/L	<0.35
Allerg, Bluegrass	15.50	H	KU/L	<0.35
Allerg, Pigweed	5.10	H	KU/L	<0.35
Allerg, Mulberry	0.80	H	KU/L	<0.35
Allerg, Helminth	<0.10		KU/L	<0.35
Phys, Addr, Phone	NOT GIVEN			
FAX RESULTS				
FAX PHONE NUMBER	348 8546			

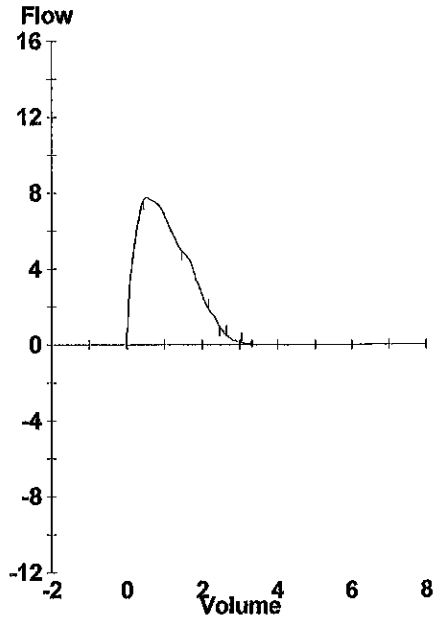
End of Report

*meets inclusion criteria*  
*W McInnis MD*  
*03 Oct 2013*

Name: BJK,  
 Gender: Female  
 Age: 58 Race: Caucasian  
 Height(in): 62.0 Weight(lb): 100  
 Any Info:

Id: AKP-015  
 Date: 10/16/13  
 Temp: 19 PBar: 631  
 Physician:  
 Technician:

Spirometry		(BTPS)	PRE-RX		POST-RX		Post
		Ref	Pre	Pre	Post	Post	Post
			Meas	% Ref	Meas	% Ref	% Chg
FVC	Liters	2.80	3.35	120			
FEV1	Liters	2.29	2.66	116			
FEV1/FVC	%	84	80	95			
FEF25-75%	L/sec	2.51	2.70	108			
FEF50%	L/sec	3.21	4.48	140			
FEF75%	L/sec	1.08	0.88	82			
IC	Liters						
VC	Liters	2.80					
PEF	L/sec	5.53	** 8.75	** 158			
MVV	L/min	93					
PIF	L/sec						
FEV1/FEV6%			82				



**Lung Volumes/Plethysmography**

Parameter	Units	Value
Vtg	Liters	
VC	Liters	2.80
TLC	Liters	4.51
RV	Liters	1.66
RV/TLC	%	37
FRC PL	Liters	2.86
ERV	Liters	
IC	Liters	

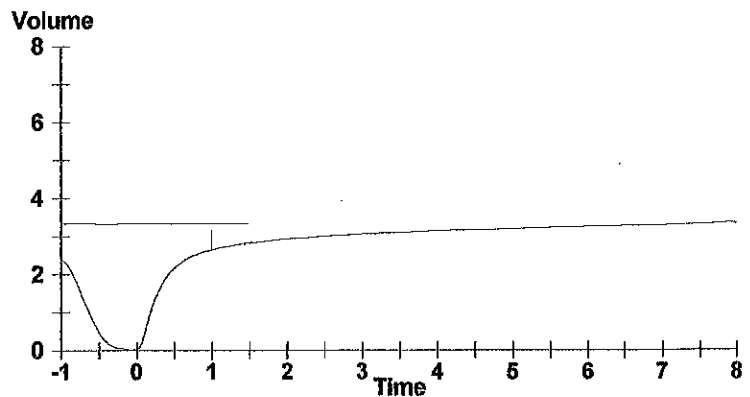
**Diffusion**

DLCO	mL/mmHg/min	15.7
DL Adj	mL/mmHg/min	15.7
DLCO/VA	mL/mHg/min/L	3.22
VA	Liters	
BHT	Sec	

**Resistance**

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.33
Gaw	L/sec/cmH2O	0.686
sRaw	cmH2O/L/s/L	3.81
sGaw	L/s/cmH2O/L	0.262
Vtg (Raw)	Liters	

Comments:



Interpretation:

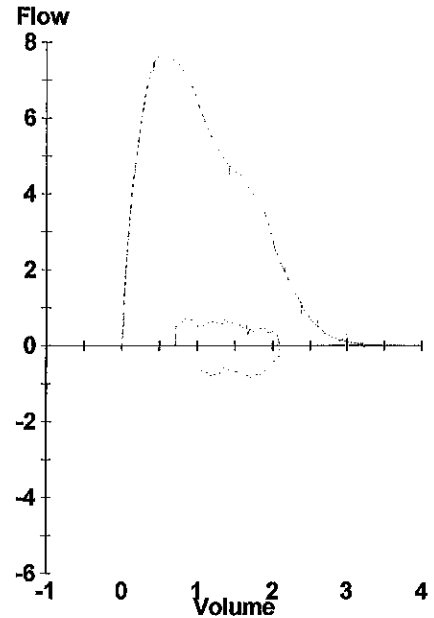


Name: BJK,  
 Gender: Female  
 Age: 58 Race: Caucasian  
 Height(in): 62.0 Weight(lb): 100  
 Any Info:

Id: AKP--015  
 Date: 10/24/13  
 Temp: 20 PBar: 634  
 Physician:  
 Technician:

Spirometry		(BTPS)	PRE-RX		POST-RX		Post
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	% Chg
FVC	Liters	2.80	3.23	116			
FEV1	Liters	2.29	2.66	116			
FEV1/FVC	%	84	82	98			
FEF25-75%	L/sec	2.51	2.95	118			
FEF50%	L/sec	3.21	4.34	135			
FEF75%	L/sec	1.08	0.96	89			
IC	Liters						
VC	Liters	2.80					
PEF	L/sec	5.53	7.88	143			
MVV	L/min	93					
PIF	L/sec						
FEV1/FEV6%			83				

(BTPS)



Lung Volumes/Plethysmography

Vtg	Liters	
VC	Liters	2.80
TLC	Liters	4.51
RV	Liters	1.66
RV/TLC	%	37
FRC PL	Liters	2.86
ERV	Liters	
IC	Liters	

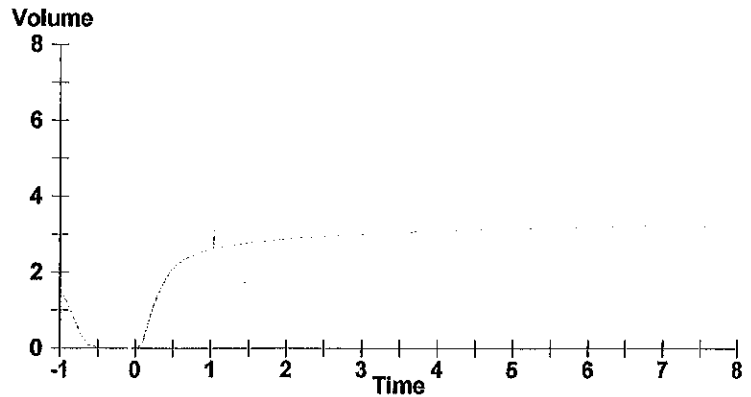
Diffusion

DLCO	mL/mmHg/min	15.7
DL Adj	mL/mmHg/min	15.7
DLCO/VA	mL/mHg/min/L	3.24
VA	Liters	
BHT	Sec	

Resistance

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.33
Gaw	L/sec/cmH2O	0.686
sRaw	cmH2O/L/s/L	3.81
sGaw	L/s/cmH2O/L	0.262
Vtg (Raw)	Liters	

Comments:



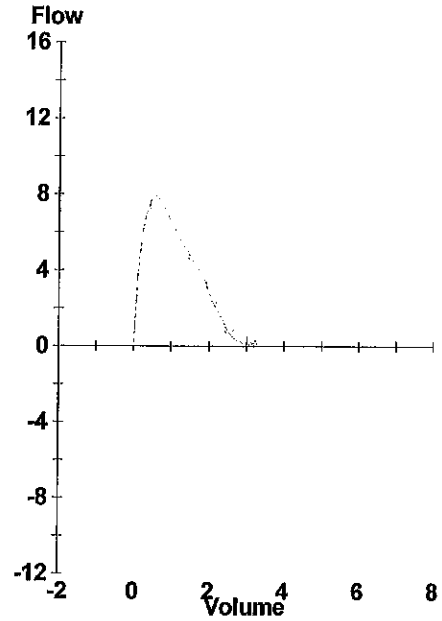
Interpretation



Name: BJK,  
 Gender: Female  
 Age: 58 Race: Caucasian  
 Height(in): 62.0 Weight(lb): 101  
 Any Info:

Id: AKP-115  
 Date: 10/30/13  
 Temp: 21 PBar: 629  
 Physician:  
 Technician: VL

Spirometry		(BTPS)	PRE-RX		POST-RX		Flow
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	Post % Chg
FVC	Liters	2.80	3.32	119			
FEV1	Liters	2.29	2.74	120			
FEV1/FVC	%	84	82	99			
FEF25-75%	L/sec	2.51	2.90	116			
FEF50%	L/sec	3.21	4.42	138			
FEF75%	L/sec	1.08	0.95	88			
IC	Liters						
VC	Liters	2.80					
PEF	L/sec	5.53	8.08	146			
MVV	L/min	93					
PIF	L/sec						
FEV1/FEV6%			85				



Lung Volumes/Plethysmography (BTPS)

Vtg	Liters	
VC	Liters	2.80
TLC	Liters	4.51
RV	Liters	1.66
RV/TLC	%	37
FRC PL	Liters	2.85
ERV	Liters	
IC	Liters	

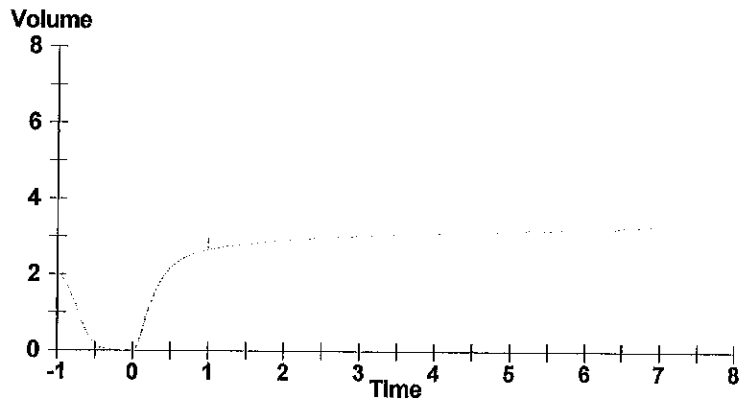
Diffusion

DLCO	mL/mmHg/min	15.8
DL Adj	mL/mmHg/min	15.8
DLCO/VA	mL/mHg/min/L	3.21
VA	Liters	
BHT	Sec	

Resistance

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.34
Gaw	L/sec/cmH2O	0.684
sRaw	cmH2O/L/s/L	3.81
sGaw	L/s/cmH2O/L	0.262
Vtg (Raw)	Liters	

Comments:



Interpretation:

Name: BJK,  
 Gender: Female  
 Age: 58 Race: Caucasian  
 Height(in): 62.0 Weight(lb): 104  
 Any Info:

Id: AKP-015  
 Date: 11/06/13  
 Temp: 19 PBar: 637  
 Physician:  
 Technician: VL

Spirometry		(BTPS)	PRE-RX		POST-RX		Post
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	% Chg
FVC	Liters	2.80	3.31	118			
FEV1	Liters	2.29	2.68	117			
FEV1/FVC	%	84	81	97			
FEF25-75%	L/sec	2.51	2.89	115			
FEF50%	L/sec	3.21	5.01	156			
FEF75%	L/sec	1.08	0.81	75			
IC	Liters						
VC	Liters	2.80					
PEF	L/sec	5.53	7.51	136			
MVV	L/min	93					
PIF	L/sec		0.30				
FEV1/FEV6%			83				

**Lung Volumes/Plethysmography**

Vtg	Liters	
VC	Liters	2.80
TLC	Liters	4.51
RV	Liters	1.66
RV/TLC	%	37
FRC PL	Liters	2.83
ERV	Liters	
IC	Liters	

**Diffusion**

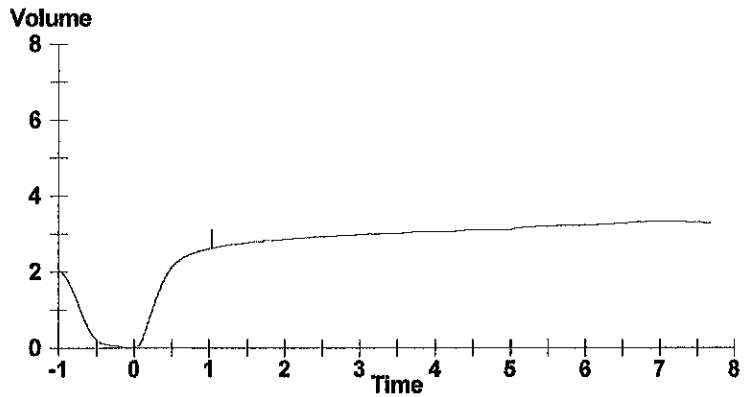
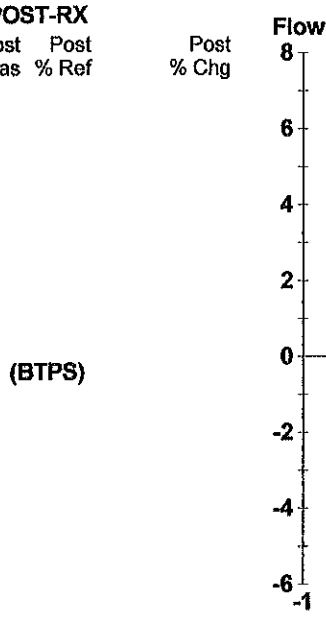
DLCO	mL/mmHg/min	16.1
DL Adj	mL/mmHg/min	16.1
DLCO/VA	mL/mHg/min/L	3.26
VA	Liters	
BHT	Sec	

**Resistance**

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.35
Gaw	L/sec/cmH2O	0.679
sRaw	cmH2O/L/s/L	3.81
sGaw	L/s/cmH2O/L	0.262
Vtg (Raw)	Liters	

Comments:

Interpretation:



EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (SCREEN DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

DAY	-7	-6	-5	-4	-3	-2	-1	0	0
AM	10/09/13	10/10/13	10/11/13	10/12/13	10/13/13	10/14/13	10/15/13	10/16/13	10/17/13
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
DAY PM	-7	-6	-5	-4	-3	-2	-1	0	0
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

SCALE 0 to 3

- 0= No symptoms (no symptoms detected)
- 1= Mild symptoms (symptoms present but easily tolerated)
- 2= Moderate symptoms (awareness of symptoms; bothersome but tolerable)
- 3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)
- Y=Yes N=No

10/16/13  
10/16/13

SUBJECT NUMBER: BJK DATE COMPLETED: 10/9/13 - 10/16/13 SUBJECT INITIALS AND DATE: 10:16:13 BJK  
AKP015



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Scientific Resources  
 Clin Trials-Leslie Byatt  
 2441 Ridgecrest Dr SE  
 Albuquerque, NM 87108

Client Nbr  
 24664

PATIENT NAME: **BJK, BJK** PATIENT ID: **AAGF5252** DOB: **06/08/1955** SEX: **F** REPORT STATUS: **Final** PAGE: **1**  
 PHYSICIAN: **Unlisted Physician,** COLLECT DATE & TIME: **10/16/2013 11:00** RECEIVE DATE & TIME: **10/16/2013 20:17** PRINT DATE & TIME: **10/17/2013 06:08**  
 REQUISITION NO.: **30920898** PT. PHONE NO.: **0** PATIENT NO.: **AKP015**  
 COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Comp Metabolic Panel					
Sodium	138		mmol/L	134-144	
Potassium		3.4	L	3.5-5.1	
Chloride	101		mmol/L	98-111	
CO2	28		mmol/L	20-30	
Anion Gap	9			6-14	
Glucose	88		mg/dL	60-100	
BUN	8		mg/dL	7-31	
Creatinine	0.84		mg/dL	0.50-1.40	
Creatinine method is IDMS traceable. EstGFR calculation has been adjusted. Please note new reference range effective 5/23/2013.					
eGFR non-African Am	>60		mL/min/1.73m2	>60	
GFR Comment	Estimated GFR values are not accurate in acute kidney failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, the very old or very young, races other than Caucasian or African American, people with acute illnesses, or amputations.				
Calcium	8.7		mg/dL	8.4-10.4	
Total Protein	6.9		gm/dL	6.1-8.2	
Albumin	3.6		gm/dL	3.4-4.7	
Globulin	3.3		gm/dL	2.4-4.2	
Bilirubin, total	0.3		mg/dL	0.3-1.2	
Alk Phos	113		U/L	38-150	
AST(SGOT)	25		U/L	6-58	
ALT(SGPT)	25		U/L	14-67	
Fasting Phosphorus	2.8		mg/dL	2.3-5.6	
CBC					
WBC		2.4	L	4.0-10.6	NCS 10/18/13
RBC		3.90	L	4.00-5.36	NCS 10/18/13
Hgb	14.8		gm/dL	12.0-16.0	
Hct	42		%	36-48	
MCV		109	H	81-98	NCS 10/18/13
MCHC	34.9		gm/dL	31.2-35.2	
RDW	12.6		%	11.0-14.5	
Platelets	273		x10E3	150-400	
Eos, Respiratory		Few	*	NS	
Phys, Addr, Phone	Not given				

End of Report

*NCS Jhalper PI 18 Oct 2013*

*Randomization*



**EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT**

Newf. A. P. P. t  
@ 11:00am

**DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)**

**CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS**

DAY AM	1	2	3	4	5	6	7	8	9
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
<b>DAY PM</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>	<b>9</b>
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

**SCALE 0 to 3**

- 0= No symptoms (no symptoms detected)
  - 1= Mild symptoms (symptoms present but easily tolerated)
  - 2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)
  - 3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)
- Y=Yes N=No

SUBJECT NUMBER: AKP 0015 DATE COMPLETED: 10/24/13

SUBJECT INITIALS AND DATE: BTK 10/24/13

Start here →

BTK



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505 ) 938-8922

Lovelace Scientific Resources  
Leslie Byatt, MD  
2441 Ridgcrest Dr SE  
Albuquerque, NM 87108-5129

Client Nbr  
24664

PATIENT NAME **BJK, BJK** PATIENT ID **AAGF5252** DOB **06/08/1955** SEX **F** REPORT STATUS **Final** PAGE **1**  
 PHYSICIAN **Unlisted Physician,** COLLECT DATE & TIME **10/24/2013 13:14** RECEIVE DATE & TIME **10/24/2013 17:54** PRINT DATE & TIME **10/25/2013 06:09**  
 REQUISITION NO. **30920971** PT. PHONE NO. **0** PATIENT NO. **AKP015**  
 COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Eos, Respiratory Phys, Addr, Phone	None seen	Not given		NS	

End of Report

*MDM Sub I  
29 Oct 2013*

**EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT**

**DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)**

**CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS**

DAY AM	7	8	9	10	11	12	13	14	15
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
<b>DAY PM</b>	<b>7</b>	<b>8</b>	<b>9</b>	<b>10</b>	<b>11</b>	<b>12</b>	<b>13</b>	<b>14</b>	<b>15</b>
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

**SCALE 0 to 3**

- 0 = No symptoms (no symptoms detected)
  - 1 = Mild symptoms (symptoms present but easily tolerated)
  - 2 = Moderate symptoms (awareness of symptoms, bothersome but tolerable)
  - 3 = Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)
- Y=Yes N=No

SUBJECT NUMBER: AKP015 BTK DATE COMPLETED: 10/30/13 SUBJECT INITIALS AND DATE: BTK



1001 Woodward Pl, N.E. Albuquerque, NM 87102 (505 ) 938-8922

Lovelace Scientific Resources  
Leslie Byatt, Clin Trials  
2441 Ridgecrest Dr SE  
Albuquerque, NM 87108-5129

Client Nbr  
24664

PATIENT NAME **BJK, BJK** PATIENT ID **AAGF5252** DOB **06/08/1955** SEX **F** REPORT STATUS **Final** PAGE **1**  
 PHYSICIAN **Unlisted Physician,** COLLECT DATE & TIME **10/30/2013 11:10** RECEIVE DATE & TIME **10/30/2013 20:05** PRINT DATE & TIME **10/31/2013 06:06**  
 REQUISITION NO. **30920965** PT. PHONE NO. **0** PATIENT NO. **AKP015**  
 COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Eos, Respiratory Phys, Addr, Phone	None seen	Not given		NS	

End of Report

*NCS  
 J. Sakur PI  
 1 November 2013*

Study Identification: 2749

LSR Study #: \_\_\_\_\_

Subject Number: AKP 015

Subject Initials: BJK

### ADVERSE EVENT LOG

Adverse Event (DD/MM/YY)	** Start Date (DD/MM/YY)	SEVERITY	Relationship to Study Drug (Suspected/Not Suspected)	** End Date (DD/MM/YY)	Action Taken	Investigator Initials/Date
<u>BURNING STINGING at application site</u>	<u>16/OCT/2013</u>	<u>mod</u>	<u>Suspected</u>	<u>09/NOV/2013</u>	<u>NONE</u>	<u>BJK 27 Feb 14</u>

\*\* If day is unknown, write UNK in space provided, but every effort should be made to be as specific as possible\*\*

Investigator Signature (at end of study): MM Auguineau Date: 27 Feb 2014

SC Signature (at end of study): Walter Byatt Date: 2/20/14

Study Identification: 2749 LSR #: \_\_\_\_\_

Subject Number: AKP015 Subject Initials: BTK

### CONCOMITANT MEDICATION LOG

List all prescription medications you are taking. Also include over-the-counter medications, vitamins and supplements.

Name of Medication	Indication (What you take it for)	Dose	Unit	Frequency	Route	* Start Date (Day/Month/Year)	Stop Date	Ongoing at EOS (for Clinic use)
EXAMPLE	Diabetes	500	MG	2 Tabs per day	Oral	UNK/AUG/1999		<input type="checkbox"/>
FIONASE	Seasonal allergies	2-3	sprays	2 times per day	INH	--/--/2002	01/sep/2013	<input type="checkbox"/>
Allegra	Seasonal allergies	60 mg	mg	QD	oral	--/--/2003	01/sep/2013	<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>

\* If day or month of medication date is unknown, write UNK in space provided

Investigator Signature (at end of study): [Signature] Date: 27 Feb 2014

SC Signature (at end of study): [Signature] Date: 2/28/14

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

DAY	14	15	16	17	18	19	20	21	22
AM	10/30/13	10/31/13	11/01/13	11/03/13	11/02/13	11/03/13	11/04/13	11/05/13	11/06/13
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
DAY PM	14	15	16	17	18	19	20	21	22
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N=No

SUBJECT NUMBER: AKP 015

DATE COMPLETED: 11/06/13

SUBJECT INITIALS AND DATE: AKP 11/06/13

AKP 11/06/13

TriCore Reference Laboratories  
1001 Woodward Pl NE  
Albuquerque, NM 87102  
(505)938-8922

Patient Name: X, BJK  
Medical Record: AAGH2720  
DOB: 06/08/1955 Age: 58Y Sex: F  
Account Number: 30920958  
Attending MD: Unlisted Physician  
Patient ID: AKP015  
Patient Phone: 0

W3391759 COLL: 11/06/2013 11:00 REC: 11/06/2013 22:03 PHYS: Unlisted Physician  
Req#: 30920958

Comp Metabolic Panel

Sodium	139	[134-144]	mmol/L
Potassium	3.6	[3.5-5.1]	mmol/L
Chloride	104	[98-111]	mmol/L
CO2	28	[20-30]	mmol/L
Anion Gap	7	[6-14]	
Glucose	72	[60-100]	mg/dL
BUN	14	[7-31]	mg/dL
Creatinine	0.74	[0.50-1.40]	mg/dL

Creatinine method is IDMS traceable. EstGFR Calculation has been adjusted.

Please note new reference range effective 5/23/2013.

eGFR non-African Am  
GFR Comment

>60 [ >60 ] mL/min/1.73m2

Estimated GFR values are not accurate in acute kidney failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, the very old or very young, races other than Caucasian or African American, people with acute illnesses, or amputations.

Calcium	8.5	[8.4-10.4]	mg/dL
Total Protein	7.0	[6.1-8.2]	gm/dL
Albumin	4.1	[3.4-4.7]	gm/dL
Globulin	2.9	[2.4-4.2]	gm/dL
Bilirubin, total	0.4	[0.3-1.2]	mg/dL
Alk Phos	118	[38-150]	U/L
AST (SGOT)	24	[6-58]	U/L
ALT (SGPT)	21	[14-67]	U/L

Fasting NOT GIVEN

CBC

WBC	7.2	[4.0-10.6]	x10E3
RBC	L 3.57	[4.00-5.36]	x10E6
Hgb	13.3	[12.0-16.0]	gm/dL
Hct	41	[36-48]	%
MCV	H 113	[81-98]	fL
MCHC	32.8	[31.2-35.2]	gm/dL
RDW	12.5	[11.0-14.5]	%
Platelets	246	[150-400]	x10E3

Eos, Respiratory None seen [NS]

CONTINUED

Printed: 02/27/2014 07:58

Patient Name: X, BJK  
Medical Record #: AAGH2720  
Location: CORE

INTERIM REPORT

Page: 1

*Wendy Guine*  
27 Feb 2014



BJK  
AKP015  
11/6/13

Effects of AkPharma's Calcium Glycerophosphate  
Nasal Spray wash (AkP 010112A) on Patient-Perceived Breathing Comfort

SATISFACTION QUESTIONNAIRE:

Would you use / purchase this nasal wash product in the future?"  YES  NO

You are also encouraged to make any free comments regarding your experience in the use of this product regarding your opinion of any of its effects not covered specifically in the Daily Diary:

Kinda Burns when putting  
it in nose

[Type text]

Subject initials and Date

11/6/13  
BJK

Study Staff Initials and Date

EM 11/6/13

**AKP-021**

2749 AKPharma PERENNIAL ALLERGIES  
SCREENING/VISIT 1 SOURCE DOCUMENTS

Initials: UFV Site #:      Subject #: AKP021

**PATIENT DEMOGRAPHICS**

**Patient Demographics**

Date of Birth: 11 / Aug / 1945 (dd/mmm/yyyy)

Gender:  Male  Female

If female, Indicate Childbearing Potential

Childbearing  Surgically sterilized  Post-Menopausal

Ethnicity:  Hispanic  Non Hispanic

Race:  Asian  Black  Caucasian  American Indian

Pacific Islander  Other, Specify \_\_\_\_\_

**Smoking History**

Smoking Status:  None (smoked less than 100 cigarettes in lifetime)

Former (previously smoked more than 100 cigarettes in lifetime)

Current (smokes now)

If subject is a former or current smoker, please indicate:

Years smoked: 24 Cigarettes per day: 20

CRC Signature: Uahm Bgout Date: 14 Oct 2013 (dd/mmm/yy)



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Scientific Resources  
 Leslie Byatt, Clin Trials  
 2441 Ridgecrest Dr SE  
 Albuquerque, NM 87108-5129

Client Nbr  
 24664

PATIENT NAME: X, UFV  
 PHYSICIAN: Unlisted Physician,  
 REQUISITION NO.: 30920936  
 COMMENTS:

PATIENT ID: AAGH4686  
 COLLECT DATE & TIME: 11/11/2013 13:05  
 PATIENT NO.: AKP021

DOB: 08/11/1945  
 RECEIVE DATE & TIME: 11/11/2013 19:57

SEX: M  
 REPORT STATUS: Final  
 PRINT DATE & TIME: 11/13/2013 06:09

PAGE 1

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Allerg, Panel 18					
Allerg, Juniper		5.60 H	KU/L	<0.35	
Allerg, Cottonwood		1.00 H	KU/L	<0.35	
Allerg, West. Ragweed	0.10		KU/L	<0.35	
Allerg, Russian Thistle		7.00 H	KU/L	<0.35	
Allerg, Bermuda Grass		2.20 H	KU/L	<0.35	
Allerg, Alternaria	0.10		KU/L	<0.35	
Allerg, Mesquite		1.10 H	KU/L	<0.35	
Allerg, Cockroach	<0.10		KU/L	<0.35	
Allerg, Derm. pter.	<0.10		KU/L	<0.35	

The standard classification system utilizes the following class cutoffs.

Class	ku/L	Interpretation
0	<0.35	Negative for Allergen
I	0.35-0.69	Positive for Allergen
II	0.70-3.49	Strongly Positive
III	3.5-17.49	Strongly Positive
IV	17.5-52.49	Strongly Positive
V	52.5-99.99	Strongly Positive
VI	>100	Strongly Positive

Results with allergens scoring in Class 1 should be considered weakly positive or equivocal. Class 2 and higher should be considered positive. Although increasing class ranges (0-VI) are reflective of increasing concentrations of allergen-specific IgE, this may not correlate with the degree of clinical response when challenged with the specific allergen. The correlation of allergy laboratory results with clinical history is essential. A negative test may not rule out clinical allergy.

Allerg, Derm. farinae	0.10		KU/L	<0.35
Allerg, Clad. herb.	<0.10		KU/L	<0.35
Allerg, Firebush		1.70 H	KU/L	<0.35
Allerg, Cat Dander Ep		5.70 H	KU/L	<0.35
Allerg, Dog Dander		0.40 H	KU/L	<0.35
Allerg, Bluegrass		2.00 H	KU/L	<0.35
Allerg, Pigweed		1.40 H	KU/L	<0.35
Allerg, Mulberry	0.20		KU/L	<0.35
Allerg, Helminth	<0.10		KU/L	<0.35
Phys, Addr, Phone	NOT GIVEN			

End of Report

*Handwritten signature*  
 13 Nov 2013

Name: UFV,  
 Gender: Male  
 Age: 68 Race: Hispanic  
 Height(in): 67.0 Weight(lb): 180  
 Any Info:

Id: AKP-021  
 Date: 11/27/13  
 Temp: 19 PBar: 637  
 Physician:  
 Technician: VL

Spirometry		(BTPS)	PRE-RX		POST-RX		Post % Chg
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	
FVC	Liters	3.54	2.95	83			
FEV1	Liters	2.80	2.17	78			
FEV1/FVC	%	79	74	93			
FEF25-75%	L/sec	2.86	1.58	55			
FEF50%	L/sec	3.60	2.44	68			
FEF75%	L/sec	1.22	0.48	39			
IC	Liters						
VC	Liters	3.54					
PEF	L/sec	7.62	7.62	100			
MVV	L/min	120					
PIF	L/sec		5.09				
FEV1/FEV6%			76				

**Lung Volumes/Plethysmography**

Vtg	Liters	
VC	Liters	3.54
TLC	Liters	5.82
RV	Liters	2.30
RV/TLC	%	40
FRC PL	Liters	3.23
ERV	Liters	
IC	Liters	

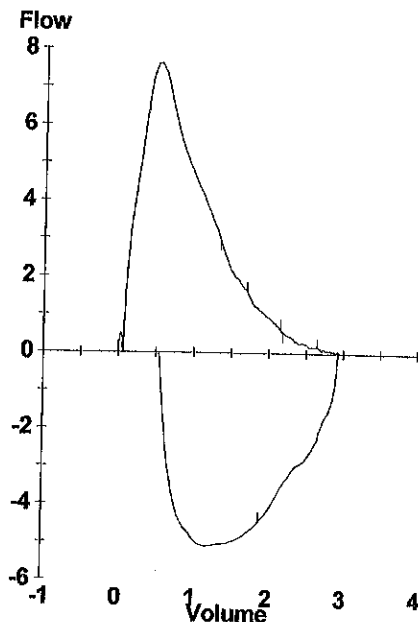
**Diffusion**

DLCO	mL/mmHg/min	20.6
DL Adj	mL/mmHg/min	20.6
DLCO/VA	mL/mHg/min/L	3.05
VA	Liters	
BHT	Sec	

**Resistance**

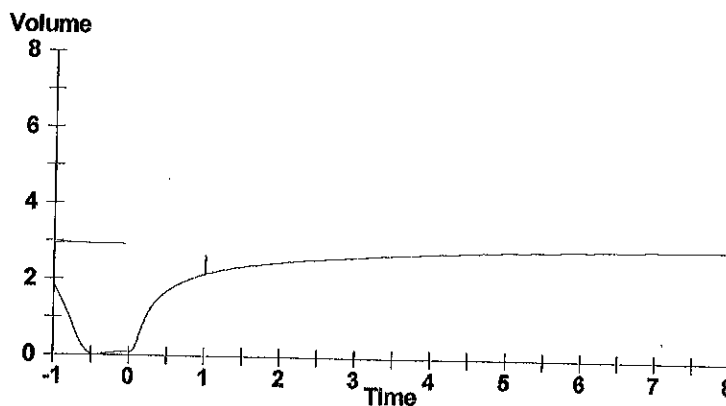
Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.43
Gaw	L/sec/cmH2O	0.775
sRaw	cmH2O/L/s/L	4.61
sGaw	L/s/cmH2O/L	0.217
Vtg (Raw)	Liters	

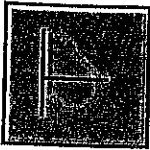
Comments:



(BTPS)

Interpretation:

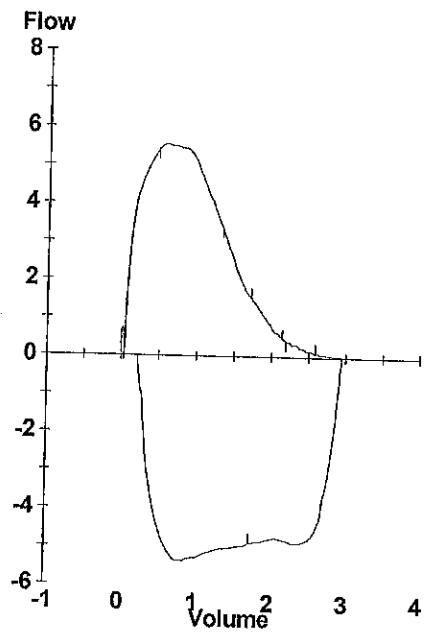




Name: AKP,  
 Gender: Male  
 Age: 68 Race:  
 Height(in): 67.0 Weight(lb): 179  
 Any Info:

Id: 021  
 Date: 12/04/13  
 Temp: 19 PBar: 622  
 Physician:  
 Technician: CRD

Spirometry		(BTPS)	PRE-RX		POST-RX		Post
		Ref	Pre	Pre	Post	Post	% Chg
			Meas	% Ref	Meas	% Ref	
FVC	Liters	3.54	2.96	84			
FEV1	Liters	2.80	2.17	77			
FEV1/FVC	%	79	73	92			
FEF25-75%	L/sec	2.86	1.51	53			
FEF50%	L/sec	3.60	3.03	84			
FEF75%	L/sec	1.22	0.41	33			
IC	Liters						
VC	Liters	3.54					
PEF	L/sec	7.62	6.71	88			
MVV	L/min	120					
PIF	L/sec		5.37				
FEV1/FEV6%			78				



**Lung Volumes/Plethysmography**

		(BTPS)
Vtg	Liters	
VC	Liters	3.54
TLC	Liters	5.82
RV	Liters	2.30
RV/TLC	%	40
FRC PL	Liters	3.24
ERV	Liters	
IC	Liters	

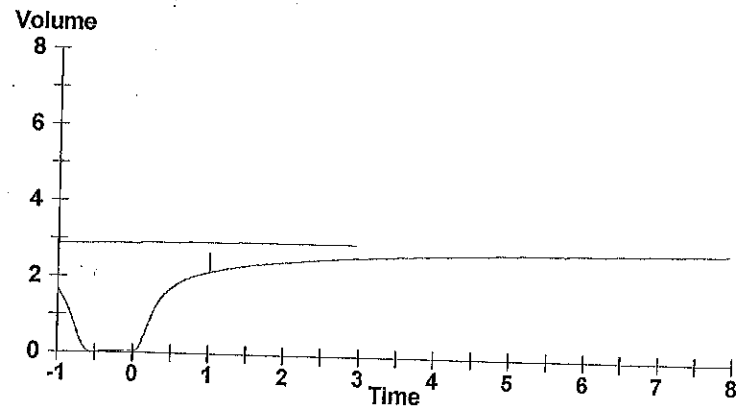
**Diffusion**

DLCO	mL/mmHg/min	20.5
DL Adj	mL/mmHg/min	20.5
DLCO/VA	mL/mHg/min/L	2.97
VA	Liters	
BHT	Sec	

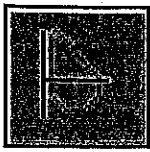
**Resistance**

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.42
Gaw	L/sec/cmH2O	0.777
sRaw	cmH2O/L/s/L	4.61
sGaw	L/s/cmH2O/L	0.217
Vtg (Raw)	Liters	

Comments:



Interpretation:



Name: AKPO21,  
 Gender: Male  
 Age: 68 Race:  
 Height(in): 67.0 Weight(lb): 179  
 Any Info:

Id: AKP021  
 Date: 12/12/13  
 Temp: 19 PBar: 638  
 Physician:  
 Technician: CRD

Spirometry		(BTPS)	PRE-RX		POST-RX		Post
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	% Chg
FVC	Liters	3.54	3.05	86			
FEV1	Liters	2.80	2.17	77			
FEV1/FVC	%	79	71	90			
FEF25-75%	L/sec	2.86	1.32	46			
FEF50%	L/sec	3.60	2.77	77			
FEF75%	L/sec	1.22	0.34	27			
IC	Liters						
VC	Liters	3.54					
PEF	L/sec	7.62	7.66	100			
MVV	L/min	120					
PIF	L/sec		4.79				
FEV1/FEV6%			76				

**Lung Volumes/Plethysmography**

Parameter	Units	Value
Vtg	Liters	
VC	Liters	3.54
TLC	Liters	5.82
RV	Liters	2.30
RV/TLC	%	40
FRC PL	Liters	3.24
ERV	Liters	
IC	Liters	

**Diffusion**

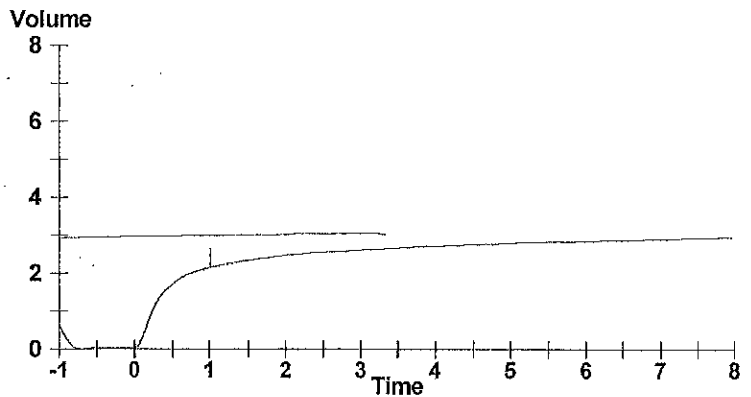
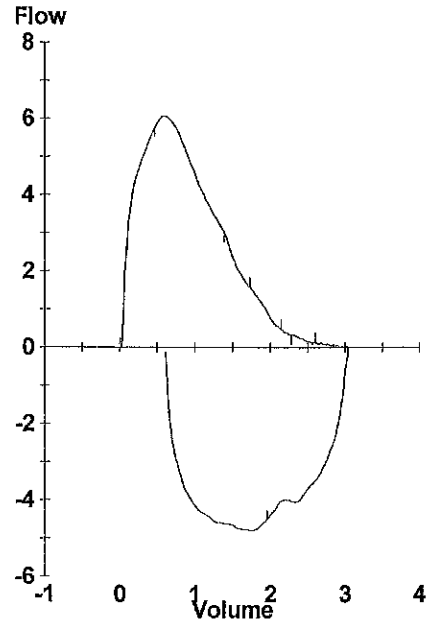
DLCO	mL/mmHg/min	20.5
DL Adj	mL/mmHg/min	20.5
DLCO/VA	mL/mHg/min/L	3.06
VA	Liters	
BHT	Sec	

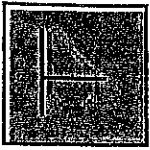
**Resistance**

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.42
Gaw	L/sec/cmH2O	0.777
sRaw	cmH2O/L/s/L	4.61
sGaw	L/s/cmH2O/L	0.217
Vtg (Raw)	Liters	

Comments:

Interpretation:





Name: Ufv,  
 Gender: Male  
 Age: 68 Race: Hispanic  
 Height(in): 67.0 Weight(lb): 181  
 Any Info:

Id: akp021  
 Date: 12/18/13  
 Temp: 20 PBar: 634  
 Physician:  
 Technician: DG

Spirometry		(BTPS)	PRE-RX		POST-RX		Post % Chg
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	
FVC	Liters	3.54	3.07	87			
FEV1	Liters	2.80	2.22	79			
FEV1/FVC	%	79	72	91			
FEF25-75%	L/sec	2.86	1.47	51			
FEF50%	L/sec	3.60	2.17	60			
FEF75%	L/sec	1.22	0.43	35			
IC	Liters						
VC	Liters	3.54					
PEF	L/sec	7.62	8.15	107			
MVV	L/min	120					
PIF	L/sec		6.26				
FEV1/FEV6%			75				

**Lung Volumes/Plethysmography**

Vtg	Liters	
VC	Liters	3.54
TLC	Liters	5.82
RV	Liters	2.30
RV/TLC	%	40
FRC PL	Liters	3.22
ERV	Liters	
IC	Liters	

**Diffusion**

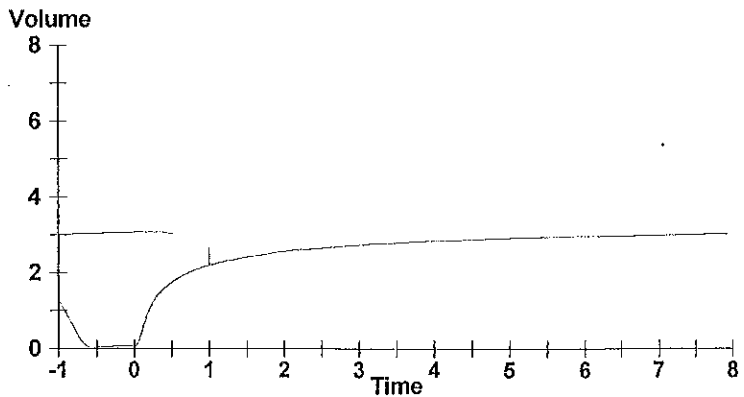
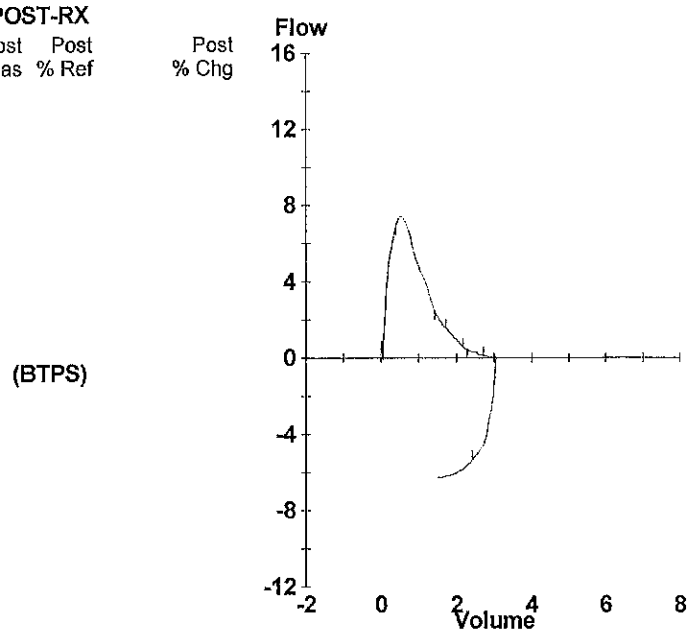
DLCO	mL/mmHg/min	20.6
DL Adj	mL/mmHg/min	20.6
DLCOVA	mL/mHg/min/L	3.04
VA	Liters	
BHT	Sec	

**Resistance**

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.43
Gaw	L/sec/cmH2O	0.773
sRaw	cmH2O/L/s/L	4.62
sGaw	L/s/cmH2O/L	0.217
Vtg (Raw)	Liters	

Comments:

Interpretation:





EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (SCREEN DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

DAY AM	11/20	11/21	11/22	11/23	11/24	11/25	11/26	11/27	11/28
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
DAY PM	-7	-6	-5	-4	-3	-2	-1	0	0
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

SCALE 0 to 3

- 0= No symptoms (no symptoms detected)
- 1= Mild symptoms (symptoms present but easily tolerated)
- 2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)
- 3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)
- Y=Yes N= NO

SUBJECT NUMBER: AKP 021 DATE COMPLETED: 11/20/13

SUBJECT INITIALS AND DATE: LLK ✓ 11/27/13

Start →  
here



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Scientific Resources  
 Leslie Byatt, MD  
 2441 Ridgcrest Dr SE  
 Albuquerque, NM 87108-5129

