LETTER OF MEDICAL NECESSITY

Infinite Allergy Labs FAST Panel

Date:_____

Practitioner Name:_____
Clinic Name:_____
Address:_____
City, State Zip:_____

Dear sir or madam:
I am writing to request full coverage or at least in-network benefit coverage for the diagnostic Food Allergy/Sensitivity Test performed by Infinite Allergy Labs for my patient [Patient Name]. I am [Patient Name]'s physician practicing at [Clinic Name] I consider this test a medically necessary step in the diagnosis and treatment of my patient,

PATIENT INFORMATION

Patient: _____

ID:_____

Provider:_____

Date of service: _____

My patient has a history of:

NETWORK PROVIDER SERVICES

I chose Infinite Allergy Labs to perform the Infinite Allergy Labs FAST Panel instead of alternative in-network laboratory testing because Infinite Allergy Labs offers both Allergy, sensitivity and specificity that can help exclude or confirm true reactions to dietary antigens.

There is no in-network laboratory in my area able to provide comparable testing.

Test Description

Food Allergy/sensitivities affect more than 100 million people worldwide. Food sensitivities cause a range of illness and symptoms, including skin rashes and chronic intestinal diseases.

The Infinite Allergy Labs FAST Panel yields many benefits, including uncovering which foods are causing inflammation and disease, developing a personalized nutritional guide, and improving a patient's state of health and energy levels. The test is the most sensitive food test available using the most up to date technology.

The Infinite Allergy Labs FAST Panel employs unique methods that detect both IgG, IgE, and C3b/d antibodies and complement antigen together to determine the reactivity of each sample against a wide variety of food antigens. These methods yield more complete profiles of the various foods that may cause food sensitivities.

The Infinite Allergy Labs FAST Panel is the highest quality and most sensitive food sensitivity test available which can measure up to 88 of the most common foods and additives.

The Infinite Allergy Labs FAST Panel is a multi-pathway delayed food allergy & sensitivity test. The test uses new technology that measures both IgG/ IgE and Immune Complexes, the most common food-related pathways in the body.

Food elimination based on the Infinite Allergy Labs FAST Panel results reduces symptoms a patient is experiencing.

We are focused on Personalized medicine looking at identifying tests which help physicians with individualized results whish aids in treatment of underlying symptoms with focus on Food Sensitivity Testing with our Infinite Allergy Labs FAST Panel.

Clinical Research

Allergy is a form of exaggerated sensitivity or hypersensitivity to a substance that is either inhaled, ingested, injected, or encounters the skin or eye. The term allergy is used to describe situations where hypersensitivity results from heightened or altered reactivity of the immune system in response to external substances. Allergic or hypersensitivity disorders may be manifested by generalized systemic reactions as well as localized reactions in any part of the body. The reactions may be acute, subacute, or chronic, immediate, or delayed, and may be caused by a variety of offending agents such as: pollen, molds, mites, dust, feathers, animal fur or dander, venoms, foods, drugs, etc.

Food intolerances are believed to arise when certain, incompletely digested food particles enter your bloodstream and are treated as foreign substances. This results in your imm1me system producing tailor-made antibodies (IgG), which attack the food in question. Some researchers believe this inflammatory response in the body can increase certain symptoms. Food sensitivities have been associated with Irritable Bowel Syndrome (TBS), bloating, tiredness, constipation, diarrhea, cramping, eczema, chronic inflammation, headaches, and migraines,

The detection of food-specific IgG shows a physiologic response of the immune system to exposure to food. For IgG4 in particular, this may be normal human response. Immunoglobulins G antibodies directed at specific foods can be found in healthy children as well as adults. Higher levels of IgG4 to

foods in infancy may be associated with tolerance to those foods later in childhood. The relation between IgG4 and food has been further explored through the recent developments in oral immunotherapy to foods. Efforts to induce permanent tolerance to allergens such as milk or peanuts have been accompanied by increases io patients' IgG4 levels to those foods. Therefore, IgG4 is believed to be a marker of exposure to food and possibly of tolerance. Further research is required to clarify any role for specific IgG measurement in the assessment of a patient with potential food allergy.

