

Now with Revolutionary Immunofluorescent Bead Technology



# What Makes the IgG Food MAP a Superior Test?



#### **Assesses 190 Foods**

Includes a wide range of foods, common in the Western, Asian, and Mediterranean diets. We have added a hemp allergy marker because it is very common now as a food source or as medical CBD. We are able to run the IgG Food MAP on both serum and dried blood spot samples.



#### **Upgraded Technology**

Antigen-specific IgG antibodies are captured on multiplexed magnetic beads, using xMAP® (Multiple Analyte Profiling) technology. The xMAP® bead-based immunoassay allows for the simultaneous detection of IgG antibodies to all 190 foods in two single test wells, reducing sample volume requirements and reagents while increasing sensitivity and specificity as compared to traditional platebased ELISA tests. The upgraded immunoassay is cost and time effective, easy to perform and reproducible. We have now fully automated all steps of our testing processes, leading to even better precision.



#### **Greater Reliability of Results**

In the multiplexed bead-based immunoassay, food antigenic proteins are first covalently bound to beads. The beads are mixed with the patient's sample where bead-bound antigens capture the specific IgG antibodies present in the sample. The food-specific IgG antibody level of each sample is detected with a fluorescent-labeled antibody against IgG. Every reaction with a patient sample also contains control beads to ensure accurate results. The fluorescent signal is measured using an xMAP® analyzer. The amount of foodspecific antibody detected per allergen specific bead is directly proportional to the fluorescent signals. The higher the fluorescence, the more specific IgG antibodies are present in the sample. Once test results are available for review, our Quality Assurance (QA) team carefully verifies that quality control measures are within instrument and assay specifications.



#### **Upgraded Sensitivity and Specificity**

MDX's xMAP® immunoassay with fluorescence readout has proven to be even more sensitive than ELISA tests. The IgG Food MAP test detects all food antibodies with greater precision than ELISA tests thanks to the superior technology we've developed for the test.



#### **Ecofriendly Technology**

The xMAP® bead-based immunoassay is environmentally friendly, reducing plastic pollution. In the ELISA, a panel for 190 foods would require 190 wells (2 plates) per sample. In contrast, the bead-based platform only requires two wells per sample. In other words, the bead-based immunoassay would use just one plastic microtiter plate for testing 48 samples, while the ELISA would use 96 plates to test the same number of samples.



### Tests for Specific Food Antigenic Proteins

MDX has upgraded from the ELISA's single analyte detection to multiple analyte detection. The multi-plexed, bead-based assay only detects IgGs against food antigenic proteins that were covalently bound to the beads, making this assay more specific to proteins than the ELISA. In the ELISA, there is no covalent binding of proteins; instead, proteins or other antigens are bound to the surface of a plastic well by adsorption. This non-specificity of the surface allows the binding of glycan-rich molecules such as Candida and yeast. Because of this, MDX is providing a separate report for the yeasts which will be tested by ELISA, rather than the xMAP® immunoassay.

### What is IgG?

IgG is the major antibody found in serum. IgGs are composed of two fragment antigen binding (Fab) regions that contain the antigen binding sites and the Fc region, which is responsible for most of the biologic activity of the antibodies (Figure 1). An antigen is a substance that causes the immune system to produce an antibody that specifically reacts with it. IgG-mediated reactions to food antigens may be delayed by several hours or days, whereas IgE food antibody reactions are quite immediate.

Human IgG is separated into four subclasses denoted IgG1 IgG2, IgG3, and IgG4. Each subclass varies in abundance and biological function. IgG1 and IgG3 are predominantly responsible for antibody protection against reinfection. IgG2 antibodies are opsonic (marking a pathogen for ingestion and destruction) and develop in response to carbohydrate polysaccharide antigens. IgG4 molecules function as skin-sensitizing immunoglobulins and are thought to block antibodies produced in response to chronic exposure to antigens.

