

Allergy, Asthma, & Respiratory Care Medical Center, Inc.

Medical Director: **Kenneth T. Kim, M.D.**

Diplomate American Board of Allergy and Immunology

Diplomate of American Board of Internal Medicine

Long Beach Office :

2600 Redondo Ave., Suite 400

Long Beach, CA 90806-2325

(562) 997-7888

Fax (562) 997-8884

Newport Office:

4030 Birch St., Suite 103

Newport Beach, CA 2660-2254

(949) 724-8801

Fax (949) 724-8810

INFORMED CONSENT FOR LATEX ALLERGY TESTING

This information sheet is to explain the status of latex allergy testing done in this office and the rest of the country. At the present time, there is no FDA approved skin test for latex allergy testing. The standard of care in the community is for an allergist to take gloves that a claimant might bring in or gloves that he or she has in stock, soak them in some saline, take an aliquot of that saline and use it as a latex skin test reagent. The wheal and flare reaction is then measured and any adverse reactions are noted. The problem with this standard of care treatment is that one does not know the allergen content of these home made extracts. Given that this is the standard of care that is commonly being followed, Allergy, Asthma, & Respiratory Care Medical Center also does latex allergy testing. However, the difference is we have gone through the trouble of actually quantitating the amount of latex protein per cc of aliquot. We, therefore, know whether we have 0, 1 mcg, 10 mcg, 100 mcg, 500 mcg, or 1 mg strength extracts. This extract is also home made, however, we feel it is safer because we actually have quantitated the actual amount of protein that is in the extract and we, therefore, know exactly the strength of the extracts we are using.

This office was involved in submitting clinical data for two of the blood tests that are now FDA approved. This office was also 1 of 12 sites involved in a multicenter study that was performed in the late 1990's. The skin test reagent that was used in the multicenter study was made by Greer and was on protocol and is not being used for any testing here. The strengths of those extracts have been published. The strengths of those extracts in that multicenter study was 1 mcg, 100 mc, and 1 mg strengths. Since that reagent is not commercially available, our offices use similar strength extracts and we feel confident that this gives us fairly comparable results to the multicenter study.

In any evaluation of latex allergy testing, we would typically blind the person who is being tested. So if you are being tested, we will not be telling you whether you are getting tested to latex allergen or some other allergen or what strength extract you are being tested to. We always perform these tests in an incremental fashion. Sometimes the testing can go over several days or may need to be repeated if the results

are not clear. At the very end of this testing, we will sit down with you and review what we tested you for, the reactions you had, and our overall clinical impression. It may be frustrating prior to that getting tested because neither the staff nor the doctors will be informing you what strength of extract you are being tested to.

The risks of testing include an allergic reaction such as itchy eyes, watery eyes, itchy or runny nose, wheezy, shortness of breath, anaphylaxis and even death.

I, _____, understand that I will be getting
(PATIENT NAME)

latex skin prick testing. I understand that this is not under any clinical research protocol and that there is no IRB approval needed because we are not conducting any research but only trying to help diagnose my condition. I understand that the only difference between what is being done in Allergy, Asthma, & Respiratory Care Medical Center and what is done in the community is that Allergy, Asthma, & Respiratory Care Medical Center has quantitated the amount of allergen that is present in its extracts. I understand that I may not be informed of what I am being tested to on a particular day until testing is completely completed.

All of my questions concerning the risks and benefits of the testing have been answered, and I am willing to proceed.

Signature

Date: _____