Immunoglobulin G (IgG) food allergy testing has made vast advancements since the year 2003 when the American Academy of Allergy, Asthma, and Immw1ology published a statement that "Measurement of specific IgG antibodies to foods is also unproven as a diagnostic tool"(l) Most of the IgG food allergy throughout the world is done using the same immunochemical technique. First, soluble food proteins in solution are reacted to a solid phase that chemically binds to a variety of proteins. The use of plastic microtiter trays with one to several hundred wells has become the most common material used as the solid phase. Then these trays are washed, dried, and stored for later use. A sample of diluted serum is then added to each of the wells. Antibodies of all types in the diluted serum bind to the specific food molecules that are attached to the plastic wells of the tray. Next, the plates are washed to remove any nonspecific antibodies in the diluted serum. At this time, food antibodies from all the five major immunoglobulin classes called G, A, M, E, and D may be attached to the food antigens on the plate. The next step confers specificity on the assay, Antisera from sheep, goats, rabbits, or other animals that specifically binds to lgG is added to microtiter wells and only binds to IgG, not to IgA, lgM, IgD, or lgE . This antibody to IgG has previously been modified by the attachment of an enzyme that can be measured conveniently. The amount of enzyme bound to food antigen-IgG complexes on the plate is directly related to how much IgG antibody is attached to a given food. The overall technique is tem1ed Enzyme Linked Immuno Assay or ELISA. If IgG4 is measured, an antiserum specific for IgG4 only must be used for the final step.

The usefulness of IgG food allergy to design customized elimination diets has now been documented in scientific studies.

IGG4 FOOD ALLERGY

Immunoglobulin G (IgG) is classified into several subclasses termed 1, 2, 3, and 4. IgGs are composed of two heavy chain-light chain pairs (half-molecules), which are connected via inter-heavy chain disulfide bonds situated in the hinge region (Figure 1). IgG4 antibodies usually represent less than 6% of the total IgG antibodies. IgG4 antibodies differ functionally from other IgG subclasses in their lack of inflammatory activity, which includes a poor ability to induce complement and immune cell activation because of low affinity for Clq (the q fragment of the first component of complement). Consequently, IgG4 has become the preferred subclass for immunotherapy, in which IgG4 antibodies to antigens are increased to reduce severe antigen reactions mediated by IgE. If antigens preferentially react with lgG4 antibodies, the antigens cannot react with IgE antibodies that might cause anaphylaxis or other severe reactions. Thus, IgG4 antibodies are often termed blocking antibodies. Another property of blood derived IgG4 is its inability to cross-link identical antigens, which is referred to as “functional monovalency". IgG4 antibodies are dynamic molecules that exchange half of the antibody molecule specific for one antigen with a heavy-light chain pair from another molecule specific for a different antigen, resulting in bi-specific antibodies that are unable to form large, cross-linked antibodies that bind complement and thus cause subsequent inflammation (16). In specific immunotherapy with

allergen in allergic rhinitis, for example, increases in allergen specific IgG4 levels indeed correlate with improved clinical responses. IgG4 antibodies not only block mediated food allergies the reactions of food antigens with other lgG subclasses, reducing inflammatory reactions caused by the other lgG subclasses of antibodies to food antigens.

In IgG mediated food allergy testing, the goal is to identify foods that can cause inflammation that can trigger many adverse reactions. lgG 1, lgG2, and lgG3 all can cause inflammation because these antibodies do not exchange heavy and light chains with other antibodies to form bispecific antibodies. Thus, IgG 1, IgG2, and lgG3 antibodies to food antigens can and do form large immune complexes or lattices that fix complement and increase inflammation. The presence of lgG4 antibodies to food antigens indicates the presence of antibodies to foods that will not usually cause inflammation even though high amounts of these antibodies do indicate the presence of immune reactions against food antigens. Testing only for IgG4 antibodies in foods limits the ability of the clinician to determine those foods that are causing significant clinical reactions that are affecting their patients.

LABORATORY PERFORMING TEST:

Infinite Allergy Labs - a high complexity CLIA laboratory located at 3885 Crestwood Pkwy Suite 550 Duluth GA 30096.

CLIA ID#: 11D2142105

Phone: 1-833-FOODALLERGY

www.infiniteallergyalabs.com

Please approve full coverage for Infinite Allergy Labs or at least apply in-network benefit coverage for this test.

Thank you for your prompt attention. I look forward to receiving a written response from you within two weeks.

Sincerely,

Practitioner Name:_____
Clinic Name:_____
Address:_____
City, State Zip:_____
Phone:_____