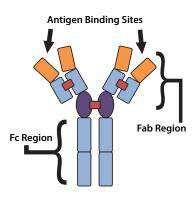


Figure 1

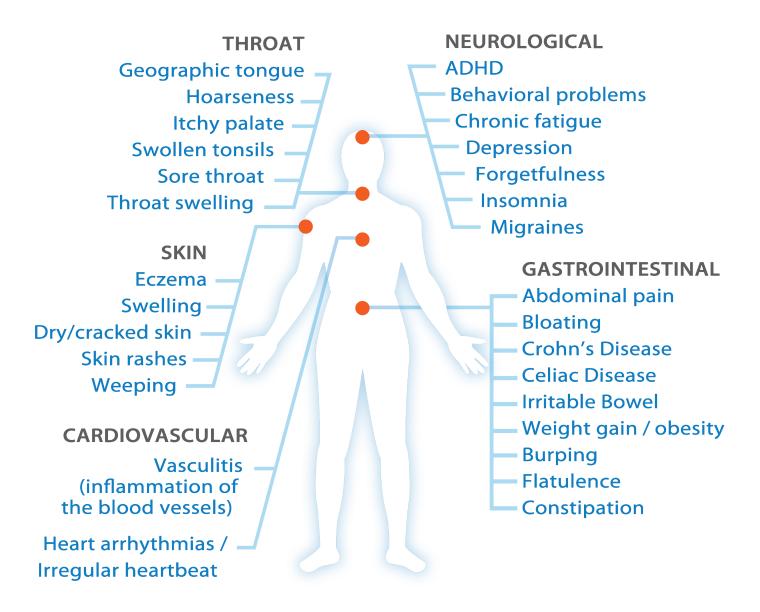
### Why Test IgG Sensitivities?

Immunoglobulin G (IgG) food testing is a useful guide for structuring elimination diets for patients with many chronic conditions. Individuals with neurological, gastrointestinal, movement, and behavioral disorders often suffer from IgG food sensitivities. People may continue to eat offending foods unaware of their potential adverse effects. Symptoms associated with food sensitivities may occur hours or days after the offending food was eaten because IgG food anti-bodies remain for a much longer time than IgE antibodies. IgE food allergy causes the release of histamine, producing an immediate hypersensitivity reaction. In contrast, IgG food sensitivity is triggered by the binding of complement to IgG food antigen complexes, causing an inflammatory response. This is a delayed hypersensitivity reaction in which symptoms appear anywhere from hours to days after eating the offending food. Elimination of IgG-positive foods may improve symptoms of irritable bowel syndrome, Autism Spectrum Disorders, AD(H)D, cystic fibrosis, rheumatoid arthritis, and epilepsy, according to numerous clinical studies.

### Clinical Significance of IgG Testing

The clinical significance of IgG food testing was illustrated in an early article published by an otolaryngologist who reported that the majority of his patients had substantial health improvements after eliminating foods found positive by IgG food allergy testing. The study demonstrated a 71% success rate for all symptoms, achieving at least a 75% relief. Of particular interest was the group of patients with chronic, disabling symptoms, unresponsive to other intensive treatments. Symptoms most commonly improved (75%-100%) on the elimination diets included asthma, coughing, ringing in the ears, chronic fatigue, headaches, gas, bloating, diarrhea, skin rash and itching, and nasal congestion. The most common IgG food allergies were to cow's milk, garlic, mustard, egg yolk, tea, and chocolate. A recent study reported that 93% of non-celiac, gluten-sensitive patients showed anti-gliadin IgG antibody disappearance after a six-month adherence to a gluten-free diet. The IgG disappearance was closely related to a significant improvement of both gastrointestinal and extra-intestinal symptoms.

High IgG antibody levels have frequently been found in children with diabetes mellitus, Crohn's disease, celiac disease, and in those considered to be obese. IgG food test results are often used to develop food antibody-guided exclusion/elimination diets. The implementation of such diets has been shown to alleviate symptoms associated with non-celiac gluten sensitivity and food sensitivity-induced atopic conditions, reduce the frequency of migraine headaches, decrease the occurrence of diarrhea, decrease failure-to-thrive among children with cystic fibrosis, reduce symptoms of irritable bowel syndrome, improve rectal compliance, decrease stool frequency in Crohn's disease, prevent seizures and hyperkinetic behavior in children with epilepsy, and ameliorate kidney function in glomerulonephritis. Food elimination diets also hold promise for the improvement of behaviors associated with attention-deficit hyperactivity disorder.



## Significance of Total IgG Versus IgG4

The goal of IgG-mediated food allergy testing is to identify foods that are capable of triggering many adverse reactions. IgG1, IgG2, and IgG3 are all capable of causing inflammation. IgG1, IgG2, and IgG3 antibodies to food antigens form large immune complexes or lattices that activate complement proteins and increase inflammation. IgG4 antibodies to food antigens will not usually trigger inflammation because IgG4 antibodies do not bind complement. However high levels of these antibodies indicate the presence of immune reactions against food antigens. Similarly IgA antibodies are not as clinically significant due to their inability to bind complement and trigger inflammation.

While most laboratories only provide a measurement of IgG4 molecules, Mosaic Diagnostics provides a measurement of total IgG antibodies to various food-based antigens and Candida, a genus of yeast native to the GI tract. Testing for only IgG4 antibodies limits the ability of the clinician to identify those foods that may be causing significant clinical reactions in their patients. IgG4 antibodies usually represent less than 6% of the total IgG antibodies. The importance of measuring all subtypes of IgG antibodies is highlighted in an article by Kemeny et al. They found that IgG1 antibodies to gluten were elevated in all patients with celiac disease but none of the patients had elevated IgG4 antibodies to gluten.

