Patient History - Allergy Diagnosis

Name _____
Occupation _____
Phone _____ Age _____
E-Mail _____ Sex _____

Which of the following symptoms have you experienced? Please circle all that apply.

Hay Fever Runny Nose Stuffy Nose Sinus Problems
Sneezing Itchy Eyes Post Nasal Drip Ear Problems
Asthma Cough Cough (night only) Wheezing
Shortness of Breath Tight Chest Exercise Symptoms
Phlegm or Mucus Headache Diarrhea Hives
Fatigue Eczema Rashes Abdominal Symptoms
Severe Acne Nausea

How long have you had these symptoms?
0-1 years 1-5 years 5-10 years 10+ years

Times of year your symptoms worsen?
Spring Summer Fall Winter No Change

What about your other allergy symptoms?

Are you aware of anything you are allergic to?

_____

What do you think you might be allergic to?

_____

Do you have pets / animals?

_____

Are you allergic to any medication?

_____

If you smoke, how often? ___ How many years? ___

Have you ever had an allergy test? _____

Do your symptoms interfere with your:
Sleep? _____ Play? _____ Work? _____
Comfort? _____ Other? _____

Are your symptoms worse in the AM or PM? _____

Are your symptoms worse indoors our out? _____

Who gets Allergies?

Over the past decade, allergies have increased dramatically in western culture. Twenty to 40 percent of the population suffers from allergy and it is generally noted that at least one out of every four children suffers from allergies.[1,2] In fact, even if only one parent has allergies, about 25 percent of the time a child will too, and if both parents have allergies, there is more than a 50 percent chance of having an allergic child.[3]

People who suffer from allergies are often sensitive to more than one allergen. Symptoms may not appear until they are exposed to an intolerable amount of a single allergen or smaller amounts of multiple allergens. This makes it important to identify the specific allergens responsible. With this information, a plan for prevention or treatment can make the difference between a chronic illness and a productive, healthy lifestyle.

Always follow your doctor's instructions carefully.

Do you have these symptoms?

- Runny, drippy nose
- Fits of sneezing
- Tearing, itchy eyes
- Itchy throat and palate

If so, you may be suffering from allergies. Complete the Patient History Form on the next page and talk to your doctor about your symptoms.

Hitachi Chemical Diagnostics, Inc.

Hitachi Chemical Diagnostics is a global leader of in vitro allergy diagnostics with headquarters in the heart of Silicon Valley and offices around the world. Our sense of community and legacy of innovation in allergy diagnosis are our strengths.

We were one of the first companies to introduce an assay system using chemiluminescent technology and the first to introduce a multiple format test capable of reporting individual results.

An integral member of the Hitachi group, we work with industry leaders, laboratories and distributors in more than 40 countries every day. Our mission is to provide the medical community and you with access to the latest allergy testing technology.

Please ask your health care provider for more information about our *CLA® Allergy Test*.

[1] Sly RM, Changing Prevalence of Allergic Rhinitis and Asthma, Annals of Allergy, Asthma & Immunology, Vol. 82, March 1999, p233-248

[2] Nolte H, Undiagnosed Asthma & Allergy; Nursing & Patient Care - Allergy Diagnosis, Private Hospital Healthcare Europe; 2001

[3] American Academy of Allergy Asthma & Immunology, Allergy & Asthma Advocate: Spring 2006, www.aaaai.org/patients/advocate/2006/spring/child_allergist.asp

[4] Christensen SN, Backer V, Dubuske, L, Nolte H, In Vitro Diagnostics Evaluation of Patients with Inhalant Allergies: Summary of Probability Outcomes Comparing Results of CLA and CAP-Specific Immunoglobulin E Test Systems, Allergy and Asthma Proceedings, 2003, Vol. 24, No. 4, pages 253-258

[5] Poon AW, Goodman CS, Rubin RJ, In Vitro and Skin Testing for Allergy: Comparable Clinical Utility and Costs, The American Journal of Managed Care, 1998, Vol. 4, No. 7, pages 969-985

United States Office
Hitachi Chemical Diagnostics, Inc.
630 Clyde Court
Mountain View
CA 94043-2239
650.961.550
800.233.6278
www.hcdiagnostics.com

European Office
Hitachi Chemical Diagnostics, Inc.
Hitachi Europe Ltd.
Whitebrook Park
Lower Cookham Road
Maidenhead, Berkshire, SL6 8YA
United Kingdom
44 (0) 1628.585.590

Doc. No. 0736 Rev. 00

A Guide to Allergies

AND THE CLA® ALLERGEN-SPECIFIC IgE ASSAY

HITACHI
Inspire the Next

What is an Allergy?

An allergy is an overreaction of the body's immune system to an ordinarily harmless substance. Allergies are not just seasonal. They exist throughout the year, indoors and out, and affect people of all ages. Allergies can impair performance, interfering with sleep, cognitive skills and even physical ability. Occasionally, allergies can cause anaphylaxis, a potentially life threatening reaction.

Many things in our every day lives can trigger an allergic reaction, including animal dander, housedust mites, foods, grasses, trees, weeds, and molds.

Animal Dander… Traditionally, fur is believed to cause allergic reaction to animals, but researchers have found the cause to be proteins secreted by oil glands in the animal's skin. Dander, saliva, and urine, which carry these proteins, eventually dry up and release the proteins into the air.

Housedust Mites… This allergic reaction results from the airborne waste product of Dust Mites, tiny organisms that live in the dust of areas inhabited by people like bedding, upholstered furniture, drapes, and carpets.