Client Nbr  
 24664

PATIENT NAME: **UFV, UFV**      PATIENT ID: **AAGH3348**      DOB: **08/11/1945**      SEX: **M**      REPORT STATUS: **Final**      PAGE: **1**  
 PHYSICIAN: **Unlisted Physician,**      COLLECT DATE & TIME: **11/27/2013 12:50**      RECEIVE DATE & TIME: **11/27/2013 18:38**      PRINT DATE & TIME: **11/28/2013 06:11**  
 REQUISITION NO.: **30920930**      PT. PHONE NO.: **0**      PATIENT NO.: **AKP021**  
 COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
<b>Comp Metabolic Panel</b>					
Sodium	140		mmol/L	134-144	
Potassium	4.1		mmol/L	3.5-5.1	
Chloride	105		mmol/L	98-111	
CO2	28		mmol/L	20-30	
Anion Gap	7			6-14	
Glucose	74		mg/dL	60-100	
BUN	16		mg/dL	7-31	
Creatinine	1.36		mg/dL	0.62-1.66	
Creatinine method is IDMS traceable. EstGFR Calculation has been adjusted. Please note new reference range effective 5/23/2013.					
eGFR non-African Am	52	L	mL/min/1.73m2	>60	<i>NCS [signature]</i>
GFR Comment	Estimated GFR values are not accurate in acute kidney failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, the very old or very young, races other than Caucasian or African American, people with acute illnesses, or amputations.				
Calcium	9.3		mg/dL	8.4-10.4	
Total Protein	7.1		gm/dL	6.1-8.2	
Albumin	3.9		gm/dL	3.4-4.7	
Globulin	3.2		gm/dL	2.4-4.2	
Bilirubin, total	1.1		mg/dL	0.3-1.2	
Alk Phos	97		U/L	38-150	
AST(SGOT)	20		U/L	6-58	
ALT(SGPT)	36		U/L	14-67	
Fasting Phosphorus	NO				
Phosphorus	3.3		mg/dL	2.3-5.6	
<b>CBC</b>					
WBC	6.3		x10E3	4.0-10.6	
RBC		6.05	H	x10E6	4.64-6.00 <i>NCS [signature]</i>
Hgb		18.5	H	gm/dL	14.5-17.7 <i>NCS [signature]</i>
Hct		56	H	%	42-53 <i>NCS [signature]</i>
MCV	93		fL	81-98	
MCHC	33.0		gm/dL	31.2-35.2	
RDW	13.4		%	11.0-14.5	
Platelets	192		x10E3	150-400	
Eos, Respiratory Phys, Addr, Phone	None seen			NS	

End of Report

*[Handwritten signature]*  
 03 Dec 2013

**EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT**

*in e*  
*delete 12/12/13*

**DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)**

**CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS**

DAY AM	1	2	3	4	5	6	7	8	9
Runny Nose 0 to 3	11/27/13 0 1 2 3	11/28/13 0 1 2 3	11/29/13 0 1 2 3	11/30/13 0 1 2 3	12/1/13 0 1 2 3	12/2/13 0 1 2 3	12/3/13 0 1 2 3	12/4/13 0 1 2 3	12/5/13 0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
DAY PM	1	2	3	4	5	6	7	8	9
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

*12/12/13*

**SCALE 0 to 3**

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N=No

SUBJECT NUMBER: VFV 1021 DATE COMPLETED: 12/4/13 SUBJECT INITIALS AND DATE: UJ 12/12/13

Returned 12/12/13



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505 ) 938-8922

Lovelace Scientific Resources  
Leslie Byatt, Clin Trials  
2441 Ridgecrest Dr SE  
Albuquerque, NM 87108-5129

Client Nbr  
24664

PATIENT NAME **UFV, UFV** PATIENT ID **AAG15590** DOB **08/11/1945** SEX **M** REPORT STATUS **Final** PAGE **1**  
 PHYSICIAN **Unlisted Physician,** COLLECT DATE & TIME **12/04/2013 14:10** RECEIVE DATE & TIME **12/04/2013 20:06** PRINT DATE & TIME **12/05/2013 06:16**  
 REQUISITION NO. **31033173** PT. PHONE NO. **0** PATIENT NO. **AKP021**  
 COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Eos, Respiratory Phys, Addr, Phone	NOT GIVEN	Rare *		NS	

End of Report

*Handwritten:* NCS  
10 Dec 2013

**EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT**

**DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)**

**CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS**

DAY AM	7 12/04/13	8 12/05/13	9 12/06/13	10 12/07/13	11 12/08/13	12 12/09/13	13 12/10/13	14 12/11/13	15 12/12/13
Runny Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Itchy Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Congestion 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Sneezing 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Voice Hoarse Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO
Throat Clearing Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO
<b>DAY PM</b>	<b>7</b>	<b>8</b>	<b>9</b>	<b>10</b>	<b>11</b>	<b>12</b>	<b>13</b>	<b>14</b>	<b>15</b>
Runny Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Itchy Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Congestion 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Sneezing 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Voice Hoarse Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO
Throat Clearing Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO

**SCALE 0 to 3**

- 0= No symptoms (no symptoms detected)
- 1= Mild symptoms (symptoms present but easily tolerated)
- 2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)
- 3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)
- Y=Yes N= No

SUBJECT NUMBER: AKP001 DATE COMPLETED: 12/12/13 SUBJECT INITIALS AND DATE: MFV 12/12/13



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505 ) 938-8922

Lovelace Scientific Resources  
Leslie Byatt, Clin Trials  
2441 Ridgecrest Dr SE  
Albuquerque, NM 87108-5129

Client Nbr  
24664

PATIENT NAME **UFV, UFV** PATIENT ID **AAGI9605** DOB **08/21/1945** SEX **M** REPORT STATUS **Final** PAGE **1**

PHYSICIAN **Unlisted Physician,** COLLECT DATE & TIME **12/12/2013 14:00** RECEIVE DATE & TIME **12/12/2013 20:32** PRINT DATE & TIME **12/13/2013 08:14**

REQUISITION NO. **31033182** PT. PHONE NO. **0** PATIENT NO. **AKP021**

COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Eos, Respiratory Phys, Addr, Phone		Many *		NS	
	PHYS UNKN				

End of Report

*NCS [unclear] Sub I  
17 Dec 2013*

Study Identification: 2749 LSR Study #: \_\_\_\_\_

Subject Number: AKP021 Subject Initials: UEV

ADVERSE EVENT LOG

Adverse Event	** Start Date (DD/MMM/YYYY)	SEVERITY	Relationship to Study Drug (Suspected/Not Suspected)	** End Date (DD/MMM/YYYY)	Action Taken	Investigator Initials/Date
<del>No AEs reported EM 2/18/13</del>						

\*\* if day is unknown, write UNK in space provided, but every effort should be made to be as specific as possible\*\*

Investigator Signature (at end of study): [Signature] Date: 27 Feb 2014  
SC Signature (at end of study): [Signature] Date: 2/26/14

Study Identification: AK Pharma

LSR #: 2749

Subject Number: 101113 Akhtar AKP

Subject Initials: W.F.V

**CONCOMITANT MEDICATION LOG**

List all prescription medications you are taking. Also include over-the-counter medications, vitamins and supplements.

Name of Medication	Indication (What you take it for)	Dose	Unit	Frequency	Route	* Start Date (Day/Month/Year)	Stop Date	Ongoing at EOS (for Clinic use)
EXAMPLE	Diabetes	500	MG			UNK/AUG/1999		<input type="checkbox"/>
Loratadine	allergies	10	mg	QD	PO	9/21/13	11/13/13	<input checked="" type="checkbox"/>
Zyrtec	allergies	5	mg	prn	PO	7008	<del>10/10/13</del> 11/11/13	<input checked="" type="checkbox"/>
Loratadine	allergies	10	mg	prn	PO	2000	9/20/13	<input checked="" type="checkbox"/>
Fluticasone	allergies	50	mcg	prn	inh.	2011	10/9/13	<input checked="" type="checkbox"/>
Utinopid	htn.	30	mg	QD	PO	2012		<input checked="" type="checkbox"/>
ASA	CAD prophylaxis	325	mg	QHS	PO	2003		<input checked="" type="checkbox"/>
Vita D3	Supplement	1000	IU	QHS	PO	2012		<input checked="" type="checkbox"/>
Tamulosin	BPH	4	mg	QHS	PO	8/2013		<input checked="" type="checkbox"/>
Cholestyrl	↑ lipids	3000	mg	QHS	PO	2012		<input checked="" type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>

\* If day or month of medication date is unknown, write UNK in space provided

Investigator Signature (at end of study): W.A. McGuire MD

Date: 18 Dec 2013

SC Signature (at end of study): Brecca Macedo

Date: 12-18-13



EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

DAY	14	15	16	17	18	19	20	21	22
AM	12/12/13	12/13/13	12/14/13	12/15/13	12/16/13	12/17/13	12/18/13	12/19/13	
Runny Nose 0 to 3	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0
Itchy Nose 0 to 3	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0
Congestion 0 to 3	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0
Sneezing 0 to 3	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0
Voice Hoarse Y/N	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES
Throat Clearing Y/N	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES
DAY PM	14	15	16	17	18	19	20	21	22
Runny Nose 0 to 3	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0
Itchy Nose 0 to 3	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0
Congestion 0 to 3	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0
Sneezing 0 to 3	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0
Voice Hoarse Y/N	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES
Throat Clearing Y/N	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES

SCALE 0 to 3

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- 2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)
- 3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)
- Y=Yes N= No

SUBJECT NUMBER: UFV  
AKP021

DATE COMPLETED: 12/18/13

SUBJECT INITIALS AND DATE: AKV 12/18/13



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Sci. Resources  
 Leslie Byatt, Clin. Trials  
 2441 Ridgecrest Dr SE  
 Albuquerque, NM 87108-5129

Client Nbr  
 24664

PATIENT NAME: **UFV, UFV** PATIENT ID: **AAGH3348** DOB: **08/11/1945** SEX: **M** REPORT STATUS: **Final** PAGE: **1**

PHYSICIAN: **Unlisted Physician,** COLLECT DATE & TIME: **12/18/2013 13:55** RECEIVE DATE & TIME: **12/18/2013 18:43** PRINT DATE & TIME: **12/19/2013 06:09**

REQUISITION NO. **31033197** PT. PHONE NO. **0** PATIENT NO. **AKP021**

COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Comp Metabolic Panel					
Sodium	143		mmol/L	134-144	
Potassium	4.4		mmol/L	3.5-5.1	
Chloride	106		mmol/L	98-111	
CO2	26		mmol/L	20-30	
Anion Gap	11			6-14	
Glucose		158	H mg/dL	60-100	<i>MDM UCS</i>
BUN	19		mg/dL	7-31	
Creatinine	1.40		mg/dL	0.62-1.66	

Creatinine method is IDMS traceable. EstGFR calculation has been adjusted.  
 Please note new reference range effective 5/23/2013.

eGFR non-African Am GFR Comment: **50 L mL/min/1.73m2 >80** *MDM UCS*

Estimated GFR values are not accurate in acute kidney failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, the very old or very young, races other than Caucasian or African American, people with acute illnesses, or amputations.

Calcium	9.7		mg/dL	8.4-10.4	
Total Protein	7.1		gm/dL	6.1-8.2	
Albumin	3.6		gm/dL	3.4-4.7	
Globulin	3.5		gm/dL	2.4-4.2	
Bilirubin, total	0.9		mg/dL	0.3-1.2	
Alk Phos	94		U/L	38-150	
AST(SGOT)	16		U/L	6-58	
ALT(SGPT)	28		U/L	14-67	
Fasting Phosphorus	NO				
Phosphorus	3.6		mg/dL	2.3-5.6	
CBC					
WBC	5.7		x10E3	4.0-10.6	
RBC	5.67		x10E6	4.64-6.00	
Hgb	17.6		gm/dL	14.5-17.7	
Hct	52		%	42-53	
MCV	92		fL	81-98	
MCHC	33.8		gm/dL	31.2-35.2	
RDW	13.2		%	11.0-14.5	
Platelets	205		x10E3	150-400	
Eos, Respiratory		Rare	*	NS	<i>MDM UCS</i>
Phys, Addr, Phone	Unknown				

End of Report

*MDM Fine MD*  
 19 Dec 2013

U1FV  
AKPD21

Effects of AkPharma's Calcium Glycerophosphate  
Nasal Spray wash (AkP 010112A) on Patient-Perceived Breathing Comfort

SATISFACTION QUESTIONNAIRE:

Would you use / purchase this nasal wash product in the future?"  YES  NO

You are also encouraged to make any free comments regarding your experience in the use of this product regarding your opinion of any of its effects not covered specifically in the Daily Diary:

I NOTICED RELIEF AFTER 15-20 MINUTES  
BY THE TIME IT WAS TIME FOR MORNING  
SPRAY MY NOSE & EYES WERE  
STILL IRRITATED AGAIN.

[Type text]

Subject initials and Date U1FV 12/18/12

Study Staff Initials and Date Em 12/18/13

**AKP-032**

4749 AKPharma PERENNIAL ALLERGIES  
SCREENING/VISIT 1 SOURCE DOCUMENTS

Initials: FSN Site #: \_\_\_\_\_ Subject #: 032

PATIENT DEMOGRAPHICS

**Patient Demographics**

Date of Birth: 26/Jan/1945 (dd/mm/yyyy)

Gender:  Male  Female

If female, Indicate Childbearing Potential

Childbearing  Surgically sterilized  Post-Menopausal

Ethnicity:  Hispanic  Non Hispanic

Race:  Asian  Black  Caucasian  American Indian

Pacific Islander  Other, Specify \_\_\_\_\_

**Smoking History**

Smoking Status:  None (smoked less than 100 cigarettes in lifetime)  
 Former (previously smoked more than 100 cigarettes in lifetime)  
 Current (smokes now)

If subject is a former or current smoker, please indicate:

Years smoked: 1962-2002

Cigarettes per day: 3

1 ppd → 1962-1988 1988-2002 3 cig. Per day

CRC Signature: Erica Maldonado Date: 04/NOV/2013 (dd/mm/yyyy)



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Lovelace Scientific Resources  
 Leslie Byatt, MD  
 2441 Ridgecrest Dr SE  
 Albuquerque, NM 87108-5129

Client Nbr  
 24664

PATIENT NAME: **ESN, ESN**      PATIENT ID: **AAGH1347**      DOB: **01/26/1945**      SEX: **F**      REPORT STATUS: **Final**      PAGE: **1**  
 PHYSICIAN: **Unlisted Physician,**      COLLECT DATE & TIME: **11/04/2013 15:07**      RECEIVE DATE & TIME: **11/04/2013 20:18**      PRINT DATE & TIME: **11/05/2013 06:10**  
 REQUISITION NO.: **30920876**      PT. PHONE NO.: **0**      PATIENT NO.: **032**  
 COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Allerg, Panel 18					
Allerg, Juniper		6.00	H	<0.35	
Allerg, Cottonwood	0.30			<0.35	
Allerg, West. Ragweed	<0.10			<0.35	
Allerg, Russian Thistle		19.10	H	<0.35	
Allerg, Bermuda Grass		6.50	H	<0.35	
Allerg, Alternaria		7.90	H	<0.35	
Allerg, Mesquite		1.50	H	<0.35	
Allerg, Cockroach	<0.10			<0.35	
Allerg, Derm. pter.	0.30			<0.35	

The standard classification system utilizes the following class cutoffs.

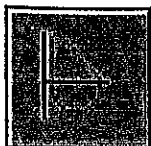
Class	ku/L	Interpretation
0	<0.35	Negative for Allergen
I	0.35-0.69	Positive for Allergen
II	0.70-3.49	Strongly Positive
III	3.5-17.49	Strongly Positive
IV	17.5-52.49	Strongly Positive
V	52.5-99.99	Strongly Positive
VI	>100	Strongly Positive

Results with allergens scoring in Class 1 should be considered weakly positive or equivocal. Class 2 and higher should be considered positive. Although increasing class ranges (0-VI) are reflective of increasing concentrations of allergen-specific IgE, this may not correlate with the degree of clinical response when challenged with the specific allergen. The correlation of allergy laboratory results with clinical history is essential. A negative test may not rule out clinical allergy.

Allerg, Derm. farinae	0.10			ku/L	<0.35
Allerg, Clad. herb.	0.20			ku/L	<0.35
Allerg, Firebush		3.10	H	ku/L	<0.35
Allerg, Cat Dander Ep	0.20			ku/L	<0.35
Allerg, Dog Dander		1.00	H	ku/L	<0.35
Allerg, Bluegrass		3.30	H	ku/L	<0.35
Allerg, Pigweed		8.90	H	ku/L	<0.35
Allerg, Mulberry		8.00	H	ku/L	<0.35
Allerg, Helminth		0.50	H	ku/L	<0.35
Phys, Addr, Phone	PHYS UNKN				

End of Report

*Handwritten signature and date:*  
 07 Nov 2013



Name: ESN,  
 Gender: Female  
 Age: 68 Race:  
 Height(in): 65.0 Weight(lb): 145  
 Any Info: 2749

Id: 032  
 Date: 11/25/13  
 Temp: 19 PBar: 632  
 Physician:  
 Technician: CRD26

Spirometry		(BTPS)	PRE-RX		POST-RX		Post % Chg
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	
FVC	Liters	2.98	3.42	115			
FEV1	Liters	2.37	2.02	85			
FEV1/FVC	%	82	59	72			
FEF25-75%	L/sec	2.44	1.01	41			
FEF50%	L/sec	3.23	**1.25	**39			
FEF75%	L/sec	0.96	0.41	43			
IC	Liters						
VC	Liters	2.98					
PEF	L/sec	5.65	4.53	80			
MVV	L/min	86					
PIF	L/sec		3.94				
FEV1/FEV6%			64				

**Lung Volumes/Plethysmography**

Vtg	Liters	
VC	Liters	2.98
TLC	Liters	5.03
RV	Liters	2.00
RV/TLC	%	40
FRC PL	Liters	2.92
ERV	Liters	
IC	Liters	

**Diffusion**

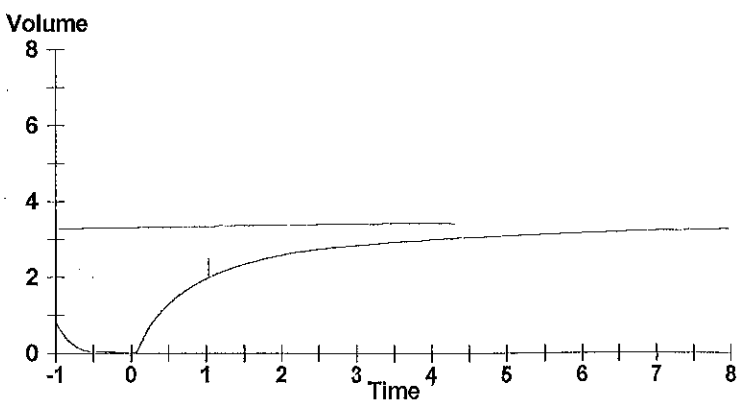
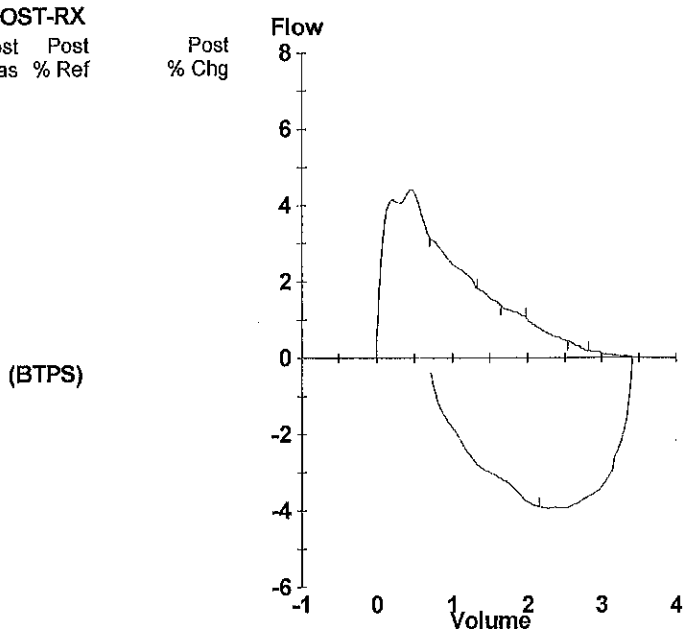
DLCO	mL/mmHg/min	19.3
DL Adj	mL/mmHg/min	19.3
DLCO/VA	mL/mHg/min/L	3.03
VA	Liters	
BHT	Sec	

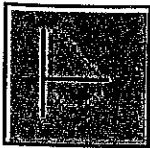
**Resistance**

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.30
Gaw	L/sec/cmH2O	0.700
sRaw	cmH2O/L/s/L	3.80
sGaw	L/s/cmH2O/L	0.263
Vtg (Raw)	Liters	

Comments:

Interpretation:





Name: ESN,  
 Gender: Female  
 Age: 68 Race: Caucasian  
 Height(in): 65.0 Weight(lb): 145  
 Any Info:

Id: AKP-032  
 Date: 12/02/13  
 Temp: 20 PBar: 632  
 Physician:  
 Technician: VL

Spirometry		(BTPS)	PRE-RX		POST-RX		Post
		Ref	Pre	Pre	Post	Post	Post
			Meas	% Ref	Meas	% Ref	% Chg
FVC	Liters	2.98	3.04	102			
FEV1	Liters	2.37	1.81	76			
FEV1/FVC	%	82	59	73			
FEF25-75%	L/sec	2.44	0.87	36			
FEF50%	L/sec	3.23	** 1.19	** 37			
FEF75%	L/sec	0.96	0.34	36			
IC	Liters						
VC	Liters	2.98					
PEF	L/sec	5.65	4.24	75			
MVV	L/min	86					
PIF	L/sec		4.37				
FEV1/FEV6%			64				

**Lung Volumes/Plethysmography**

Parameter	Units	Value
Vtg	Liters	
VC	Liters	2.98
TLC	Liters	5.03
RV	Liters	2.00
RV/TLC	%	40
FRC PL	Liters	2.92
ERV	Liters	
IC	Liters	

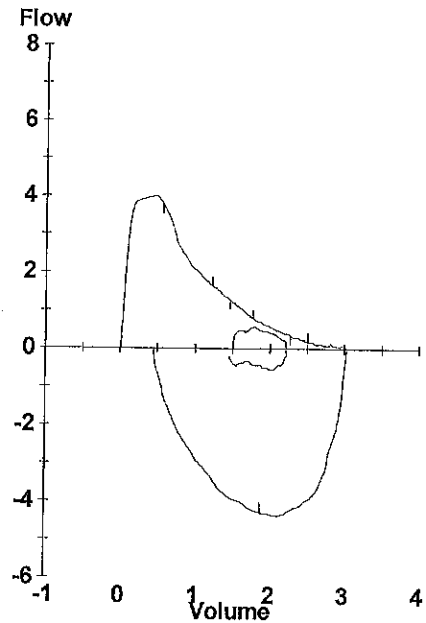
**Diffusion**

DLCO	mL/mmHg/min	19.3
DL Adj	mL/mmHg/min	19.3
DLCO/VA	mL/mHg/min/L	3.03
VA	Liters	
BHT	Sec	

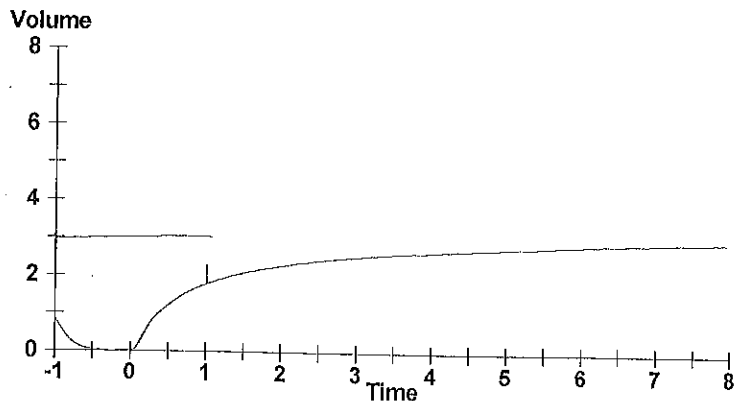
**Resistance**

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.30
Gaw	L/sec/cmH2O	0.700
sRaw	cmH2O/L/s/L	3.80
sGaw	L/s/cmH2O/L	0.263
Vtg (Raw)	Liters	

(BTPS)

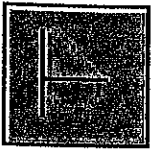


Comments:



Interpretation:

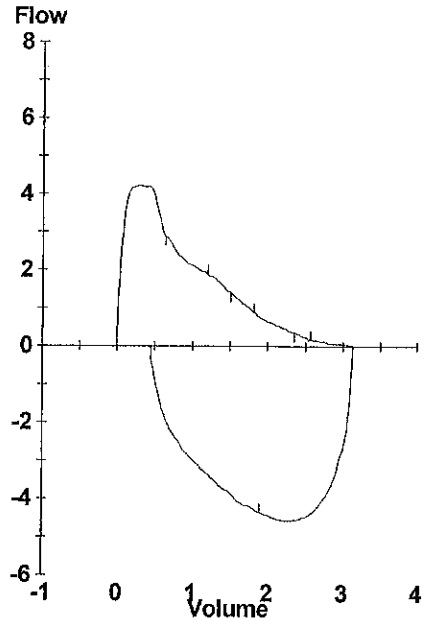




Name: ESN,  
 Gender: Female  
 Age: 68 Race: Caucasian  
 Height(in): 65.0 Weight(lb): 145  
 Any Info:

Id: AKP-032  
 Date: 12/09/13  
 Temp: 19 PBar: 630  
 Physician:  
 Technician: VL

Spirometry		(BTPS)	PRE-RX		POST-RX		
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	Post % Chg
FVC	Liters	2.98	3.18	107			
FEV1	Liters	2.37	1.86	79			
FEV1/FVC	%	82	58	72			
FEF25-75%	L/sec	2.44	0.89	36			
FEF50%	L/sec	3.23	** 1.26	** 39			
FEF75%	L/sec	0.96	0.34	36			
IC	Liters						
VC	Liters	2.98					
PEF	L/sec	5.65	4.42	78			
MVV	L/min	86					
PIF	L/sec		4.56				
FEV1/FEV6%			64				



**Lung Volumes/Plethysmography**

Parameter	Units	Value
Vtg	Liters	
VC	Liters	2.98
TLC	Liters	5.03
RV	Liters	2.00
RV/TLC	%	40
FRC PL	Liters	2.92
ERV	Liters	
IC	Liters	

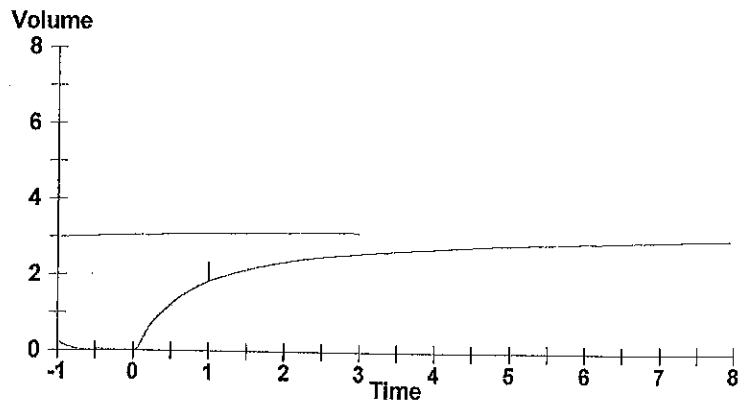
**Diffusion**

DLCO	mL/mmHg/min	19.3
DL Adj	mL/mmHg/min	19.3
DLCO/VA	mL/mHg/min/L	3.02
VA	Liters	
BHT	Sec	

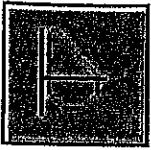
**Resistance**

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.30
Gaw	L/sec/cmH2O	0.700
sRaw	cmH2O/L/s/L	3.80
sGaw	L/s/cmH2O/L	0.263
Vtg (Raw)	Liters	

Comments:



Interpretation:



Name: AKP-032,

Id: AKP-032

Gender: Female

Date: 12/16/13

Age: 68 Race:

Temp: 19

PBar: 637

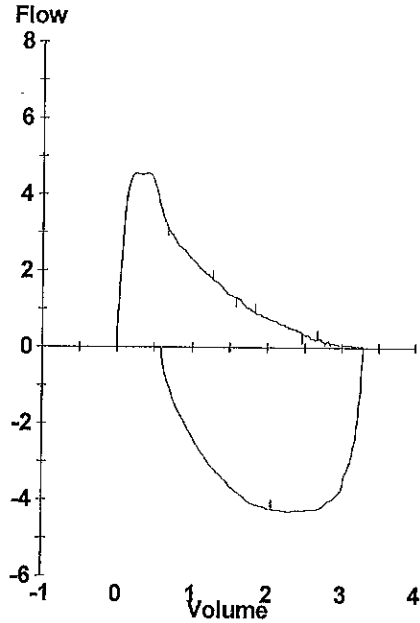
Height(in): 65.0 Weight(lb): 146

Physician:

Any Info:

Technician: CRD

Spirometry		(BTPS)	PRE-RX		POST-RX		Post
		Ref	Pre	Pre	Post	Post	% Chg
			Meas	% Ref	Meas	% Ref	
FVC	Liters	2.98	3.29	110			
FEV1	Liters	2.37	1.90	80			
FEV1/FVC	%	82	58	71			
FEF25-75%	L/sec	2.44	0.88	36			
FEF50%	L/sec	3.23	** 1.18	** 37			
FEF75%	L/sec	0.96	0.34	35			
IC	Liters						
VC	Liters	2.98					
PEF	L/sec	5.65	4.57	81			
MVV	L/min	86					
PIF	L/sec		4.29				
FEV1/FEV6%			63				



**Lung Volumes/Plethysmography** (BTPS)

Vtg	Liters	
VC	Liters	2.98
TLC	Liters	5.03
RV	Liters	2.00
RV/TLC	%	40
FRC PL	Liters	2.91
ERV	Liters	
IC	Liters	

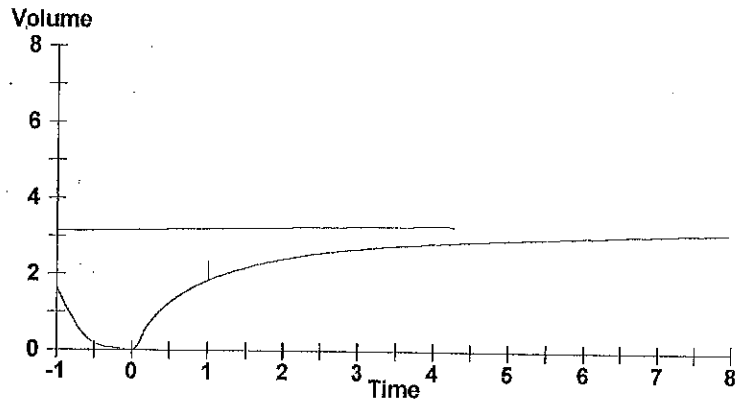
**Diffusion**

DLCO	mL/mmHg/min	19.4
DL Adj	mL/mmHg/min	19.4
DLCO/VA	mL/mHg/min/L	3.05
VA	Liters	
BHT	Sec	

**Resistance**

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.31
Gaw	L/sec/cmH2O	0.698
sRaw	cmH2O/L/s/L	3.80
sGaw	L/s/cmH2O/L	0.263
Vtg (Raw)	Liters	

Comments:



Interpretation:

**EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT**

**DAILY SYMPTOMS SCORE SHEET (SCREEN DIARY)**

**CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS**

DAY AM	-7	-6	-5	-4	-3	-2	-1	0	0
Runny Nose 0 to 3	0 1 <u>2</u> 3	0 1 <u>2</u> 3	0 1 2 <u>3</u>	0 <u>1</u> 2 3	0 1 <u>2</u> 3	0 1 <u>2</u> 3	0 <u>1</u> 2 3	0 <u>1</u> 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 <u>2</u> 3	0 1 <u>2</u> 3	0 1 <u>2</u> 3	0 <u>1</u> 2 3	0 1 2 <u>3</u>	0 1 <u>2</u> 3	0 <u>1</u> 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 <u>2</u> 3	0 1 2 <u>3</u>	0 1 2 <u>3</u>	0 1 2 <u>3</u>	0 1 2 <u>3</u>	0 1 <u>2</u> 3	0 <u>1</u> 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 <u>2</u> 3	0 1 <u>2</u> 3	0 1 2 <u>3</u>	0 1 <u>2</u> 3	0 1 2 <u>3</u>	0 1 <u>2</u> 3	0 <u>1</u> 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES <u>NO</u>	YES <u>NO</u>	YES <u>NO</u>	YES <u>NO</u>	YES <u>NO</u>	YES <u>NO</u>	YES <u>NO</u>	YES NO	YES NO
Throat Clearing Y/N	YES <u>NO</u>	YES <u>NO</u>	YES <u>NO</u>	YES <u>NO</u>	YES <u>NO</u>	YES <u>NO</u>	YES <u>NO</u>	YES NO	YES NO
<b>DAY PM</b>	<b>-7</b>	<b>-6</b>	<b>-5</b>	<b>-4</b>	<b>-3</b>	<b>-2</b>	<b>-1</b>	<b>0</b>	<b>0</b>
Runny Nose 0 to 3	0 1 <u>2</u> 3	0 1 <u>2</u> 3	0 1 <u>2</u> 3	0 1 <u>2</u> 3	0 1 <u>2</u> 3	0 1 <u>2</u> 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 <u>1</u> 2 3	0 <u>1</u> 2 3	0 <u>1</u> 2 3	0 <u>1</u> 2 3	0 <u>1</u> 2 3	0 <u>1</u> 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 <u>2</u> 3	0 1 <u>2</u> 3	0 1 2 <u>3</u>	0 1 2 <u>3</u>	0 <u>1</u> 2 3	0 1 <u>2</u> 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 <u>2</u> 3	0 1 <u>2</u> 3	0 1 <u>2</u> 3	0 <u>1</u> 2 3	0 <u>1</u> 2 3	0 1 <u>2</u> 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES <u>NO</u>	YES <u>NO</u>	YES <u>NO</u>	YES <u>NO</u>	YES <u>NO</u>	YES <u>NO</u>	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES <u>NO</u>	YES <u>NO</u>	YES <u>NO</u>	YES <u>NO</u>	YES <u>NO</u>	YES <u>NO</u>	YES NO	YES NO	YES NO

**SCALE 0 to 3**

- 0 = No symptoms (no symptoms detected)
  - 1 = Mild symptoms (symptoms present but easily tolerated)
  - 2 = Moderate symptoms (awareness of symptoms, bothersome but tolerable)
  - 3 = Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)
- Y=Yes N=No

SUBJECT NUMBER: AKP0032 DATE COMPLETED: 11/25/13

SUBJECT INITIALS AND DATE: PA 11-25-13

Start in  
M and  
C  
11/18/13



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505 ) 938-8922

Lovelace Scientific Resources  
Leslie Byatt, Clin Trials  
2441 Ridgecrest Dr SE  
Albuquerque, NM 87108-5129

Client Nbr  
24664

PATIENT NAME **ESN, ESN** PATIENT ID **AAGH1347** DOB **01/26/1945** SEX **F** REPORT STATUS **Final** PAGE **1**  
 PHYSICIAN **Unlisted Physician,** COLLECT DATE & TIME **11/25/2013 11:22** RECEIVE DATE & TIME **11/25/2013 20:32** PRINT DATE & TIME **11/26/2013 06:04**  
 REQUISITION NO. **30920940** PT. PHONE NO. **0** PATIENT NO. **032**  
 COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Eos, Respiratory Phys, Addr, Phone	NOT GIVEN	Many *		NS	

End of Report

*[Handwritten Signature]*  
27 Nov 2013

**EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT**

**DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)**

**CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS**

DAY AM	1 11/25/13	2 11/26/13	3 11/27/13	4 11/28/13	5 11/29/13	6 11/30/13	7 12/1/13	8 12/2/13	9 12/3/13
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
<b>DAY PM</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>	<b>9</b>
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

**SCALE 0 to 3**

- 0= No symptoms (no symptoms detected)
  - 1= Mild symptoms (symptoms present but easily tolerated)
  - 2= Moderate symptoms (awareness of symptoms; bothersome but tolerable)
  - 3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)
- Y=Yes N=No

*ESN*

SUBJECT NUMBER: AKP0032 DATE COMPLETED: 12/02/13

SUBJECT INITIALS AND DATE: ESN 12.2.13



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Scientific Resources  
Leslie Byatt, Clin Trials  
2441 Ridgecrest Dr SE  
Albuquerque, NM 87108-5129

Client Nbr  
24664

PATIENT NAME: **X, ESN** PATIENT ID: **AAGI4135** DOB: **01/26/1945** SEX: **F** REPORT STATUS: **Final** PAGE: **1**  
 PHYSICIAN: **Unlisted Physician,** COLLECT DATE & TIME: **12/02/2013 13:32** RECEIVE DATE & TIME: **12/02/2013 18:26** PRINT DATE & TIME: **12/03/2013 06:14**  
 REQUISITION NO.: **30920893** PT. PHONE NO.: **0** PATIENT NO.: **AKP032**  
 COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Comp Metabolic Panel					
Sodium	140		mmol/L	134-144	
Potassium	3.9		mmol/L	3.5-5.1	
Chloride	107		mmol/L	98-111	
CO2	26		mmol/L	20-30	
Anion Gap	7			6-14	
Glucose	88		mg/dL	60-100	
BUN	23		mg/dL	7-31	
Creatinine	0.72		mg/dL	0.60-1.40	
Creatinine method is IDMS traceable. EstGFR calculation has been adjusted. Please note new reference range effective 5/23/2013.					
eGFR non-African Am	>60		mL/min/1.73m2	>60	
GFR Comment	Estimated GFR values are not accurate in acute kidney failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, the very old or very young, races other than Caucasian or African American, people with acute illnesses, or amputations.				
Calcium	9.1		mg/dL	8.4-10.4	
Total Protein	6.7		gm/dL	6.1-8.2	
Albumin	4.3		gm/dL	3.4-4.7	
Globulin	2.4		gm/dL	2.4-4.2	
Bilirubin, total	0.5		mg/dL	0.3-1.2	
Alk Phos	55		U/L	38-150	
AST(SGOT)	17		U/L	8-58	
ALT(SGPT)	24		U/L	14-67	
Fasting Phosphorus	NOT GIVEN				
Phosphorus	3.4		mg/dL	2.3-5.6	
CBC					
WBC	6.0		x10E3	4.0-10.6	
RBC		3.80	L	x10E6	4.00-6.36
Hgb		11.8	L	gm/dL	12.0-16.0
Hct	36		%	36-48	
MCV	96		fL	81-98	
MCHC	32.4		gm/dL	31.2-35.2	
RDW	12.6		%	11.0-14.5	
Platelets	268		x10E3	150-400	
Eos, Respiratory Phys, Addr, Phone	NOT GIVEN	Moderate	*	NS	

End of Report

*Subs I TADP NCS  
04 Dec 2013*

**EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT**

**DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)**

**CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS**

DAY	7	8	9	10	11	12	13	14	15
AM	12-2	12-3	12-4	12-5	12-6	12-7	12-8	12-9	
Runny Nose 0 to 3	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0
Itchy Nose 0 to 3	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0
Congestion 0 to 3	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0
Sneezing 0 to 3	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0
Voice Hoarse Y/N	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES
Throat Clearing Y/N	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES
DAY PM	7	8	9	10	11	12	13	14	15
Runny Nose 0 to 3	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0
Itchy Nose 0 to 3	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0
Congestion 0 to 3	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0
Sneezing 0 to 3	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0
Voice Hoarse Y/N	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES
Throat Clearing Y/N	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES

**SCALE 0 to 3**

- 0= No symptoms (no symptoms detected)
  - 1= Mild symptoms (symptoms present but easily tolerated)
  - 2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)
  - 3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)
- Y=Yes N= No

SUBJECT NUMBER: AKP032 DATE COMPLETED: 12/09/13 SUBJECT INITIALS AND DATE: ESN 12-9-13



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505 ) 938-8922

Lovelace Scientific Resources  
Leslie Byatt, Clin Trials  
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Albuquerque, NM 87108-5129

Client Nbr  
24664

PATIENT NAME <b>ESN, ESN</b>	PATIENT ID <b>AAGH1347</b>	DOB <b>01/26/1945</b>	SEX <b>F</b>	REPORT STATUS <b>Final</b>	PAGE <b>1</b>
PHYSICIAN	COLLECT DATE & TIME <b>12/09/2013 14:10</b>	RECEIVE DATE & TIME <b>12/09/2013 19:12</b>	PRINT DATE & TIME <b>12/10/2013 09:15</b>		
REQUISITION NO. <b>31033177</b>	PT. PHONE NO. <b>0</b>	PATIENT NO. <b>032</b>			
COMMENTS :					

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Eos, Respiratory		Moderate *		NS	

End of Report

*[Handwritten Signature]*  
11 Dec 2013



1/5 11/5/13

Study Identification: 2749

LSR Study #: ~~27~~ 2749

Subject Number: AKP032

Subject Initials: ESN

ADVERSE EVENT LOG

Adverse Event	** Start Date (DD/MMM/YYYY)	SEVERITY	Relationship to Study Drug (Suspected/Not Suspected)	** End Date (DD/MMM/YYYY)	Action Taken	Investigator Initials/Date
Sinus Congestion	16/Dec/2013	mild	Suspected	21/Jan/2014	none	ESN / 21 Jan 14
Prurith	19/Dec/2013	mild	Suspected	21/Jan/2014	none	ESN / 21 Jan 14
						/
						/
						/
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						/

\*\* If day is unknown, write UNK in space provided, but every effort should be made to be as specific as possible\*\*

Investigator Signature (at end of study): [Signature] Date: 21 Jan 2014  
SC Signature (at end of study): Erica macedone-d Date: 1/17/14

Study Identification: 2749

LSR #: \_\_\_\_\_

Subject Number: 032

Subject Initials: ESN

### CONCOMITANT MEDICATION LOG

List all prescription medications you are taking. Also include over-the-counter medications, vitamins and supplements.

Name of Medication	Indication (What you take it for)	Dose	Unit	Frequency	Route	* Start Date (Day/Month/Year)	Stop Date	Ongoing at EOS (for Clinic use)
EXAMPLE	Diabetes	500	MG	2 Tabs per day	Oral	UNK/AUG/1999		<input checked="" type="checkbox"/>
Citalopram	Depression	20	mg	QD	oral	-/-/2012		<input checked="" type="checkbox"/>
Levothyroxine	Hyperthyroidism	.75	mg	QD	oral	--/--/1999		<input checked="" type="checkbox"/>
Trazadone	Insomnia	150	mg	QD	oral	--/--/1999		<input checked="" type="checkbox"/>
Fexofenadine	seasonal allergies	180	mg	PRN	oral	-/-/2001	9/18/2013	<input type="checkbox"/>
Prenatal Vitamins	Dietary Supplement	1	TAB	QD	oral	--/--/1998		<input checked="" type="checkbox"/>
Calcium	Dietary Supplement	600	mg	QD	oral	--/--/1998		<input checked="" type="checkbox"/>
Glucosamine	Dietary Supplement	1.5	MG	QD	oral	--/--/1998		<input checked="" type="checkbox"/>
Chondroitin	Dietary Supplement	100	mg	QD	oral	--/--/1998		<input checked="" type="checkbox"/>
Sodium	Dietary Supplement	40	mg	QD	oral	--/--/1998		<input checked="" type="checkbox"/>
Magnesium	Dietary Supplement	400	mg	QD	oral	--/--/1998		<input checked="" type="checkbox"/>
Vitamin E	Dietary Supplement	400	IU	QD	oral	--/--/1998		<input checked="" type="checkbox"/>

\* If day or month of medication date is unknown, write UNK in space provided

Investigator Signature (at end of study): [Signature] Date: 19 Dec 2013

SC Signature (at end of study): [Signature] Date: 19 Dec 2013

Study Identification: 2749 LSR #: \_\_\_\_\_  
 Subject Number: 032 Subject Initials: ESN

**CONCOMITANT MEDICATION LOG**

List all prescription medications, over-the-counter medications, and supplements.

Medication	Indication	Dose	Unit	Frequency	Route	* Start Date	* Stop Date (CRC Initials/Date)	Ongoing at EOS
Omega 3	Dietary Supplement	1000 mg	mg	QD	PO	--/--/1998		<input checked="" type="checkbox"/>
B-Complex	Dietary Supplement	99	mg	QD	PO	--/--/1998		<input checked="" type="checkbox"/>
Potassium	Dietary Supplement	1	TAB	QD	PO	--/--/1998		<input checked="" type="checkbox"/>
Naproxen	Right Hip	220	mg	QD	PO	09/--/2012		<input checked="" type="checkbox"/>
Ventolin	Asthma	2	inhalers	PRN	INH	--/--/1998		<input checked="" type="checkbox"/>
Atenolol	osbo	10	mg	wkly	PO	--/--/1998		<input checked="" type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>

\* Use DD/MMM/YYYY format for dates. If day or month of date in unknown, write UNK in space provided.