### The IgG and Candida Connection

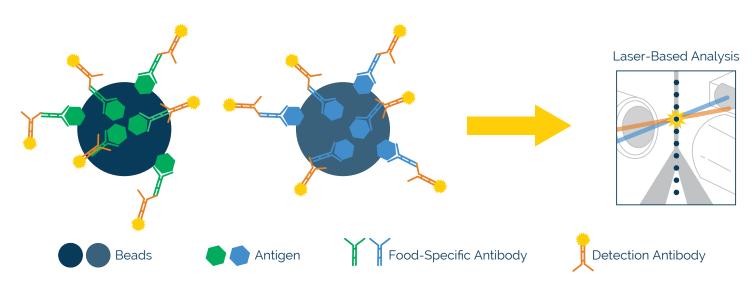
Mosaic Diagnostics tests for Candida albicans (a microscopic fungal organism and pathogenic yeast) as part of IgG food allergy testing. High levels of IgG antibodies to Candida have been found in patients who reported many symptoms of yeast overgrowth. Candida problems are caused when the benign yeast form of Candida albicans transforms to its fungal form and produces a buildup of toxins in the body. Candida can overgrow areas of the intestinal mucosa resulting in numerous symptoms, including creating microscopic holes in the lining of the intestines, leading to what is commonly known as "leaky gut" syndrome. Candida albicans proteins may trigger an inflammatory response. A wide range of disorders have been linked to Candida overgrowth including autism, multiple sclerosis, depression, chronic fatigue, fibromyalgia, migraines, and irritable bowel syndrome. Immunocompromised patients with cancer or AIDS can have life-threatening complications if Candida enters the bloodstream, resulting in systemic candidiasis. Use of antibiotics, oral contraceptives, chemotherapy, anti-inflammatory steroids, and diets high in sugar and starch increase susceptibility to Candida overgrowth.

Research has revealed a relationship between health of the gastrointestinal tract and overall well-being. Imbalance between good and bad bacteria (dysbiosis) has been shown to worsen behavior disorders, hyperactivity, aggression, and cause fatigue. Evidence is mounting that dysbiosis impairs the immune system and contributes to food allergies, digestive disorders, nutritional deficiencies, and cognitive dysfunction. Using the Food MAP (which will include a separate report for Candida and brewer's yeast) will help identify food allergies and Candida sensitivity that may be creating a variety of problems for patients. Practitioners may then recommend elimination of the identified foods and supplementation with various natural products that control Candida overgrowth and assist with healing of the gut. Depending on the levels of Candida and the severity of a patient's symptoms, further testing may be recommended, including a Comprehensive Stool Test or Organic Acids Test.

### Multiple Analyte Profiling with xMAP® Technology

The bead-based immunofluorescent assay uses color-coded magnetic beads, which are covalently coupled to 190 different food proteins specific to each protein's IgG target. The color-coding of the beads into spectrally distinct sets allows the simultaneous capture and detection of multiple food IgG analytes from a single reaction well.

The xMAP® bead-based immunoassay occurs on the surface of magnetic beads by adding a patient's serum sample and observing the classic antigen/antibody interaction, detected by using a fluorescent labeled antibody. Laser-based analysis of the fluorescent signal response is proportional to the binding of food-specific IgG antibodies onto the beads.



### Analyte List (190 Foods + Candida and Saccharomyces Cerevisiae)

#### **Dairy**

- · Beta-Lactoglobulin
- Casein
- · Cheddar Cheese
- Cow's Milk
- Goat's Milk
- Mozzarella Cheese
- Sheep's Yogurt
- Whey
- Yogurt

#### **Beans and Peas**

- · Adzuki Bean
- Black Bean
- Garbanzo Bean
- Green Bean
- · Green Pea
- Kidney Bean
- Lentil
- Lima Bean
- · Mung Bean
- Navy Bean
- Pinto Bean
- Soybean
- Tofu

#### **Fruits**

- Acai Berry
- Apple
- Apricot
- Banana
- Blueberry
- Cantaloupe
- Cherry
- Coconut
- Cranberry
- Date
- Grape
- Grapefruit
- Guava
- Jackfruit
- Kiwi
- Lemon
- Lychee
- Mango
- Orange
- Papaya
- Passion Fruit
- Peach
- Pear
- Pineapple
- Plum
- Pomegranate

- Raspberry
- Strawberry
- Watermelon

#### Grains

- Amaranth
- Barley
- Buckwheat
- Corn
- Gliadin
- Malt
- Millet
- Oat
- Quinoa
- Rice
- Rye
- Sorghum
- Teff
- Wheat Gluten
- Whole Wheat

#### Fish/Seafood

- Abalone
- Anchovy
- Bass
- Bonito
- Codfish
- Crab
- Halibut
- Jack Mackerel
- Lobster
- Octopus
- Oyster
- Pacific Mackerel (Saba)
- Pacific Saury
- Perch
- Red Snapper
- Salmon
- Sardine
- Scallop
- Shrimp
- Small Clam
- Squid
- Tilapia
- TroutTuna