Foods… In a typical food allergy, the immune system produces antibodies to a specific food. Commonly troublesome food allergens include milk, eggs, peanut and shellfish.

Grasses, Trees and Weeds… Tiny particles of pollen are released into the air during certain seasons where they can enter human noses and throats, triggering an allergic reaction. Patients suffering from seasonal "hay fever" may also have sensitivities to perennial allergens such as housedust. Sensitivities to such perennial allergens may contribute to the severity of seasonal symptoms.

Molds… Much like pollens, molds release spores into the air where they can enter human noses and throats, triggering an allergic reaction. Mold allergies can be perennial or seasonal depending on the geographic area and are most noticeable indoors in damp environments, while others are a problem outdoors on windy days.

Diagnosing Allergies

A physician's first step is to identify allergic patients. Individual patients are screened to (1) identify the allergen; (2) establish a causal relationship between exposure and the occurrence of symptoms; and (3) identify the immunological mechanism involved. To establish the immunologic mechanism, allergen-specific antibodies called IgE must be identified and measured. This is done by skin prick testing or *in vitro* allergy testing.

Skin Prick Testing… An allergy specialist usually performs skin testing after a referral from a General Practitioner. There are no age limits for skin testing. Results are usually available within 20 minutes.

Commonly performed on the forearm and sometimes the back, the skin is cleaned with alcohol and an allergen extract is pricked into the skin. If an allergy is present, a small itchy bump and surrounding redness often referred to as a "wheal and flare" will appear in approximately 15 minutes. This indicates the presence of IgE antibodies capable of recognizing the shape of that specific allergen, like a lock "recognizes" a key.

There are some side effects of skin testing. Medications with anti-histamine-like actions must usually be avoided for three to thirty or more days before testing so as not to interfere with test results. After testing, swelling and itching typically resolve within an hour however for some patients this may persist longer.

***In Vitro* Testing…** Performed *in vitro*, or 'outside the body,' this laboratory blood test can measure specific IgE levels in patient serum. Medications need not be discontinued as they do not interfere with the reliability and performance of the test. The doctor simply draws a small amount of blood during an office visit, has it tested in a lab and usually has the results within 24 hours.

The *CLA® Allergy Test* offers reliable results in agreement with skin tests.[4] In fact, many professional medical societies recommend the use of in vitro tests like the *CLA® Allergy Test* to confirm the diagnosis of allergy in symptomatic patients.[5]

Interpretation of CLA® Allergy Test Results

Test results are provided in "Luminometer Units," or "LU's," which are in turn grouped into class results. Classes are assigned from "Class 0," no measurable specific IgE, to the highest class, "Class 4," which correlates to very high levels of specific IgE. Clinical interpretation of the results should correlate with that used for skin testing where results are similarly classified from zero to four.

Class 0: No detectable allergen specific IgE.

Class 1/0: Very low level of allergen specific IgE.

Class 1: Low level of allergen specific IgE.

Class 2: Moderate level of allergen specific IgE.

Class 3: High level of allergen specific IgE.

Class 4: Very high level of allergen specific IgE.

Clinical diagnosis of allergies depends on the amount of allergen-specific IgE found and physical symptoms when exposed to that specific allergen. It is easier to predict that allergy does not exist if no allergen-specific IgE is found. Conversely, it is easier to predict that allergy does exist in patients who show increasing levels of allergen specific IgE. A doctor's ability to diagnose allergies varies from allergen to allergen and person to person depending on the context of a patient's symptoms when exposed to a specific allergen. Even high levels of allergen specific IgE may not predict allergy symptoms in some individuals for some allergens. Research in allergy and allergens is underway to assist in improving the positive predictive value of allergy tests.

Treatment Options

Once an allergy diagnosis is made, a specific treatment program can begin. Allergy management falls into three main categories: avoidance, medication and immunotherapy.

Avoidance… Once the source of an allergy is identified, one solution may be to simply remove or control it. This approach is most effective with food and animal allergies. In addition to standard heating and cooling air filters, portable devices can be especially helpful in reducing animal allergens in individual rooms. As for outdoor airborne allergens such as pollens and mold spores, it is obviously difficult to effectively diminish an individual's exposure especially during the seasons in which they are abundant.

Allergy avoidance literature is readily available and can serve as a useful tool in coping with allergy and asthma symptoms.

Pharmacotherapy (Medication)… Effective new prescription drugs can reduce allergy symptoms. Many are often effective immediately, producing benefits by neutralizing the effects of the chemicals released in the body during an allergic reaction. Medicines may have side effects and for some people are incompletely effective.

Immunotherapy (Allergy Shots)… Injections are given frequently in scheduled doses of gradually increasing concentrations using extracts containing allergens to which the patient has specific IgE antibodies. The objective is to gradually desensitize the body to the offending allergens while ultimately diminishing the frequency of the injections. Ideally, an injection program can be discontinued after several years of therapy.

Immunotherapy can be effective and should be considered only when the patient's test results, symptoms and clinical history have been carefully evaluated. There are important risks associated with immunotherapy that should be discussed with your physician.

Food allergies differ from inhalant allergies due to different routes of contact and potentially greater exposure volume. Currently, immunotherapy is not an option so avoidance of the identified food that causes specific allergic symptoms is recommended. A small percentage of individuals develop severe, life threatening sensitivity to a single food and must avoid all contact for their entire life. Most food allergies are not so severe but are generally still best treated by avoidance. A carefully crafted elimination diet is used to confirm a food allergy. If the results are not clear, the best approach is a placebo controlled food challenge performed by an allergist in a medical setting and under direct observation of the individual when exposed to the possible food allergen.