\* W. D. Mantua MD 19 Dec 2013  
 Lovelace Scientific Resources, Inc - ComMeds 10/2013

Erica Maldonado 12/18/13

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

DAY	14	15	16	17	18	19	20	21	22
AM	12/09/13	12/10/13	12/11/13	12/12/13	12/13/13	12/14/13	12/15/13	12/16/13	12/17/13
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
DAY PM	14	15	16	17	18	19	20	21	22
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N= No

SUBJECT NUMBER: ESN

DATE COMPLETED: 12/16/13

SUBJECT INITIALS AND DATE: AKP032

12-16-13

2 pm AKP 12-16-13



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Scientific Resources  
 Leslie Byatt, MD  
 2441 Ridgecrest Dr SE  
 Albuquerque, NM 87108-5129

Client Nbr  
 24664

PATIENT NAME: **ESN, ESN** PATIENT ID: **AAGJ0931** DOB: **01/26/1945** SEX: **F** REPORT STATUS: **Final** PAGE: **1**  
 PHYSICIAN: **Unlisted Physician,** COLLECT DATE & TIME: **12/16/2013 14:30** RECEIVE DATE & TIME: **12/16/2013 19:07** PRINT DATE & TIME: **12/17/2013 06:14**  
 REQUISITION NO.: **31033174** PT. PHONE NO.: **0** PATIENT NO.: **AKP032**  
 COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
<b>Comp Metabolic Panel</b>					
Sodium	140		mmol/L	134-144	
Potassium	4.3		mmol/L	3.5-5.1	
Chloride	106		mmol/L	98-111	
CO2	27		mmol/L	20-30	
Anion Gap	7			6-14	
Glucose	89		mg/dL	60-100	
BUN	25		mg/dL	7-31	
Creatinine	0.80		mg/dL	0.50-1.40	
Creatinine method is IDMS traceable. EstGFR Calculation has been adjusted. Please note new reference range effective 5/23/2013.					
eGFR non-African Am	>60		mL/min/1.73m2	>60	
GFR Comment	Estimated GFR values are not accurate in acute kidney failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, the very old or very young, races other than Caucasian or African American, people with acute illnesses, or amputations.				
Calcium	9.3		mg/dL	8.4-10.4	
Total Protein	6.9		gm/dL	6.1-8.2	
Albumin	4.2		gm/dL	3.4-4.7	
Globulin	2.7		gm/dL	2.4-4.2	
Bilirubin, total	0.5		mg/dL	0.3-1.2	
Alk Phos	55		U/L	38-150	
AST(SGOT)	18		U/L	6-58	
ALT(SGPT)	25		U/L	14-67	
Fasting Phosphorus	NO				
Phosphorus	4.1		mg/dL	2.3-5.6	
<b>CBC</b>					
WBC	6.7		x10E3	4.0-10.6	
RBC		3.91	L	x10E6	4.00-5.36
Hgb	12.4		gm/dL	12.0-16.0	
Hct	37		%	36-48	
MCV	95		fL	81-98	
MCHC	33.4		gm/dL	31.2-35.2	
RDW	12.6		%	11.0-14.5	
Platelets	263		x10E3	150-400	
Eos, Respiratory		Rare	*	NS	
Phys, Addr, Phone	Not given				

End of Report

*Adm Sub I  
 17 Dec 2013*

*Adm NCS*  
  
*Adm NCS*

Study Identification: 2749 LSR #: \_\_\_\_\_

Subject Number: 032 Subject Initials: ESN

**CONCOMITANT MEDICATION LOG**

List all prescription medications, over-the-counter medications, and supplements.

Medication	Indication	Dose	Unit	Frequency	Route	* Start Date	* Stop Date (CRC Initials/Date)	Ongoing at EOS
Omega 3	Dietary Supplement	1000	mg	QD	PO	--/--/1998		<input checked="" type="checkbox"/>
B-Complex	Dietary Supplement	99	mg	QD	PO	--/--/1998		<input checked="" type="checkbox"/>
Potassium	Dietary Supplement	1	TAB	QD	PO	--/--/1998		<input checked="" type="checkbox"/>
Naproxen	Right Foot	200	mg	QD	PO	09/--/2012		<input checked="" type="checkbox"/>
Ventolin	Asthma	2	inhalers	PRN	INH	--/--/1999		<input checked="" type="checkbox"/>
Atenolol	Osbo	10	mg	wkly	po	--/--/1998		<input checked="" type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>

\* Use DD/MMM/YYYY format for dates. If day or month of date in unknown, write UNK in space provided.

\* W. D. Santoro MD 19 Dec 2013  
Erica Maldonado 12/18/13

**AKP-035**

4749 AKPharma PERENNIAL ALLERGIES  
SCREENING/VISIT 1 SOURCE DOCUMENTS

Initials: ADS Site #:        Subject #: AKP035

**PATIENT DEMOGRAPHICS**

**Patient Demographics**

Date of Birth: 22, May 1981 (dd/mmm/yyyy)

Gender:  Male  Female

If female, Indicate Childbearing Potential

Childbearing  Surgically sterilized  Post-Menopausal

Ethnicity:  Hispanic  Non Hispanic

Race:  Asian  Black  Caucasian  American Indian

Pacific Islander  Other, Specify \_\_\_\_\_

**Smoking History**

Smoking Status:  None (smoked less than 100 cigarettes in lifetime)

Former (previously smoked more than 100 cigarettes in lifetime)

Current (smokes now)

If subject is a former or current smoker, please indicate:

Years smoked: \_\_\_\_\_ Cigarettes per day: \_\_\_\_\_

CRC Signature: [Signature] Date: 02, NOV, 2013 (dd/mmm/yy)





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Lovelace Scientific Resources  
 Leslie Byatt, MD  
 2441 Ridgecrest Dr SE  
 Albuquerque, NM 87108-5129

Client Nbr  
 24664

PATIENT NAME: **X, ADS** PATIENT ID: **AAGH4692** DOB: **05/27/1981** SEX: **F** REPORT STATUS: **Final** PAGE: **1**  
 PHYSICIAN: **Unlisted Physician,** COLLECT DATE & TIME: **11/11/2013 10:38** RECEIVE DATE & TIME: **11/11/2013 20:02** PRINT DATE & TIME: **11/13/2013 06:09**  
 REQUISITION NO.: **30920947** PT. PHONE NO.: **0** PATIENT NO.: **AKP035**  
 COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Allerg, Panel 18					
Allerg, Juniper		25.30	H	<0.35	
Allerg, Cottonwood	0.20			<0.35	
Allerg, West. Ragweed	0.20			<0.35	
Allerg, Russian Thistle		24.70	H	<0.35	
Allerg, Bermuda Grass		0.90	H	<0.35	
Allerg, Alternaria	<0.10			<0.35	
Allerg, Mesquite		1.70	H	<0.35	
Allerg, Cockroach		1.60	H	<0.35	
Allerg, Derm. pter.	0.10			<0.35	

The standard classification system utilizes the following class cutoffs.

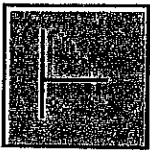
Class	ku/L	Interpretation
0	<0.35	Negative for Allergen
I	0.35-0.69	Positive for Allergen
II	0.70-3.49	Strongly Positive
III	3.5-17.49	Strongly Positive
IV	17.5-52.49	Strongly Positive
V	52.5-99.99	Strongly Positive
VI	>100	Strongly Positive

Results with allergens scoring in Class 1 should be considered weakly positive or equivocal. Class 2 and higher should be considered positive. Although increasing class ranges (0-VI) are reflective of increasing concentrations of allergen-specific IgE, this may not correlate with the degree of clinical response when challenged with the specific allergen. The correlation of allergy laboratory results with clinical history is essential. A negative test may not rule out clinical allergy.

Allerg, Derm. farinae	0.20			ku/L	<0.35
Allerg, Clad. herb.	<0.10			ku/L	<0.35
Allerg, Firebush		1.50	H	ku/L	<0.35
Allerg, Cat Dander Ep		13.50	H	ku/L	<0.35
Allerg, Dog Dander		0.50	H	ku/L	<0.35
Allerg, Bluegrass		0.90	H	ku/L	<0.35
Allerg, Pigweed		25.70	H	ku/L	<0.35
Allerg, Mulberry		0.60	H	ku/L	<0.35
Allerg, Helminth	<0.10			ku/L	<0.35
Phys, Addr, Phone	NOT GIVEN				

End of Report

*[Handwritten Signature]*  
 13 Nov 2013



Name: ADS,  
 Gender: Female  
 Age: 32 Race: Hispanic  
 Height(in): 61.0 Weight(lb): 199  
 Any Info:

Id: AKP-035  
 Date: 11/27/13  
 Temp: 19 PBar: 637  
 Physician:  
 Technician:

Spirometry		(BTPS)	PRE-RX		POST-RX		Post
		Ref	Pre	Pre	Post	Post	Post
			Meas	% Ref	Meas	% Ref	% Chg
FVC	Liters	3.15	4.77	152			
FEV1	Liters	2.72	4.04	149			
FEV1/FVC	%	87	85	98			
FEF25-75%	L/sec	3.26	4.63	142			
FEF50%	L/sec	3.77	5.57	148			
FEF75%	L/sec	1.70	2.89	170			
IC	Liters						
VC	Liters	3.15					
PEF	L/sec	6.05	6.93	115			
MVV	L/min	113					
PIF	L/sec		5.11				
FEV1/FEV6%			86				

**Lung Volumes/Plethysmography**

Lung Volumes/Plethysmography		(BTPS)
Vtg	Liters	
VC	Liters	3.15
TLC	Liters	4.52
RV	Liters	1.35
RV/TLC	%	30
FRC PL	Liters	1.96
ERV	Liters	
IC	Liters	

**Diffusion**

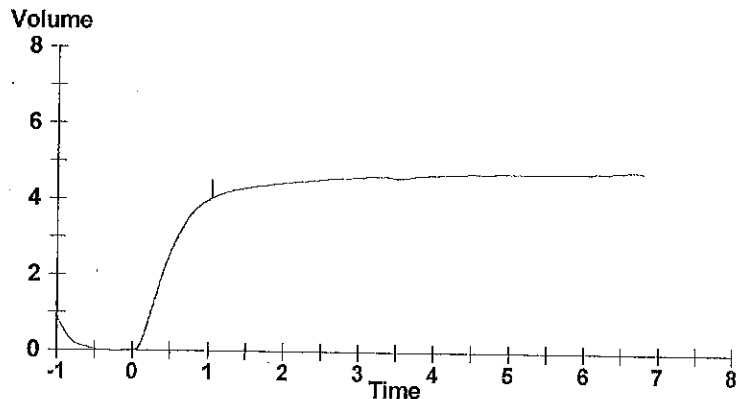
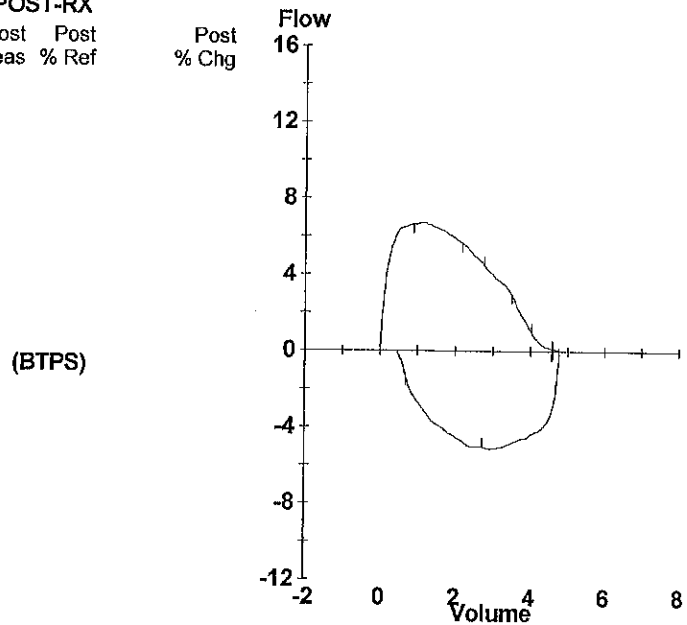
DLCO	mL/mmHg/min	26.0
DL Adj	mL/mmHg/min	26.0
DLCOVA	mL/mHg/min/L	3.79
VA	Liters	
BHT	Sec	

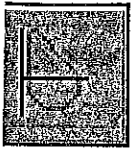
**Resistance**

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	2.04
Gaw	L/sec/cmH2O	0.471
sRaw	cmH2O/L/s/L	4.00
sGaw	L/s/cmH2O/L	0.250
Vtg (Raw)	Liters	

Comments:

Interpretation:





Name: AKP,  
 Gender: Female  
 Age: 32 Race:  
 Height(in): 61.0 Weight(lb): 199  
 Any Info:

Id: AKP035  
 Date: 12/06/13  
 Temp: 19 PBar: 631  
 Physician:  
 Technician: CRD

Spirometry		(BTPS)	PRE-RX		POST-RX		Post
		Ref	Pre	Pre	Post	Post	Post
			Meas	% Ref	Meas	% Ref	% Chg
FVC	Liters	3.15	4.76	151			
FEV1	Liters	2.72	3.96	146			
FEV1/FVC	%	87	83	96			
FEF25-75%	L/sec	3.26	4.26	131			
FEF50%	L/sec	3.77	5.48	145			
FEF75%	L/sec	1.70	1.95	114			
IC	Liters						
VC	Liters	3.15					
PEF	L/sec	6.05	** 9.64	** 159			
MVV	L/min	113					
PIF	L/sec		7.72				
FEV1/FEV6%			84				

Lung Volumes/Plethysmography

Lung Volumes/Plethysmography		(BTPS)
Vtg	Liters	
VC	Liters	3.15
TLC	Liters	4.52
RV	Liters	1.35
RV/TLC	%	30
FRC PL	Liters	1.96
ERV	Liters	
IC	Liters	

Diffusion

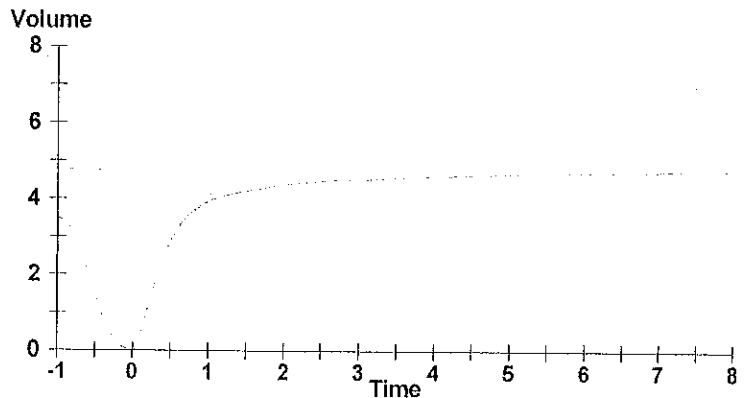
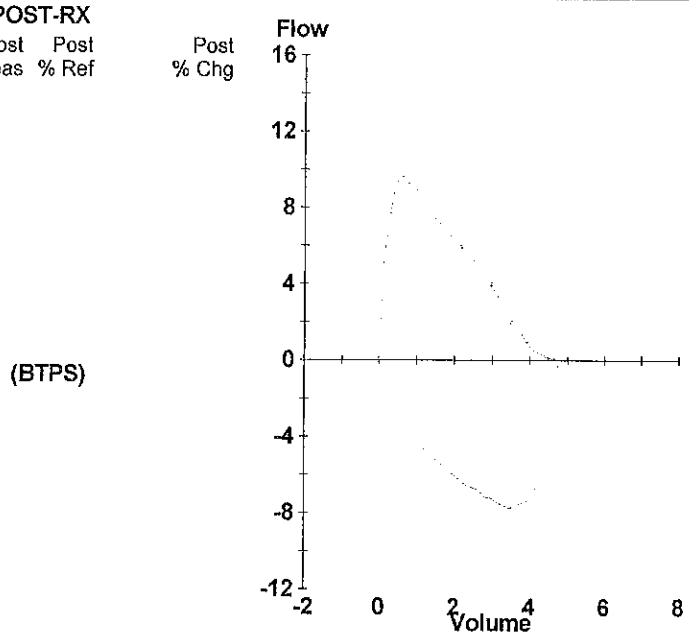
DLCO	mL/mmHg/min	26.0
DL Adj	mL/mmHg/min	26.0
DLCO/VA	mL/mHg/min/L	3.75
VA	Liters	
BHT	Sec	

Resistance

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	2.04
Gaw	L/sec/cmH2O	0.471
sRaw	cmH2O/L/s/L	4.00
sGaw	L/s/cmH2O/L	0.250
Vtg (Raw)	Liters	

Comments:

Interpretation:



Name: ADS,  
 Gender: Female  
 Age: 32 Race: Hispanic  
 Height(in): 61.0 Weight(lb): 199  
 Any Info:

Id: AKP-035  
 Date: 12/13/13  
 Temp: 22 PBar: 630  
 Physician:  
 Technician: VL

Spirometry		(BTPS)	PRE-RX		POST-RX		
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	Post % Chg
FVC	Liters	3.15	4.59	146			
FEV1	Liters	2.72	3.87	143			
FEV1/FVC %		87	84	97			
FEF25-75%L/sec		3.26	4.54	140			
FEF50% L/sec		3.77	5.58	148			
FEF75% L/sec		1.70	2.07	121			
IC	Liters						
VC	Liters	3.15					
PEF	L/sec	6.05	8.65	143			
MVV	L/min	113					
PIF	L/sec		5.25				
FEV1/FEV6%			86				

**Lung Volumes/Plethysmography**

Parameter	Units	Value
Vtg	Liters	
VC	Liters	3.15
TLC	Liters	4.52
RV	Liters	1.35
RV/TLC	%	30
FRC PL	Liters	1.96
ERV	Liters	
IC	Liters	

**Diffusion**

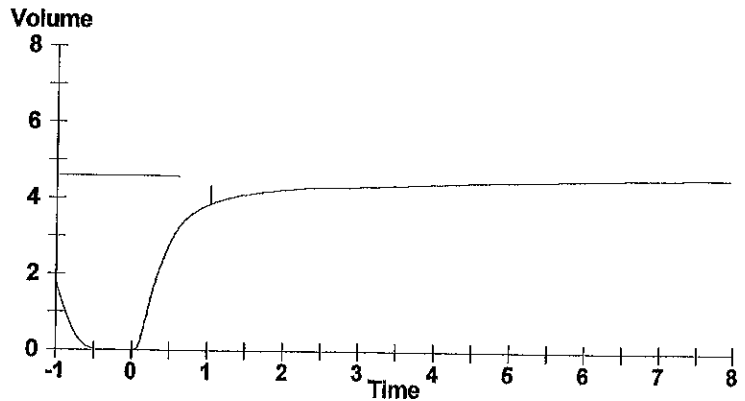
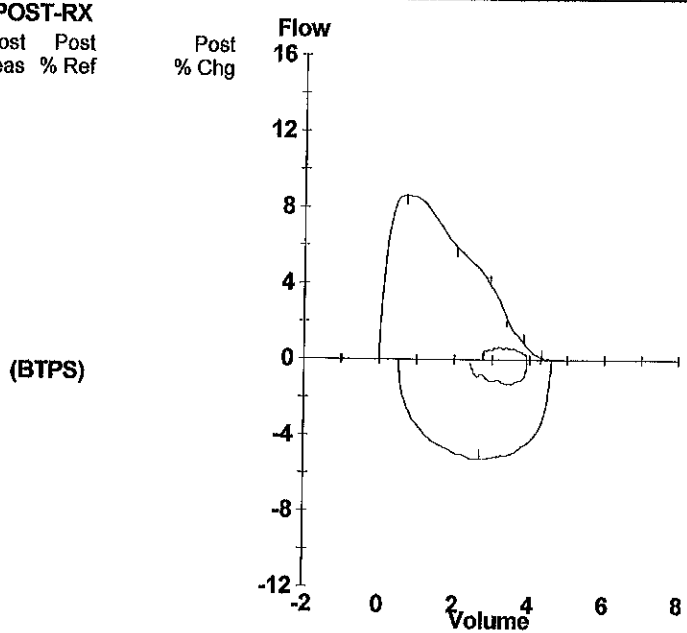
DLCO	mL/mmHg/min	26.0
DL Adj	mL/mmHg/min	26.0
DLCO/VA	mL/mHg/min/L	3.74
VA	Liters	
BHT	Sec	

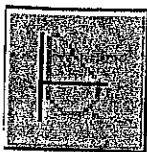
**Resistance**

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	2.04
Gaw	L/sec/cmH2O	0.471
sRaw	cmH2O/L/s/L	4.00
sGaw	L/s/cmH2O/L	0.250
Vtg (Raw)	Liters	

Comments:

Interpretation:





Name: ADS,

Id: AKP-035

Gender: Female

Date: 12/20/13

Age: 32 Race: Hispanic

Temp: 19

PBar: 624

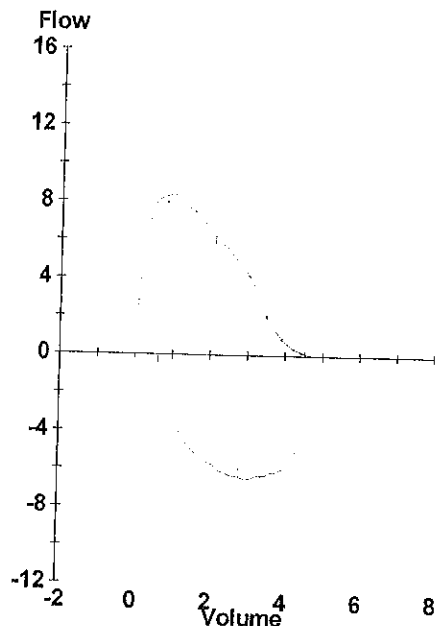
Height(in): 61.0 Weight(lb): 199

Physician:

Any Info:

Technician: VL

Spirometry		(BTPS)	PRE-RX		POST-RX		Post
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	% Chg
FVC	Liters	3.15	4.72	150			
FEV1	Liters	2.72	3.95	146			
FEV1/FVC	%	87	84	97			
FEF25-75%	L/sec	3.26	4.68	144			
FEF50%	L/sec	3.77	** 5.93	** 157			
FEF75%	L/sec	1.70	2.02	119			
IC	Liters						
VC	Liters	3.15					
PEF	L/sec	6.05	** 9.66	** 160			
MVV	L/min	113					
PIF	L/sec		6.47				
FEV1/FEV6%			85				



Lung Volumes/Plethysmography (BTPS)

Parameter	Unit	Value
Vtg	Liters	
VC	Liters	3.15
TLC	Liters	4.52
RV	Liters	1.35
RV/TLC	%	30
FRC PL	Liters	1.96
ERV	Liters	
IC	Liters	

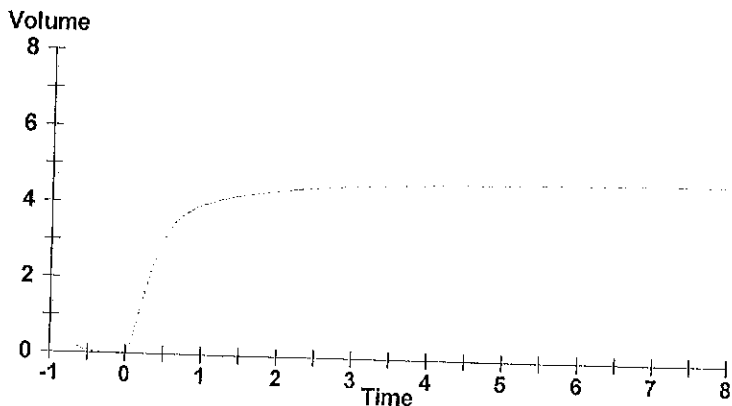
Diffusion

DLCO	mL/mmHg/min	26.0
DL Adj	mL/mmHg/min	26.0
DLCO/VA	mL/mHg/min/L	3.70
VA	Liters	
BHT	Sec	

Resistance

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	2.04
Gaw	L/sec/cmH2O	0.471
sRaw	cmH2O/L/s/L	4.00
sGaw	L/s/cmH2O/L	0.250
Vtg (Raw)	Liters	

Comments:



Interpretation:

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (SCREEN DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

DAY AM	-7	-6	-5	-4	-3	-2	-1	0
Runny Nose 0 to 3	11/20/13 0 1 2 3	11/21/13 0 1 2 3	11/22/13 0 1 2 3	11/23/13 0 1 2 3	11/24/13 0 1 2 3	11/25/13 0 1 2 3	11/26/13 0 1 2 3	11/27/13 0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
DAY PM	-7	-6	-5	-4	-3	-2	-1	0
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N= No

SUBJECT NUMBER: AKP035 DATE COMPLETED: 11/27/13

SUBJECT INITIALS AND DATE: [Signature]



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Scientific Resources  
 Leslie Byatt, MD  
 2441 Ridgecrest Dr SE  
 Albuquerque, NM 87108-5129

Client Nbr  
 24664

PATIENT NAME: **X, ADS** PATIENT ID: **AAGH4692** DOB: **05/27/1981** SEX: **F** REPORT STATUS: **Final** PAGE: **1**  
 PHYSICIAN: **Unlisted Physician,** COLLECT DATE & TIME: **11/27/2013 13:57** RECEIVE DATE & TIME: **11/27/2013 18:50** PRINT DATE & TIME: **11/28/2013 06:11**  
 REQUISITION NO.: **30920929** PT. PHONE NO.: **0** PATIENT NO.: **AKP035**  
 COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
<b>Comp Metabolic Panel</b>					
Sodium	138		mmol/L	134-144	
Potassium	4.0		mmol/L	3.5-5.1	
Chloride	107		mmol/L	98-111	
CO2	25		mmol/L	20-30	
Anion Gap	8			6-14	
Glucose	80		mg/dL	60-100	
BUN	14		mg/dL	7-31	
Creatinine	0.61		mg/dL	0.50-1.40	
Creatinine method is IDMS traceable. EstGFR Calculation has been adjusted. Please note new reference range effective 5/23/2013.					
eGFR non-African Am	>60		mL/min/1.73m2	>60	
GFR Comment	Estimated GFR values are not accurate in acute kidney failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, the very old or very young, races other than Caucasian or African American, people with acute illnesses, or amputations.				
Calcium	8.8		mg/dL	8.4-10.4	
Total Protein	7.2		gm/dL	6.1-8.2	
Albumin	4.1		gm/dL	3.4-4.7	
Globulin	3.1		gm/dL	2.4-4.2	
Bilirubin, total	0.4		mg/dL	0.3-1.2	
Alk Phos	71		U/L	38-150	
AST(SGOT)	17		U/L	6-58	
ALT(SGPT)	29		U/L	14-67	
Fasting Phosphorus	NO				
Phosphorus	3.9		mg/dL	2.3-5.6	
<b>CBC</b>					
WBC	5.8		x10E3	4.0-10.6	
RBC	5.01		x10E6	4.00-6.36	
Hgb	14.0		gm/dL	12.0-16.0	
Hct	44		%	36-48	
MCV	87		fL	81-98	
MCHC	32.0		gm/dL	31.2-35.2	
RDW	12.6		%	11.0-14.5	
Platelets	354		x10E3	150-400	
Eos, Respiratory	None seen			NS	
Phys, Addr, Phone	Not given				

End of Report

*[Signature]*  
 03 Dec 2013

**EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT**

**DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)**

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

DAY AM	1	2	3	4	5	6	7	8	9
Rummy Nose 0 to 3	11/27/13 0 1 2 3	11/28/13 0 1 2 3	11/29/13 0 1 2 3	11/30/13 0 1 2 3	12/01/13 0 1 2 3	12/02/13 0 1 2 3	12/03/13 0 1 2 3	12/04/13 0 1 2 3	12/05/13 0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
<b>DAY PM</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>	<b>9</b>
Rummy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

**SCALE 0 to 3**

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N= No

SUBJECT NUMBER: 035

DATE COMPLETED: 12/06/13

SUBJECT INITIALS AND DATE: APD. 11/10/13





1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505 ) 938-8922

Lovelace Scientific Resources  
Leslie Byatt, MD  
2441 Ridgecrest Dr SE  
Albuquerque, NM 87108-5129

Client Nbr  
24664

<b>PATIENT NAME</b> ADS, ADS	<b>PATIENT ID</b> AAG16767	<b>DOB</b> 05/27/1981	<b>SEX</b> F	<b>REPORT STATUS</b> Final	<b>PAGE</b> 1
<b>PHYSICIAN</b> Unlisted Physician,	<b>COLLECT DATE &amp; TIME</b> 12/06/2013 09:17	<b>RECEIVE DATE &amp; TIME</b> 12/06/2013 18:04	<b>PRINT DATE &amp; TIME</b> 12/09/2013 09:36		
<b>REQUISITION NO.</b> 31033176	<b>PT. PHONE NO.</b> 0	<b>PATIENT NO.</b> AKP035			
<b>COMMENTS :</b>					

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Eos, Respiratory Phys, Addr, Phone	NOT GIVEN	Rare *		NS	

End of Report

*[Signature]*  
10 Dec 2013

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

DAY AM	7	8	9	10	11	12	13	14	15
Runny Nose 0 to 3	12/06/13 0 1 2 3	12/07/13 0 1 2 3	12/08/13 0 1 2 3	12/09/13 0 1 2 3	12/10/13 0 1 2 3	12/11/13 0 1 2 3	12/12/13 0 1 2 3	12/13/13 0 1 2 3	12/14/13 0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
DAY PM	7	8	9	10	11	12	13	14	15
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N= No

SUBJECT NUMBER: AD3 DATE COMPLETED: 12/13/13 SUBJECT INITIALS AND DATE: AD3 12/13/13



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505 ) 938-8922

Lovelace Scientific Resources  
Leslie Byatt, Clin Trials  
2441 Ridgecrest Dr SE  
Albuquerque, NM 87108-5129

Client Nbr  
24664

PATIENT NAME  
**ADS, ADS**

PATIENT ID  
**AAG16767**

DOB  
**05/27/1981**

SEX  
**F**

REPORT STATUS  
**Final**

PAGE  
**1**

PHYSICIAN  
**Unlisted Physician,**

COLLECT DATE & TIME  
**12/13/2013 09:10**

RECEIVE DATE & TIME  
**12/13/2013 19:07**

PRINT DATE & TIME  
**12/16/2013 06:13**

REQUISITION NO. **31033183** PT. PHONE NO. **0**

PATIENT NO.  
**AKP035**

COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Eos, Respiratory Phys, Addr, Phone	Not given	Rare		NS	

*NCS [Signature] Sub I  
17 DEC 2013*

End of Report

Study Identification: 2749

LSR Study #: \_\_\_\_\_

Subject Number: AKP035

Subject Initials: ADS

ADVERSE EVENT LOG  
Do AE's reported error em 11/27/13

Adverse Event	** Start Date (DD/MMM/YYYY)	SEVERITY	Relationship to Study Drug (Suspected/Not Suspected)	** End Date (DD/MMM/YYYY)	Action Taken	Investigator Initials/Date
stinging at application site (post membrane)	27/Nov/2013	mod	Suspected	04/Dec/2013	NONE	EM 11/27/13
Intermittent stinging at app. site	05/Dec/2013	mild	Suspected	09/Dec/2013	NONE	EM 12/09/13

\*\* If day is unknown, write UNK in space provided, but every effort should be made to be as specific as possible\*\*

Investigator Signature (at end of study): [Signature] Date: 20 Dec 2013  
SC Signature (at end of study): [Signature] Date: 12/20/13

Study Identification: AtPharma

LSR #: 2749

Subject Number: AKP035

Subject Initials: ADS

**CONCOMITANT MEDICATION LOG**

List all prescription medications you are taking. Also include over-the-counter medications, vitamins and supplements.

Name of Medication	Indication (What you take it for)	Dose	Unit	Frequency	Route	* Start Date (Day/Month/Year)	Stop Date	Ongoing at EOS (for Clinic use)
EXAMPLE	Diabetes	500	MG	2 Tabs per day	Oral	UNK/AUG/1999		<input type="checkbox"/>
<u>Benadryl</u>	<u>allergies</u>	<u>25</u>	<u>mg</u>	<u>prn</u>	<u>PO</u>	<u>11/6/13</u>	<u>11/6/13</u>	<input type="checkbox"/>
<u>Waldrona</u>	<u>allergies</u>	<u>1</u>	<u>tbl</u>	<u>prn</u>	<u>PO</u>	<u>10/20/13</u>	<u>10/20/13</u>	<input type="checkbox"/>
<u>Ibuprofen</u>	<u>Knee pain</u>	<u>800</u>	<u>mg</u>	<u>prn</u>	<u>PO</u>	<u>10/19/13</u>		<input checked="" type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>

\* If day or month of medication date is unknown, write UNK in space provided

Investigator Signature (at end of study): [Signature] Date: 20 Dec 2013

SC Signature (at end of study): [Signature] Date: 11/27/13  
Loyce Scientific Resources, Inc. - ConMed 04/2013  
 Date: 12/20/13 PAGE: 1 of 1

**EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT**

**DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)**

**CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS**

DAY	14	15	16	17	18	19	20	21	22
AM	12/13/13	12/14/13	12/15/13	12/16/13	12/17/13	12/18/13	12/19/13	12/20/13	12/21/13
Runny Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Itchy Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Congestion 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Sneezing 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Voice Hoarse Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO
Throat Clearing Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO
DAY PM	14	15	16	17	18	19	20	21	22
Runny Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Itchy Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Congestion 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Sneezing 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Voice Hoarse Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO
Throat Clearing Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO

**SCALE 0 to 3**

- 0= No symptoms (no symptoms detected)
  - 1= Mild symptoms (symptoms present but easily tolerated)
  - 2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)
  - 3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)
- Y=Yes N= No

SUBJECT NUMBER: AKP035 DATE COMPLETED: 12/20/13 SUBJECT INITIALS AND DATE: ADS. 12/20/13



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Scientific Resources  
 Leslie Byatt, MD  
 2441 Ridgecrest Dr SE  
 Albuquerque, NM 87108-5129

Client Nbr  
 24864

PATIENT NAME: **X, ADS** PATIENT ID: **AAGJ3400** DOB: **05/27/1981** SEX: **F** REPORT STATUS: **Final** PAGE: **1**  
 PHYSICIAN: **Unlisted Physician,** COLLECT DATE & TIME: **12/20/2013 09:10** RECEIVE DATE & TIME: **12/20/2013 20:03** PRINT DATE & TIME: **12/23/2013 06:08**  
 REQUISITION NO.: **31033186** PT. PHONE NO.: **0** PATIENT NO.: **AXP035**  
 COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
<b>Comp Metabolic Panel</b>					
Sodium	139		mmol/L	134-144	
Potassium	4.2		mmol/L	3.5-5.1	
Chloride	103		mmol/L	98-111	
CO2	26		mmol/L	20-30	
Anion Gap	10			6-14	
Glucose		115 H	mg/dL	60-100	NCS [Signature]
Impaired fasting glucose (IFG) is defined as a fasting glucose level of 100-126 mg/dL. (ADA Guidelines Diabetes Care 26: (3160-3167)2003)					
BUN	11		mg/dL	7-31	
Creatinine	0.62		mg/dL	0.50-1.40	
Creatinine method is IDMS traceable. EstGFR Calculation has been adjusted. Please note new reference range effective 5/23/2013.					
eGFR non-African Am	>60		mL/min/1.73m2	>60	
GFR Comment	Estimated GFR values are not accurate in acute kidney failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, the very old or very young, races other than Caucasian or African American, people with acute illnesses, or amputations.				
Calcium	9.1		mg/dL	8.4-10.4	
Total Protein	7.2		gm/dL	6.1-8.2	
Albumin	4.1		gm/dL	3.4-4.7	
Globulin	3.1		gm/dL	2.4-4.2	
Bilirubin, total	0.5		mg/dL	0.3-1.2	
Alk Phos	70		U/L	38-150	
AST(SGOT)	14		U/L	6-58	
ALT(SGPT)	28		U/L	14-67	
Fasting Phosphorus	YES				
	3.2		mg/dL	2.3-5.6	
<b>CBC</b>					
WBC	5.5		x10E3	4.0-10.6	
RBC	5.04		x10E6	4.00-5.36	
Hgb	14.2		gm/dL	12.0-16.0	
Hct	44		%	36-48	
MCV	87		fL	81-98	
MCHC	32.3		gm/dL	31.2-35.2	
RDW	12.3		%	11.0-14.5	
Platelets	340		x10E3	150-400	
Eos, Respiratory Phys, Addr, Phone		Many *		NS	NCS [Signature]
NO PHYSICIAN LISTED					

End of Report

*[Handwritten Signature]*  
 12/26/13

ADS  
AKP035

12/20/13

Effects of AkPharma's Calcium Glycerophosphate  
Nasal Spray wash (AkP 010112A) on Patient-Perceived Breathing Comfort

SATISFACTION QUESTIONNAIRE:

Would you use / purchase this nasal wash product in the future?"  YES  NO  
for Runny nose

You are also encouraged to make any free comments regarding your experience in the use of this product regarding your opinion of any of its effects not covered specifically in the Daily Diary:

This product worked great for ~~the~~ Relief from Runny nose, but didn't Real help with anything else. It also had a slight Burn when used that went away last a few min.

[Type text]

Subject initials and Date

ADS. 12/20/13

Study Staff Initials and Date

Em 12/20/13



**AKP-037**

2.49 AKPharma PERENNIAL ALLERGIES  
SCREENING/VISIT 1 SOURCE DOCUMENTS

Initials: BITE Site #: — Subject #: AKP037

PATIENT DEMOGRAPHICS

**Patient Demographics**

Date of Birth: 02, Sep, 1952 (dd/mmm/yyyy)

Gender:  Male  Female

If female, Indicate Childbearing Potential

Childbearing  Surgically sterilized  Post-Menopausal

Ethnicity:  Hispanic  Non Hispanic

Race:  Asian  Black  Caucasian  American Indian

Pacific Islander  Other, Specify \_\_\_\_\_

**Smoking History**

Smoking Status:  None (smoked less than 100 cigarettes in lifetime)

Former (previously smoked more than 100 cigarettes in lifetime)

Current (smokes now)

If subject is a former or current smoker, please indicate:

Years smoked: 42 Cigarettes per day: 10 21 pack years

CRC Signature: Usher Byatt Date: 08, NOV, 2013 (dd/mmm/yy)



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Scientific Resources  
 Leslie Byatt, Chief Trials  
 2441 Ridgecrest Dr SE  
 Albuquerque, NM 87108-5129

Client Nbr  
 24684

PATIENT NAME: **B, HE**      PATIENT ID: **AAGI0973**      DOB: **09/02/1952**      SEX: **M**      REPORT STATUS: **Final**      PAGE: **1**  
 PHYSICIAN: **Unlisted Physician,**      COLLECT DATE & TIME: **11/22/2013 11:00**      RECEIVE DATE & TIME: **11/22/2013 17:31**      PRINT DATE & TIME: **11/25/2013 06:12**  
 REQUISITION NO.: **30920960**      PT. PHONE NO.: **0**      PATIENT NO.: **AKP037**  
 COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Allerg, Panel 18					
Allerg, Juniper		8.60	H	<0.35	
Allerg, Cottonwood	0.30			<0.35	
Allerg, West. Ragweed	0.10			<0.35	
Allerg, Russian Thistle		11.60	H	<0.35	
Allerg, Bermuda Grass		2.50	H	<0.35	
Allerg, Alternaria	<0.10			<0.35	
Allerg, Mesquite		0.50	H	<0.35	
Allerg, Cockroach	<0.10			<0.35	
Allerg, Derm. pter.		0.40	H	<0.35	

The standard classification system utilizes the following class cutoffs.

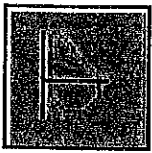
Class	ku/L	Interpretation
0	<0.35	Negative for Allergen
I	0.35-0.69	Positive for Allergen
II	0.70-3.49	Strongly Positive
III	3.5-17.49	Strongly Positive
IV	17.5-52.49	Strongly Positive
V	52.5-99.99	Strongly Positive
VI	>100	Strongly Positive

Results with allergens scoring in class 1 should be considered weakly positive or equivocal. Class 2 and higher should be considered positive. Although increasing class ranges (0-VI) are reflective of increasing concentrations of allergen-specific IgE, this may not correlate with the degree of clinical response when challenged with the specific allergen. The correlation of allergy laboratory results with clinical history is essential. A negative test may not rule out clinical allergy.