#### Meat/Fowl

- Beef
- Chicken
- Duck
- Egg White
- Egg Yolk

- Goose
- Lamb
- Pork
- Turkey

#### Nuts/Seeds

- Almond
- Brazil Nut
- Cashew
- Chestnut
- · Chia Seed
- Flax Seed
- Hazelnut
- Hemp SeedMacadamia Nut
- Peanut
- Pecan
- Pine Nut
- Pistachio
- Pumpkin Seed
- Sesame Seed
- Sunflower SeedWalnut

# Vegetables

- Artichoke
- Asparagus
- Avocado
- Bamboo Shoot
- Bean Sprout
- Beet
- Bell Pepper
- Bitter Gourd
- Broccoli
- Brussel Sprout
- Burdock Root
- Cabbage
- Cabba
   Carrot
- Cauliflower
- Celery
- Chili Pepper
- Cucumber
- Eggplant
- Enoki Mushroom
- Garlic
- Kale
- Leek
- Lettuce
- Lotus RootNapa Cabbage
- · Olive (Green)
- Onion
- Portabella Mushroom

- Potato
- Pumpkin
- Radish
- · Seaweed Kombu Kelp
- Seaweed Nori
- Seaweed Wakame
- Shitake Mushroom
- Spinach
- Sweet Potato
- Tomato
- Yam
- Yellow Squash
- Yuca
- Zucchini

# Herbs/Spices

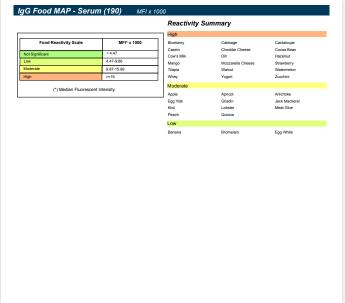
- 51 03/ 3
- BasilBay Leaf
- Black Pepper
- Cayenne Pepper
- CayenneCilantro
- Cinnamon
- Cloves
- Cumin
- Curry
- Dill
- GingerHops
- Mint
- Miso
- Mustard Seed
- OreganoPaprika
- Rosemary
- SageTarragon
- Thyme
- TurmericVanilla Bean
- Miscellaneous
  Bromelain
  - · Cane Sugar
  - Cocoa Bean
  - CoffeeGreen Tea
  - HoneyMeat glue
  - Oolong Tea

### Sample Report







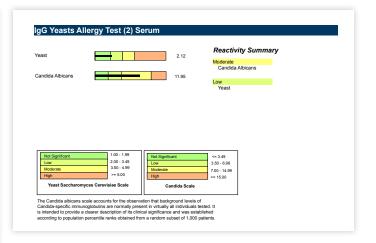


#### Sample Report, Continued



Day 1	Day 2	Day 3	Day 4
Dairy		Goat's Milk Sheep's Yogurt	
Beans and Peas Black Bean Green Bean	Adzuki Bean Mung Bean Soybean	Lentil Lima Bean	Garbanzo Bean Green Pea
Kidney Bean Navy Bean Pinto Bean	Tofu		
Fruits			
Date Jackfruit Lychee Passion Fruit Pear	Acai Berry Grapefruit Guava Lemon Orange Pomegranate	Cherry Cranberry Fig Grape Plum Raspberry	Banana Coconut Papaya Pineapple
Grains			
Millet Sorghum Teff Wheat Gluten Whole Wheat	Amaranth Buckwheat Oat	Corn	Barley Mat Rice Rye





The Candida and Yeast antigens were not suitable for the xMAP® technology. Therefore, antibodies to these antigens were measured by ELISA and this report is provided at no additional charge.

"I believe Mosaic Diagnostics IgG Food Allergy Test is a phenomenal tool that I have implemented in my practice on a daily basis to help treat patients for a wide variety of symptoms like headaches, IBS, fatigue, abdominal pain, dermatitis, hair loss, joint pain, acne, thyroid disorders, and vitamin deficiencies. I believe I am a better physician due to this testing transforming my ability to properly diagnose and treat patients effectively."

- Bridget, M.D.

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# The Benefits of Testing

- IgG testing determines if food reactions are contributing to physical or mental symptoms, and much more quickly than eliminating and then reintroducing each suspect food one-by-one over a period of time.
- Removal of highly reactive foods from the diet is a non-invasive therapy that often mitigates a patient's symptoms.
- Research and clinical studies suggest food allergies identified by IgG testing can be major contributing factors to many chronic health conditions.
- Eliminating all identified IgG-positive foods after testing can reduce stress on the immune system, decrease inflammation (helping to heal "leaky gut"), resolve food cravings, and reduce the potential for eating disorders.



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