Allerg, Derm. farinae		0.80	H	ku/L	<0.35
Allerg, Clad. herb.	<0.10			ku/L	<0.35
Allerg, Firebush		1.40	H	ku/L	<0.35
Allerg, Cat Dander Ep		0.40	H	ku/L	<0.35
Allerg, Dog Dander	0.10			ku/L	<0.35
Allerg, Bluegrass		1.80	H	ku/L	<0.35
Allerg, Pigweed		0.90	H	ku/L	<0.35
Allerg, Mulberry	<0.10			ku/L	<0.35
Allerg, Helminth	<0.10			ku/L	<0.35
Phys, Addr, Phone	Not given				

End of Report

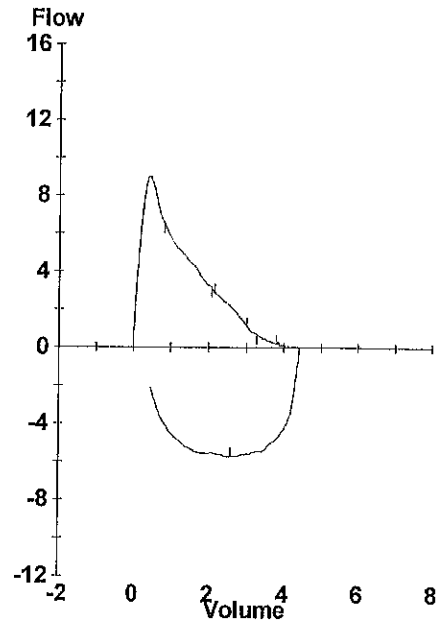
*Handwritten signature and date:*  
 26 Nov 2013



Name: BHE,  
 Gender: Male  
 Age: 61 Race:  
 Height(in): 77.5 Weight(lb): 282  
 Any Info:

Id: AKP037  
 Date: 12/03/13  
 Temp: 19 PBar: 625  
 Physician:  
 Technician: CRD

Spirometry	(BTPS)	PRE-RX		POST-RX		Post % Chg
		Ref	Pre Meas	Pre % Ref	Post Meas	
FVC	Liters	6.03	4.46	74		
FEV1	Liters	4.80	3.06	64		
FEV1/FVC %		78	69	88		
FEF25-75%L/sec		4.67	1.86	40		
FEF50%	L/sec	5.70	**2.65	**47		
FEF75%	L/sec	2.22	**0.60	**27		
IC	Liters					
VC	Liters	6.03				
PEF	L/sec	10.37	9.04	87		
MVV	L/min	164				
PIF	L/sec		5.74			
FEV1/FEV6%			74			



**Lung Volumes/Plethysmography**

Parameter	Units	Value
Vtg	Liters	
VC	Liters	6.03
TLC	Liters	8.44
RV	Liters	2.90
RV/TLC	%	38
FRC PL	Liters	4.19
ERV	Liters	
IC	Liters	

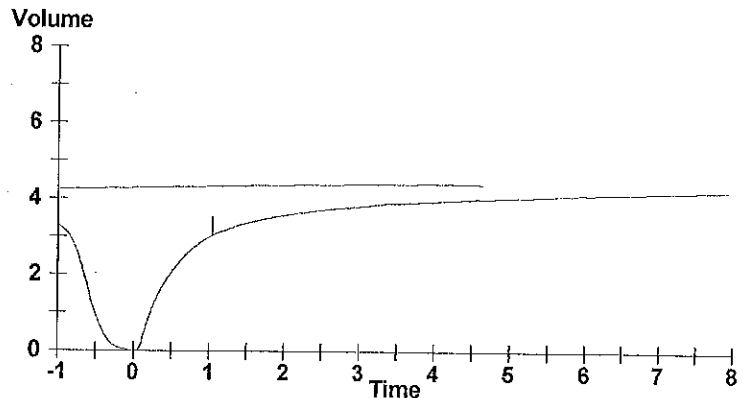
**Diffusion**

DLCO	mL/mmHg/min	32.6
DL Adj	mL/mmHg/min	32.6
DLCO/VA	mL/mHg/min/L	3.13
VA	Liters	
BHT	Sec	

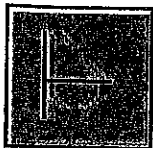
**Resistance**

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.03
Gaw	L/sec/cmH2O	1.006
sRaw	cmH2O/L/s/L	4.32
sGaw	L/s/cmH2O/L	0.231
Vtg (Raw)	Liters	

Comments:



Interpretation:



Name: AKP-037,

Id: AKP-037

Gender: Male

Date: 12/10/13

Age: 61 Race:

Temp: 16

PBar: 637

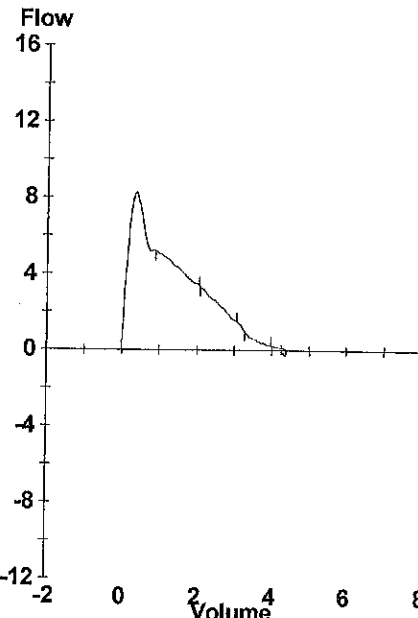
Height(in): 77.5 Weight(lb): 282

Physician:

Any Info:

Technician: CRD

Spirometry	(BTPS)	PRE-RX		POST-RX		Post % Chg
		Ref	Pre Meas	Pre % Ref	Post Meas	
FVC Liters	6.03	4.40	73			
FEV1 Liters	4.80	3.10	65			
FEV1/FVC %	78	70	90			
FEF25-75%L/sec	4.67	2.20	47			
FEF50% L/sec	5.70	**2.88	**50			
FEF75% L/sec	2.22	0.86	39			
IC Liters						
VC Liters	6.03					
PEF L/sec	10.37	8.35	80			
MVV L/min	164					
PIF L/sec		0.30				
FEV1/FEV6%		71				



**Lung Volumes/Plethysmography**

(BTPS)

Vtg	Liters	
VC	Liters	6.03
TLC	Liters	8.44
RV	Liters	2.90
RV/TLC	%	38
FRC PL	Liters	4.19
ERV	Liters	
IC	Liters	

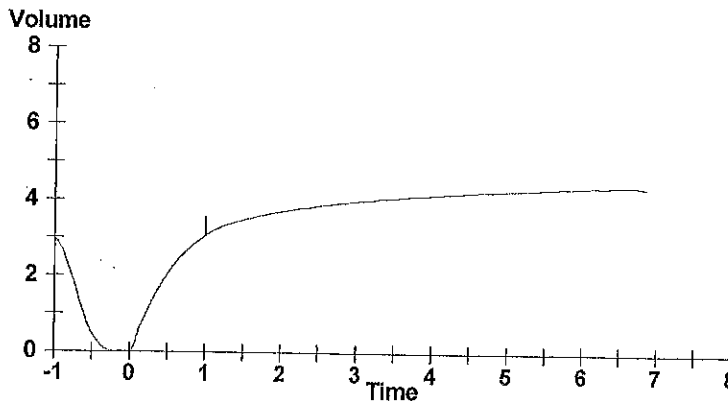
**Diffusion**

DLCO	mL/mmHg/min	32.6
DL Adj	mL/mmHg/min	32.6
DLCO/VA	mL/mHg/min/L	3.19
VA	Liters	
BHT	Sec	

**Resistance**

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.03
Gaw	L/sec/cmH2O	1.006
sRaw	cmH2O/L/s/L	4.32
sGaw	L/s/cmH2O/L	0.231
Vtg (Raw)	Liters	

Comments:



Interpretation:

Name: BHE,  
 Gender: Male  
 Age: 61 Race: Caucasian  
 Height(in): 78.0 Weight(lb): 282  
 Any Info:

Id: AKP-037  
 Date: 12/17/13  
 Temp: 18 PBar: 638  
 Physician:  
 Technician: VL

Spirometry		(BTPS)	PRE-RX		POST-RX		Post	Flow
		Ref	Pre	Pre	Post	Post	% Chg	16
			Meas	% Ref	Meas	% Ref		12
FVC	Liters	6.11	4.36	71				8
FEV1	Liters	4.87	2.96	61				4
FEV1/FVC	%	78	68	87				0
FEF25-75%	L/sec	4.73	1.68	35				-4
FEF50%	L/sec	5.77	** 2.43	** 42				-8
FEF75%	L/sec	2.25	** 0.48	** 21				-12
IC	Liters							-2
VC	Liters	6.11						0
PEF	L/sec	10.49	7.67	73				2
MVV	L/min	166						4
PIF	L/sec		4.96					6
FEV1/FEV6%			73					8

**Lung Volumes/Plethysmography**

Vtg	Liters	
VC	Liters	6.11
TLC	Liters	8.56
RV	Liters	2.94
RV/TLC	%	38
FRC PL	Liters	4.28
ERV	Liters	
IC	Liters	

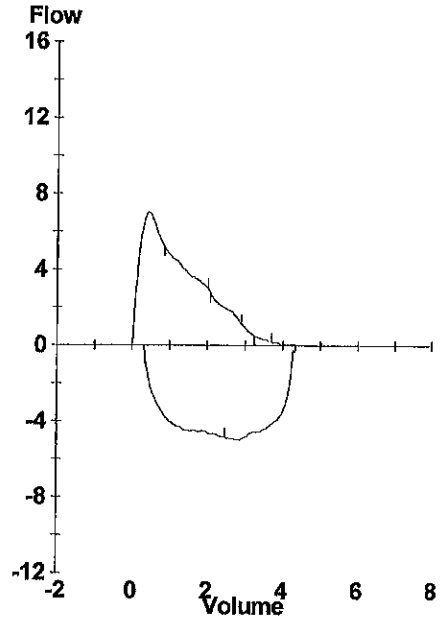
**Diffusion**

DLCO	mL/mmHg/min	32.8
DL Adj	mL/mmHg/min	32.8
DLCO/VA	mL/mHg/min/L	3.20
VA	Liters	
BHT	Sec	

**Resistance**

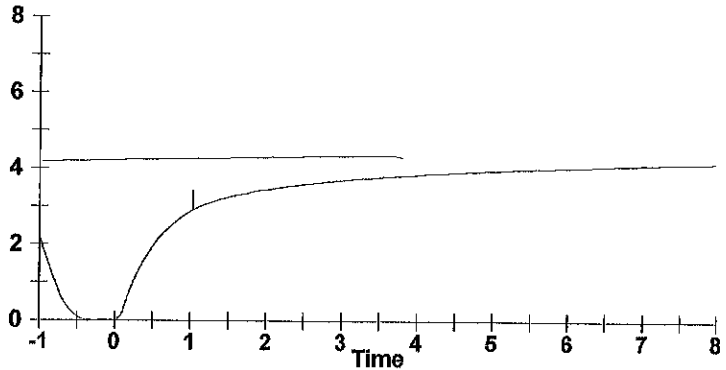
Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.01
Gaw	L/sec/cmH2O	1.027
sRaw	cmH2O/L/s/L	4.30
sGaw	L/s/cmH2O/L	0.232
Vtg (Raw)	Liters	

(BTPS)

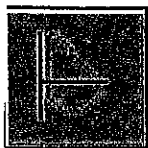


Comments:

Volume



Interpretation:



Name: AKP-037,  
 Gender: Male  
 Age: 61 Race:  
 Height(in): 77.5 Weight(lb): 282  
 Any Info:

Id: AKP-037  
 Date: 12/23/13  
 Temp: 18 PBar: 637  
 Physician:  
 Technician: CRD

Spirometry	(BTPS)	PRE-RX		POST-RX		Post % Chg
		Ref	Pre Meas	Pre % Ref	Post Meas	
FVC	Liters	6.03	4.77	79		
FEV1	Liters	4.80	3.17	66		
FEV1/FVC	%	78	66	85		
FEF25-75%	L/sec	4.67	1.78	38		
FEF50%	L/sec	5.70	** 2.95	** 52		
FEF75%	L/sec	2.22	** 0.54	** 24		
IC	Liters					
VC	Liters	6.03				
PEF	L/sec	10.37	8.50	82		
MVV	L/min	164				
PIF	L/sec		5.88			
FEV1/FEV6%			72			

**Lung Volumes/Plethysmography**

Vtg	Liters	
VC	Liters	6.03
TLC	Liters	8.44
RV	Liters	2.90
RV/TLC	%	38
FRC PL	Liters	4.19
ERV	Liters	
IC	Liters	

**Diffusion**

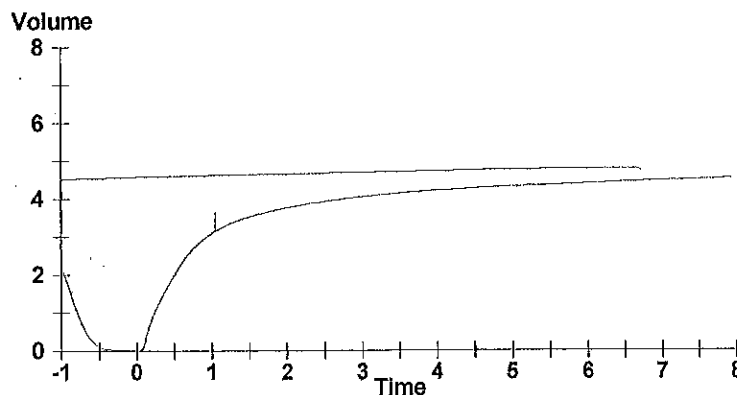
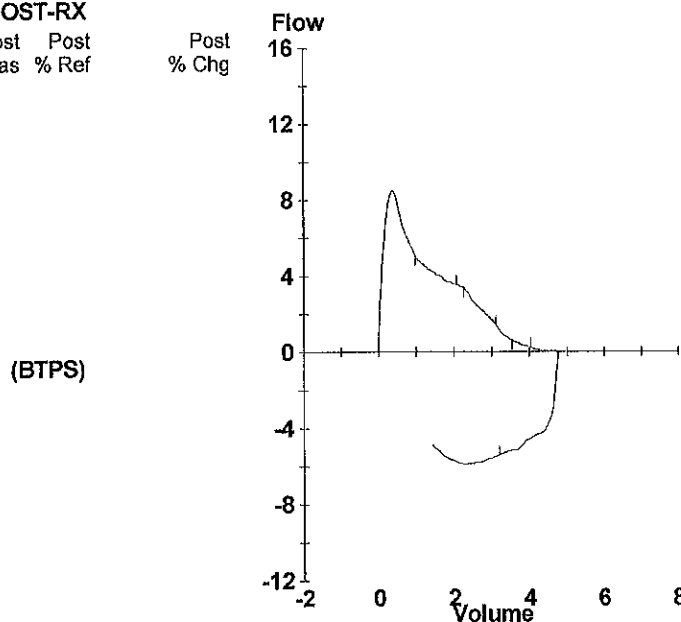
DLCO	mL/mmHg/min	32.6
DL Adj	mL/mmHg/min	32.6
DLCO/VA	mL/mHg/min/L	3.19
VA	Liters	
BHT	Sec	

**Resistance**

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.03
Gaw	L/sec/cmH2O	1.006
sRaw	cmH2O/L/s/L	4.32
sGaw	L/s/cmH2O/L	0.231
Vtg (Raw)	Liters	

Comments:

Interpretation:





1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505 ) 938-8922

Lovelace Sc i/o Resources  
 Leslie Byatt, Clin Trials  
 2441 Ridgcrest Dr SE  
 Albuquerque, NM 87108-5129

Client Nbr  
 24864

PATIENT NAME: X, BHE  
 PATIENT ID: AAG14836  
 DOB: 09/02/1952  
 SEX: M  
 REPORT STATUS: Final  
 PAGE: 1  
 PHYSICIAN: Unlisted Physician,  
 COLLECT DATE & TIME: 12/03/2013 10:25  
 RECEIVE DATE & TIME: 12/03/2013 19:53  
 PRINT DATE & TIME: 12/04/2013 06:08  
 REQUISITION NO.: 30920931  
 PT. PHONE NO.: 0  
 PATIENT NO.: AKP037  
 COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Comp Metabolic Panel					
Sodium	140		mmol/L	134-144	
Potassium	3.9		mmol/L	3.5-5.1	
Chloride	107		mmol/L	98-111	
CO2	24		mmol/L	20-30	
Anion Gap	9			6-14	
Glucose		101 H	mg/dL	60-100	
Impaired fasting glucose (IFG) is defined as a fasting glucose level of 100-126 mg/dL. (ADA Guidelines Diabetes Care 26: (3160-3167)2003)					
BUN	13		mg/dL	7-31	
Creatinine	0.72		mg/dL	0.62-1.66	
Creatinine method is IDMS traceable. EstGFR Calculation has been adjusted. Please note new reference range effective 5/23/2013.					
eGFR non-African Am	>60		mL/min/1.73m2	>60	
GFR Comment	Estimated GFR values are not accurate in acute kidney failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, the very old or very young, races other than Caucasian or African American, people with acute illnesses, or amputations.				
Calcium	9.3		mg/dL	8.4-10.4	
Total Protein	7.4		gm/dL	6.1-8.2	
Albumin	4.2		gm/dL	3.4-4.7	
Globulin	3.2		gm/dL	2.4-4.2	
Bilirubin, total	0.5		mg/dL	0.3-1.2	
Alk Phos	48		U/L	38-150	
AST(SGOT)	24		U/L	6-58	
ALT(SGPT)	48		U/L	14-67	
Fasting Phosphorus	NO				
Phosphorus	3.0		mg/dL	2.3-5.6	
CBC					
WBC	7.6		x10E3	4.0-10.6	
RBC	5.30		x10E6	4.64-6.00	
Hgb	16.1		gm/dL	14.5-17.7	
Hct	48		%	42-53	
MCV	90		fL	81-98	
MCHC	33.9		gm/dL	31.2-36.2	
RDW	13.8		%	11.0-14.5	
Platelets	274		x10E3	150-400	
Eos, Respiratory Phys, Addr, Phone	NOT GIVEN	Many *		NS	

*NCS [Signature]*  
 12 Dec 13

*NCS [Signature]*  
 12 Dec 13

*[Signature]*  
 12 Dec 2013

End of Report



2/26/14 - Subject started diary on 11/26/13, date of Day -7 visit. Data was collected correctly. *Very clearly*

**EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT**

**DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)**  
*5-7-14*  
**CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS**

DAY AM	1	2	3	4	5	6	7	8	9
Runny Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Itchy Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Congestion 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Sneezing 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Voice Hoarse Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO
Throat Clearing Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO
<b>DAY PM</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>	<b>9</b>
Runny Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Itchy Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Congestion 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Sneezing 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Voice Hoarse Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO
Throat Clearing Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO

**SCALE 0 to 3**  
 0= No symptoms (no symptoms detected)  
 1= Mild symptoms (symptoms present but easily tolerated)  
 2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)  
 3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)  
 Y=Yes N=No

SUBJECT NUMBER: AKP037 DATE COMPLETED: 12/03/13  
*BTZ*

SUBJECT INITIALS AND DATE: BTZ

K14H17

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)  
CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

DAY AM	1	2	3	4	5	6	7	8	9
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
DAY PM	1	2	3	4	5	6	7	8	9
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

SCALE 0 to 3  
0 = No symptoms (no symptoms detected)  
1 = Mild symptoms (symptoms present but easily tolerated)  
2 = Moderate symptoms (awareness of symptoms, bothersome but tolerable)  
3 = Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)  
Y=Yes N=No

SUBJECT NUMBER: AKP037 DATE COMPLETED: 12/10/13

BHC

SUBJECT INITIALS AND DATE: 12-8 12-10-13

12-8 put on cologne + sprayed nose a lot of sneezing  
12-5 wake up coughing

XTRA SPRAY  
12-3 5 pm  
12-4 5 pm  
12-5 5 pm  
12-6 5 pm  
12-7 2 pm



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505 ) 938-8922

Lovelace Scientific Resources  
 Leslie Byatt, MD  
 2441 Ridgcrest Dr SE  
 Albuquerque, NM 87108-5129

Client Nbr  
 24664

PATIENT NAME <b>BHE, BHE</b>	PATIENT ID <b>AAG18221</b>	DOB <b>09/02/1952</b>	SEX <b>M</b>	REPORT STATUS <b>Final</b>	PAGE <b>1</b>
PHYSICIAN <b>Unlisted Physician,</b>	COLLECT DATE & TIME <b>12/10/2013 10:45</b>	RECEIVE DATE & TIME <b>12/10/2013 20:14</b>	PRINT DATE & TIME <b>12/11/2013 09:17</b>		
REQUISITION NO. <b>31033178</b>	PT. PHONE NO. <b>0</b>	PATIENT NO. <b>AKP037</b>			
COMMENTS :					

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Eos, Respiratory Phys, Addr, Phone	NOT INDICATED	Rare *		NS	

End of Report

*[Handwritten Signature]*  
 11 Dec 2013

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

DAY AM	7	8	9	10	11	12	13	14	15
Runny Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Itchy Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Congestion 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Sneezing 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Voice Hoarse Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO
Throat Clearing Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO
<b>DAY PM</b>	<b>7</b>	<b>8</b>	<b>9</b>	<b>10</b>	<b>11</b>	<b>12</b>	<b>13</b>	<b>14</b>	<b>15</b>
Runny Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Itchy Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Congestion 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Sneezing 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Voice Hoarse Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO
Throat Clearing Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N= No

XTRA Spray  
12-10 - 5 PM  
11 5 PM  
12 5 PM  
13 5 PM  
14 2 PM

Sax nite  
10 pm - a lot  
of sneezing  
congestion all  
nite  
Sunday Am  
sneezing  
congestion

SUBJECT NUMBER: BHE 037 DATE COMPLETED: 12/17/13 SUBJECT INITIALS AND DATE: AKP 12-12-13



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505 ) 938-8922

Lovelace Scientific Resources  
Leslie Byatt, MD  
2441 Ridgcrest Dr SE  
Albuquerque, NM 87108-5129

Client Nbr  
24864

PATIENT NAME <b>BHE, BHE</b>	PATIENT ID <b>AAG18221</b>	DOB <b>09/02/1952</b>	SEX <b>M</b>	REPORT STATUS <b>Final</b>	PAGE <b>1</b>
PHYSICIAN <b>Unlisted Physician,</b>	COLLECT DATE & TIME <b>12/17/2013 10:00</b>	RECEIVE DATE & TIME <b>12/17/2013 19:27</b>	PRINT DATE & TIME <b>12/18/2013 07:01</b>		
REQUISITION NO. <b>31033185</b>	PT. PHONE NO. <b>0</b>	PATIENT NO. <b>AKP037</b>			
COMMENTS :					

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Eos, Respiratory Phys, Addr, Phone	Not given	Rare *		NS	NCS

End of Report

*DM Guire MD*  
*18 Dec 2013*

Study Identification: 2749 LSR Study #: 2749  
 Subject Number: AKP037 Subject Initials: BHE

ADVERSE EVENT LOG

Adverse Event	** Start Date (DD/MMM/YYYY)	SEVERITY	Relationship to Study Drug (Suspected/Not Suspected)	** End Date (DD/MMM/YYYY)	Action Taken	Investigator Initials/Date
worsening of sneezing	08/Dec/2013	Mod	Suspected	08/Dec/2013	NONE	BHE 12/8/13
Intermittent coughing	09/Dec/2013	Mild	Suspected	26/Dec/2013	NONE	BHE 12/26/13
runny congestion	14/Dec/2013	mod	Not suspected	16/Dec/2013	NONE	BHE 12/16/13
worsening of sneezing	14/Dec/2013	mod	Suspected	16/Dec/2013	NONE	BHE 12/16/13
						/ /
						/ /
						/ /
						/ /
						/ /
						/ /
						/ /
						/ /

\*\* If day is unknown, write UNK in space provided, but every effort should be made to be as specific as possible \*\*

Investigator Signature (at end of study): [Signature] Date: 23 Dec 2013  
 SC Signature (at end of study): Erica Maldonado Date: 12/23/13  
 Lovelace Scientific Resources, Inc - AdverseEvents 04/2013 PAGE: 1 of 1



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Lovelace Scientific Resources  
Leslie Byatt, CLIn Trials  
2441 Ridgecrest Dr SE  
Albuquerque, NM 87108-5129

Client Nbr  
24864

PATIENT NAME: **X, BHE** PATIENT ID: **AAGJ4038** DOB: **09/02/1952** SEX: **M** REPORT STATUS: **Final** PAGE: **1**  
 PHYSICIAN: **Unlisted Physician,** COLLECT DATE & TIME: **12/23/2013 09:59** RECEIVE DATE & TIME: **12/23/2013 19:01** PRINT DATE & TIME: **12/24/2013 06:03**  
 REQUISITION NO.: **31033196** PT. PHONE NO.: **0** PATIENT NO.: **AKP037**  
 COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
<b>Comp Metabolic Panel</b>					
Sodium	141		mmol/L	134-144	
Potassium	3.6		mmol/L	3.5-5.1	
Chloride	109		mmol/L	98-111	
CO2	22		mmol/L	20-30	
Anion Gap	10			6-14	
Glucose	100		mg/dL	60-100	
Impaired fasting glucose (IFG) is defined as a fasting glucose level of 100-126 mg/dL. (ADA Guidelines Diabetes Care 26: (3160-3167)2003)					
BUN	15		mg/dL	7-31	
Creatinine	0.82		mg/dL	0.62-1.66	
Creatinine method is IDMS traceable. EstGFR Calculation has been adjusted. Please note new reference range effective 5/23/2013.					
eGFR non-African Am	>60		mL/min/1.73m2	>60	
GFR Comment	Estimated GFR values are not accurate in acute kidney failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, the very old or very young, races other than Caucasian or African American, people with acute illnesses, or amputations.				
Calcium	9.0		mg/dL	8.4-10.4	
Total Protein	7.0		gm/dL	6.1-8.2	
Albumin	4.1		gm/dL	3.4-4.7	
Globulin	2.9		gm/dL	2.4-4.2	
Bilirubin, total	0.6		mg/dL	0.3-1.2	
Alk Phos	49		U/L	38-150	
AST(SGOT)	36		U/L	6-58	
ALT(SGPT)	63		U/L	14-67	
Fasting Phosphorus	NO				
Phosphorus	3.4		mg/dL	2.3-5.6	
<b>CBC</b>					
WBC	7.1		x10E3	4.0-10.6	
RBC	5.13		x10E6	4.64-6.00	
Hgb	16.0		gm/dL	14.5-17.7	
Hct	45		%	42-53	
MCV	88		fL	81-98	
MCHC		35.4	H	31.2-35.2	NCS [Signature]
RDW	13.3		%	11.0-14.5	
Platelets	244		x10E3	150-400	NCS [Signature]
Eos, Respiratory Phys, Addr, Phone		Many	*	NS	

NO PHYSICIAN LISTED

End of Report

*Handwritten signature and date:*  
2 Jan 2014

Study Identification: AKpharma

LSR #: 2749

Subject Number: AKP037

Subject Initials: BHE

**CONCOMITANT MEDICATION LOG**

List all prescription medications you are taking. Also include over-the-counter medications, vitamins and supplements.

Name of Medication	Indication (What you take it for)	Dose	Unit	Frequency	Route	* Start Date (Day/Month/Year)	Stop Date	Ongoing at EOS (for Clinic use)
EXAMPLE	Diabetes	500	MG		Ora	UNK/AUG/1999		<input type="checkbox"/>
MVI	Supplement	1	tab	QD	PO	2008		<input checked="" type="checkbox"/>
Vit. D3	Supplement	2000	mg	QD	PO	2010		<input checked="" type="checkbox"/>
Benzospral/HCTZ	htn	20/12.5	mg	QD	PO	2012		<input checked="" type="checkbox"/>
Allopurinol	Gout	150	mg	QD	PO	2012		<input checked="" type="checkbox"/>
simvastatin	T lipids	20	mg	QD	PO	2010		<input checked="" type="checkbox"/>
finasteride	↓ T w/ supplm.	5	mg	QD	PO	2011		<input checked="" type="checkbox"/>
Amlodipine	htn	10	mg	QD	PO	2010		<input checked="" type="checkbox"/>
meja-kruel	Supplement	300	mg	QD	PO	10/2013		<input checked="" type="checkbox"/>
Diclofenac	Shin pain	75	mg	BID prn	PO	10/4/13		<input checked="" type="checkbox"/>
Fluticasone	Allergies	50	mcg	4-5x/week	inh	10/4/13	11/6/13	<input type="checkbox"/>
- HC	Allergies	15	mg	5x/week	PO	2012		<input type="checkbox"/>

\* If day or month of medication date is unknown, write UNK in space provided

Investigator Signature (at end of study): [Signature] Date: 12/26/13

SC Signature (at end of study): [Signature] Date: 12/23/13



Study Identification: AK Pharma LSR #: 2749  
 Subject Number: AKP037 Subject Initials: BHE

**CONCOMITANT MEDICATION LOG**

List all prescription medications you are taking. Also include over-the-counter medications, vitamins and supplements.

Name of Medication	Indication (What you take it for)	Dose	Unit	Frequency <small>2 Tabs per day</small>	Route	* Start Date (Day/Month/Year) <small>UNK/AUG/1999</small>	Stop Date	Ongoing at EOS (for Clinic use)
<u>Compound Testosterone</u>	<u>Diabetes</u> <u>↓ T</u>	<u>500</u> <u>7.5</u>	<u>MG</u> <u>mg</u>	<u>QD</u>	<u>PO</u>	<u>2012</u>		<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>

\* If day or month of medication date is unknown, write UNK in space provided

Investigator Signature (at end of study): [Signature] Date: 12/26/13  
 SC Signature (at end of study): [Signature] Date: 12/23/13

Study Identification: AK Pharma LSR #: 2749

Subject Number: AK P037 Subject Initials: BHE

**CONCOMITANT MEDICATION LOG**

List all prescription medications you are taking. Also include over-the-counter medications, vitamins and supplements.

Name of Medication	Indication (What you take it for)	Dose	Unit	Frequency	Route	* Start Date (Day/Month/Year)	Stop Date	Ongoing at EOS (for Clinic use)
EXAMPLE	Diabetes	500	MG	2 Tabs per day	Oral	UNK/AUG/1999		<input type="checkbox"/>
Compound Teotaterone	↓ T	7.5	%	QD	PO	2012		<input checked="" type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
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								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>

\* If day or month of medication date is unknown, write UNK in space provided

Investigator Signature (at end of study): [Signature] Date: 12/26/13

SC Signature (at end of study): [Signature] Date: 12/23/13

**EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT**

**DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)**

*CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS*

DAY AM	14	15	16	17	18	19	20	21	22
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
<b>DAY PM</b>	<b>14</b>	<b>15</b>	<b>16</b>	<b>17</b>	<b>18</b>	<b>19</b>	<b>20</b>	<b>21</b>	<b>22</b>
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

**SCALE 0 to 3**

- 0= No symptoms (no symptoms detected)
  - 1= Mild symptoms (symptoms present but easily tolerated)
  - 2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)
  - 3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)
- Y=Yes N=No

SUBJECT NUMBER: AKP037 DATE COMPLETED: 12/23/13

SUBJECT INITIALS AND DATE: AKS 12-23-13

*XTRAX SPRAY  
12-17 SPAN  
12-18 SPAN  
12-19 SPAN  
12-20 SPAN  
12-21 SPAN*

BHE  
AKP037

12/23/13

Effects of AkPharma's Calcium Glycerophosphate  
Nasal Spray wash (AkP 010112A) on Patient-Perceived Breathing Comfort

SATISFACTION QUESTIONNAIRE:

Would you use / purchase this nasal wash product in the future?"  YES  NO

You are also encouraged to make any free comments regarding your experience in the use of this product regarding your opinion of any of its effects not covered specifically in the Daily Diary:

Product seemed to help  
I would buy this.

when product comes on Market  
Let me know so I can buy it  
easy to use

the study was easy

Erica was very nice all the time

let me know when I can buy it.!!

[Type text]

Subject initials and Date

BHE 12-23-13

Study Staff Initials and Date

EM 12/23/13

**AKP-038**

2749 AKPharma PERENNIAL ALLERGIES  
SCREENING/VISIT 1 SOURCE DOCUMENTS

Initials: DRR Site #: — Subject #: AKP 038

**PATIENT DEMOGRAPHICS**

**Patient Demographics**

Date of Birth: 09, Oct, 1946 (dd/mmm/yyyy)

Gender:  Male  Female

If female, Indicate Childbearing Potential

Childbearing  Surgically sterilized  Post-Menopausal

Ethnicity:  Hispanic  Non Hispanic

Race:  Asian  Black  Caucasian  American Indian

Pacific Islander  Other, Specify \_\_\_\_\_

**Smoking History**

Smoking Status:  None (smoked less than 100 cigarettes in lifetime)

Former (previously smoked more than 100 cigarettes in lifetime)

Current (smokes now)

If subject is a former or current smoker, please indicate:

Years smoked: 16 Cigarettes per day: 20

CRC Signature: Walter Byatt Date: 12, NOV, 13 (dd/mmm/yy)



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Lovelace Scientific Resources  
Leslie Byatt, MD  
2441 Ridgecrest Dr SE  
Albuquerque, NM 87108-5129

Client Nbr  
24664

PATIENT NAME: DRR, DRR      PATIENT ID: AAGH5323      DOB: 10/09/1946      SEX: M      REPORT STATUS: Final      PAGE: 1

PHYSICIAN: Unlisted Physician,      COLLECT DATE & TIME: 11/12/2013 10:30      RECEIVE DATE & TIME: 11/12/2013 20:12      PRINT DATE & TIME: 11/14/2013 06:10

REQUISITION NO.: 30920945      PT. PHONE NO.: 0      PATIENT NO.: AKP038

COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Allerg, Panel 18					
Allerg, Juniper		9.70	KU/L	<0.35	
Allerg, Cottonwood	<0.10		KU/L	<0.35	
Allerg, West. Ragweed	<0.10		KU/L	<0.35	
Allerg, Russian Thistle		14.40	KU/L	<0.35	
Allerg, Bermuda Grass		0.70	KU/L	<0.35	
Allerg, Alternaria	0.30		KU/L	<0.35	
Allerg, Mesquite		0.80	KU/L	<0.35	
Allerg, Cockroach	<0.10		KU/L	<0.35	
Allerg, Derm. pter.	<0.10		KU/L	<0.35	

The standard classification system utilizes the following class cutoffs.

Class	ku/L	Interpretation
0	<0.35	Negative for Allergen
I	0.35-0.69	Positive for Allergen
II	0.70-3.49	Strongly Positive
III	3.5-17.49	Strongly Positive
IV	17.5-52.49	Strongly Positive
V	52.5-99.99	Strongly Positive
VI	>100	Strongly Positive

Results with allergens scoring in Class 1 should be considered weakly positive or equivocal. Class 2 and higher should be considered positive. Although increasing class ranges (0-VI) are reflective of increasing concentrations of allergen-specific IgE, this may not correlate with the degree of clinical response when challenged with the specific allergen. The correlation of allergy laboratory results with clinical history is essential. A negative test may not rule out clinical allergy.

Allerg, Derm. farinae	<0.10		KU/L	<0.35
Allerg, Clad. herb.	<0.10		KU/L	<0.35
Allerg, Firebush		3.90	KU/L	<0.35
Allerg, Cat Dander Ep		3.60	KU/L	<0.35
Allerg, Dog Dander		0.40	KU/L	<0.35
Allerg, Bluegrass		0.60	KU/L	<0.35
Allerg, Pigweed		12.10	KU/L	<0.35
Allerg, Mulberry	0.10		KU/L	<0.35
Allerg, Helminth	<0.10		KU/L	<0.35
Phys, Addr, Phone	Not given			

Callback Accession Comments:

T3463932

EALTE, EBERGR, ECATDA, ECLAHE, ECOCKR, ECOTTO, EDERFA, EDERPT, EDOGDA, EFIREB, EHELHA, EJUNIP, EKENBL, EMESQU, EMULBE, EROUPI, ERUSTH, EWESRA

11/13/2013 08:13 pm FAXED TO 3488546 NC CS11630

11/13/2013 08:14 pm FAXED TO 3488546 NC CS11630

Continued on next page

DRR, DRR

11/14/2013 06:10

FAX24664

*Inclusion Criteria*  
*Inclusion Criteria*

*Immuno Cap results demonstrates reactivity to perennial allergens cat dander, cat epithelium + dog dander*

*Jalayer PI 18 Nov 2013*



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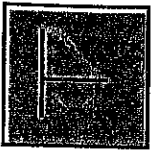
Client Nbr  
24664

PATIENT NAME <b>DRR, DRR</b>	PATIENT ID <b>AAGH5323</b>	DOB <b>10/09/1946</b>	SEX <b>M</b>	REPORT STATUS <b>Final</b>	PAGE <b>2</b>
PHYSICIAN <b>Unlisted Physician,</b>	COLLECT DATE & TIME <b>11/12/2013 10:30</b>	RECEIVE DATE & TIME <b>11/12/2013 20:12</b>	PRINT DATE & TIME <b>11/14/2013 06:10</b>		
REQUISITION NO.      PT. PHONE NO.	PATIENT NO.				
<b>30920945</b> <b>0</b>	<b>AKP038</b>				
COMMENTS :					

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
<b>End of Report</b>					

*Salzer PI*  
*18 Nov 2013*





Name: DRR,  
 Gender: Male  
 Age: 67 Race: Caucasian  
 Height(in): 72.0 Weight(lb): 195  
 Any Info:

Id: AKP038  
 Date: 11/27/13  
 Temp: 19 PBar: 637  
 Physician:  
 Technician: CRD

Spirometry		(BTPS)	PRE-RX		POST-RX		Post
		Ref	Pre	Pre	Post	Post	Post
			Meas	% Ref	Meas	% Ref	% Chg
FVC	Liters	4.67	5.49	118			
FEV1	Liters	3.70	3.35	90			
FEV1/FVC	%	78	61	78			
FEF25-75%	L/sec	3.65	1.27	35			
FEF50%	L/sec	4.52	2.12	47			
FEF75%	L/sec	1.65	0.33	20			
IC	Liters						
VC	Liters	4.67					
PEF	L/sec	8.85	9.20	104			
MVV	L/min	138					
PIF	L/sec		6.26				
FEV1/FEV6%			71				

**Lung Volumes/Plethysmography**

Parameter	Units	Value
Vtg	Liters	
VC	Liters	4.67
TLC	Liters	7.03
RV	Liters	2.63
RV/TLC	%	40
FRC PL	Liters	3.94
ERV	Liters	
IC	Liters	

**Diffusion**

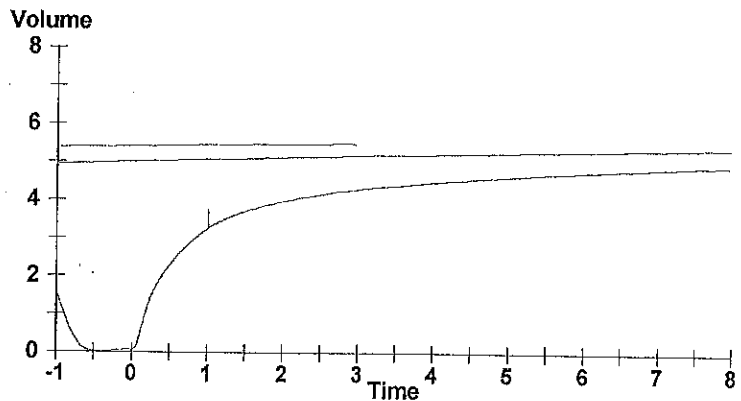
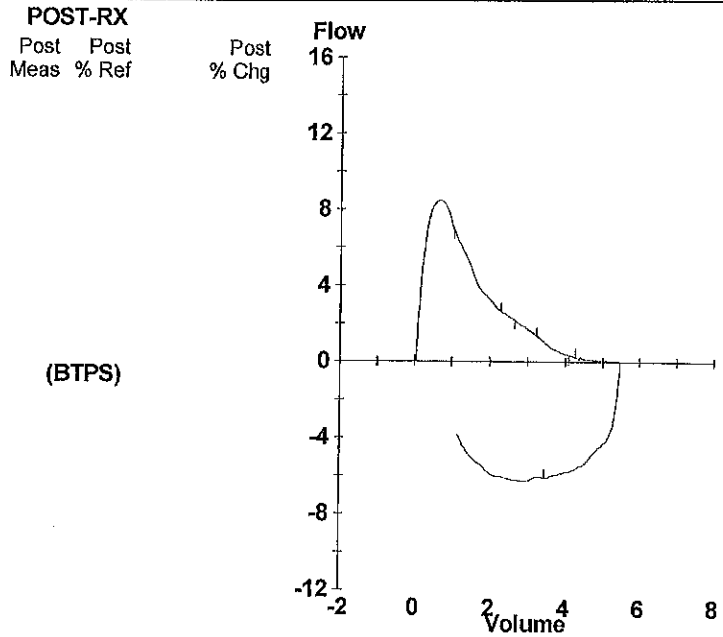
DLCO	mL/mmHg/min	23.5
DL Adj	mL/mmHg/min	23.5
DLCO/VA	mL/mHg/min/L	3.07
VA	Liters	
BHT	Sec	

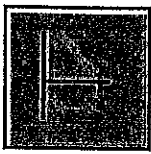
**Resistance**

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.11
Gaw	L/sec/cmH2O	0.947
sRaw	cmH2O/L/s/L	4.38
sGaw	L/s/cmH2O/L	0.228
Vtg (Raw)	Liters	

Comments:

Interpretation:





Name: AKP,  
 Gender: Male  
 Age: 67 Race:  
 Height(in): 72.0 Weight(lb): 195  
 Any Info:

Id: 038  
 Date: 12/04/13  
 Temp: 19 PBar: 622  
 Physician:  
 Technician: CRD

Spirometry	(BTPS)	PRE-RX		POST-RX		Post % Chg
		Ref	Pre Meas	Pre % Ref	Post Meas	
FVC	Liters	4.67	4.89	105		
FEV1	Liters	3.70	3.10	84		
FEV1/FVC %		78	64	81		
FEF25-75%L/sec		3.65	1.22	34		
FEF50%	L/sec	4.52	2.19	48		
FEF75%	L/sec	1.65	0.35	21		
IC	Liters					
VC	Liters	4.67				
PEF	L/sec	8.85	8.22	93		
MVV	L/min	138				
PIF	L/sec					
FEV1/FEV6%			71			

Lung Volumes/Plethysmography

	(BTPS)
Vtg	Liters
VC	Liters
TLC	Liters
RV	Liters
RV/TLC	%
FRC PL	Liters
ERV	Liters
IC	Liters

Diffusion

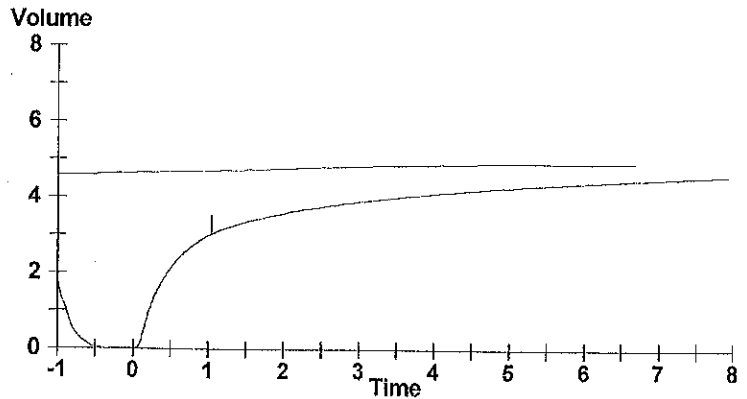
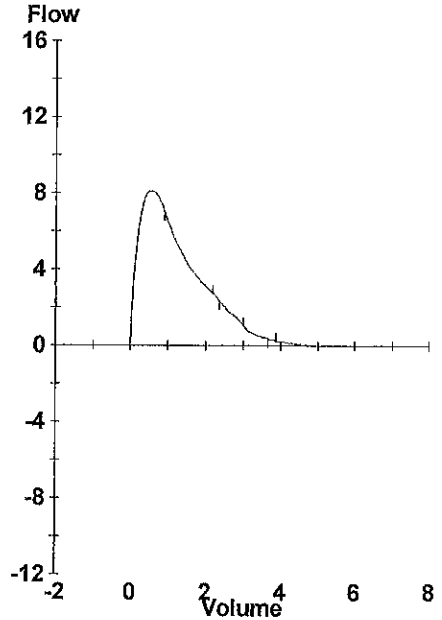
DLCO	mL/mmHg/min	23.5
DL Adj	mL/mmHg/min	23.5
DLCO/VA	mL/miHg/min/L	2.99
VA	Liters	
BHT	Sec	

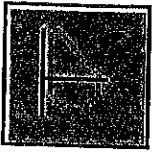
Resistance

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.11
Gaw	L/sec/cmH2O	0.947
sRaw	cmH2O/L/s/L	4.38
sGaw	L/s/cmH2O/L	0.228
Vtg (Raw)	Liters	

Comments:

Interpretation:

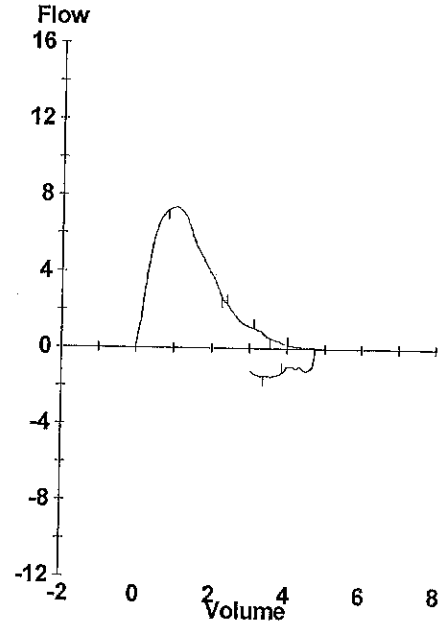




Name: DRR,  
 Gender: Male  
 Age: 67 Race: Caucasian  
 Height(in): 72.0 Weight(lb): 195  
 Any Info:

Id: AKP-038  
 Date: 12/11/13  
 Temp: 17 PBar: 634  
 Physician:  
 Technician: VL

Spirometry	(BTPS)	PRE-RX		POST-RX		Post % Chg
		Ref	Pre Meas	Pre % Ref	Post Meas	
FVC	Liters	4.67	4.75	102		
FEV1	Liters	3.70	3.16	85		
FEV1/FVC %		78	66	85		
FEF25-75%L/sec		3.65	1.77	48		
FEF50%	L/sec	4.52	2.48	55		
FEF75%	L/sec	1.65	0.55	33		
IC	Liters					
VC	Liters	4.67				
PEF	L/sec	8.85	9.34	106		
MVV	L/min	138				
PIF	L/sec		1.48			
FEV1/FEV6%			72			



Lung Volumes/Plethysmography (BTPS)

Vtg	Liters	
VC	Liters	4.67
TLC	Liters	7.03
RV	Liters	2.63
RV/TLC	%	40
FRC PL	Liters	3.94
ERV	Liters	
IC	Liters	

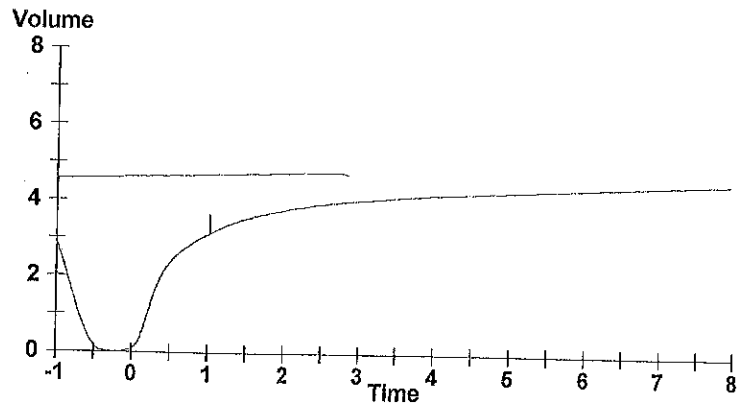
Diffusion

DLCO	mL/mmHg/min	23.5
DL Adj	mL/mmHg/min	23.5
DLCO/VA	mL/mHg/min/L	3.06
VA	Liters	
BHT	Sec	

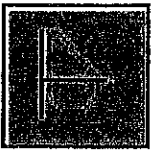
Resistance

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.11
Gaw	L/sec/cmH2O	0.947
sRaw	cmH2O/L/s/L	4.38
sGaw	L/s/cmH2O/L	0.228
Vtg (Raw)	Liters	

Comments:



Interpretation:



Name: AKP-038,  
 Gender: Male  
 Age: 67 Race:  
 Height(in): 72.0 Weight(lb): 195  
 Any Info:

Id: AKP-038  
 Date: 12/18/13  
 Temp: 20 PBar: 634  
 Physician:  
 Technician: CRD

Spirometry		(BTPS)	PRE-RX		POST-RX		
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	Post % Chg
FVC	Liters	4.67	5.12	110			
FEV1	Liters	3.70	3.21	87			
FEV1/FVC	%	78	63	80			
FEF25-75%	L/sec	3.65	1.38	38			
FEF50%	L/sec	4.52	2.23	49			
FEF75%	L/sec	1.65	0.38	23			
IC	Liters						
VC	Liters	4.67					
PEF	L/sec	8.85	9.00	102			
MVV	L/min	138					
PIF	L/sec						
FEV1/FEV6%			71				

**Lung Volumes/Plethysmography**

		(BTPS)
Vtg	Liters	
VC	Liters	4.67
TLC	Liters	7.03
RV	Liters	2.63
RV/TLC	%	40
FRC PL	Liters	3.94
ERV	Liters	
IC	Liters	

**Diffusion**

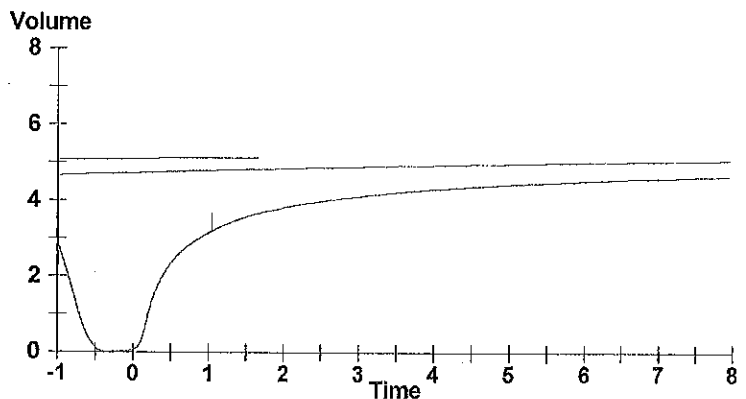
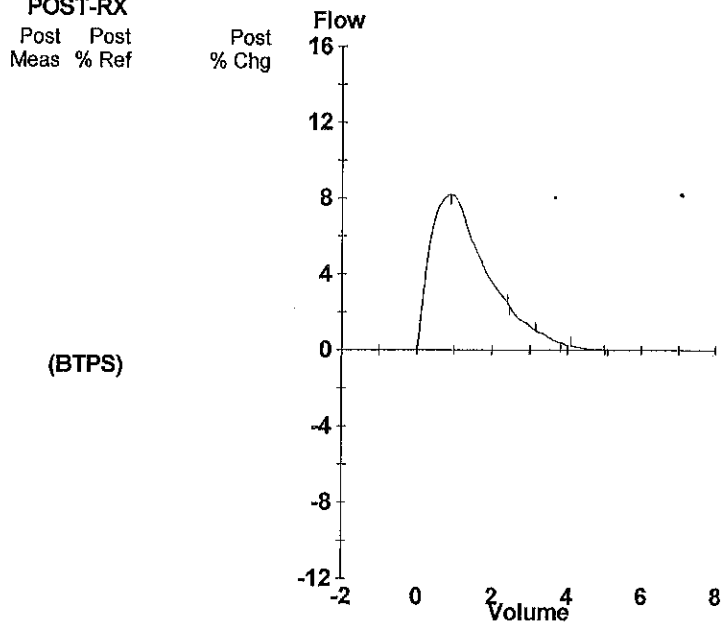
DLCO	mL/mmHg/min	23.5
DL Adj	mL/mmHg/min	23.5
DLCO/VA	mL/mHg/min/L	3.06
VA	Liters	
BHT	Sec	

**Resistance**

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.11
Gaw	L/sec/cmH2O	0.947
sRaw	cmH2O/L/s/L	4.38
sGaw	L/s/cmH2O/L	0.228
Vtg (Raw)	Liters	

Comments:

Interpretation:



EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (SCREEN DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

DAY AM	-7	-6	-5	-4	-3	-2	-1	0	0
Runny Nose 0 to 3	11/20/13 0 1 2 3	11/21/13 0 1 2 3	11/22/13 0 1 2 3	11/23/13 0 1 2 3	11/24/13 0 1 2 3	11/25/13 0 1 2 3	11/26/13 0 1 2 3	11/27/13 0 1 2 3	11/28/13 0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
DAY PM	-7	-6	-5	-4	-3	-2	-1	0	0
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

SCALE 0 to 3

- 0= No symptoms (no symptoms detected)
- 1= Mild symptoms (symptoms present but easily tolerated)
- 2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)
- 3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)
- Y=Yes N= No

AKP  
SUBJECT NUMBER: 038  
DATE COMPLETED: 11/27/13  
SUBJECT INITIALS AND DATE: DRD 11-27-13



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505 ) 938-8922

Lovelace Scientific Resources  
Leslie Byatt, MD  
2441 Ridgecrest Dr SE  
Albuquerque, NM 87108-5129

Client Nbr  
24664

PATIENT NAME <b>X, DRR</b>	PATIENT ID <b>AAG13116</b>	DOB <b>10/09/1946</b>	SEX <b>M</b>	REPORT STATUS <b>Final</b>	PAGE <b>1</b>
PHYSICIAN <b>Unlisted Physician,</b>	COLLECT DATE & TIME <b>11/27/2013 10:20</b>	RECEIVE DATE & TIME <b>11/27/2013 18:44</b>	PRINT DATE & TIME <b>11/28/2013 06:11</b>		
REQUISITION NO. <b>30920902</b>	PT. PHONE NO. <b>0</b>	PATIENT NO. <b>AKP038</b>			
COMMENTS :					

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Eos, Respiratory Phys, Addr, Phone	None seen	Not given		NS	

End of Report

*NS Pattern  
03 Dec 2013*

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

DAY	1	2	3	4	5	6	7	8	9
DAY AM	11/27/13	11/28/13	11/29/13	11/30/13	12/1/13	12/2/13	12/3/13	12/4/13	12/5/13
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
DAY PM	1	2	3	4	5	6	7	8	9
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N=No

SUBJECT NUMBER: AKP038 DATE COMPLETED: 12/4/13

SUBJECT INITIALS AND DATE: AKP 12/4/13



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Scientific Resources  
 Leslie Byatt, MD  
 2441 Ridgecrest Dr SE  
 Albuquerque, NM 87108-5129

Client Nbr  
 24664

PATIENT NAME: **DRR, DRR**      PATIENT ID: **AAGI5588**      DOB: **10/09/1946**      SEX: **M**      REPORT STATUS: **Final**      PAGE: **1**  
 PHYSICIAN: **Unlisted Physician,**      COLLECT DATE & TIME: **12/04/2013 10:16**      RECEIVE DATE & TIME: **12/04/2013 20:05**      PRINT DATE & TIME: **12/05/2013 06:16**  
 REQUISITION NO.: **31033175**      PT. PHONE NO.: **0**      PATIENT NO.: **AKP038**  
 COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
<b>Comp Metabolic Panel</b>					
Sodium	140		mmol/L	134-144	
Potassium	4.3		mmol/L	3.5-5.1	
Chloride	106		mmol/L	98-111	
CO2	26		mmol/L	20-30	
Anion Gap	8			6-14	
Glucose	63		mg/dL	60-100	
BUN	31		mg/dL	7-31	
Creatinine	1.05		mg/dL	0.62-1.66	
Creatinine method is IDMS traceable. EstGFR calculation has been adjusted. Please note new reference range effective 5/23/2013.					
eGFR non-African Am	>60		mL/min/1.73m2	>60	
GFR Comment	Estimated GFR values are not accurate in acute kidney failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, the very old or very young, races other than Caucasian or African American, people with acute illnesses, or amputations.				
Calcium	9.0		mg/dL	8.4-10.4	
Total Protein	7.0		gm/dL	6.1-8.2	
Albumin	4.1		gm/dL	3.4-4.7	
Globulin	2.9		gm/dL	2.4-4.2	
Bilirubin, total	0.9		mg/dL	0.3-1.2	
Alk Phos	107		U/L	38-150	
AST(SGOT)	32		U/L	6-58	
ALT(SGPT)	53		U/L	14-87	
Fasting Phosphorus	NO				
Phosphorus	2.3		mg/dL	2.3-5.6	
<b>CBC</b>					
WBC	7.3		x10E3	4.0-10.6	
RBC	4.83		x10E6	4.64-6.00	
Hgb	15.5		gm/dL	14.5-17.7	
Hct	46		%	42-53	
MCV	94		fL	81-98	
MCHC	34.1		gm/dL	31.2-35.2	
RDW	13.0		%	11.0-14.5	
Platelets	269		x10E3	150-400	
Eos, Respiratory Phys, Addr, Phone	None seen			NS	
	NOT GIVEN				

End of Report

*From NCS  
 10 Dec 2013*



**EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT**

**DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)  
CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS**

DAY	7	8	9	10	11	12	13	14	15
AM	12/04/13	12/05/13	12/06/13	12/07/13	12/08/13	12/09/13	12/10/13	12/11/13	12/12/13
Runny Nose	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
0 to 3	0	1	2	3	0	1	2	3	0
Itchy Nose	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
0 to 3	0	1	2	3	0	1	2	3	0
Congestion	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
0 to 3	0	1	2	3	0	1	2	3	0
Sneezing	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
0 to 3	0	1	2	3	0	1	2	3	0
Voice Hoarse	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Y/N	YES	NO	YES	NO	YES	NO	YES	NO	YES
Throat Clearing	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Y/N	YES	NO	YES	NO	YES	NO	YES	NO	YES
DAY PM	7	8	9	10	11	12	13	14	15
Runny Nose	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
0 to 3	0	1	2	3	0	1	2	3	0
Itchy Nose	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
0 to 3	0	1	2	3	0	1	2	3	0
Congestion	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
0 to 3	0	1	2	3	0	1	2	3	0
Sneezing	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
0 to 3	0	1	2	3	0	1	2	3	0
Voice Hoarse	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Y/N	YES	NO	YES	NO	YES	NO	YES	NO	YES
Throat Clearing	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Y/N	YES	NO	YES	NO	YES	NO	YES	NO	YES

**SCALE 0 to 3**

- 0= No symptoms (no symptoms detected)
- 1= Mild symptoms (symptoms present but easily tolerated)
- 2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)
- 3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)
- Y=Yes N=No

SUBJECT NUMBER: AKP038 DATE COMPLETED: 12/11/13

SUBJECT INITIALS AND DATE: DRR 12/11/13



REFERENCE LABORATORIES  
1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505 ) 938-8922

Lovelace Scientific Resources  
Leslie Byatt, Clin Trials  
2441 Ridgecrest Dr SE  
Albuquerque, NM 87108-5129

Client Nbr  
24664

PATIENT NAME  
DRR, DRR

PATIENT ID  
AAGH5323

DOB  
10/09/1946

SEX  
M

REPORT STATUS  
Final

PAGE  
1

PHYSICIAN

COLLECT DATE & TIME  
12/11/2013 13:00

RECEIVE DATE & TIME  
12/11/2013 19:14

PRINT DATE & TIME  
12/12/2013 06:13

Unlisted Physician,

REQUISITION NO.

PT. PHONE NO.

PATIENT NO.

31033180

0

AKP038

COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Eos, Respiratory Phys, Addr, Phone	None seen	Not given		NS	

End of Report

*MM*  
12 Dec 13

Study Identification: 2749

LSR Study #: \_\_\_\_\_

Subject Number: AKP038

Subject Initials: DRR

**ADVERSE EVENT LOG**

\* Use DD/MMM/YYYY format for dates. If day is unknown, write UNK in the space provided. \*

Adverse Event	Is AE an SAE?	* Start Date	Severity	Action Taken	* End Date	Relationship to Study Drug (Refer to Protocol)	Investigator Initials / Date
Hypoglycemia	No	18/Dec/13	Mild	Followed up with his PCP Normal Results	03/Jan/2014	Not related	DRR / 21 Jan 14
							/
							/
							/
							/
							/
							/
							/

**SEVERITY KEY** (If severity changes in intensity, refer to protocol on how to record)  
 Mild: causes minimal discomfort; does not interfere with normal daily activities.  
 Moderate: causes sufficient discomfort to interfere with normal daily activities.  
 Severe: prevents normal daily activities.

*DRR* 27 Feb 2014

*Walter Byatt 2/26/14*

Study Identification 2749 Subject Initials DRK

Subject Number: AKP038 Date 11/21/13

Concomitant Medication Sheet

List all medications, including over the counter vitamins & supplements, that you currently take:

Name Of Medication	Indication	Dose/Unit Frequency	Route	Start Date	Stop Date
Atenolol	HBP	50mg/day	PO	2000	ongoing
ATORVASTATIN	cholesterol	40mg/day	PO	2013	ongoing
Azelastine HCl	Itchy eyes	1 drop/day	Eye	2013	ongoing
HCTZ	HBP	25mg/day	PO	2000	ongoing
LISINAPRIL Potassium	HBP	25mg/day	PO	2013	ongoing
Multivitamin	supplement	1/day	PO	2000	ongoing
ASA (81mg)	CAD prophylaxis	1 every other day	PO	2000	ongoing
THEOPHYLLINE	itchy eyes	PPN	Eye	2000	ongoing

*[Signature]* Sub E 18 Dec 2013

INVESTIGATOR SIGNATURE: *[Signature]* DATE: 12 Nov 2013

CRC SIGNATURE: *[Signature]* DATE: 18/Dec/13

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

DAY AM	14	15	16	17	18	19	20	21	22
Runny Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Itchy Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Congestion 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Sneezing 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Voice Hoarse Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO
Throat Clearing Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO
DAY PM	14	15	16	17	18	19	20	21	22
Runny Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Itchy Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Congestion 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Sneezing 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Voice Hoarse Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO
Throat Clearing Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO

SCALE 0 to 3

- 0= No symptoms (no symptoms detected)
  - 1= Mild symptoms (symptoms present but easily tolerated)
  - 2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)
  - 3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)
- Y=Yes N=No

SUBJECT NUMBER: DRR AKP/038 DATE COMPLETED: 12/18/13

SUBJECT INITIALS AND DATE: DMC 12/18/13



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Scientific Resources  
Leslie Byatt, Clinical Trials  
2441 Ridgcrest Dr SE  
Albuquerque, NM 87108-5129

Client Nbr  
24684

PATIENT NAME: **DRR, DRR**  
 PATIENT ID: **AAGJ2119** DOB: **10/09/1946** SEX: **M** REPORT STATUS: **Final** PAGE: **1**  
 PHYSICIAN: **Unlisted Physician,** COLLECT DATE & TIME: **12/18/2013 10:15** RECEIVE DATE & TIME: **12/18/2013 18:54** PRINT DATE & TIME: **12/19/2013 06:09**  
 REQUISITION NO.: **31033198** PT. PHONE NO.: **0** PATIENT NO.: **AKP038**  
 COMMENTS:

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
<b>Comp Metabolic Panel</b>					
Sodium	142		mmol/L	134-144	
Potassium	4.2		mmol/L	3.5-5.1	
Chloride	107		mmol/L	98-111	
CO2	29		mmol/L	20-30	
Anion Gap	6			6-14	
Glucose		44	mg/dL	60-100	
	verified by repeat analysis <i>See below</i> *L				
BUN	29		mg/dL	7-31	
Creatinine	0.98		mg/dL	0.62-1.66	
	Creatinine method is IDMS traceable. EstGFR calculation has been adjusted. Please note new reference range effective 5/23/2013.				
eGFR non-African Am	>60		mL/min/1.73m2	>60	
GFR Comment	Estimated GFR values are not accurate in acute kidney failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, the very old or very young, races other than Caucasian or African American, people with acute illnesses, or amputations.				
Calcium	9.5		mg/dL	8.4-10.4	
Total Protein	7.2		gm/dL	6.1-8.2	
Albumin	4.3		gm/dL	3.4-4.7	
Globulin	2.9		gm/dL	2.4-4.2	
Bilirubin, total	0.8		mg/dL	0.3-1.2	
Alk Phos	116		U/L	38-150	
AST(SGOT)	33		U/L	6-58	
ALT(SGPT)	51		U/L	14-67	
Fasting Phosphorus	NO				
Phosphorus	3.1		mg/dL	2.3-5.6	
<b>CBC</b>					
WBC	7.9		x10E3	4.0-10.6	
RBC	4.91		x10E6	4.64-6.00	
Hgb	16.0		gm/dL	14.5-17.7	
Hct	46		%	42-53	
MCV	94		fL	81-98	
MCHC	34.9		gm/dL	31.2-35.2	
RDW	12.9		%	11.0-14.5	
Platelets	284		x10E3	150-400	
Eos, Respiratory	None seen			NS	
Phys, Addr, Phone	Not given				

*MS  
19 Dec 2013*

Callback Accession Comments:

W3494863

GLU

12/18/2013 08:10 pm GIVEN TO lunch & NC CS11630

End of Report

*Patient has no hx of diabetes and is not on medication likely to decrease blood glucose. Will contact patient, who was asymptomatic in office for exam yesterday, 18 Dec 2013.*

*MDM Guino MD Sub-I  
19 Dec 2013*

DRR, DRR

12/19/2013 06:09

FAX24684

DRR/ AKP038  
12/18/13

**Effects of AkPharma's Calcium Glycerophosphate  
Nasal Spray wash (AkP 010112A) on Patient-Perceived Breathing Comfort**

**SATISFACTION QUESTIONNAIRE:**

Would you use / purchase this nasal wash product in the future?"  YES  NO

You are also encouraged to make any free comments regarding your experience in the use of this product regarding your opinion of any of its effects not covered specifically in the Daily Diary:

Overall, I really noticed no changes  
in my allergy symptoms

[Type text]

Subject initials and Date

DRR 12/18/13

Study Staff Initials and Date

Em 12/18/13

**AKP-039**



2,49 AKPharma PERENNIAL ALLERGIES  
SCREENING/VISIT 1 SOURCE DOCUMENTS

Initials: EAW Site #:      Subject #: AKP039

**PATIENT DEMOGRAPHICS**

**Patient Demographics**

Date of Birth: 13 Feb, 1962 (dd/mmm/yyyy)

Gender:  Male  Female

If female, Indicate Childbearing Potential

Childbearing  Surgically sterilized  Post-Menopausal

Ethnicity:  Hispanic  Non Hispanic

Race:  Asian  Black  Caucasian  American Indian

Pacific Islander  Other, Specify \_\_\_\_\_

**Smoking History**

Smoking Status:  None (smoked less than 100 cigarettes in lifetime)

Former (previously smoked more than 100 cigarettes in lifetime)

Current (smokes now)

If subject is a former or current smoker, please indicate:

Years smoked: \_\_\_\_\_

Cigarettes per day: \_\_\_\_\_

CRC Signature: Ushu Byatt Date: 12, NOV, 13 (dd/mmm/yy)



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Scientific Resources  
 Leslie Byatt, MD  
 2441 Ridgecrest Dr SE  
 Albuquerque, NM 87108-5129

Client Nbr  
 24664

PATIENT NAME **EAW, EAW** PATIENT ID **AAGH8333** DOB **02/13/1962** SEX **F** REPORT STATUS **Final** PAGE **1**

PHYSICIAN **AKP039** COLLECT DATE & TIME **11/18/2013 10:05** RECEIVE DATE & TIME **11/18/2013 20:28** PRINT DATE & TIME **11/20/2013 06:09**

REQUISITION NO. **30920942** PT. PHONE NO. **0** PATIENT NO. **AKP039**

COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Allerg, Panel 18					
Allerg, Juniper	<0.10		kU/L	<0.35	
Allerg, Cottonwood	<0.10		kU/L	<0.35	
Allerg, West. Ragweed	<0.10	0.90 H	kU/L	<0.35	
Allerg, Russian Thistle	<0.10		kU/L	<0.35	
Allerg, Bermuda Grass	<0.10		kU/L	<0.35	
Allerg, Alternaria	<0.10	0.70 H	kU/L	<0.35	
Allerg, Mesquite	<0.10		kU/L	<0.35	
Allerg, Cockroach	<0.10		kU/L	<0.35	
Allerg, Derm. pter.	<0.10		kU/L	<0.35	

The standard classification system utilizes the following class cutoffs.

Class	ku/L	Interpretation
0	<0.35	Negative for Allergen
I	0.35-0.69	Positive for Allergen
II	0.70-3.49	Strongly Positive
III	3.5-17.49	Strongly Positive
IV	17.5-52.49	Strongly Positive
V	52.5-99.99	Strongly Positive
VI	>100	Strongly Positive

Results with allergens scoring in Class 1 should be considered weakly positive or equivocal. Class 2 and higher should be considered positive. Although increasing class ranges (0-VI) are reflective of increasing concentrations of allergen-specific IgE, this may not correlate with the degree of clinical response when challenged with the specific allergen. The correlation of allergy laboratory results with clinical history is essential. A negative test may not rule out clinical allergy.

Allerg, Derm. farinae	<0.10	kU/L	<0.35
Allerg, Clad. herb.	<0.10	kU/L	<0.35
Allerg, Firebush	<0.10	kU/L	<0.35
Allerg, Cat Dander Ep	<0.10	kU/L	<0.35
Allerg, Dog Dander	<0.10	kU/L	<0.35
Allerg, Bluegrass	<0.10	kU/L	<0.35
Allerg, Pigweed	<0.10	kU/L	<0.35
Allerg, Mulberry	<0.10	kU/L	<0.35
Allerg, Helminth	<0.10	kU/L	<0.35

End of Report

*Salzer PI*  
 22 Nov 2013



Name: EAW,  
 Gender: Female  
 Age: 51 Race: Black  
 Height(in): 66.0 Weight(lb): 281  
 Any Info:

Id: AKP-039  
 Date: 12/03/13  
 Temp: 19 PBar: 625  
 Physician:  
 Technician: VL

Spirometry		(BTPS)	PRE-RX		POST-RX		Post
		Ref	Pre	Pre	Post	Post	Post
			Meas	% Ref	Meas	% Ref	% Chg
FVC	Liters	3.40	2.02	59			
FEV1	Liters	2.79	1.92	69			
FEV1/FVC	%	83	95	114			
FEF25-75%	L/sec	3.06	3.73	122			
FEF50%	L/sec	3.73	5.53	148			
FEF75%	L/sec	1.45	2.08	144			
IC	Liters						
VC	Liters	3.40					
PEF	L/sec	6.20	6.89	111			
MVV	L/min	99					
PIF	L/sec		2.42				
FEV1/FEV6%			98				

**Lung Volumes/Plethysmography**

Vtg	Liters	
VC	Liters	3.40
TLC	Liters	5.37
RV	Liters	1.92
RV/TLC	%	35
FRC PL	Liters	2.01
ERV	Liters	
IC	Liters	

**Diffusion**

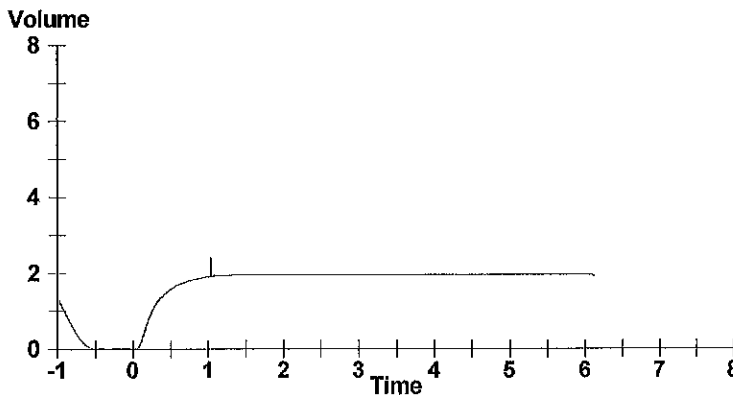
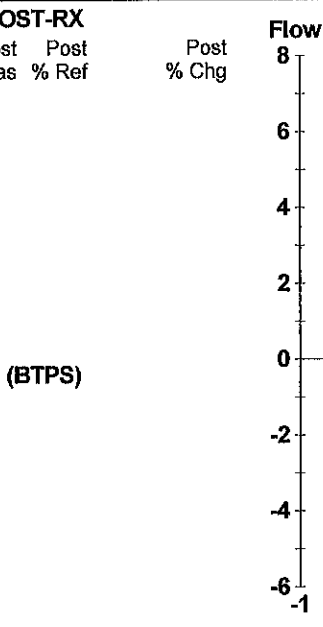
DLCO	mL/mmHg/min	30.4
DL Adj	mL/mmHg/min	30.4
DLCO/VA	mL/mHg/min/L	3.33
VA	Liters	
BHT	Sec	

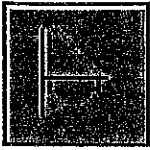
**Resistance**

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.99
Gaw	L/sec/cmH2O	0.481
sRaw	cmH2O/L/s/L	3.99
sGaw	L/s/cmH2O/L	0.251
Vtg (Raw)	Liters	

Comments:

Interpretation:





Name: AKP-039,  
 Gender: Female  
 Age: 51 Race:  
 Height(in): 66.0 Weight(lb): 281  
 Any Info:

Id: AKP-039  
 Date: 12/10/13  
 Temp: 16 PBar: 637  
 Physician:  
 Technician: CRD

Spirometry		(BTPS)	PRE-RX		POST-RX		Post
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	% Chg
FVC	Liters	3.40	2.40	71			
FEV1	Liters	2.79	2.12	76			
FEV1/FVC %		83	88	106			
FEF25-75%L/sec		3.06	3.11	102			
FEF50%	L/sec	3.73	** 5.79	** 155			
FEF75%	L/sec	1.45	1.26	87			
IC	Liters						
VC	Liters	3.40					
PEF	L/sec	6.20	6.76	109			
MVV	L/min	99					
PIF	L/sec		2.76				
FEV1/FEV6%			89				

**Lung Volumes/Plethysmography**

Parameter	Units	Value
Vtg	Liters	
VC	Liters	3.40
TLC	Liters	5.37
RV	Liters	1.92
RV/TLC	%	35
FRC PL	Liters	2.01
ERV	Liters	
IC	Liters	

**Diffusion**

DLCO	mL/mmHg/min	30.4
DL Adj	mL/mmHg/min	30.4
DLCO/VA	mL/mHg/min/L	3.40
VA	Liters	
BHT	Sec	

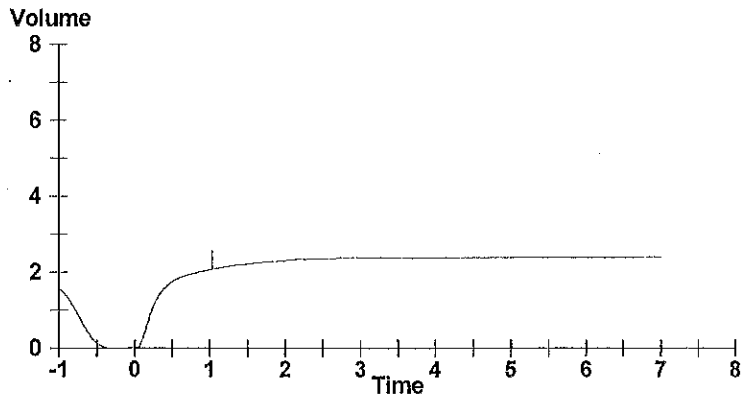
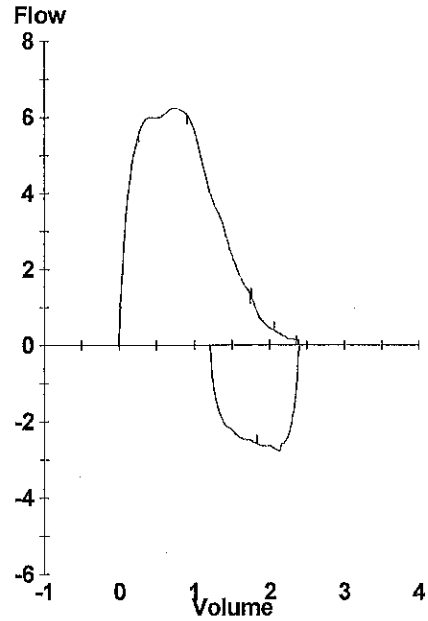
**Resistance**

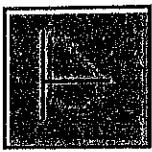
Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.99
Gaw	L/sec/cmH2O	0.481
sRaw	cmH2O/L/s/L	3.99
sGaw	L/s/cmH2O/L	0.251
Vtg (Raw)	Liters	

Comments:

Interpretation:

(BTPS)





Name: EAW,  
 Gender: Female  
 Age: 51 Race: Black  
 Height(in): 66.0 Weight(lb): 281  
 Any Info:

Id: AKP-039  
 Date: 12/17/13  
 Temp: 18 PBar: 638  
 Physician:  
 Technician: VL

Spirometry		(BTPS) Ref	PRE-RX		POST-RX		Post % Chg
			Pre Meas	Pre % Ref	Post Meas	Post % Ref	
FVC	Liters	3.40	2.34	69			
FEV1	Liters	2.79	2.11	76			
FEV1/FVC	%	83	90	109			
FEF25-75%	L/sec	3.06	2.94	96			
FEF50%	L/sec	3.73	4.68	125			
FEF75%	L/sec	1.45	1.29	90			
IC	Liters						
VC	Liters	3.40					
PEF	L/sec	6.20	7.05	114			
MVV	L/min	99					
PIF	L/sec		2.63				
FEV1/FEV6%			93				

**Lung Volumes/Plethysmography**

Parameter	Units	Value
Vtg	Liters	
VC	Liters	3.40
TLC	Liters	5.37
RV	Liters	1.92
RV/TLC	%	35
FRC PL	Liters	2.01
ERV	Liters	
IC	Liters	

**Diffusion**

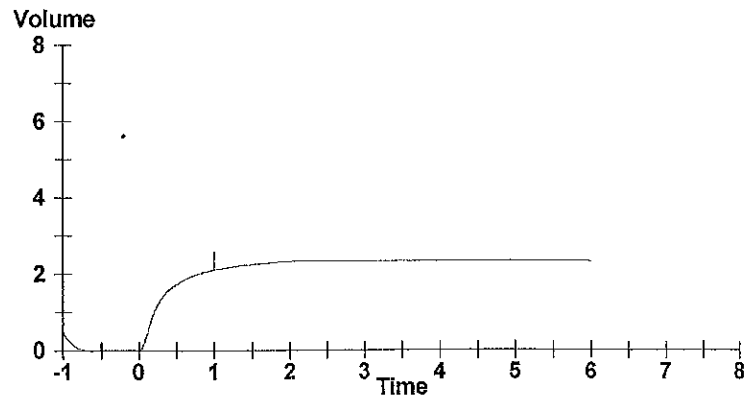
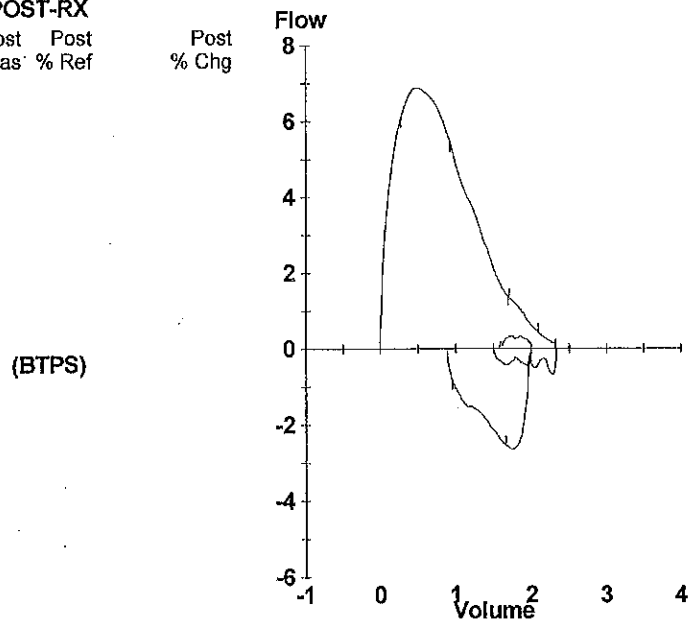
DLCO	mL/mmHg/min	30.4
DL Adj	mL/mmHg/min	30.4
DLCO/VA	mL/mHg/min/L	3.40
VA	Liters	
BHT	Sec	

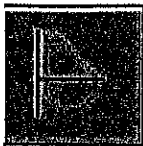
**Resistance**

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.99
Gaw	L/sec/cmH2O	0.481
sRaw	cmH2O/L/s/L	3.99
sGaw	L/s/cmH2O/L	0.251
Vtg (Raw)	Liters	

Comments:

Interpretation:





Name: AKP-039,  
 Gender: Female  
 Age: 51 Race:  
 Height(in): 66.0 Weight(lb): 281  
 Any Info:

Id: AKP-039  
 Date: 12/23/13  
 Temp: 18 PBar: 637  
 Physician:  
 Technician: CRD

Spirometry		(BTPS)	PRE-RX		POST-RX		Post
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	% Chg
FVC	Liters	3.40	2.36	69			
FEV1	Liters	2.79	2.03	73			
FEV1/FVC %		83	86	103			
FEF25-75%L/sec		3.06	2.43	79			
FEF50%	L/sec	3.73	3.88	104			
FEF75%	L/sec	1.45	0.87	60			
IC	Liters						
VC	Liters	3.40					
PEF	L/sec	6.20	6.92	112			
MVV	L/min	99					
PIF	L/sec		2.18				
FEV1/FEV6%			86				

**Lung Volumes/Plethysmography**

	Units	Value
Vtg	Liters	
VC	Liters	3.40
TLC	Liters	5.37
RV	Liters	1.92
RV/TLC	%	35
FRC PL	Liters	2.01
ERV	Liters	
IC	Liters	

**Diffusion**

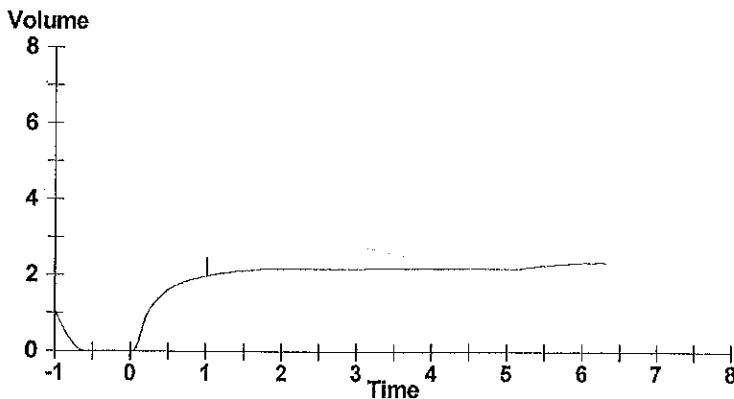
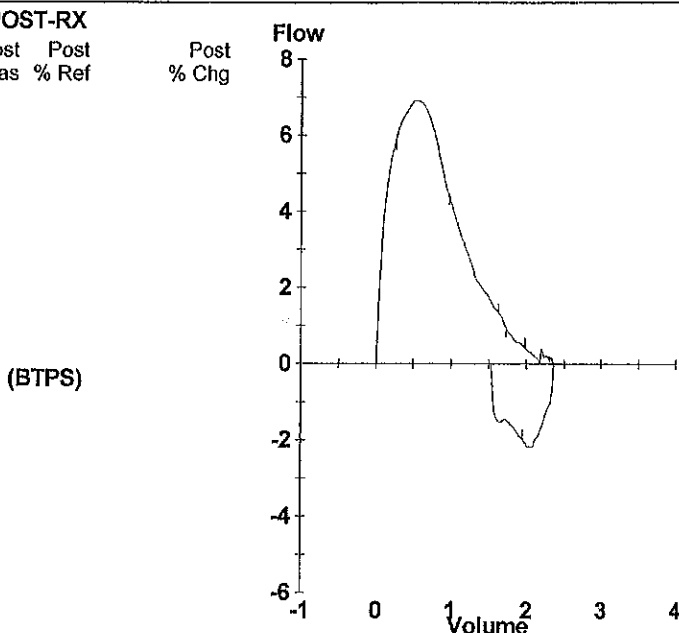
DLCO	mL/mmHg/min	30.4
DL Adj	mL/mmHg/min	30.4
DLCO/VA	mL/mHg/min/L	3.40
VA	Liters	
BHT	Sec	

**Resistance**

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.99
Gaw	L/sec/cmH2O	0.481
sRaw	cmH2O/L/s/L	3.99
sGaw	L/s/cmH2O/L	0.251
Vtg (Raw)	Liters	

Comments:

Interpretation:



EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT

Next visit @ 12:00

DAILY SYMPTOMS SCORE SHEET (SCREEN DIARY)  
CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

DAY AM	11/25	11/26	11/27	11/28	11/29	11/30	12/1	12/2	12/3
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
DAY PM	-7	-6	-5	-4	-3	-2	-1	0	0
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

Mon 12/23 11 AM

12/3

Start here.

SCALE 0 to 3

- 0= No symptoms (no symptoms detected)
- 1= Mild symptoms (symptoms present but easily tolerated)
- 2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)
- 3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)
- Y=Yes N= No

SUBJECT NUMBER: AKP037 DATE COMPLETED: 12/3/13

SUBJECT INITIALS AND DATE: EAW 12/3/2013



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Scientific Resources  
 Leslie Byatt, MD  
 2441 Ridgcrest Dr SE  
 Albuquerque, NM 87108-5129

Client Nbr  
 24664

PATIENT NAME: **X, EAW** PATIENT ID: **AAG14838** DOB: **02/13/1962** SEX: **F** REPORT STATUS: **Final** PAGE: **1**  
 PHYSICIAN: **Unlisted Physician,** COLLECT DATE & TIME: **12/03/2013 14:30** RECEIVE DATE & TIME: **12/03/2013 19:55** PRINT DATE & TIME: **12/04/2013 06:08**  
 REQUISITION NO.: **30920933** PT. PHONE NO.: **0** PATIENT NO.: **AKP039**  
 COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
<b>Comp Metabolic Panel</b>					
Sodium	142		mmol/L	134-144	
Potassium	4.0		mmol/L	3.5-5.1	
Chloride	108		mmol/L	98-111	
CO2	27		mmol/L	20-30	
Anion Gap	7			6-14	
Glucose	99		mg/dL	60-100	
BUN	13		mg/dL	7-31	
Creatinine	0.73		mg/dL	0.50-1.40	
Creatinine method is IDMS traceable. EstGFR Calculation has been adjusted. Please note new reference range effective 5/23/2013.					
eGFR non-African Am	>60		mL/min/1.73m2	>60	
GFR Comment	Estimated GFR values are not accurate in acute kidney failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, the very old or very young, races other than Caucasian or African American, people with acute illnesses, or amputations.				
Calcium	9.1		mg/dL	8.4-10.4	
Total Protein	7.3		gm/dL	6.1-8.2	
Albumin	3.7		gm/dL	3.4-4.7	
Globulin	3.6		gm/dL	2.4-4.2	
Bilirubin, total	0.3		mg/dL	0.3-1.2	
Alk Phos	100		U/L	38-150	
AST(SGOT)	18		U/L	6-58	
ALT(SGPT)	29		U/L	14-67	
Fasting	NO				
Phosphorus	4.3		mg/dL	2.3-5.6	
<b>CBC</b>					
WBC	8.6		x10E3	4.0-10.6	
RBC	4.47		x10E6	4.00-5.36	
Hgb		11.8	gm/dL	12.0-16.0	
Hct	39		%	36-48	
MCV	86		fL	81-98	
MCHC		30.6	gm/dL	31.2-35.2	
RDW		15.3	%	11.0-14.5	
Platelets	310		x10E3	150-400	
Eos, Respiratory		Few	*	NS	
Phys, Addr, Phone	NOT GIVEN				

*NCS [Signature]*  
*NCS [Signature]*  
*NCS [Signature]*  
 12 Dec 13

*[Signature]*  
 12 Dec 2013

End of Report



**EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT**

**DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)**

**CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS**

DAY AM	1 12/3/13	2 12/4/13	3 12/5/13	4 12/6/13	5 12/7/13	6 12/8/13	7 12/9/13	8 12/10/13	9 12/11/13
Runny Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Itchy Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Congestion 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Sneezing 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Voice Hoarse Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO
Throat Clearing Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO
<b>DAY PM</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>	<b>9</b>
Runny Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Itchy Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Congestion 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Sneezing 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Voice Hoarse Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO
Throat Clearing Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO

**SCALE 0 to 3**

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N= No

SUBJECT NUMBER: AKP 039 DATE COMPLETED: 12/10/13 SUBJECT INITIALS AND DATE: EAW 12/10/2013



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505 ) 938-8922

Lovelace Scientific Resources  
Leslie Byatt, CPH Trials  
2441 Ridgecrest Dr SE  
Albuquerque, NM 87108-5129

Client Nbr  
24664

PATIENT NAME **EAW, EAW** PATIENT ID **AAGH8333** DOB **02/13/1962** SEX **F** REPORT STATUS **Final** PAGE **1**

PHYSICIAN **Unlisted Physician,** COLLECT DATE & TIME **12/10/2013 14:12** RECEIVE DATE & TIME **12/10/2013 20:09** PRINT DATE & TIME **12/11/2013 09:17**

REQUISITION NO. **31033179** PT. PHONE NO. **0** PATIENT NO. **AKP039**

COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Eos, Respiratory Phys, Addr, Phone	NOT INDICATED	Rare *		NS	

End of Report

*Handwritten:* 11 Dec 2013  
*Handwritten:* 11 Dec 13

**EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT**

**DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)**

*CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS*

DAY AM	14	15	16	17	18	19	20	21	22
Runny Nose 0 to 3	12/10/13 0 1 2 3	12/11/13 0 1 2 3	12/12/13 0 1 2 3	12/13/13 0 1 2 3	12/14/13 0 1 2 3	12/15/13 0 1 2 3	12/16/13 0 1 2 3	12/17/13 0 1 2 3	12/18/13 0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
DAY PM	14	15	16	17	18	19	20	21	22
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

**SCALE 0 to 3**

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N= No

SUBJECT NUMBER: AKP039 DATE COMPLETED: \_\_\_\_\_

SUBJECT INITIALS AND DATE: EAW 12/17/2013



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505 ) 938-8922

Lovelace Scie Resources  
Leslie Byatt, Chir Trials  
2441 Ridgecrest Dr SE  
Albuquerque, NM 87108-5129

Client Nbr  
24664

PATIENT NAME **EAW, EAW** PATIENT ID **AAGH8333** DOB **02/13/1962** SEX **F** REPORT STATUS **Final** PAGE **1**

PHYSICIAN **Unlisted Physician,** COLLECT DATE & TIME **12/17/2013 13:30** RECEIVE DATE & TIME **12/17/2013 19:17** PRINT DATE & TIME **12/18/2013 07:01**

REQUISITION NO. **31033199** PT. PHONE NO. **0** PATIENT NO. **AKP039**

COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Eos, Respiratory Phys, Addr, Phone	None seen Not given			NS	

End of Report

*Normal Sub-I  
18 Dec 2013*



Study Identification: AKPharm LSR #: 2749

Subject Number: AKP039 Subject Initials: EPW.

**CONCOMITANT MEDICATION LOG**

List all prescription medications you are taking. Also include over-the-counter medications, vitamins and supplements.

Name of Medication	Indication (What you take it for)	Dose	Unit	Frequency	Route	* Start Date (Day/Month/Year)	Stop Date	Ongoing at EOS (for Clinic use)
EXAMPLE	Diabetes	500	MG	2 Tabs per day	Oral	UNK/AUG/1999		<input type="checkbox"/>
ASA	CAD prophylaxis	81	mg	QD	PO	2008		<input checked="" type="checkbox"/>
MVI	Supplement	1	tab	QD	PO	2002		<input checked="" type="checkbox"/>
Biotin	Supplement	1000	mg	QD	PO	2002		<input checked="" type="checkbox"/>
Vit. D3	Supplement	1000	IU	QD	PO	2002		<input checked="" type="checkbox"/>
Super B complex	Supplement	1	tab	QD	PO	2002		<input checked="" type="checkbox"/>
Folic Acid	Iron deficiency	400	mcg	QD	PO	2002		<input checked="" type="checkbox"/>
Co Q10	Supplement	100	mg	QD	PO	2008		<input checked="" type="checkbox"/>
Zyrtec	allergies	10	mg	<del>QD</del> prn	PO	2010	10/2013	<input type="checkbox"/>
Allegra	allergies	60	mg	prn	PO	2010	11/11/2013	<input type="checkbox"/>
Zaditor eye drops	allergies	1	drop	prn	drop	2010		<input checked="" type="checkbox"/>

\* If day or month of medication date is unknown, write UNK in space provided

Investigator Signature (at end of study): [Signature] Date: 23 Dec 2013  
 SC Signature (at end of study): [Signature] Date: 12/23/13

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

DAY	14	15	16	17	18	19	20	21	22
AM	12/17/13	12/18/13	12/19/13	12/20/13	12/21/13	12/22/13	12/23/13	12/24/13	12/25/13
Runny Nose 0 to 3	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0
Itchy Nose 0 to 3	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0
Congestion 0 to 3	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0
Sneezing 0 to 3	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0
Voice Hoarse Y/N	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES
Throat Clearing Y/N	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES
DAY PM	14	15	16	17	18	19	20	21	22
Runny Nose 0 to 3	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0
Itchy Nose 0 to 3	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0
Congestion 0 to 3	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0
Sneezing 0 to 3	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0	0 1 2 3 0
Voice Hoarse Y/N	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES
Throat Clearing Y/N	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES	YES NO YES

SCALE 0 to 3

- 0= No symptoms (no symptoms detected)
  - 1= Mild symptoms (symptoms present but easily tolerated)
  - 2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)
  - 3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)
- Y=Yes N= No

SUBJECT NUMBER: 039 DATE COMPLETED: 12/23/13 SUBJECT INITIALS AND DATE: EAW 12/23/2013



Lovelace Scientific Resources  
Leslie Byatt, MD  
2441 Ridgecrest Dr SE  
Albuquerque, NM 87108-5129

Client Nbr  
24664

PATIENT NAME: **EAW, EAW** PATIENT ID: **AAGH8333** DOB: **02/13/1962** SEX: **F** REPORT STATUS: **Final** PAGE: **1**  
 PHYSICIAN: **Unlisted Physician,** COLLECT DATE & TIME: **12/23/2013 11:30** RECEIVE DATE & TIME: **12/23/2013 18:38** PRINT DATE & TIME: **12/24/2013 06:03**  
 REQUISITION NO.: **31033188** PT. PHONE NO.: **0** PATIENT NO.: **AKP039**  
 COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
<b>Comp Metabolic Panel</b>					
Sodium	142		mmol/L	134-144	
Potassium	4.3		mmol/L	3.5-5.1	
Chloride	107		mmol/L	98-111	
CO2	26		mmol/L	20-30	
Anion Gap	9			6-14	
Glucose	94		mg/dL	60-100	
BUN	13		mg/dL	7-31	
Creatinine	0.63		mg/dL	0.50-1.40	
Creatinine method is IDMS traceable. EstGFR Calculation has been adjusted. Please note new reference range effective 5/23/2013.					
eGFR non-African Am	>60		mL/min/1.73m2	>60	
GFR Comment	Estimated GFR values are not accurate in acute kidney failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, the very old or very young, races other than Caucasian or African American, people with acute illnesses, or amputations.				
Calcium	9.7		mg/dL	8.4-10.4	
Total Protein	7.6		gm/dL	6.1-8.2	
Albumin	3.8		gm/dL	3.4-4.7	
Globulin	3.8		gm/dL	2.4-4.2	
Bilirubin, total		0.2 L	mg/dL	0.3-1.2	NCS WDP
Alk Phos	101		U/L	38-150	
AST(SGOT)	16		U/L	6-58	
ALT(SGPT)	30		U/L	14-67	
Fasting Phosphorus	Not given		mg/dL	2.3-5.6	
<b>CBC</b>					
WBC	8.6		x10E3	4.0-10.6	
RBC	4.62		x10E6	4.00-5.36	
Hgb	12.4		gm/dL	12.0-16.0	
Hct	39		%	36-48	
MCV	85		fL	81-98	
MCHC	31.5		gm/dL	31.2-35.2	
RDW		14.6 H	%	11.0-14.5	NCS WDP
Platelets	315		x10E3	150-400	
Eos, Respiratory Phys, Addr, Phone	Not given	Rare *		NS	NCS WDP

End of Report

*MDM*  
Sub-I  
2 Jan 2014



EAW  
AKPO39

12/23/13

Effects of AkPharma's Calcium Glycerophosphate  
Nasal Spray wash (AkP 010112A) on Patient-Perceived Breathing Comfort

SATISFACTION QUESTIONNAIRE:

Would you use / purchase this nasal wash product in the future?"  YES  NO

You are also encouraged to make any free comments regarding your experience in the use of this product regarding your opinion of any of its effects not covered specifically in the Daily Diary:

This nasal wash did decrease my symptoms of runny nose, itchy nose and congestion. I would suggest a different bottle, may a pump spray bottle for ease of use.

My nasal passages were dry most of the day after my morning use.

[Type text]

Subject initials and Date

EAW 12/23/2013

Study Staff Initials and Date

Em 12/23/13

**AKP-040**

2/49 AKPharma PERENNIAL ALLERGIES  
SCREENING/VISIT 1 SOURCE DOCUMENTS

Initials: AMC Site #:      Subject #: AKP040

PATIENT DEMOGRAPHICS

**Patient Demographics**

Date of Birth: 14 / NOV / 1981 (dd/mmm/yyyy)

Gender:  Male  Female

If female, Indicate Childbearing Potential

Childbearing  Surgically sterilized  Post-Menopausal

Ethnicity:  Hispanic  Non Hispanic

Race:  Asian  Black  Caucasian  American Indian

Pacific Islander  Other, Specify \_\_\_\_\_

**Smoking History**

Smoking Status:  None (smoked less than 100 cigarettes in lifetime)

Former (previously smoked more than 100 cigarettes in lifetime)

Current (smokes now)

If subject is a former or current smoker, please indicate:

Years smoked: \_\_\_\_\_ Cigarettes per day: \_\_\_\_\_

CRC Signature: Uska Byatt Date: 14 / NOV / 13 (dd/mmm/yy)

TriCore Reference Laboratories  
1001 Woodward Pl NE  
Albuquerque, NM 87102  
(505) 938-8922

Patient Name: AMC, AMC  
Medical Record: AAGH9651  
DOB: 11/14/1981 Age: 32Y Sex: M  
Account Number: 30920961  
Attending MD: Unlisted Physician  
Patient ID: AKP040  
Patient Phone: 0

W3426315 COLL: 11/20/2013 11:49 REC: 11/20/2013 20:13 PHYS: Unlisted Physician  
Req# : 30920961

Allerg, Panel 18

Allerg, Juniper	H	52.10	[<0.35]	kU/L	<i>NCS of 11/22/13</i>
Allerg, Cottonwood	H	18.80	[<0.35]	kU/L	<i>NCS of 11/22/13</i>
Allerg, West. Ragweed	H	8.00	[<0.35]	kU/L	<i>NCS of 11/22/13</i>
Allerg, Russian Thist	H	48.00	[<0.35]	kU/L	<i>NCS of 11/22/13</i>
Allerg, Bermuda Grass	H	31.50	[<0.35]	kU/L	<i>NCS of 11/22/13</i>
Allerg, Alternaria	H	<del>47.30</del>	[<0.35]	kU/L	<i>NCS of 11/22/13</i>
Allerg, Mesquite	H	12.30	[<0.35]	kU/L	<i>NCS of 11/22/13</i>
Allerg, Cockroach	H	<del>1.10</del>	[<0.35]	kU/L	<i>NCS of 11/22/13</i>
Allerg, Derm. pter.		<0.10	[<0.35]	kU/L	<i>NCS of 11/22/13</i>

The standard classification system utilizes the following class cutoffs.

Class	kU/L	Interpretation
0	<0.35	Negative for Allergen
I	0.35-0.69	Positive for Allergen
II	0.70-3.49	Strongly Positive
III	3.5-17.49	Strongly Positive
IV	17.5-52.49	Strongly Positive
V	52.5-99.99	Strongly Positive
VI	>100	Strongly Positive

Results with allergens scoring in Class 1 should be considered weakly positive or equivocal. Class 2 and higher should be considered positive. Although increasing class ranges (0-VI) are reflective of increasing concentrations of allergen-specific IgE, this may not correlate with the degree of clinical response when challenged with the specific allergen. The correlation of allergy laboratory results with clinical history is essential. A negative test may not rule out clinical allergy.

Allerg, Derm. farinae	0.10	[<0.35]	kU/L
Allerg, Clad. herb.	<0.10	[<0.35]	kU/L

CONTINUED

Printed: 11/22/2013 15:28

INTERIM REPORT

Patient Name: AMC, AMC  
Medical Record #: AAGH9651  
Location: CORE

Page: 1

*J. Salzer - Sub PI*  
*22 Nov 2013*

TriCore Reference Laboratories  
1001 Woodward Pl NE  
Albuquerque, NM 87102  
(505) 938-8922

Patient Name: AMC,AMC  
Medical Record: AAGH9651  
DOB:11/14/1981 Age:32Y Sex:M  
Account Number: 30920961  
Attending MD: Unlisted Physician  
Patient ID:AKP040  
Patient Phone:0

W3426315 COLL: 11/20/2013 11:49 REC: 11/20/2013 20:13 PHYS: Unlisted Physician  
Req# : 30920961

Allerg, Panel 18		(CONTINUED)		
Allerg, Firebush	H	9.50	[<0.35]	kU/L
Allerg, Cat Dander	Ep	12.30	[<0.35]	kU/L
Allerg, Dog Dander	Ep	2.40	[<0.35]	kU/L
Allerg, Bluegrass	H	21.80	[<0.35]	kU/L
Allerg, Pigweed	H	31.50,	[<0.35]	kU/L
Allerg, Mulberry	H	4.30	[<0.35]	kU/L
Allerg, Helminth		0.30	[<0.35]	kU/L

*NCS of 11/22/13*  
*NCS of 11/22/13*  
*NCS of 11/22/13*  
*NCS of 11/22/13*  
*NCS of 11/22/13*  
*NCS of 11/22/13*

W3426316 COLL: 11/20/2013 11:49 REC: 11/20/2013 20:13 PHYS: Unlisted Physician  
Req# : 30920961

Phys, Addr, Phone NO PHYSICIAN GIVEN

*J. Salza PI*  
*22 Nov 2013*

END OF REPORT

Printed: 11/22/2013 15:28

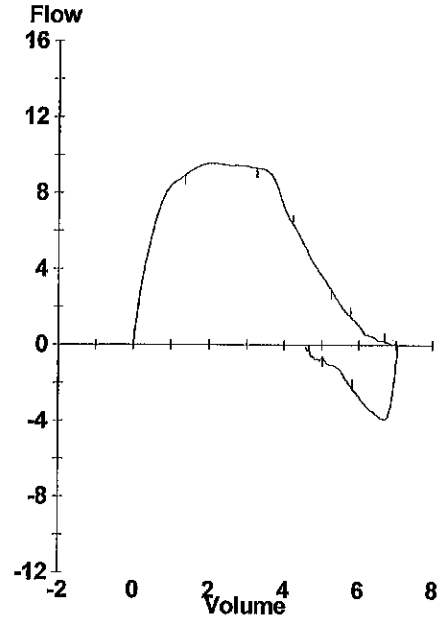
INTERIM REPORT

Patient Name: AMC,AMC  
Medical Record #: AAGH9651  
Location: CORE

Name: AMC,  
 Gender: Male  
 Age: 32 Race: Caucasian  
 Height(in): 72.0 Weight(lb): 308  
 Any Info:

Id: AKP-040  
 Date: 12/11/13  
 Temp: 17 PBar: 634  
 Physician:  
 Technician: VL

Spirometry		(BTPS)	PRE-RX		POST-RX		Post
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	% Chg
FVC	Liters	5.71	7.06	124			
FEV1	Liters	4.72	5.80	123			
FEV1/FVC	%	83	82	99			
FEF25-75%	L/sec	4.92	6.38	130			
FEF50%	L/sec	5.81	** 9.24	** 159			
FEF75%	L/sec	2.45	2.88	117			
IC	Liters						
VC	Liters	5.71					
PEF	L/sec	10.07	10.10	100			
MVV	L/min	182					
PIF	L/sec		3.89				
FEV1/FEV6%			83				



**Lung Volumes/Plethysmography**

Parameter	Units	Value
Vtg	Liters	
VC	Liters	5.71
TLC	Liters	7.56
RV	Liters	2.03
RV/TLC	%	28
FRC PL	Liters	3.13
ERV	Liters	
IC	Liters	

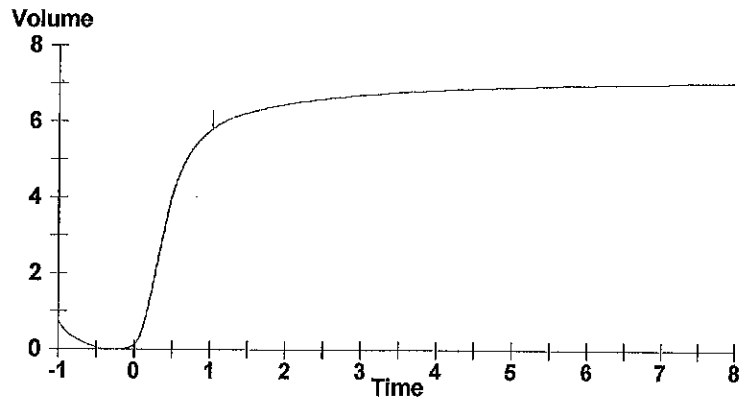
**Diffusion**

DLCO	mL/mmHg/min	38.9
DL Adj	mL/mmHg/min	38.9
DLCO/VA	mL/mHg/min/L	3.77
VA	Liters	
BHT	Sec	

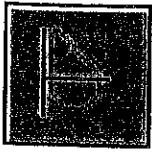
**Resistance**

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.48
Gaw	L/sec/cmH2O	0.752
sRaw	cmH2O/L/s/L	4.65
sGaw	L/s/cmH2O/L	0.215
Vtg (Raw)	Liters	

Comments:



Interpretation:



Name: AKP-040,  
 Gender: Male  
 Age: 32 Race:  
 Height(in): 71.5 Weight(lb): 308  
 Any Info:

Id: AKP-040  
 Date: 12/18/13  
 Temp: 20 PBar: 634  
 Physician:  
 Technician: CRD

Spirometry		(BTPS)	PRE-RX		POST-RX		Post
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	% Chg
FVC	Liters	5.63	7.28	129			
FEV1	Liters	4.65	5.95	128			
FEV1/FVC	%	83	82	98			
FEF25-75%	L/sec	4.86	6.20	128			
FEF50%	L/sec	5.74	8.14	142			
FEF75%	L/sec	2.42	2.35	97			
IC	Liters						
VC	Liters	5.63					
PEF	L/sec	9.95	** 15.04	** 151			
MVV	L/min	181					
PIF	L/sec		6.92				
FEV1/FEV6%			84				

**Lung Volumes/Plethysmography**

Parameter	Units	Value
Vtg	Liters	
VC	Liters	5.63
TLC	Liters	7.44
RV	Liters	2.00
RV/TLC	%	28
FRC PL	Liters	3.05
ERV	Liters	
IC	Liters	

**Diffusion**

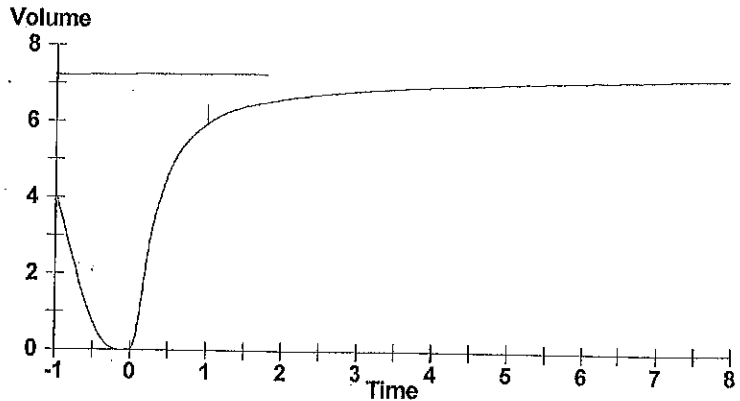
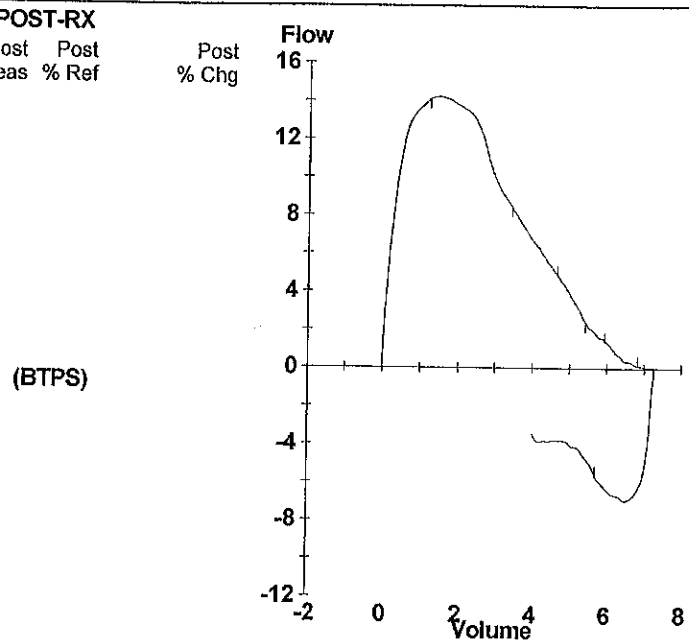
DLCO	mL/mmHg/min	38.7
DL Adj	mL/mmHg/min	38.7
DLCO/VA	mL/mHg/min/L	3.77
VA	Liters	
BHT	Sec	

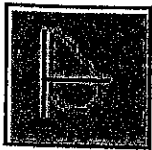
**Resistance**

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.54
Gaw	L/sec/cmH2O	0.732
sRaw	cmH2O/L/s/L	4.69
sGaw	L/s/cmH2O/L	0.213
Vtg (Raw)	Liters	

Comments:

Interpretation:





Name: AMC,  
 Gender: Male  
 Age: 32 Race: Hispanic  
 Height(in): 72.0 Weight(lb): 308  
 Any Info:

Id: AKP-040  
 Date: 12/26/13  
 Temp: 17 PBar: 637  
 Physician:  
 Technician: VL

Spirometry		(BTPS)	PRE-RX		POST-RX		
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	Post % Chg
FVC	Liters	5.71	7.64	134			
FEV1	Liters	4.72	6.22	132			
FEV1/FVC	%	83	81	98			
FEF25-75%	L/sec	4.92	6.61	134			
FEF50%	L/sec	5.81	** 8.96	** 154			
FEF75%	L/sec	2.45	2.57	105			
IC	Liters						
VC	Liters	5.71					
PEF	L/sec	10.07	** 15.11	** 150			
MVV	L/min	182					
PIF	L/sec		2.09				
FEV1/FEV6%			83				

Lung Volumes/Plethysmography

Lung Volumes/Plethysmography		(BTPS)
Vtg	Liters	
VC	Liters	5.71
TLC	Liters	7.56
RV	Liters	2.03
RV/TLC	%	28
FRC PL	Liters	3.13
ERV	Liters	
IC	Liters	

Diffusion

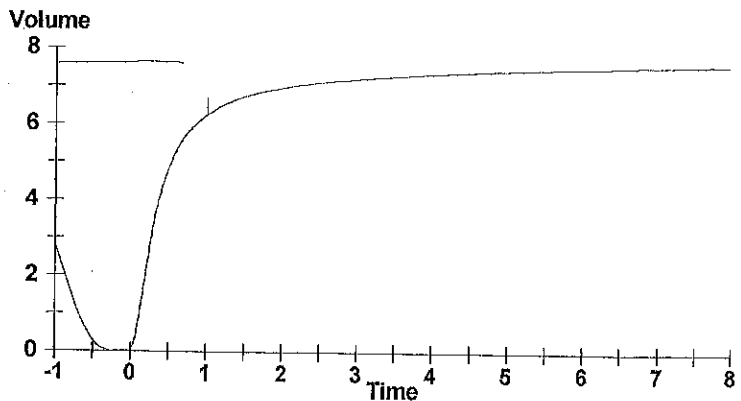
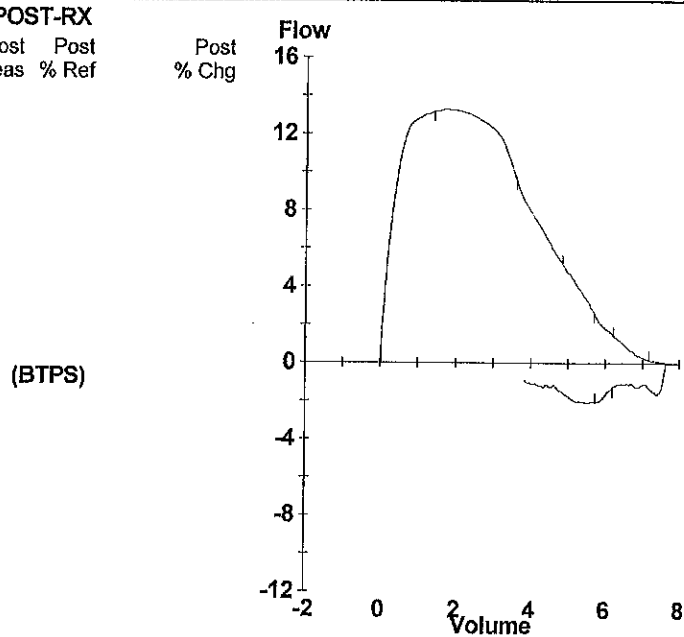
DLCO	mL/mmHg/min	38.9
DL Adj	mL/mmHg/min	38.9
DLCOVA	mL/mHg/min/L	3.79
VA	Liters	
BHT	Sec	

Resistance

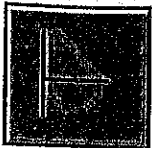
Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.48
Gaw	L/sec/cmH2O	0.752
sRaw	cmH2O/L/s/L	4.65
sGaw	L/s/cmH2O/L	0.215
Vtg (Raw)	Liters	

Comments:

Interpretation:







Name: AMC,  
 Gender: Male  
 Age: 32 Race:  
 Height(in): 71.5 Weight(lb): 308  
 Any Info:

Id: AKP-040  
 Date: 01/02/14  
 Temp: 18 PBar: 637  
 Physician:  
 Technician: CRD

Spirometry		(BTPS)	PRE-RX		POST-RX		
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	Post % Chg
FVC	Liters	5.63	7.00	124			
FEV1	Liters	4.65	5.70	122			
FEV1/FVC	%	83	82	98			
FEF25-75%	L/sec	4.86	5.74	118			
FEF50%	L/sec	5.74	7.33	128			
FEF75%	L/sec	2.42	2.56	106			
IC	Liters						
VC	Liters	5.63					
PEF	L/sec	9.95	13.47	135			
MVV	L/min	181					
PIF	L/sec		4.85				
FEV1/FEV6%			82				

**Lung Volumes/Plethysmography**

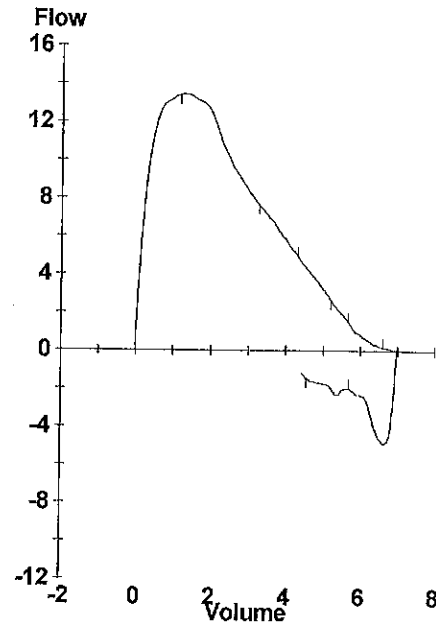
		(BTPS)
Vtg	Liters	
VC	Liters	5.63
TLC	Liters	7.44
RV	Liters	2.00
RV/TLC	%	28
FRC PL	Liters	3.05
ERV	Liters	
IC	Liters	

**Diffusion**

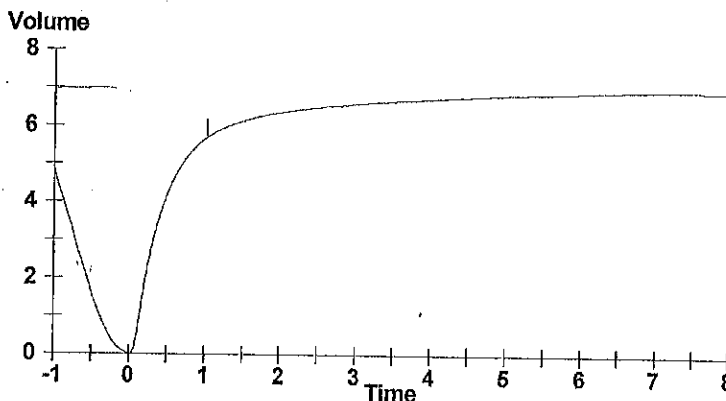
DLCO	mL/mmHg/min	38.7
DL Adj	mL/mmHg/min	38.7
DLCOVA	mL/mHg/min/L	3.79
VA	Liters	
BHT	Sec	

**Resistance**

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.54
Gaw	L/sec/cmH2O	0.732
sRaw	cmH2O/L/s/L	4.69
sGaw	L/s/cmH2O/L	0.213
Vtg (Raw)	Liters	



Comments:



Interpretation:

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (SCREEN DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

DAY AM	-7	-6	-5	-4	-3	-2	-1	0	0
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
DAY PM	-7	-6	-5	-4	-3	-2	-1	0	0
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

SCALE 0 to 3

- 0= No symptoms (no symptoms detected)
- 1= Mild symptoms (symptoms present but easily tolerated)
- 2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)
- 3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)
- Y=Yes N= No

SUBJECT NUMBER: AKP040 DATE COMPLETED: 12/11/13

SUBJECT INITIALS AND DATE: AMC 12-11-13



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505 ) 938-8922

Lovelace Scientific Resources  
Leslie Byatt, MD  
2441 Ridgecrest Dr SE  
Albuquerque, NM 87108-5129

Client Nbr  
24664

PATIENT NAME **AMC, AMC** PATIENT ID **AAGH9651** DOB **11/14/1981** SEX **M** REPORT STATUS **Final** PAGE **1**

PHYSICIAN **Unlisted Physician,** COLLECT DATE & TIME **12/11/2013 11:30** RECEIVE DATE & TIME **12/11/2013 19:31** PRINT DATE & TIME **12/12/2013 06:13**

REQUISITION NO. **31033170** PT. PHONE NO. **0** PATIENT NO. **AKP040**

COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
<b>Comp Metabolic Panel</b>					
Sodium	138		mmol/L	134-144	
Potassium	4.2		mmol/L	3.5-5.1	
Chloride	106		mmol/L	98-111	
CO2	23		mmol/L	20-30	
Anion Gap	9			6-14	
Glucose		105 H	mg/dL	60-100	<i>NCS NDM 12 Dec 13</i>
Impaired fasting glucose (IFG) is defined as a fasting glucose level of 100-126 mg/dL. (ADA Guidelines Diabetes Care 26: (3160-3167)2003)					
BUN	7		mg/dL	7-31	
Creatinine	0.92		mg/dL	0.62-1.66	
Creatinine method is IDMS traceable. EstGFR Calculation has been adjusted. Please note new reference range effective 5/23/2013.					
eGFR non-African Am	>60		mL/min/1.73m2	>60	
GFR Comment	Estimated GFR values are not accurate in acute kidney failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, the very old or very young, races other than Caucasian or African American, people with acute illnesses, or amputations.				
Calcium	8.9		mg/dL	8.4-10.4	
Total Protein	7.0		gm/dL	6.1-8.2	
Albumin	3.8		gm/dL	3.4-4.7	
Globulin	3.2		gm/dL	2.4-4.2	
Bilirubin, total	0.4		mg/dL	0.3-1.2	
Alk Phos	79		U/L	38-150	
AST(SGOT)	28		U/L	6-58	
ALT(SGPT)		80 H	U/L	14-67	<i>NCS NDM 12 Dec 13</i>
Fasting Phosphorus	NO				
Phosphorus	2.9		mg/dL	2.3-5.6	
<b>CBC</b>					
WBC	4.9		x10E3	4.0-10.6	
RBC	5.82		x10E6	4.64-6.00	
Hgb	17.0		gm/dL	14.5-17.7	
Hct	50		%	42-53	
MCV	86		fL	81-98	
MCHC	34.1		gm/dL	31.2-35.2	
RDW	12.6		%	11.0-14.5	
Platelets	191		x10E3	150-400	
Eos, Respiratory	None seen			NS	
Phys, Addr, Phone	Not given				

End of Report

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

DAY AM	12/11/13	12/12/13	12/13/13	12/14/13	12/15/13	12/16/13	12/17/13	12/18/13	12/19/13
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
<b>DAY PM</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>	<b>9</b>
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

**SCALE 0 to 3**

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N= No

SUBJECT NUMBER: AKP010112A DATE COMPLETED: 12-18-13

SUBJECT INITIALS AND DATE: 12-18-13 AC



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505 ) 938-8922

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Albuquerque, NM 87108-5129

Client Nbr  
24664

PATIENT NAME: **AMC, AMC**      PATIENT ID: **AAGH9651**      DOB: **11/14/1981**      SEX: **M**      REPORT STATUS: **Final**      PAGE: **1**

PHYSICIAN: **Unlisted Physician,**      COLLECT DATE & TIME: **12/18/2013 11:10**      RECEIVE DATE & TIME: **12/18/2013 18:49**      PRINT DATE & TIME: **12/19/2013 06:09**

REQUISITION NO.: **31033200**      PT. PHONE NO.: **0**      PATIENT NO.: **AKP040**

COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Eos, Respiratory Phys, Addr, Phone	None seen	Unknown		NS	

End of Report

*Not available  
19 Dec 2013*

**EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT**

**DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)**

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

DAY	7	8	9	10	11	12	13	14	15
AM	12/18/13	12/19/13	12/20/13	12/21/13	12/22/13	12/23/13	12/24/13	12/25/13	12/26/13
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
DAY PM	7	8	9	10	11	12	13	14	15
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

**SCALE 0 to 3**

- 0= No symptoms (no symptoms detected)
- 1= Mild symptoms (symptoms present but easily tolerated)
- 2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)
- 3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

SUBJECT NUMBER: AMC

DATE COMPLETED: 12/26/13

SUBJECT INITIALS AND DATE: 12-26-13 JFC



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505 ) 938-8922

Lovelace Scientific Resources  
Leslie Byatt, MD  
2441 Ridgecrest Dr SE  
Albuquerque, NM 87108-5129

Client Nbr  
24664

PATIENT NAME <b>AMC, AMC</b>	PATIENT ID <b>AAGH9651</b>	DOB <b>11/14/1981</b>	SEX <b>M</b>	REPORT STATUS <b>Final</b>	PAGE <b>1</b>
PHYSICIAN <b>Unlisted Physician,</b>	COLLECT DATE & TIME <b>12/26/2013 11:09</b>	RECEIVE DATE & TIME <b>12/26/2013 18:42</b>	PRINT DATE & TIME <b>12/27/2013 06:03</b>		
REQUISITION NO. <b>31033201</b>	PT. PHONE NO. <b>0</b>	PATIENT NO. <b>AKP040</b>			
COMMENTS :					

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Eos, Respiratory Phys, Addr, Phone	None seen NOT INDICATED			NS	

End of Report

*Handwritten signature and date: 2 Jan 2014*

Study Identification: AK Pharma LSR Study #: 2749

Subject Number: AKP040 Subject Initials: AMC

ADVERSE EVENT LOG

Adverse Event	** Start Date (DD/MMM/YYYY)	SEVERITY	Relationship to Study Drug (Suspected/Not Suspected)	** End Date (DD/MMM/YYYY)	Action Taken	Investigator Initials/Date
<i>Intermittent headaches after study med application</i>	<i>29 Dec/2013</i>	<i>Mild</i>	<i>Suspected</i>	<i>29/Dec/2013</i>	<i>med taken</i>	<i>AMC 27 Feb 14</i>

\*\* If day is unknown, write UNK in space provided, but every effort should be made to be as specific as possible \*\*

Investigator Signature (at end of study): [Signature] Date: 27 Feb 2014  
SC Signature (at end of study): [Signature] Date: 2/21/14  
PAGE: 2 of 1



Study Identification: AKPharmc

LSR #: 2749

Subject Number: AKP040

Subject Initials: AMC

### CONCOMITANT MEDICATION LOG

List all prescription medications you are taking. Also include over-the-counter medications, vitamins and supplements.

Name of Medication	Indication (What you take it for)	Dose	Unit	Frequency	Route	* Start Date (Day/Month/Year)	Stop Date	Ongoing at EOS (for Clinic use)
EXAMPLE	Diabetes	500	MG	2 Tabs per day	Oral	UNK/AUG/1999		<input type="checkbox"/>
<u>omeprazole</u>	<u>heartburn</u>	<u>40</u>	<u>mg</u>	<u>QD</u>	<u>PO</u>	<u>8/2013</u>		<input checked="" type="checkbox"/>
<u>Benadryl</u>	<u>Allergys</u>	<u>60</u>	<u>mg</u>	<u>prn</u>	<u>PO</u>	<u>1990</u>	<u>11/13/13</u>	<input type="checkbox"/>
<u>Zyrtec</u>	<u>Allergys</u>	<u>10</u>	<u>mg</u>	<u>prn</u>	<u>PO</u>	<u>2011</u>	<u>9/2013</u>	<input type="checkbox"/>
<u>Steroid inj.</u>	<u>Allergys</u>	<u>1</u>	<u>mg</u>	<u>QD</u>	<u>PO</u>	<u>9/2013</u>	<u>9/2013</u>	<input type="checkbox"/>
<u>Aspirin</u>	<u>Headache-</u>	<u>325</u>	<u>mg</u>	<u>PRN</u>	<u>PO</u>	<u>20/Dec/2013</u>	<u>29/Dec/2013</u>	<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>

\* If day or month of medication date is unknown, write UNK in space provided

Investigator Signature (at end of study): [Signature]

Date: 27 Feb 2014

SC Signature (at end of study): [Signature]

Date: 2/27/14

**EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT**

**DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)**

**CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS**

DAY AM	14	15	16	17	18	19	20	21	22
Runny Nose 0 to 3	12/26/13 0 1 2 3	12/27/13 0 1 2 3	12/28/13 0 1 2 3	12/29/13 0 1 2 3	12/30/13 0 1 2 3	12/31/13 0 1 2 3	01/01/14 0 1 2 3	01/02/14 0 1 2 3	01/03/14 0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
<b>DAY PM</b>	<b>14</b>	<b>15</b>	<b>16</b>	<b>17</b>	<b>18</b>	<b>19</b>	<b>20</b>	<b>21</b>	<b>22</b>
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

**SCALE 0 to 3**

- 0 = No symptoms (no symptoms detected)
  - 1 = Mild symptoms (symptoms present but easily tolerated)
  - 2 = Moderate symptoms (awareness of symptoms, bothersome but tolerable)
  - 3 = Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)
- Y=Yes N=No

SUBJECT NUMBER: AKP04D

DATE COMPLETED: 1-2-14

SUBJECT INITIALS AND DATE: [Signature]

1-2-14



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Sci. Resources  
 Leslie Byatt, Clin Trials  
 2441 Ridgecrest Dr SE  
 Albuquerque, NM 87108-5129

Client Nbr  
 24664

PATIENT NAME: **AMC, AMC** PATIENT ID: **AAGH9651** DOB: **11/14/1981** SEX: **M** REPORT STATUS: **Final** PAGE: **1**  
 PHYSICIAN: **Unlisted Physician,** COLLECT DATE & TIME: **01/02/2014 10:00** RECEIVE DATE & TIME: **01/02/2014 19:08** PRINT DATE & TIME: **01/03/2014 06:02**  
 REQUISITION NO.: **30920925** PT. PHONE NO.: **0** PATIENT NO.: **AKP040**  
 COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
<b>Comp Metabolic Panel</b>					
Sodium	140		mmol/L	134-144	
Potassium	4.0		mmol/L	3.5-5.1	
Chloride	107		mmol/L	98-111	
CO2	24		mmol/L	20-30	
Anion Gap	9			6-14	
Glucose		149	mg/dL	60-100	NCS [Signature]
BUN	9		mg/dL	7-31	
Creatinine	0.91		mg/dL	0.62-1.66	
Creatinine method is IDMS traceable. EstGFR Calculation has been adjusted. Please note new reference range effective 5/23/2013.					
eGFR non-African Am	>60		mL/min/1.73m2	>60	
GFR Comment	Estimated GFR values are not accurate in acute kidney failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, the very old or very young, races other than Caucasian or African American, people with acute illnesses, or amputations.				
Calcium	8.5		mg/dL	8.4-10.4	
Total Protein	6.9		gm/dL	6.1-8.2	
Albumin	3.7		gm/dL	3.4-4.7	
Globulin	3.2		gm/dL	2.4-4.2	
Bilirubin, total	0.3		mg/dL	0.3-1.2	
Alk Phos	90		U/L	38-150	
AST(SGOT)	24		U/L	6-58	
ALT(SGPT)		74	U/L	14-87	NCS [Signature]
Fasting Phosphorus	YES				
Phosphorus	2.4		mg/dL	2.3-5.6	
<b>CBC</b>					
WBC	5.0		x10E3	4.0-10.6	
RBC		6.01	x10E6	4.64-6.00	NCS [Signature]
Hgb	17.2		gm/dL	14.5-17.7	
Hct	51		%	42-53	
MCV	84		fL	81-98	
MCHC	33.9		gm/dL	31.2-35.2	
RDW	12.8		%	11.0-14.5	
Platelets	197		x10E3	150-400	
Eos, Respiratory		Moderate	*	NS	NCS [Signature]
Phys, Addr, Phone	NOT GIVEN				

End of Report

*[Handwritten Signature]*  
 Sub I  
 7 Jan 2014

AMC1040

1/2/14

Effects of AkPharma's Calcium Glycerophosphate  
Nasal Spray wash (AkP 010112A) on Patient-Perceived Breathing Comfort

SATISFACTION QUESTIONNAIRE:

Would you use / purchase this nasal wash product in the future?"  YES  NO

You are also encouraged to make any free comments regarding your experience in the use of this product regarding your opinion of any of its effects not covered specifically in the Daily Diary:

I didnt notice a huge change  
It did seem to dry out my  
nose which ~~was~~ helped I would  
like to try it for a longer ~~per~~  
period to see what other benefits it  
may offer.

[Type text]

Subject initials and Date

*AC* 1-2-14

Study Staff Initials and Date

*EM* 1-2-14

**AKP-041**

49 AKPharma PERENNIAL ALLERGIES  
SCREENING/VISIT 1 SOURCE DOCUMENTS

Initials: NLD Site #: \_\_\_\_\_ Subject #: 041

PATIENT DEMOGRAPHICS

**Patient Demographics**

Date of Birth: 02, Feb 1988 (dd/mmm/yyyy)

Gender:  Male  Female

If female, Indicate Childbearing Potential

Childbearing  Surgically sterilized  Post-Menopausal

Ethnicity:  Hispanic  Non Hispanic

Race:  Asian  Black  Caucasian  American Indian

Pacific Islander  Other, Specify \_\_\_\_\_

**Smoking History**

Smoking Status:  None (smoked less than 100 cigarettes in lifetime)

Former (previously smoked more than 100 cigarettes in lifetime)

Current (smokes now)

If subject is a former or current smoker, please indicate:

Years smoked: \_\_\_\_\_ Cigarettes per day: \_\_\_\_\_

CRC Signature: Erica Maldonado Date: 15 NOV 13 (dd/mmm/yy)



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Lovelace Scientific Resources  
 Leslie Byatt, MD  
 2441 Ridgcrest Dr SE  
 Albuquerque, NM 87108-5129

Client Nbr  
 24684

PATIENT NAME: **NLD, NLD** PATIENT ID: **AAGH8310** DOB: **02/02/1988** SEX: **F** REPORT STATUS: **Final** PAGE: **1**  
 PHYSICIAN: **Unlisted Physician,** COLLECT DATE & TIME: **11/15/2013 14:16** RECEIVE DATE & TIME: **11/18/2013 19:56** PRINT DATE & TIME: **11/20/2013 06:09**  
 REQUISITION NO.: **30920941** PT. PHONE NO.: **0** PATIENT NO.: **AKP041**  
 COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Allerg, Panel 18					
Allerg, Juniper		31.20 H	KU/L	<0.35	
Allerg, Cottonwood		1.50 H	KU/L	<0.35	
Allerg, West. Ragweed	<0.10		KU/L	<0.35	
Allerg, Russian Thistle		2.60 H	KU/L	<0.35	
Allerg, Bermuda Grass	<0.10		KU/L	<0.35	
Allerg, Alternaria		5.30 H	KU/L	<0.35	
Allerg, Mesquite		0.90 H	KU/L	<0.35	
Allerg, Cockroach		0.90 H	KU/L	<0.35	
Allerg, Derm. pter.		0.40 H	KU/L	<0.35	

The standard classification system utilizes the following class cutoffs.

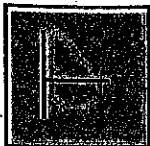
Class	ku/L	Interpretation
0	<0.35	Negative for Allergen
I	0.35-0.69	Positive for Allergen
II	0.70-3.49	Strongly Positive
III	3.5-17.49	Strongly Positive
IV	17.5-52.49	Strongly Positive
V	52.5-99.99	Strongly Positive
VI	>100	Strongly Positive

Results with allergens scoring in Class 1 should be considered weakly positive or equivocal. Class 2 and higher should be considered positive. Although increasing class ranges (0-VI) are reflective of increasing concentrations of allergen-specific IgE, this may not correlate with the degree of clinical response when challenged with the specific allergen. The correlation of allergy laboratory results with clinical history is essential. A negative test may not rule out clinical allergy.

Allerg, Derm. farinae		0.40 H	KU/L	<0.35
Allerg, Clad. herb.	<0.10		KU/L	<0.35
Allerg, Firebush		0.50 H	KU/L	<0.35
Allerg, Cat Dander Ep		3.70 H	KU/L	<0.35
Allerg, Dog Dander	0.30		KU/L	<0.35
Allerg, Bluegrass		0.40 H	KU/L	<0.35
Allerg, Pigweed	0.30		KU/L	<0.35
Allerg, Mulberry		0.50 H	KU/L	<0.35
Allerg, Helminth	<0.10		KU/L	<0.35
Phys, Addr, Phone	Unknown			

End of Report

*Handwritten signature*  
 20 Nov 2013



Name: NLD,  
 Gender: Female  
 Age: 25 Race: Hispanic  
 Height(in): 63.0 Weight(lb): 162  
 Any Info:

Id: AKP-041  
 Date: 11/27/13  
 Temp: 19 PBar: 637  
 Physician:  
 Technician:

Spirometry		(BTPS)	PRE-RX		POST-RX		Post
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	% Chg
FVC	Liters	3.49	4.84	139			
FEV1	Liters	3.02	4.03	134			
FEV1/FVC %		87	83	96			
FEF25-75%	L/sec	3.62	4.30	119			
FEF50%	L/sec	4.10	4.98	122			
FEF75%	L/sec	1.97	2.43	123			
IC	Liters						
VC	Liters	3.49					
PEF	L/sec	6.48	6.83	106			
MVV	L/min	119					
PIF	L/sec		2.44				
FEV1/FEV6%							

**Lung Volumes/Plethysmography**

Vtg	Liters	
VC	Liters	3.49
TLC	Liters	4.97
RV	Liters	1.45
RV/TLC	%	28
FRC PL	Liters	2.52
ERV	Liters	
IC	Liters	

**Diffusion**

DLCO	mL/mmHg/min	25.0
DL Adj	mL/mmHg/min	25.0
DLCO/VA	mL/mHg/min/L	3.93
VA	Liters	
BHT	Sec	

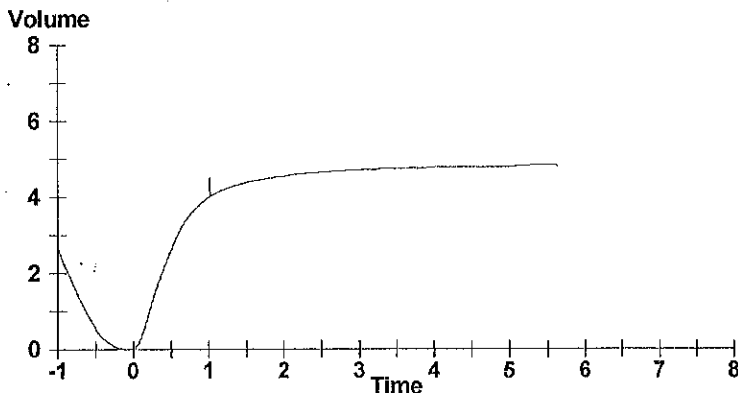
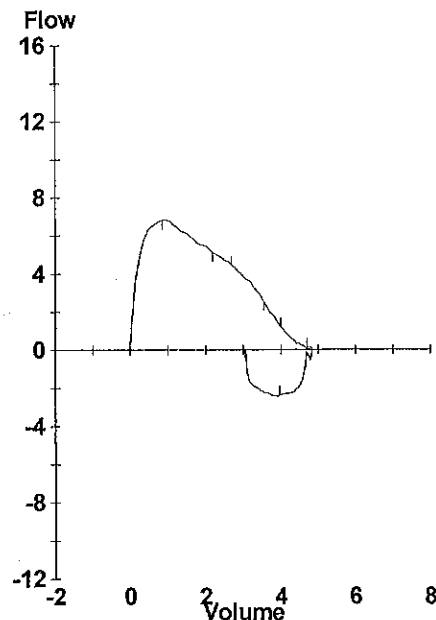
**Resistance**

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.53
Gaw	L/sec/cmH2O	0.604
sRaw	cmH2O/L/s/L	3.86
sGaw	L/s/cmH2O/L	0.259
Vtg (Raw)	Liters	

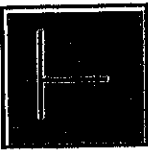
Comments:

Interpretation:

(BTPS)







Name: NLD,  
 Gender: Female  
 Age: 25 Race: Hispanic  
 Height(in): 63.0 Weight(lb): 162  
 Any Info:

Id: AKP-041  
 Date: 12/06/13  
 Temp: 19 PBar: 631  
 Physician:  
 Technician: VL

Spirometry		(BTPS)	PRE-RX		POST-RX		Post
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	% Chg
FVC	Liters	3.49	4.91	141			
FEV1	Liters	3.02	3.95	131			
FEV1/FVC	%	87	80	93			
FEF25-75%	L/sec	3.62	3.94	109			
FEF50%	L/sec	4.10	4.84	118			
FEF75%	L/sec	1.97	2.00	101			
IC	Liters						
VC	Liters	3.49					
PEF	L/sec	6.48	6.25	96			
MVV	L/min	119					
PIF	L/sec		2.26				
FEV1/FEV6%			82				

**Lung Volumes/Plethysmography**

Vtg	Liters	
VC	Liters	3.49
TLC	Liters	4.97
RV	Liters	1.45
RV/TLC	%	28
FRC PL	Liters	2.52
ERV	Liters	
IC	Liters	

**Diffusion**

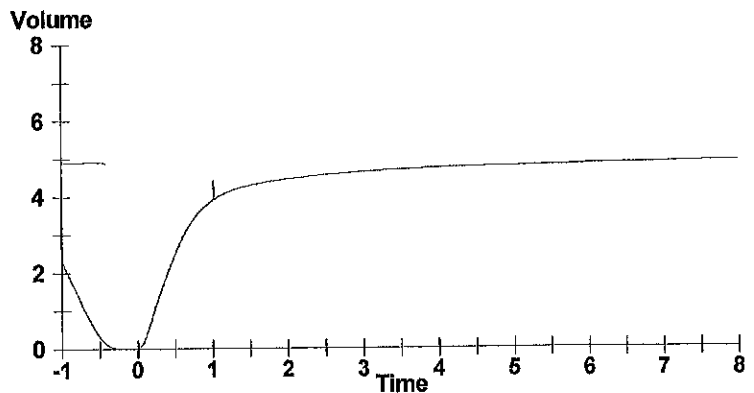
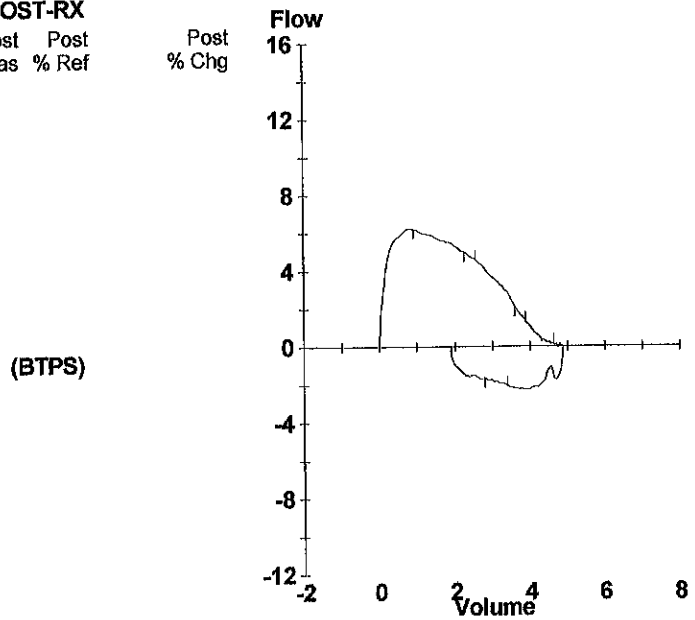
DLCO	mL/mmHg/min	25.0
DL Adj	mL/mmHg/min	25.0
DLCO/VA	mL/mHg/min/L	3.89
VA	Liters	
BHT	Sec	

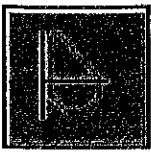
**Resistance**

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.53
Gaw	L/sec/cmH2O	0.604
sRaw	cmH2O/L/s/L	3.86
sGaw	L/s/cmH2O/L	0.259
Vtg (Raw)	Liters	

Comments:

Interpretation:

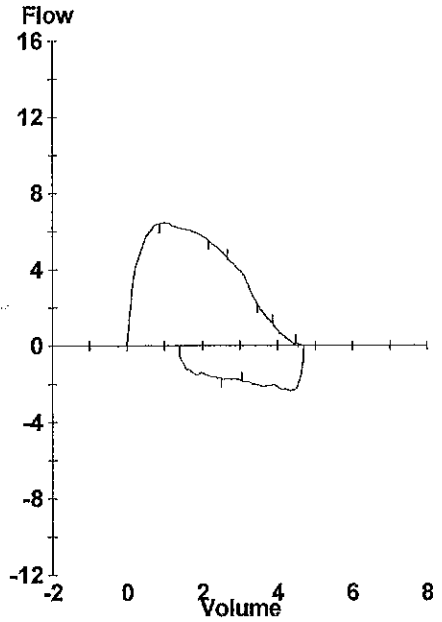




Name: NLD,  
 Gender: Female  
 Age: 25 Race: Hispanic  
 Height(in): 63.0 Weight(lb): 162  
 Any Info:

Id: AKP-041  
 Date: 12/13/13  
 Temp: 22 PBar: 630  
 Physician:  
 Technician: VL

Spirometry		(BTPS)	PRE-RX		POST-RX		Post
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	% Chg
FVC	Liters	3.49	4.71	135			
FEV1	Liters	3.02	3.90	129			
FEV1/FVC	%	87	83	95			
FEF25-75%	L/sec	3.62	4.31	119			
FEF50%	L/sec	4.10	5.31	130			
FEF75%	L/sec	1.97	2.08	106			
IC	Liters						
VC	Liters	3.49					
PEF	L/sec	6.48	7.10	110			
MVV	L/min	119					
PIF	L/sec		2.36				
FEV1/FEV6%			84				



**Lung Volumes/Plethysmography**

Parameter	Units	Value
Vtg	Liters	
VC	Liters	3.49
TLC	Liters	4.97
RV	Liters	1.45
RV/TLC	%	28
FRC PL	Liters	2.52
ERV	Liters	
IC	Liters	

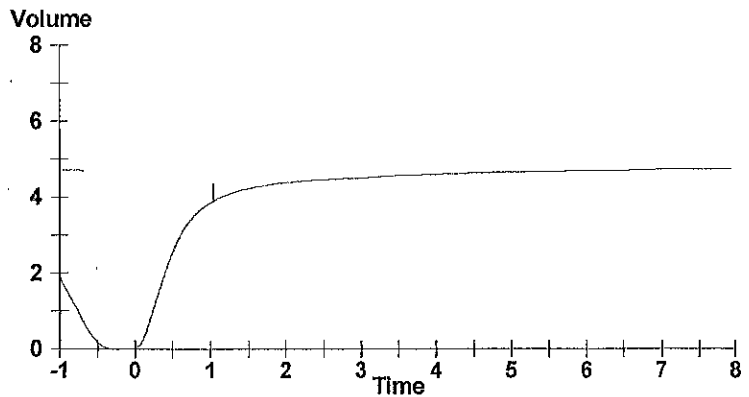
**Diffusion**

DLCO	mL/mmHg/min	25.0
DL Adj	mL/mmHg/min	25.0
DLCOVA	mL/mHg/min/L	3.88
VA	Liters	
BHT	Sec	

**Resistance**

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.53
Gaw	L/sec/cmH2O	0.604
sRaw	cmH2O/L/s/L	3.86
sGaw	L/s/cmH2O/L	0.259
Vtg (Raw)	Liters	

Comments:



Interpretation:

Name: AKP-041,

Gender: Female

Age: 25 Race:

Height(in): 63.0 Weight(lb): 162

Any Info:

Id: AKP-041

Date: 12/20/13

Temp: 19

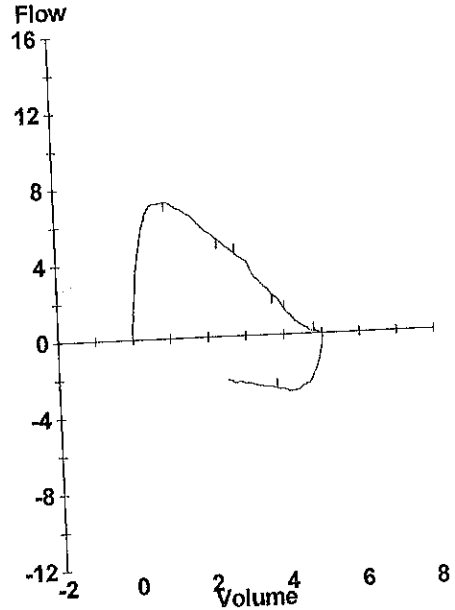
PBar: 624

Physician:

Technician: CRD

		(BTSP)	PRE-RX		POST-RX	
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref
Spirometry						
FVC	Liters	3.49	5.04	145		
FEV1	Liters	3.02	4.07	135		
FEV1/FVC	%	87	81	93		
FEF25-75%	L/sec	3.62	3.99	110		
FEF50%	L/sec	4.10	4.94	121		
FEF75%	L/sec	1.97	2.07	105		
IC	Liters					
VC	Liters	3.49	7.90	122		
PEF	L/sec	6.48				
MVV	L/min	119				
PIF	L/sec		2.98			
FEV1/FEV6%			81			

(BTSP)



Lung Volumes/Plethysmography

Vtg	Liters	
VC	Liters	3.49
TLC	Liters	4.97
RV	Liters	1.45
RV/TLC	%	28
FRC PL	Liters	2.52
ERV	Liters	
IC	Liters	

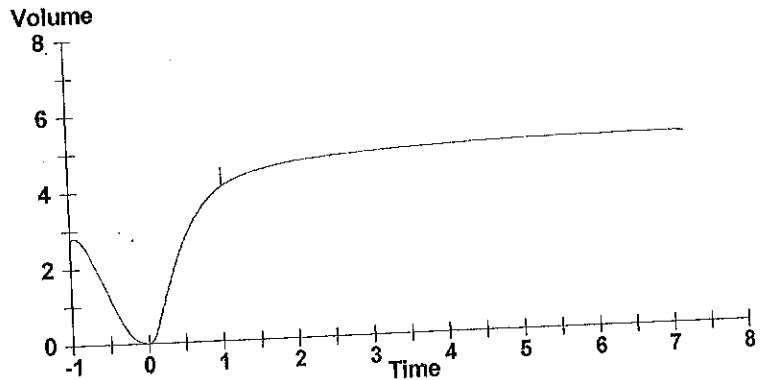
Diffusion

DLCO	mL/mmHg/min	25.0
DL Adj	mL/mmHg/min	25.0
DLCO/VA	mL/mHg/min/L	3.84
VA	Liters	
BHT	Sec	

Resistance

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.53
Gaw	L/sec/cmH2O	0.604
sRaw	cmH2O/L/s/L	3.86
sGaw	L/s/cmH2O/L	0.259
Vtg (Raw)	Liters	

Comments:



Interpretation:



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505 ) 938-8922

Lovelace Scientific Resources  
 Leslie Byatt, MD  
 2441 Ridgcrest Dr SE  
 Albuquerque, NM 87108-5129

Client Nbr  
 24664

PATIENT NAME: **X, NLD** PATIENT ID: **AAGI3129** DOB: **02/02/1988** SEX: **F** REPORT STATUS: **Final** PAGE: **1**

PHYSICIAN: **Unlisted Physician,** COLLECT DATE & TIME: **11/27/2013 13:20** RECEIVE DATE & TIME: **11/27/2013 18:53** PRINT DATE & TIME: **11/28/2013 06:11**

REQUISITION NO.: **30920924** PT. PHONE NO.: **0** PATIENT NO.: **AKP041**

COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
<b>Comp Metabolic Panel</b>					
Sodium	138		mmol/L	134-144	
Potassium	3.9		mmol/L	3.5-5.1	
Chloride	104		mmol/L	98-111	
CO2	25		mmol/L	20-30	
Anion Gap	9			6-14	
Glucose	72		mg/dL	60-100	
BUN	13		mg/dL	7-31	
Creatinine	0.56		mg/dL	0.50-1.40	
Creatinine method is IDMS traceable. EstGFR Calculation has been adjusted. Please note new reference range effective 5/23/2013.					
eGFR non-African Am	>60		mL/min/1.73m2	>60	
GFR Comment	Estimated GFR values are not accurate in acute kidney failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, the very old or very young, races other than Caucasian or African American, people with acute illnesses, or amputations.				
Calcium	9.0		mg/dL	8.4-10.4	
Total Protein	7.3		gm/dL	6.1-8.2	
Albumin	3.9		gm/dL	3.4-4.7	
Globulin	3.4		gm/dL	2.4-4.2	
Bilirubin, total	0.4		mg/dL	0.3-1.2	
Alk Phos	91		U/L	38-150	
AST(SGOT)	10		U/L	8-58	
ALT(SGPT)	19		U/L	14-67	
Fasting Phosphorus	NO				
Phosphorus	4.1		mg/dL	2.3-5.6	
<b>CBC</b>					
WBC	7.4		x10E3	4.0-10.6	
RBC	4.55		x10E6	4.00-5.38	
Hgb	13.3		gm/dL	12.0-16.0	
Hct	43		%	36-48	
MCV	94		fL	81-98	
MCHC	31.2		gm/dL	31.2-35.2	
RDW	12.6		%	11.0-14.5	
Platelets	284		x10E3	150-400	
Eos, Respiratory		Rare	*	NS	
Phys, Addr, Phone	Not given				

*NCS [Signature]*

*03 Dec 2013 [Signature]*

End of Report

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (SCREEN DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

DAY AM	-7	-6	-5	-4	-3	-2	-1	0	0
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
<b>DAY PM</b>	<b>-7</b>	<b>-6</b>	<b>-5</b>	<b>-4</b>	<b>-3</b>	<b>-2</b>	<b>-1</b>	<b>0</b>	<b>0</b>
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

Start  
here  
→

SCALE 0 to 3

- 0= No symptoms (no symptoms detected)
  - 1= Mild symptoms (symptoms present but easily tolerated)
  - 2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)
  - 3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)
- Y=Yes N=No

SUBJECT NUMBER: AKP041

DATE COMPLETED: 11/20-11/27/13

SUBJECT INITIALS AND DATE: NLD 11/27/13

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

DAY AM	1	2	3	4	5	6	7	8	9
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
DAY PM	1	2	3	4	5	6	7	8	9
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N= No

SUBJECT NUMBER: AKPOL 1 DATE COMPLETED: 11/27/13 - 12/5/13 SUBJECT INITIALS AND DATE: NLD 12/06/13

TriCore Reference Laboratories  
1001 Woodward Pl NE  
Albuquerque, NM 87102  
(505) 938-8922

Patient Name: NLD,NLD  
Medical Record: AAGI6777  
DOB:02/02/1988 Age:25Y Sex:F  
Account Number: 31033172  
Attending MD: Unlisted Physician  
Patient ID:AKP041  
Patient Phone:0

F3332962 COLL: 12/06/2013 11:15 REC: 12/06/2013 18:12 PHYS: Unlisted Physician  
Req# : 31033172

2/07/2013 07:17 am FAXED TO 488546NCCS11533

Eos, Respiratory \* Rare [NS]

Phys, Addr, Phone NOT GIVEN

*MCM NCS  
10 Dec 2013*

END OF REPORT

Printed: 12/07/2013 07:14

INTERIM REPORT

Patient Name: NLD,NLD  
Medical Record #: AAGI6777  
Location: CORE

Page: 1

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

DAY AM	7	8	9	10	11	12	13	14	15
Runny Nose 0 to 3	12/6/13 0 1 2 3	12/07/13 0 1 2 3	12/08/13 0 1 2 3	12/09/13 0 1 2 3	12/10/13 0 1 2 3	12/11/13 0 1 2 3	12/12/13 0 1 2 3	12/13/13 0 1 2 3	12/14/13 0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
DAY PM	7	8	9	10	11	12	13	14	15
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N=No

NLD

SUBJECT NUMBER: AKPD41 DATE COMPLETED: 12/13/13

SUBJECT INITIALS AND DATE: NLD 12-13-13





1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Scientific Resources  
Leslie Byatt, Clinical Trials  
2441 Ridgecrest Dr SE  
Albuquerque, NM 87108-5129

Client Nbr  
24664

PATIENT NAME: **NLD, NLD**      PATIENT ID: **AAGH8310**      DOB: **02/02/1988**      SEX: **F**      REPORT STATUS: **Final**      PAGE: **1**

PHYSICIAN: **Unlisted Physician,**      COLLECT DATE & TIME: **12/13/2013 11:25**      RECEIVE DATE & TIME: **12/13/2013 19:28**      PRINT DATE & TIME: **12/16/2013 06:13**

REQUISITION NO.: **31033184**      PT. PHONE NO.: **0**      PATIENT NO.: **AKP041**

COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Eos, Respiratory Phys, Addr, Phone	None seen	Not given		NS	

*MDM Sub I  
17 Dec 2013*

End of Report

Study Identification: AK Pharma LSR Study #: 2749  
 Subject Number: AKP041 Subject Initials: NLD

ADVERSE EVENT LOG

Adverse Event	** Start Date (DD/MMM/YYYY)	SEVERITY	Relationship to Study Drug (Suspected/Not Suspected)	** End Date (DD/MMM/YYYY)	Action Taken	Investigator Initials/Date
sinusitis	08/dec/13	mild	Not suspected	08/dec/2013	none	NLD 27 Feb 14
throat burning w/ dry	27/Nov/13	mild	suspected	11/Dec/2013	none	NLD 27 Feb 14
Upper Respiratory Infection	17/Dec/13	mod	Not suspected			NLD 27 Feb 14
						/
						/
						/
						/
						/
						/
						/
						/
						/

\*\* If day is unknown, write UNK in space provided, but every effort should be made to be as specific as possible\*\*

Investigator Signature (at end of study): [Signature] Date: 27 Feb 2014  
 SC Signature (at end of study): [Signature] Date: 2/24/14  
 Lovelace Scientific Resources, Inc - AdverseEvents 04/2013 PAGE: 1 of 1



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Scientific Resources  
 Leslie Byatt, MD  
 2441 Ridgecrest Dr SE  
 Albuquerque, NM 87108-5129

Client Nbr  
 24864

PATIENT NAME: **X, NLD** PATIENT ID: **AAGJ3404** DOB: **02/02/1988** SEX: **F** REPORT STATUS: **Final** PAGE: **1**  
 PHYSICIAN: **Unlisted Physician,** COLLECT DATE & TIME: **12/20/2013 11:26** RECEIVE DATE & TIME: **12/20/2013 20:15** PRINT DATE & TIME: **12/23/2013 06:08**  
 REQUISITION NO.: **30920953** PT. PHONE NO.: **0** PATIENT NO.: **AKP041**  
 COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
<b>Comp Metabolic Panel</b>					
Sodium	137		mmol/L	134-144	
Potassium	3.9		mmol/L	3.5-5.1	
Chloride	105		mmol/L	98-111	
CO2	26		mmol/L	20-30	
Anion Gap	6			6-14	
Glucose	76		mg/dL	60-100	
BUN	10		mg/dL	7-31	
Creatinine	0.71		mg/dL	0.50-1.40	
Creatinine method is IDMS traceable. EstGFR Calculation has been adjusted. Please note new reference range effective 5/23/2013.					
eGFR non-African Am	>60		mL/min/1.73m2	>60	
GFR Comment	Estimated GFR values are not accurate in acute kidney failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, the very old or very young, races other than Caucasian or African American, people with acute illnesses, or amputations.				
Calcium	8.8		mg/dL	8.4-10.4	
Total Protein	7.2		gm/dL	6.1-8.2	
Albumin	3.9		gm/dL	3.4-4.7	
Globulin	3.3		gm/dL	2.4-4.2	
Bilirubin, total	0.8		mg/dL	0.3-1.2	
Alk Phos	100		U/L	38-150	
AST(SGOT)	13		U/L	6-58	
ALT(SGPT)	19		U/L	14-67	
Fasting Phosphorus	YES				
Phosphorus	3.6		mg/dL	2.3-5.6	
<b>CBC</b>					
WBC	6.6		x10E3	4.0-10.6	
RBC	4.52		x10E6	4.00-5.36	
Hgb	13.6		gm/dL	12.0-16.0	
Hct	42		%	36-48	
MCV	93		fL	81-98	
MCHC	32.5		gm/dL	31.2-35.2	
RDW	12.8		%	11.0-14.5	
Platelets	281		x10E3	150-400	
Eos, Respiratory		Few	*	NS	<i>NCS</i>
Phys, Addr, Phone	NO PHYSICIAN LISTED				

End of Report

*MD Montezano MD Sub I  
 12/24/13*

Study Identification: AKPharma Allergy LSR #: 2749

Subject Number: AKP041 Subject Initials: NLD

**CONCOMITANT MEDICATION LOG**

List all prescription medications you are taking. Also include over-the-counter medications, vitamins and supplements.

Name of Medication	Indication (What you take it for)	Dose	Unit	Frequency	Route	* Start Date (Day/Month/Year)	Stop Date	Ongoing at EOS (for Clinic use)
EXAMPLE	Diabetes	500	MG	2 Tabs per day	Oral	UNK/AUG/1999		<input type="checkbox"/>
<u>None</u>								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>

\* If day or month of medication date is unknown, write UNK in space provided

Investigator Signature (at end of study): M. M. [Signature] Date: 27 Feb 2014  
SC Signature (at end of study): Walter Boyd Date: 2/27/14

**EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT**

**DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)**

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

DAY	14	15	16	17	18	19	20	21	22
AM	12/13/13	12/14/13	12/15/13	12/16/13	12/17/13	12/18/13	12/19/13	12/20/13	12/21/13
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
DAY PM	14	15	16	17	18	19	20	21	22
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

**SCALE 0 to 3**

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N= No

SUBJECT NUMBER: AKP041 DATE COMPLETED: 12/20/13 SUBJECT INITIALS AND DATE: NLD 12/20/13

NLD  
AKP041  
12/20/13

Effects of AkPharma's Calcium Glycerophosphate  
Nasal Spray wash (AkP 010112A) on Patient-Perceived Breathing Comfort

SATISFACTION QUESTIONNAIRE:

Would you use / purchase this nasal wash product in the future?"  YES  NO

You are also encouraged to make any free comments regarding your experience in the use of this product regarding your opinion of any of its effects not covered specifically in the Daily Diary:

IF the flavor was better I would buy  
it. It also doesn't squirt very well.

[Type text]

Subject initials and Date NLD 12/20/13

Study Staff Initials and Date

Em 12/20/13

**AKP-047**

49 AKPharma PERENNIAL ALLERGIES  
SCREENING/VISIT 1 SOURCE DOCUMENTS

Initials: LDR Site #: — Subject #: AKIP 047

**PATIENT DEMOGRAPHICS**

**Patient Demographics**

Date of Birth: 06 Feb 1947 (dd/mmm/yyyy)

Gender:  Male  Female

If female, Indicate Childbearing Potential

Childbearing  Surgically sterilized  Post-Menopausal

Ethnicity:  Hispanic  Non Hispanic

Race:  Asian  Black  Caucasian  American Indian

Pacific Islander  Other, Specify \_\_\_\_\_

**Smoking History**

Smoking Status:  None (Never smoked in the past  
*(smoked less than 100 cigarettes in lifetime)*)  
 Former (previously smoked more than 100 cigarettes in lifetime)  
 Current (smokes now)

If subject is a former or current smoker, please indicate:

Years smoked: \_\_\_\_\_

Cigarettes per day: \_\_\_\_\_

CRC Signature: Erica Maldonado Date: 23 Dec 13 (dd/mmm/yy)





1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Scientific Resources  
 Leslie Byatt, MD  
 2441 Ridgcrest Dr SE  
 Albuquerque, NM 87108-5129

Client Nbr  
 24864

PATIENT NAME: LDR, LDR      PATIENT ID: AAGJ4034      DOB: 02/06/1947      SEX: M      REPORT STATUS: Final      PAGE: 1

PHYSICIAN: Unlisted Physician,      COLLECT DATE & TIME: 12/23/2013 09:41      RECEIVE DATE & TIME: 12/23/2013 18:55      PRINT DATE & TIME: 12/24/2013 06:03

REQUISITION NO.: 31033191      PT. PHONE NO.: 0      PATIENT NO.: AKP047

COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Allerg, Panel 18					
Allerg, Juniper		5.30 H	KU/L	<0.35	
Allerg, Cottonwood		0.40 H	KU/L	<0.35	
Allerg, West. Ragweed	0.20		KU/L	<0.35	
Allerg, Russian Thistle		4.30 H	KU/L	<0.35	
Allerg, Bermuda Grass		3.60 H	KU/L	<0.35	
Allerg, Alternaria		2.30 H	KU/L	<0.35	
Allerg, Mesquite	0.20		KU/L	<0.35	
Allerg, Cockroach	<0.10		KU/L	<0.35	
Allerg, Derm. pter.	<0.10		KU/L	<0.35	

The standard classification system utilizes the following class cutoffs.

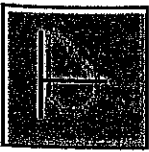
Class	ku/L	Interpretation
0	<0.35	Negative for Allergen
I	0.35-0.69	Positive for Allergen
II	0.70-3.49	Strongly Positive
III	3.5-17.49	Strongly Positive
IV	17.5-52.49	Strongly Positive
V	52.5-99.99	Strongly Positive
VI	>100	Strongly Positive

Results with allergens scoring in class 1 should be considered weakly positive or equivocal. Class 2 and higher should be considered positive. Although increasing class ranges (0-VI) are reflective of increasing concentrations of allergen-specific IgE, this may not correlate with the degree of clinical response when challenged with the specific allergen. The correlation of allergy laboratory results with clinical history is essential. A negative test may not rule out clinical allergy.

Allerg, Derm. farinae	<0.10		KU/L	<0.35
Allerg, Clad. herb.	<0.10		KU/L	<0.35
Allerg, Firebush		0.40 H	KU/L	<0.35
Allerg, Cat Dander Ep		1.30 H	KU/L	<0.35
Allerg, Dog Dander		0.90 H	KU/L	<0.35
Allerg, Bluegrass		6.80 H	KU/L	<0.35
Allerg, Pigweed		1.60 H	KU/L	<0.35
Allerg, Mulberry		2.20 H	KU/L	<0.35
Allerg, Helminth	<0.10		KU/L	<0.35
Phys, Addr, Phone	Not given			

End of Report

*AMM Guine sub-I  
 2 Jan 2014*



Name: LDR,  
 Gender: Male  
 Age: 66 Race: Caucasian  
 Height(in): 68.0 Weight(lb): 172  
 Any Info:

Id: AKP-047  
 Date: 01/14/14  
 Temp: 21 PBar: 636  
 Physician:  
 Technician: VL

Spirometry		(BTPS)	PRE-RX		POST-RX		Post
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	% Chg
FVC	Liters	3.85	4.29	111			
FEV1	Liters	3.06	3.14	103			
FEV1/FVC %		79	73	92			
FEF25-75%	L/sec	3.10	2.21	71			
FEF50%	L/sec	3.88	2.61	67			
FEF75%	L/sec	1.36	0.71	52			
IC	Liters						
VC	Liters	3.85					
PEF	L/sec	7.93	10.45	132			
MVV	L/min	126					
PIF	L/sec		2.42				
FEV1/FEV6%			80				

**Lung Volumes/Plethysmography**

Parameter	Units	Value
Vtg	Liters	
VC	Liters	3.85
TLC	Liters	6.09
RV	Liters	2.34
RV/TLC	%	39
FRC PL	Liters	3.46
ERV	Liters	
IC	Liters	

**Diffusion**

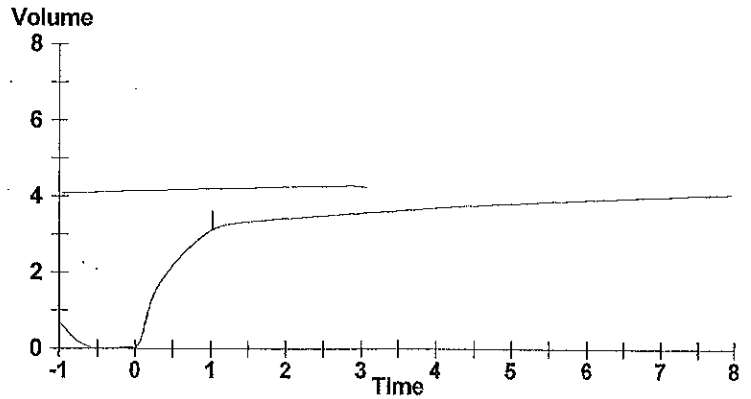
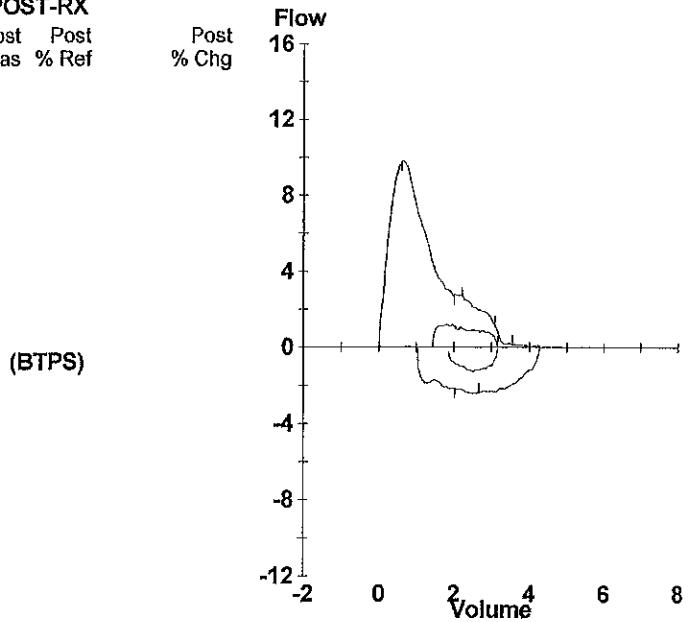
DLCO	mL/mmHg/min	20.8
DL Adj	mL/mmHg/min	20.8
DLCO/VA	mL/mHg/min/L	3.09
VA	Liters	
BHT	Sec	

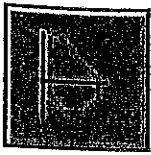
**Resistance**

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.31
Gaw	L/sec/cmH2O	0.830
sRaw	cmH2O/L/s/L	4.52
sGaw	L/s/cmH2O/L	0.221
Vtg (Raw)	Liters	

Comments:

Interpretation:





Name: LDR,  
 Gender: Male  
 Age: 66 Race: Caucasian  
 Height(in): 78.0 Weight(lb): 171  
 Any Info:

Id: AKP-047  
 Date: 01/23/14  
 Temp: 24 PBar: 633  
 Physician:  
 Technician:

Spirometry		(BTPS)	PRE-RX		POST-RX		
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	Post % Chg
FVC	Liters	5.96	4.06	68			
FEV1	Liters	4.73	2.90	61			
FEV1/FVC	%	77	72	93			
FEF25-75%	L/sec	4.55	1.99	44			
FEF50%	L/sec	5.59	3.09	55			
FEF75%	L/sec	2.14	** 0.61	** 28			
IC	Liters						
VC	Liters	5.96					
PEF	L/sec	10.32	11.31	110			
MVV	L/min	160					
PIF	L/sec						
FEV1/FEV6%			79				

**Lung Volumes/Plethysmography**

Vtg	Liters	
VC	Liters	5.96
TLC	Liters	8.48
RV	Liters	3.02
RV/TLC	%	39
FRC PL	Liters	5.18
ERV	Liters	
IC	Liters	

**Diffusion**

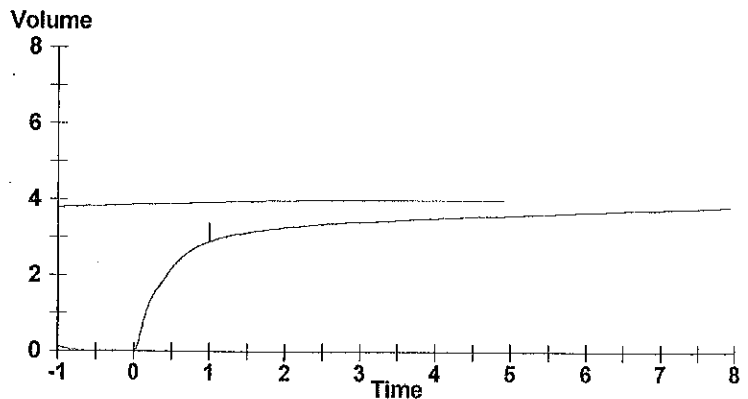
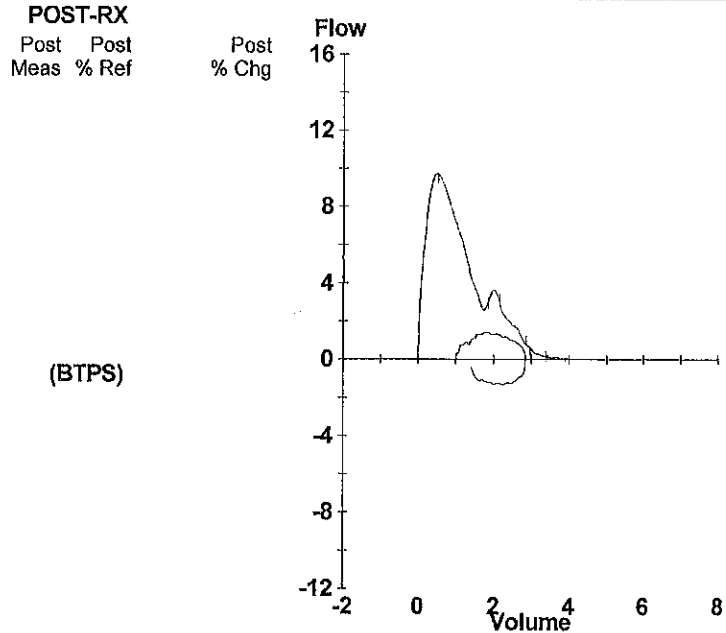
DLCO	mL/mmHg/min	23.8
DL Adj	mL/mmHg/min	23.8
DLCOVA	mL/mHg/min/L	3.07
VA	Liters	
BHT	Sec	

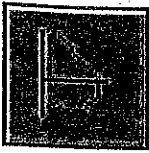
**Resistance**

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	0.80
Gaw	L/sec/cmH2O	1.242
sRaw	cmH2O/L/s/L	4.16
sGaw	L/s/cmH2O/L	0.241
Vtg (Raw)	Liters	

Comments:

Interpretation:

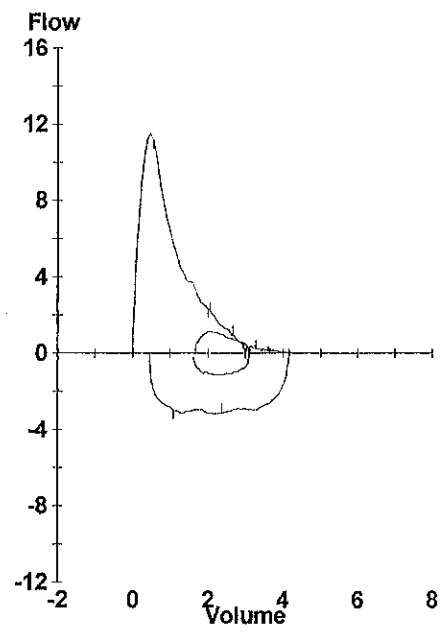




Name: LDR,  
 Gender: Male  
 Age: 66 Race: Caucasian  
 Height(in): 68.0 Weight(lb): 170  
 Any Info:

Id: AKP-047  
 Date: 01/28/14  
 Temp: 19 PBar: 631  
 Physician:  
 Technician:

Spirometry		(BTPS)	PRE-RX		POST-RX		Post % Chg
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	
FVC	Liters	3.85	4.26	111			
FEV1	Liters	3.06	2.73	89			
FEV1/FVC	%	79	64	81			
FEF25-75%	L/sec	3.10	0.90	29			
FEF50%	L/sec	3.88	2.03	52			
FEF75%	L/sec	1.36	0.29	21			
IC	Liters						
VC	Liters	3.85					
PEF	L/sec	7.93	11.54	146			
MVV	L/min	126					
PIF	L/sec		3.18				
FEV1/FEV6%			73				



**Lung Volumes/Plethysmography**

Vtg	Liters	
VC	Liters	3.85
TLC	Liters	6.09
RV	Liters	2.34
RV/TLC	%	39
FRC PL	Liters	3.48
ERV	Liters	
IC	Liters	

**Diffusion**

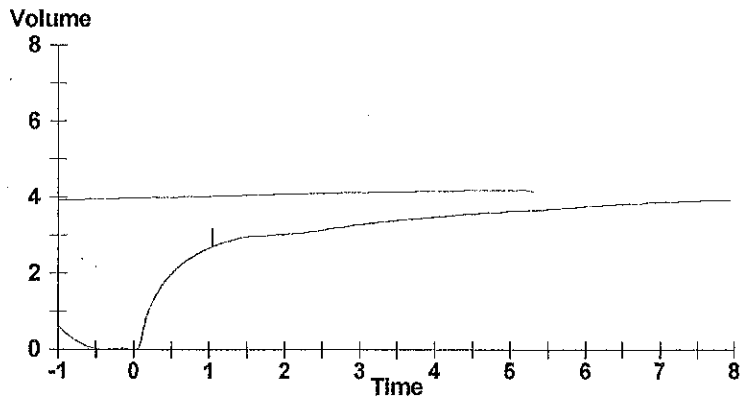
DLCO	mL/mmHg/min	20.7
DL Adj	mL/mmHg/min	20.7
DLCO/VA	mL/mHg/min/L	3.06
VA	Liters	
BHT	Sec	

**Resistance**

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.30
Gaw	L/sec/cmH2O	0.834
sRaw	cmH2O/L/s/L	4.52
sGaw	L/s/cmH2O/L	0.221
Vtg (Raw)	Liters	

Comments:

Interpretation:







1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Scientific Resources  
Leslie Byatt, Clinical Trials  
2441 Ridgcrest Dr SE  
Albuquerque, NM 87108-5129

Client Nbr  
24664

PATIENT NAME: **LDR, LDR** PATIENT ID: **AAGJ4034** DOB: **02/06/1947** SEX: **M** REPORT STATUS: **Final** PAGE: **1**  
 PHYSICIAN: **Unlisted Physician,** COLLECT DATE & TIME: **01/14/2014 08:35** RECEIVE DATE & TIME: **01/14/2014 18:29** PRINT DATE & TIME: **01/17/2014 22:24**  
 REQUISITION NO.: **31033205** PT. PHONE NO.: **0** PATIENT NO.: **AKP047**  
 COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Comp Metabolic Panel					
Sodium	136		mmol/L	134-144	
Potassium	4.0		mmol/L	3.5-5.1	
Chloride	100		mmol/L	98-111	
CO2	26		mmol/L	20-30	
Anion Gap	10			6-14	
Glucose		125 H	mg/dL	80-100	NCS [Signature]
Impaired fasting glucose (IFG) is defined as a fasting glucose level of 100-126 mg/dL. (ADA Guidelines Diabetes Care 26: (3160-3167)2003)					
BUN	15		mg/dL	7-31	
Creatinine	0.88		mg/dL	0.62-1.66	
Creatinine method is IDMS traceable. EstGFR Calculation has been adjusted. Please note new reference range effective 5/23/2013.					
eGFR non-African Am	>60		mL/min/1.73m2	>60	
GFR Comment	Estimated GFR values are not accurate in acute kidney failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, the very old or very young, races other than Caucasian or African American, people with acute illnesses, or amputations.				
Calcium	9.7		mg/dL	8.4-10.4	
Total Protein	7.9		gm/dL	6.1-8.2	
Albumin	4.6		gm/dL	3.4-4.7	
Globulin	3.3		gm/dL	2.4-4.2	
Bilirubin, total	0.6		mg/dL	0.3-1.2	
Alk Phos	66		U/L	38-150	
AST(SGOT)	42		U/L	6-58	
ALT(SGPT)		87 H	U/L	14-87	NCS [Signature]
Fasting Phosphorus	NO				
	3.6		mg/dL	2.3-5.6	
CBC					
WBC	6.0		x10E3	4.0-10.6	
RBC		4.60 L	x10E6	4.64-6.00	NCS [Signature]
Hgb	14.7		gm/dL	14.5-17.7	
Hct	43		%	42-53	
MCV	94		fL	81-98	
MCHC	33.9		gm/dL	31.2-35.2	
RDW	12.6		%	11.0-14.5	
Platelets	257		x10E3	150-400	

Phys, Addr, Phone

NO PHYSICIAN GIVEN  
CORRECTED ON 01/14 AT 1832: PREVIOUSLY REPORTED AS NO PHYSICIAN

Allerg, Panel 18

Allerg, Juniper	5.10	H	KU/L	<0.35
Allerg, Cottonwood	0.40	H	KU/L	<0.35
Allerg, West. Ragweed	0.10		KU/L	<0.35
Allerg, Russian Thistle	4.30	H	KU/L	<0.35
Allerg, Bermuda Grass	3.20	H	KU/L	<0.35
Allerg, Alternaria	2.50	H	KU/L	<0.35
Allerg, Mesquite	0.20		KU/L	<0.35
Allerg, Cockroach	<0.10		KU/L	<0.35
Allerg, Derm. pter.	<0.10		KU/L	<0.35

The standard classification system utilizes the following class cutoffs.  
Class KU/L Interpretation

Continued on next page

LDR, LDR

01/17/2014 22:24

*[Handwritten Signature]*  
21 Jan 2014

FAX24664

**EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT**

**DAILY SYMPTOMS SCORE SHEET (SCREEN DIARY)**

**CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS**

DAY	-7	-6	-5	-4	-3	-2	-1	0	0
<b>AM</b>	1/7/14	1/8/14	1/9/14	1/10/14	1/11/14	1/12/14	1/13/14	1/14/14	1/15/14
Runny Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Itchy Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Congestion 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Sneezing 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Voice Hoarse Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO
Throat Clearing Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO
<b>DAY PM</b>	-7	-6	-5	-4	-3	-2	-1	0	0
Runny Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Itchy Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Congestion 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Sneezing 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Voice Hoarse Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO
Throat Clearing Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO

**SCALE 0 to 3**

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N=No

SUBJECT NUMBER: AKP047 DATE COMPLETED: 1/14/14

*LDR*

SUBJECT INITIALS AND DATE: LDR 1-14-2014

*Start  
study  
today*

**EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT**

**DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)**

**CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS**

DAY AM	1	2	3	4	5	6	7	8	9
Runny Nose 0 to 3	1/14/14 0 1 2 3	1/15/14 0 1 2 3	1/16/14 0 1 2 3	1/17/14 0 1 2 3	1/18/14 0 1 2 3	1/19/14 0 1 2 3	1/20/14 0 1 2 3	1/21/14 0 1 2 3	1/22/14 0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
<b>DAY PM</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>	<b>9</b>
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

**SCALE 0 to 3**

- 0= No symptoms (no symptoms detected)
  - 1= Mild symptoms (symptoms present but easily tolerated)
  - 2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)
  - 3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)
- Y=Yes N= No

SUBJECT NUMBER: AKP047      DATE COMPLETED: 1/23/14      SUBJECT INITIALS AND DATE: DR 1-23-2014



**EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT**

**DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)**

**CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS**

DAY AM	7	8	9	10	11	12	13	14	15
Runny Nose 0 to 3	1/23/14 0 1 2 3	1/24/14 0 1 2 3	1/25/14 0 1 2 3	1/26/14 0 1 2 3	1/27/14 0 1 2 3	1/28/14 0 1 2 3	1/29/14 0 1 2 3	1/30/14 0 1 2 3	1/31/14 0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
<b>DAY PM</b>	<b>7</b>	<b>8</b>	<b>9</b>	<b>10</b>	<b>11</b>	<b>12</b>	<b>13</b>	<b>14</b>	<b>15</b>
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

**SCALE 0 to 3**

- 0= No symptoms (no symptoms detected)
  - 1= Mild symptoms (symptoms present but easily tolerated)
  - 2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)
  - 3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)
- Y=Yes N=No

SUBJECT NUMBER: LD 2      DATE COMPLETED: \_\_\_\_\_      SUBJECT INITIALS AND DATE: \_\_\_\_\_

*AKP 047*

*Copy  
Dr. Gungor  
given back  
subject to  
me  
1/23/14*



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505 ) 938-8922

Lovelace Scier Resources  
Leslie Byatt, Clin Trials  
2441 Ridgecrest Dr SE  
Albuquerque, NM 87108-5129

Client Nbr  
24664

PATIENT NAME <b>X, XLDR</b>	PATIENT ID <b>AAGK8068</b>	DOB <b>02/06/1947</b>	SEX <b>M</b>	REPORT STATUS <b>Final</b>	PAGE <b>1</b>
PHYSICIAN <b>Unlisted Physician,</b>	COLLECT DATE & TIME <b>01/23/2014 09:28</b>	RECEIVE DATE & TIME <b>01/23/2014 23:34</b>	PRINT DATE & TIME <b>01/24/2014 07:05</b>		
REQUISITION NO. <b>31033210</b>	PT. PHONE NO. <b>0</b>	PATIENT NO. <b>AKP047</b>	COMMENTS :		

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Eos, Respiratory Phys, Addr, Phone	None seen			NS	
NO PHYSICIAN LISTED					

End of Report

*PD Muirhead MD Sub I*  
29 Jan 2014

**EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT**

**DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)**

**CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS**

DAY	7	8	9	10	11	12	13	14	15
AM	1/23/14	1/24/14	1/25/14	1/26/14	1/27/14	1/28/14	1/29/14	1/30/14	1/31/14
Runny Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Itchy Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Congestion 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Sneezing 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Voice Hoarse Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO
Throat Clearing Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO
DAY PM	7	8	9	10	11	12	13	14	15
Runny Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Itchy Nose 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Congestion 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Sneezing 0 to 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3	0 1 2 3 0 1 2 3
Voice Hoarse Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO
Throat Clearing Y/N	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO	YES NO YES NO

**SCALE 0 to 3**

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N=No

SUBJECT NUMBER: AKP 047

DATE COMPLETED: 1/28/14

SUBJECT INITIALS AND DATE: LDR 1-28-2014



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505 ) 938-8922

Lovelace Scientific Resources  
Leslie Byatt, Clinical Trials  
2441 Ridgcrest Dr SE  
Albuquerque, NM 87108-5129

Client Nbr  
24664

PATIENT NAME  
**LDR, LDR**

PATIENT ID  
**AAGJ4034**

DOB  
**02/06/1947**

SEX  
**M**

REPORT STATUS  
**Final**

PAGE  
**1**

PHYSICIAN

COLLECT DATE & TIME  
**01/28/2014 08:45**

RECEIVE DATE & TIME  
**01/28/2014 18:46**

PRINT DATE & TIME  
**01/29/2014 06:07**

**Unlisted Physician,**

REQUISITION NO.

PT. PHONE NO.

PATIENT NO.

**31033207**

**0**

**AKP047**

COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Eos, Respiratory Phys, Addr, Phone		<b>Moderate</b> *		NS	

NO ORDERING PHYSICIAN INDICATED

**End of Report**

*Handwritten signature*  
05 Feb 2014



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Scientific Resources  
Leslie Byatt, Clinical  
2441 Ridgecrest Dr SE  
Albuquerque, NM 87108-5129

Client Nbr  
24864

PATIENT NAME: **LDR, LDR**      PATIENT ID: **AAGJ4034**      DOB: **02/06/1947**      SEX: **M**      REPORT STATUS: **Final**      PAGE: **1**  
 PHYSICIAN: **Unlisted Physician,**      COLLECT DATE & TIME: **02/05/2014 08:50**      RECEIVE DATE & TIME: **02/05/2014 19:47**      PRINT DATE & TIME: **02/06/2014 06:07**  
 REQUISITION NO.: **31033204**      PT. PHONE NO.: **0**      PATIENT NO.: **AKP047**  
 COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
<b>Comp Metabolic Panel</b>					
Sodium	134		mmol/L	134-144	
Potassium	3.9		mmol/L	3.5-5.1	
Chloride	99		mmol/L	98-111	
CO2	24		mmol/L	20-30	
Anion Gap	11			6-14	
Glucose		152 H	mg/dL	60-100	<i>NCS [Signature]</i>
BUN	15		mg/dL	7-31	
Creatinine	1.04		mg/dL	0.62-1.66	
Creatinine method is IDMS traceable. EstGFR Calculation has been adjusted. Please note new reference range effective 5/23/2013.					
eGFR non-African Am	>60		mL/min/1.73m2	>60	
GFR Comment	Estimated GFR values are not accurate in acute kidney failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, the very old or very young, races other than Caucasian or African American, people with acute illnesses, or amputations.				
Calcium	10.0		mg/dL	8.4-10.4	
Total Protein	7.7		gm/dL	6.1-8.2	
Albumin	4.5		gm/dL	3.4-4.7	
Globulin	3.2		gm/dL	2.4-4.2	
Bilirubin, total	0.6		mg/dL	0.3-1.2	
Alk Phos	61		U/L	38-150	
AST(SGOT)	37		U/L	6-58	
ALT(SGPT)	67		U/L	14-67	
Fasting	NO				
Phosphorus	3.3		mg/dL	2.3-5.6	
Eos, Respiratory	None seen			NS	
Phys, Addr, Phone	Unknown				
<b>CBC</b>					
WBC	5.8		x10E3	4.0-10.6	
RBC	4.70		x10E6	4.64-6.00	
Hgb	15.0		gm/dL	14.5-17.7	
Hct	44		%	42-53	
MCV	95		fL	81-98	
MCHC	33.8		gm/dL	31.2-35.2	
RDW	12.9		%	11.0-14.5	
Platelets	233		x10E3	150-400	

End of Report

*Proteinuria no Sub I*

**EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT**

**DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)**

**CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS**

DAY AM	14	15	16	17	18	19	20	21	22
Runny Nose 0 to 3	1/28 0 1 2 3	1/29 0 1 2 3	1/30 0 1 2 3	1/31 0 1 2 3	2/1 0 1 2 3	2/2 0 1 2 3	2/3 0 1 2 3	2/4 0 1 2 3	2/5 0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
<b>DAY PM</b>	<b>14</b>	<b>15</b>	<b>16</b>	<b>17</b>	<b>18</b>	<b>19</b>	<b>20</b>	<b>21</b>	<b>22</b>
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

Start here →

**SCALE 0 to 3**

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N= No

SUBJECT NUMBER: AKP047

DATE COMPLETED: 1/28/14 → 2/5/14

SUBJECT INITIALS AND DATE: R. J. R. 2-5-2014

Study Identification: 2749

Subject Number: AKP047

LSR Study #: \_\_\_\_\_

Subject Initials: CDR

ADVERSE EVENT LOG

Adverse Event	** Start Date (DD/MMM/YYYY)	SEVERITY	Relationship to Study Drug (Suspected/Not Suspected)	** End Date (DD/MMM/YYYY)	Action Taken	Investigator Initials/Date
<u>Rawly lower neck</u>	<u>20/Jan/2014</u>	<u>mild.</u>	<u>Not Suspected</u>	<u>0000</u>	<u>CORTISONE CLEAN.</u>	<u>[Signature] 27 Feb 2014</u>

\*\* If day is unknown, write UNK in space provided, but every effort should be made to be as specific as possible \*\*

Investigator Signature (at end of study): [Signature] Date: 27 Feb 2014

SC Signature (at end of study): [Signature] Date: 2/5/14

Study Identification: 2749

LSR #: \_\_\_\_\_

Subject Number: AKP047

Subject Initials: LDR

**CONCOMITANT MEDICATION LOG**

List all prescription medications you are taking. Also include over-the-counter medications, vitamins and supplements.

Name of Medication	Indication (What you take it for)	Dose	Unit	Frequency	Route	* Start Date (Day/Month/Year)	Stop Date	Ongoing at EOS (for Clinic Use)
<i>EXAMPLE</i>	Diabetes	500	MG		Oral			<input type="checkbox"/>
Crestor	Hypercholesterolemia	20	mg	QD	oral	---/---/1999	cont	<input checked="" type="checkbox"/>
Allopurinol	Gout	300	mg	QD	oral	---/---/1995	cont	<input checked="" type="checkbox"/>
Zosartan Potassium	Hypertension	12.5	mg	QD	oral	--/---/2005	cont	<input checked="" type="checkbox"/>
Amlipodine	Hypertension	2.5	mg	QD	oral	--/---/2005	cont	<input checked="" type="checkbox"/>
Metformin	Diabetes	500	mg	QD	oral	--/---/2005		<input checked="" type="checkbox"/>
Flexitine	Anxiety	10	mg	QD	oral	--/---/2010		<input checked="" type="checkbox"/>
Pantoprazole	Acid Reflux	40	mg	QD	oral	--/---/1998		<input checked="" type="checkbox"/>
Zyrtec	Allergies	10	mg	QD	oral	--/---/2010	30 Nov/2013	<input type="checkbox"/>
Benadryl	Allergies	25	mg	QD	oral	--/---/2010	30 Nov/2013	<input type="checkbox"/>
Baby Aspirin	Cardiac	81	mg	QD	oral	--/---/2003		<input checked="" type="checkbox"/>
Multivitamin Mineral	Dietary supplement	1	TAB	QD	oral	--/---/1983		<input checked="" type="checkbox"/>

\* If day or month of medication date is unknown, write UNK in space provided

Investigator Signature (at end of study): [Signature] Date: 05 Feb 2014

SC Signature (at end of study): [Signature] Date: 2/5/14



Study Identification: AK Pharma

LSR #: 2749

Subject Number: AKP047

Subject Initials: LDR

**CONCOMITANT MEDICATION LOG**

List all prescription medications you are taking. Also include over-the-counter medications, vitamins and supplements.

Name of Medication	Indication (What you take it for)	Dose	Unit	Frequency	Route	* Start Date (Day/Month/Year)	Stop Date	Ongoing at EOS (for Clinic use)
EXAMPLE cortisone cream	Diabetes	500	MG	2 Tabs per day	Oral	UNK/AUG/1999		<input type="checkbox"/>
	Rash	1/2	tab	QAM.	top	1/22/14	back	<input checked="" type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>
								<input type="checkbox"/>

\* If day or month of medication date is unknown, write UNK in space provided

Investigator Signature (at end of study): [Signature] Date: 05 Feb 2014

SC Signature (at end of study): [Signature] Date: 2/5/14

Effects of AkPharma's Calcium Glycerophosphate  
Nasal Spray wash (AkP 010112A) on Patient-Perceived Breathing Comfort

SATISFACTION QUESTIONNAIRE:

Would you use / purchase this nasal wash product in the future?"  YES  NO

You are also encouraged to make any free comments regarding your experience in the use of this product regarding your opinion of any of its effects not covered specifically in the Daily Diary:

*This worked as well or better than my antihistamines.*

[Type text]

Subject initials and Date

*LM 2-5-2014*

Study Staff Initials and Date

*LB 2/5/14*

**AKP-049**

2749 AKPharma PERENNIAL ALLERGIES  
SCREENING/VISIT 1 SOURCE DOCUMENTS

Initials: ERB Site #: — Subject #: 049 <sup>AKP</sup>

PATIENT DEMOGRAPHICS

**Patient Demographics**

Date of Birth: 28 / JUN / 1957 (dd/mmm/yyyy)

Gender:  Male  Female

If female, Indicate Childbearing Potential

Childbearing  Surgically sterilized  Post-Menopausal

Ethnicity:  Hispanic  Non Hispanic

Race:  Asian  Black  Caucasian  American Indian

Pacific Islander  Other, Specify \_\_\_\_\_

**Smoking History**

Smoking Status:  None (smoked less than 100 cigarettes in lifetime)

Former (previously smoked more than 100 cigarettes in lifetime)

Current (smokes now)

If subject is a former or current smoker, please indicate:

Years smoked: \_\_\_\_\_ Cigarettes per day: \_\_\_\_\_

CRC Signature: S. Jickel Malcolm Date: 16 JAN 14 (dd/mmm/yy)



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Scientific Resources  
 Leslie Byatt, Clinical Trials  
 2441 Ridgecrest Dr SE  
 Albuquerque, NM 87108-5129

Client Nbr  
 24664

PATIENT NAME: **ERB, ERB** PATIENT ID: **AAGK4096** DOB: **06/28/1954** SEX: **F** REPORT STATUS: **Final** PAGE: **1**  
 PHYSICIAN: **Unlisted Physician,** COLLECT DATE & TIME: **01/16/2014 10:41** RECEIVE DATE & TIME: **01/16/2014 18:28** PRINT DATE & TIME: **01/20/2014 06:10**  
 REQUISITION NO.: **31033189** PT. PHONE NO.: **0** PATIENT NO.: **049**  
 COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Allerg, Panel 18					
Allerg, Juniper		1.50 H	KU/L	<0.35	
Allerg, Cottonwood	<0.10		KU/L	<0.35	
Allerg, West. Ragweed	<0.10		KU/L	<0.35	
Allerg, Russian Thistle		2.30 H	KU/L	<0.35	
Allerg, Bermuda Grass	<0.10		KU/L	<0.35	
Allerg, Alternaria	<0.10		KU/L	<0.35	
Allerg, Mesquite		0.40 H	KU/L	<0.35	
Allerg, Cockroach		0.40 H	KU/L	<0.35	
Allerg, Derm. pter.	0.20		KU/L	<0.35	

The standard classification system utilizes the following class cutoffs.

Class	ku/L	Interpretation
0	<0.35	Negative for Allergen
I	0.35-0.69	Positive for Allergen
II	0.70-3.49	Strongly Positive
III	3.5-17.49	Strongly Positive
IV	17.5-52.49	Strongly Positive
V	52.5-99.99	Strongly Positive
VI	>100	Strongly Positive

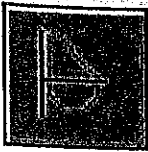
Results with allergens scoring in Class 1 should be considered weakly positive or equivocal. Class 2 and higher should be considered positive. Although increasing class ranges (0-VI) are reflective of increasing concentrations of allergen-specific IgE, this may not correlate with the degree of clinical response when challenged with the specific allergen. The correlation of allergy laboratory results with clinical history is essential. A negative test may not rule out clinical allergy.

Allerg, Derm. farinae	0.20		KU/L	<0.35
Allerg, Clad. herb.	<0.10		KU/L	<0.35
Allerg, Firebush	0.20		KU/L	<0.35
Allerg, Cat Dander Ep		1.60 H	KU/L	<0.35
Allerg, Dog Dander		0.50 H	KU/L	<0.35
Allerg, Bluegrass	<0.10		KU/L	<0.35
Allerg, Pigweed		1.30 H	KU/L	<0.35
Allerg, Mulberry		12.20 H	KU/L	<0.35
Allerg, Helminth	<0.10		KU/L	<0.35

NO ORDERING PHYSICIAN PROVIDED

End of Report

*Handwritten signature and date:*  
 21 Jan 2014



Name: ERB,  
 Gender: Female  
 Age: 59 Race: Hispanic  
 Height(in): 58.6 Weight(lb): 164  
 Any Info:

Id: 0AKP49  
 Date: 01/29/14  
 Temp: 20 PBar: 633  
 Physician:  
 Technician: TKA

Spirometry		(BTPS)	PRE-RX		POST-RX		Post
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	% Chg
FVC	Liters	2.42	2.56	106			
FEV1	Liters	2.00	1.98	99			
FEV1/FVC	%	84	77	92			
FEF25-75%	L/sec	2.24	1.73	77			
FEF50%	L/sec	2.93	3.38	116			
FEF75%	L/sec	0.91	0.45	49			
IC	Liters						
VC	Liters	2.42					
PEF	L/sec	5.08	6.76	133			
MVV	L/min	93					
PIF	L/sec		3.12				
FEV1/FEV6%			82				

**Lung Volumes/Plethysmography**

Vtg	Liters	
VC	Liters	2.42
TLC	Liters	3.82
RV	Liters	1.40
RV/TLC	%	37
FRC PL	Liters	1.91
ERV	Liters	
IC	Liters	

**Diffusion**

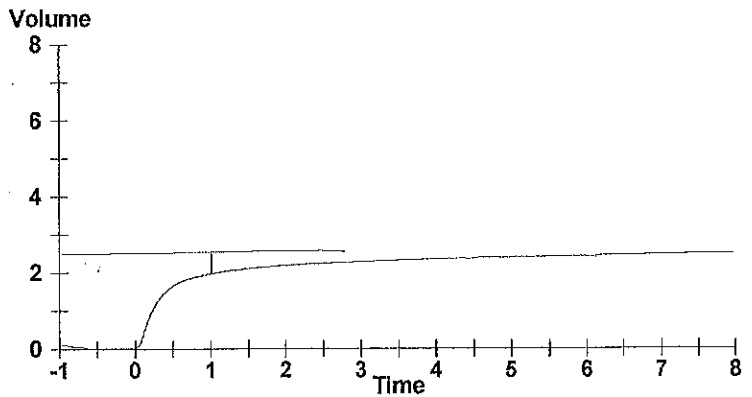
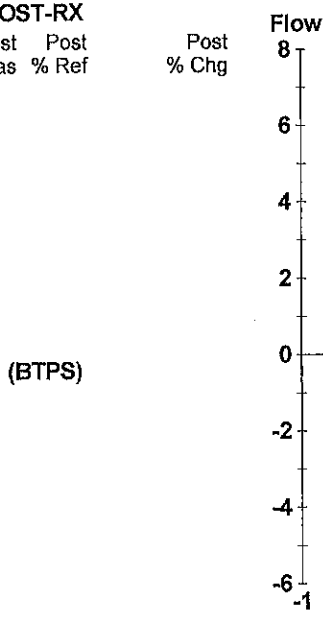
DLCO	mL/mmHg/min	19.7
DL Adj	mL/mmHg/min	19.7
DLCOVA	mL/mHg/min/L	3.21
VA	Liters	
BHT	Sec	

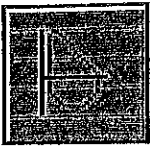
**Resistance**

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	2.11
Gaw	L/sec/cmH2O	0.458
sRaw	cmH2O/L/s/L	4.02
sGaw	L/s/cmH2O/L	0.249
Vtg (Raw)	Liters	

Comments:

Interpretation:





Name: ERB,  
 Gender: Female  
 Age: 59 Race: Hispanic  
 Height(in): 60.0 Weight(lb): 165  
 Any Info:

Id: AKP-049  
 Date: 02/05/14  
 Temp: 19 PBar: 631  
 Physician:  
 Technician: VL

Spirometry		(BTPS)	PRE-RX		POST-RX		Post
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	% Chg
FVC	Liters	2.56	2.50	98			
FEV1	Liters	2.10	2.01	96			
FEV1/FVC %		84	81	96			
FEF25-75%L/sec		2.33	2.00	86			
FEF50%	L/sec	3.03	3.88	128			
FEF75%	L/sec	0.96	0.62	64			
IC	Liters						
VC	Liters	2.56					
PEF	L/sec	5.25	5.51	105			
MVV	L/min	93					
PIF	L/sec		2.10				
FEV1/FEV6%			83				

**Lung Volumes/Plethysmography**

Lung Volumes/Plethysmography		(BTPS)
Vtg	Liters	
VC	Liters	2.56
TLC	Liters	4.10
RV	Liters	1.51
RV/TLC	%	37
FRC PL	Liters	2.09
ERV	Liters	
IC	Liters	

**Diffusion**

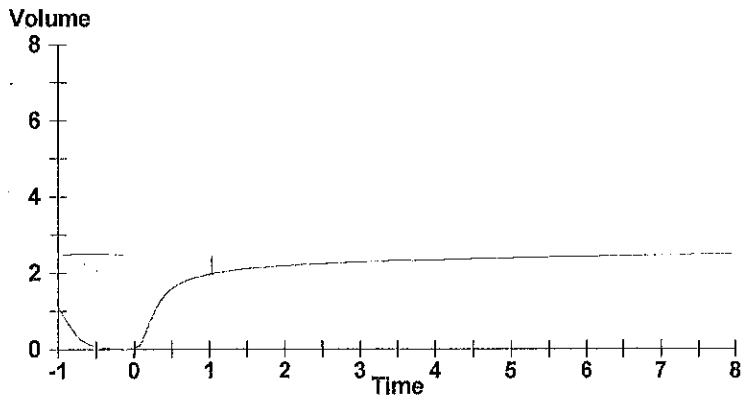
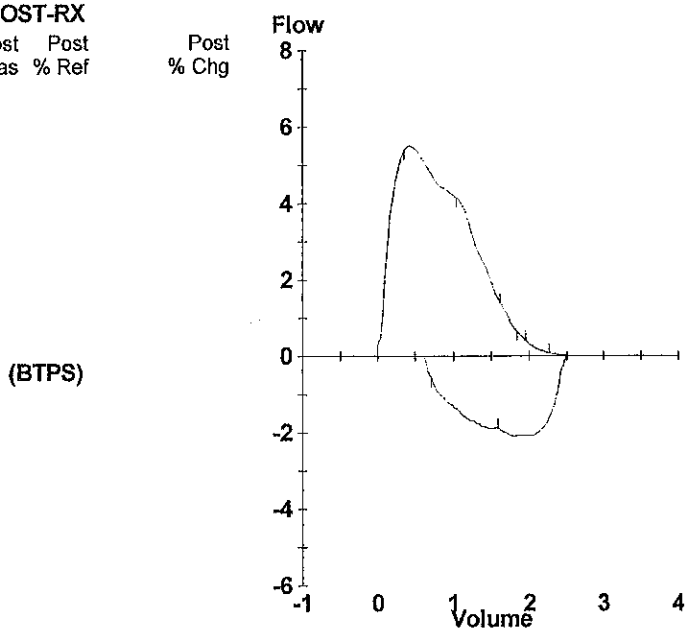
DLCO	mL/mmHg/min	20.2
DL Adj	mL/mmHg/min	20.2
DLCO/VA	mL/mHg/min/L	3.20
VA	Liters	
BHT	Sec	

**Resistance**

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.90
Gaw	L/sec/cmH2O	0.501
sRaw	cmH2O/L/s/L	3.96
sGaw	L/s/cmH2O/L	0.252
Vtg (Raw)	Liters	

Comments:

Interpretation:





Name: ERB,  
 Gender: Female  
 Age: 59 Race: Hispanic  
 Height(in): 60.0 Weight(lb): 165  
 Any Info:

Id: AKP-049  
 Date: 02/12/14  
 Temp: 20 PBar: 634  
 Physician:  
 Technician: VL

Spirometry		(BTPS)	PRE-RX		POST-RX		Post
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	% Chg
FVC	Liters	2.56	2.54	99			
FEV1	Liters	2.10	2.04	97			
FEV1/FVC	%	84	81	96			
FEF25-75%	L/sec	2.33	2.21	95			
FEF50%	L/sec	3.03	4.60	152			
FEF75%	L/sec	0.96	0.63	65			
IC	Liters						
VC	Liters	2.56					
PEF	L/sec	5.25	6.19	118			
MVV	L/min	93					
PIF	L/sec		1.60				
FEV1/FEV6%			82				

Lung Volumes/Plethysmography

Vtg	Liters	
VC	Liters	2.56
TLC	Liters	4.10
RV	Liters	1.51
RV/TLC	%	37
FRC PL	Liters	2.09
ERV	Liters	
IC	Liters	

Diffusion

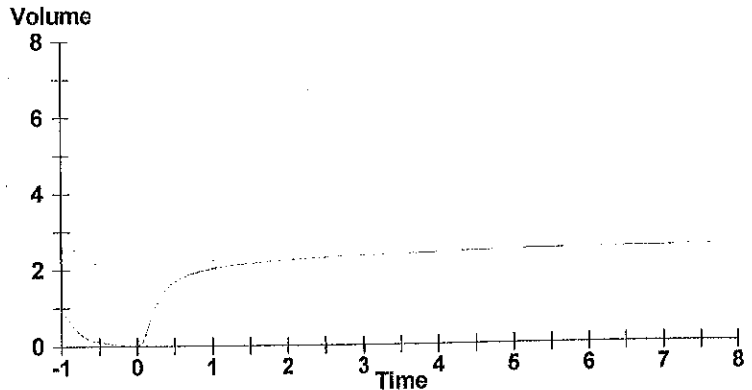
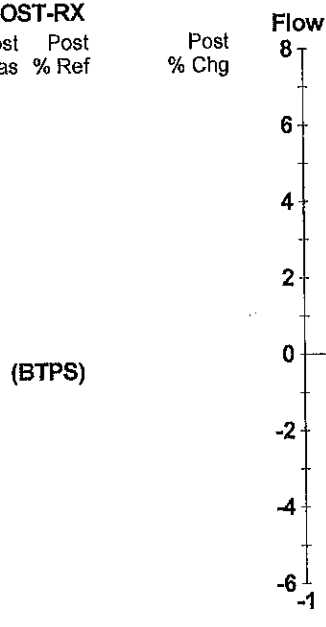
DLCO	mL/mmHg/min	20.2
DL Adj	mL/mmHg/min	20.2
DLCOVA	mL/mHg/min/L	3.22
VA	Liters	
BHT	Sec	

Resistance

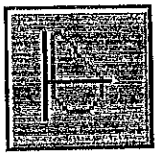
Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	1.90
Gaw	L/sec/cmH2O	0.501
sRaw	cmH2O/L/s/L	3.96
sGaw	L/s/cmH2O/L	0.252
Vtg (Raw)	Liters	

Comments:

Interpretation:







Name: ERB,  
 Gender: Female  
 Age: 59 Race:  
 Height(in): 59.0 Weight(lb): 164  
 Any Info:

Id: AKP-049  
 Date: 02/19/14  
 Temp: 21 PBar: 627  
 Physician:  
 Technician: CRD

Spirometry		(BTPS)	PRE-RX		POST-RX		Post
		Ref	Pre Meas	Pre % Ref	Post Meas	Post % Ref	% Chg
FVC	Liters	2.47	2.63	107			
FEV1	Liters	2.04	2.09	103			
FEV1/FVC	%	84	80	94			
FEF25-75%	L/sec	2.27	2.21	97			
FEF50%	L/sec	2.96	4.49	152			
FEF75%	L/sec	0.93	0.65	70			
IC	Liters						
VC	Liters	2.47					
PEF	L/sec	5.13	6.81	133			
MVV	L/min	93					
PIF	L/sec		1.71				
FEV1/FEV6%			83				

Lung Volumes/Plethysmography

Vtg	Liters	
VC	Liters	2.47
TLC	Liters	3.90
RV	Liters	1.43
RV/TLC	%	37
FRC PL	Liters	1.96
ERV	Liters	
IC	Liters	

Diffusion

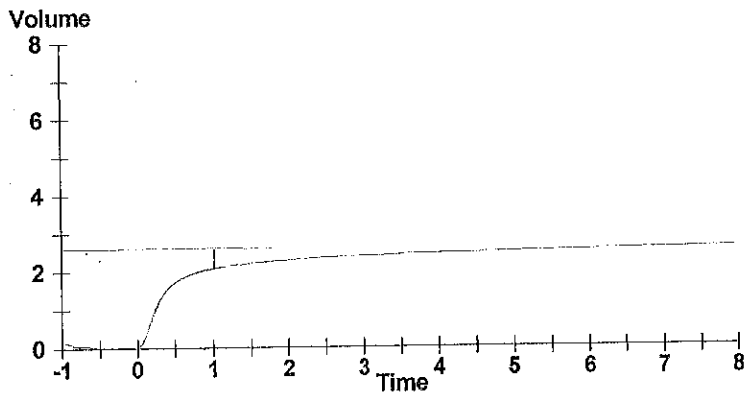
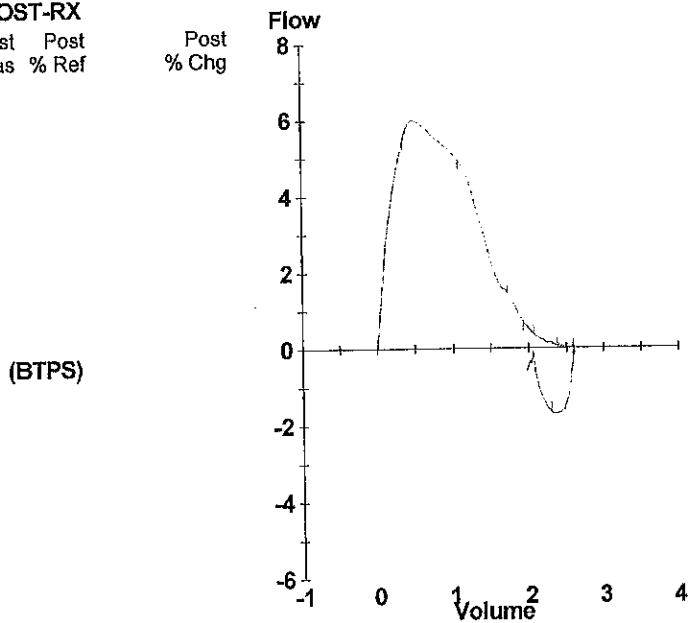
DLCO	mL/mmHg/min	19.9
DL Adj	mL/mmHg/min	19.9
DLCO/VA	mL/mHg/min/L	3.18
VA	Liters	
BHT	Sec	

Resistance

Raw Total	cmH2O/L/sec	
Raw Insp	cmH2O/L/sec	
Raw Exp	cmH2O/L/sec	
Raw	cmH2O/L/sec	2.04
Gaw	L/sec/cmH2O	0.471
sRaw	cmH2O/L/s/L	4.00
sGaw	L/s/cmH2O/L	0.250
Vtg (Raw)	Liters	

Comments:

Interpretation:



**EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT**

**DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)**

**CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS**

DAY	1	2	3	4	5	6	7	8	9
AM	01/20/14	01/21/14	01/22/14	01/23/14	01/24/14	01/25/14	01/26/14	01/27/14	01/28/14
Runny Nose 0 to 3	0 1 (2) 3	0 1 (2) 3	0 1 (2) 3	0 1 2 (3)	0 1 2 (3)	0 1 2 (3)	0 1 2 (3)	0 1 2 (3)	0 1 2 (3)
Itchy Nose 0 to 3	0 1 (2) 3	0 1 (2) 3	0 1 (2) 3	0 1 2 (3)	0 1 2 (3)	0 1 2 (3)	0 1 2 (3)	0 1 2 (3)	0 1 2 (3)
Congestion 0 to 3	(0) 1 2 3	(0) 1 2 3	(0) 1 2 3	0 (1) 2 3	0 (1) 2 3	0 (1) 2 3	0 (1) 2 3	0 (1) 2 3	0 (1) 2 3
Sneezing 0 to 3	0 1 2 (3)	0 1 2 (3)	0 1 2 (3)	0 1 2 (3)	0 1 2 (3)	0 1 2 (3)	0 1 2 (3)	0 1 2 (3)	0 1 2 (3)
Voice Hoarse Y/N	YES (NO)	YES (NO)	YES (NO)	YES (NO)	YES (NO)	YES (NO)	YES (NO)	YES (NO)	YES (NO)
Throat Clearing Y/N	(YES) NO	(YES) NO	(YES) NO	(YES) NO	(YES) NO	(YES) NO	(YES) NO	(YES) NO	(YES) NO
<b>DAY PM</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>	<b>9</b>
Runny Nose 0 to 3	0 1 2 (3)	0 1 (2) 3	0 1 (2) 3	0 1 2 (3)	0 1 2 (3)	0 1 2 (3)	0 1 2 (3)	0 1 2 (3)	0 1 2 (3)
Itchy Nose 0 to 3	0 1 (2) 3	0 1 (2) 3	0 1 (2) 3	0 1 (2) 3	0 1 (2) 3	0 1 2 (3)	0 1 2 (3)	0 1 2 (3)	0 1 (2) 3
Congestion 0 to 3	(0) 1 2 3	(0) 1 2 3	(0) 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 (3)	0 1 2 (3)	0 1 2 (3)	0 1 2 (3)	0 1 2 (3)	0 1 2 (3)	0 1 2 (3)	0 1 2 (3)	0 1 2 (3)
Voice Hoarse Y/N	YES (NO)	YES (NO)	YES (NO)	YES (NO)	YES (NO)	YES (NO)	YES (NO)	YES (NO)	YES (NO)
Throat Clearing Y/N	(YES) NO	(YES) NO	(YES) NO	(YES) NO	(YES) NO	(YES) NO	(YES) NO	(YES) NO	(YES) NO

**SCALE 0 to 3**

- 0= No symptoms (no symptoms detected)
  - 1= Mild symptoms (symptoms present but easily tolerated)
  - 2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)
  - 3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)
- Y=Yes N=No

SUBJECT NUMBER: ERB AKP049 DATE COMPLETED: 1-29-14

SUBJECT INITIALS AND DATE: ERB 1-29-14

**EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT**

**DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)**

*CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS*

DAY AM	7	8	9	10	11	12	13	14	15
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
<b>DAY PM</b>	<b>7</b>	<b>8</b>	<b>9</b>	<b>10</b>	<b>11</b>	<b>12</b>	<b>13</b>	<b>14</b>	<b>15</b>
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

**SCALE 0 to 3**

- 0= No symptoms (no symptoms detected)
  - 1= Mild symptoms (symptoms present but easily tolerated)
  - 2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)
  - 3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)
- Y=Yes N=No

SUBJECT NUMBER: AKP0149

DATE COMPLETED: 1/29/14

SUBJECT INITIALS AND DATE: ERB 1-29-14



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Scier Resources  
 Leslie Byatt, Clin Trials  
 2441 Ridgecrest Dr SE  
 Albuquerque, NM 87108-5129

Client Nbr  
 24664

PATIENT NAME: **X, XERB** PATIENT ID: **AAGL1165** DOB: **06/28/1954** SEX: **F** REPORT STATUS: **Final** PAGE: **1**  
 PHYSICIAN: **Unlisted Physician,** COLLECT DATE & TIME: **01/29/2014 16:19** RECEIVE DATE & TIME: **01/29/2014 19:55** PRINT DATE & TIME: **01/30/2014 06:04**  
 REQUISITION NO.: **31033194** PT. PHONE NO.: **0** PATIENT NO.: **AKP049**  
 COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
<b>Comp Metabolic Panel</b>					
Sodium	140		mmol/L	134-144	
Potassium	4.0		mmol/L	3.5-5.1	
Chloride	107		mmol/L	98-111	
CO2	27		mmol/L	20-30	
Anion Gap	6			6-14	
Glucose	88		mg/dL	60-100	
BUN	9		mg/dL	7-31	
Creatinine	0.63		mg/dL	0.50-1.40	
Creatinine method is IDMS traceable. ESTGFR Calculation has been adjusted. Please note new reference range effective 5/23/2013.					
eGFR non-African Am	>60		mL/min/1.73m2	>60	
GFR Comment	Estimated GFR values are not accurate in acute kidney failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, the very old or very young, races other than Caucasian or African American, people with acute illnesses, or amputations.				
Calcium	9.6		mg/dL	8.4-10.4	
Total Protein	7.1		gm/dL	6.1-8.2	
Albumin	3.8		gm/dL	3.4-4.7	
Globulin	3.3		gm/dL	2.4-4.2	
Bilirubin, total	0.6		mg/dL	0.3-1.2	
Alk Phos	81		U/L	38-150	
AST(SGOT)		65	U/L	6-58	NCS [Signature]
ALT(SGPT)		91	U/L	14-67	NCS [Signature]
Fasting Phosphorus	NO				
Phosphorus	2.8		mg/dL	2.3-5.6	
<b>CBC</b>					
WBC	6.1		x10E3	4.0-10.6	
RBC	4.72		x10E6	4.00-5.36	
Hgb	13.4		gm/dL	12.0-16.0	
Hct	41		%	36-48	
MCV	88		fL	81-98	
MCHC	32.4		gm/dL	31.2-35.2	
RDW	13.7		%	11.0-14.5	
Platelets	177		x10E3	150-400	
Eos, Respiratory	None seen			NS	
Phys, Addr, Phone	NO PHYSICIAN LISTED				

End of Report

*[Handwritten Signature]*  
 05 Feb 2014

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)  
CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

DAY AM	7	8	9	10	11	12	13	14	15
Runny Nose 0 to 3	1/29/14 0 1 2 3	1/30/14 0 1 2 3	1/31/14 0 1 2 3	2/1/14 0 1 2 3	2/2/14 0 1 2 3	2/3/14 0 1 2 3	2/4/14 0 1 2 3	2/5/14 0 1 2 3	2/6/14 0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
<b>DAY PM</b>	<b>7</b>	<b>8</b>	<b>9</b>	<b>10</b>	<b>11</b>	<b>12</b>	<b>13</b>	<b>14</b>	<b>15</b>
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

ERB 2/5/14

SCALE 0 to 3  
0= No symptoms (no symptoms detected)  
1= Mild symptoms (symptoms present but easily tolerated)  
2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)  
3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)  
Y=Yes N= No

SUBJECT NUMBER: AKP049 DATE COMPLETED: 2/5/14 SUBJECT INITIALS AND DATE: ERB 2/6/14

TriCore Reference Laboratories  
1001 Woodward Pl NE  
Albuquerque, NM 87102  
(505)938-8922

Patient Name: ERB, ERB  
Medical Record: AAGL4964  
DOB: 06/02/1954 Age: 59Y Sex: F  
Account Number: 31033211  
Attending MD: Unlisted Physician  
Patient ID: AKP049  
Patient Phone: 0

W3605701 COLL: 02/05/2014 13:18 REC: 02/05/2014 19:49 PHYS: Unlisted Physician  
Req# : 31033211

Eos, Respiratory                      None seen      [NS]  
Phys, Addr, Phone                    Unknown

*AD M. Guzman*  
27 Feb 2014

END OF REPORT

Printed: 02/27/2014 10:21

INTERIM REPORT

Patient Name: ERB, ERB  
Medical Record #: AAGL4964  
Location: CORE

Page: 1

**EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT**

**DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)**

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

DAY AM	7	8	9	10	11	12	13	14	15
Runny Nose 0 to 3	2/5/14 0 1 2 3	2/6/14 0 1 2 3	2/7/14 0 1 2 3	2/8/14 0 1 2 3	2/9/14 0 1 2 3	2/10/14 0 1 2 3	2/11/14 0 1 2 3	2/12/14 0 1 2 3	2/13/14 0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
<b>DAY PM</b>	<b>7</b>	<b>8</b>	<b>9</b>	<b>10</b>	<b>11</b>	<b>12</b>	<b>13</b>	<b>14</b>	<b>15</b>
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

2/12/14  
EB

**SCALE 0 to 3**

- 0= No symptoms (no symptoms detected)
- 1= Mild symptoms (symptoms present but easily tolerated)
- 2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)
- 3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)
- Y=Yes N=No

SUBJECT NUMBER: AKP049 DATE COMPLETED: 2/12/14 Cam  
 2/5/14 - (pm)  
 EB 2/12/14

SUBJECT INITIALS AND DATE: EB 2/12/14



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505 ) 938-8922

Lovelace Scientific Resources  
Leslie Byatt, Clinical  
2441 Ridgecrest Dr SE  
Albuquerque, NM 87108-5129

Client Nbr  
24664

PATIENT NAME **ERB, ERB** PATIENT ID **AAGK4096** DOB **06/28/1954** SEX **F** REPORT STATUS **Final** PAGE **1**

PHYSICIAN **Unlisted Physician,** COLLECT DATE & TIME **02/12/2014 13:00** RECEIVE DATE & TIME **02/12/2014 19:37** PRINT DATE & TIME **02/13/2014 06:06**

REQUISITION NO. **31033206** PT. PHONE NO. **0** PATIENT NO. **049**

COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
Eos, Respiratory Phys, Addr, Phone FAX RESULTS FAX PHONE NUMBER	PHYS UNKN	Rare		NS	
	348	8546			

End of Report

*Mr. Gail MD*  
13 Feb 2014



Study Identification: 27114 2749 2014

LSR Study #: \_\_\_\_\_

Subject Number: AKP049

Subject Initials: ERB

ADVERSE EVENT LOG

Adverse Event	** Start Date (DD/MMM/YYYY)	SEVERITY	Relationship to Study Drug (Suspected/Not Suspected)	** End Date (DD/MMM/YYYY)	Action Taken	Investigator Initials/Date
Upper Respiratory Infection	22/feb/2014	mod	Not suspected	13/feb/2014	med taken	ERB 20 Feb 2014
						/
						/
						/
						/
						/
						/
						/
						/
						/
						/
						/

\*\* If day is unknown, write UNK in space provided, but every effort should be made to be as specific as possible\*\*

Investigator Signature (at end of study): EMM Mankin MD Date: 20 Feb 2014

SC Signature (at end of study): Ericka Maldonado Date: 2/19/14

Study Identification: 2749  
 LSR #: \_\_\_\_\_  
 Subject Number: AKP  
 Subject Initials: ERG

**CONCOMITANT MEDICATION LOG**

List all prescription medications you are taking. Also include over-the-counter medications, vitamins and supplements.

Name of Medication	Indication (What you take it for)	Dose	Unit	Frequency	Route	* Start Date (Day/Month/Year)	Stop Date	Ongoing at EOS (for Clinic use)
EXAMPLE	Diabetes	500	MG	2 Tabs per day	Oral	UNK/AUG/1999		<input type="checkbox"/>
Abilify	Anxiety	5	mg	QD	PO	--/--/2010		<input checked="" type="checkbox"/>
Clonazepam	Anxiety post	2	mg	QD	PO	--/--/2010		<input checked="" type="checkbox"/>
Estronipate	menopausal	1.5	mg	QD	PO	--/--/1990		<input checked="" type="checkbox"/>
Fexofenadine	Depression	15	mg	QD	PO	--/--/1999		<input checked="" type="checkbox"/>
Mirtazapine	Anxiety	15	mg	QD	PO	--/--/1999		<input checked="" type="checkbox"/>
Simvastatin	<del>hyperlipidemia</del> hypertension	20	mg	QD	PO	--/--/2010		<input checked="" type="checkbox"/>
Zolpidem	Insomnia	10	mg	QHS	PO	--/--/2004		<input checked="" type="checkbox"/>
Allegra	allergies	10	mg	QD	PO	--/--/2012	Nov/2013	<input type="checkbox"/>
Nuquin Colibz FIC	respiratory infection	2	TAB	PRN	PO	04/Feb/2014	05/Feb/14	<input type="checkbox"/>

\* If day or month of medication date is unknown, write UNK in space provided

Investigator Signature (at end of study): [Signature] Date: 27 Feb 2014  
 SC Signature (at end of study): [Signature] Date: 2/24/14  
 PAGE: 1 of \_\_\_\_\_

**EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)  
ON PATIENT-PERCEIVED BREATHING COMFORT**

**DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)**

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

DAY AM	14	15	16	17	18	19	20	21	22
Runny Nose 0 to 3	2/12 0 1 2 3	2/13 0 1 2 3	2/14 0 1 2 3	2/15 0 1 2 3	2/16 0 1 2 3	2/17 0 1 2 3	2/18 0 1 2 3	2/19 0 1 2 3	2/20 0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
<b>DAY PM</b>	<b>14</b>	<b>15</b>	<b>16</b>	<b>17</b>	<b>18</b>	<b>19</b>	<b>20</b>	<b>21</b>	<b>22</b>
Runny Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Itchy Nose 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Congestion 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Sneezing 0 to 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
Voice Hoarse Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
Throat Clearing Y/N	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

**SCALE 0 to 3**

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N=No

SUBJECT NUMBER: AKP049 DATE COMPLETED: 2/19/14

SUBJECT INITIALS AND DATE: EB 2/19/14



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Scier. Resources  
 Leslie Byatt, Clin rials  
 2441 Ridgcrest Dr SE  
 Albuquerque, NM 87108-5129

Client Nbr  
 24664

PATIENT NAME **ERB, ERB** PATIENT ID **AAGM2177** DOB **06/28/1957** SEX **F** REPORT STATUS **Final** PAGE **1**  
 PHYSICIAN **Unlisted Physician,** COLLECT DATE & TIME **02/19/2014 12:46** RECEIVE DATE & TIME **02/19/2014 21:52** PRINT DATE & TIME **02/20/2014 06:04**  
 REQUISITION NO. **31033214** PT. PHONE NO. **0** PATIENT NO. **AKP049**  
 COMMENTS :

Test	Result		Units	Reference Range	Site Code
	In Range	Out of Range			
<b>Comp Metabolic Panel</b>					
Sodium	139		mmol/L	134-144	
Potassium	3.7		mmol/L	3.5-5.1	
Chloride	108		mmol/L	98-111	
CO2	23		mmol/L	20-30	
Anion Gap	8			6-14	
Glucose		143 H	mg/dL	60-100	NCS [Signature]
BUN	7		mg/dL	7-31	
Creatinine	0.72		mg/dL	0.50-1.40	
Creatinine method is IDMS traceable. EstGFR Calculation has been adjusted. Please note new reference range effective 5/23/2013.					
eGFR non-African Am	>60		mL/min/1.73m2	>60	
GFR Comment	Estimated GFR values are not accurate in acute kidney failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, the very old or very young, races other than Caucasian or African American, people with acute illnesses, or amputations.				
Calcium	9.8		mg/dL	8.4-10.4	
Total Protein	7.2		gm/dL	6.1-8.2	
Albumin	3.9		gm/dL	3.4-4.7	
Globulin	3.3		gm/dL	2.4-4.2	
Bilirubin, total	0.7		mg/dL	0.3-1.2	
Alk Phos	90		U/L	38-150	
AST(SGOT)		71 H	U/L	6-58	NCS [Signature]
ALT(SGPT)		91 H	U/L	14-67	NCS [Signature]
Fasting Phosphorus	NO				
Phosphorus	2.6		mg/dL	2.3-5.6	
<b>CBC</b>					
WBC	6.8		x10E3	4.0-10.6	
RBC	5.08		x10E6	4.00-5.36	
Hgb	14.2		gm/dL	12.0-16.0	
Hct	45		%	36-48	
MCV	88		fL	81-98	
MCHC	31.9		gm/dL	31.2-35.2	
RDW	13.6		%	11.0-14.5	
Platelets	206		x10E3	150-400	
Eos, Respiratory	None seen			NS	
Phys, Addr, Phone	Unknown				

End of Report

*[Handwritten Signature]*  
 20 Feb 2014

ERB  
AKP049  
2/19/14

Effects of AkPharma's Calcium Glycerophosphate  
Nasal Spray wash (AkP 010112A) on Patient-Perceived Breathing Comfort

SATISFACTION QUESTIONNAIRE:

Would you use / purchase this nasal wash product in the future?"  YES  NO

You are also encouraged to make any free comments regarding your experience in the use of this product regarding your opinion of any of its effects not covered specifically in the Daily Diary:

*This product was very help for my nasal passage. Clear air born products and allergent. Would have love to keep the remaining product to use. I was able to breath at night.*

[Type text]

Subject initials and Date ep 2/19/14

Study Staff Initials and Date EM 2/19/14