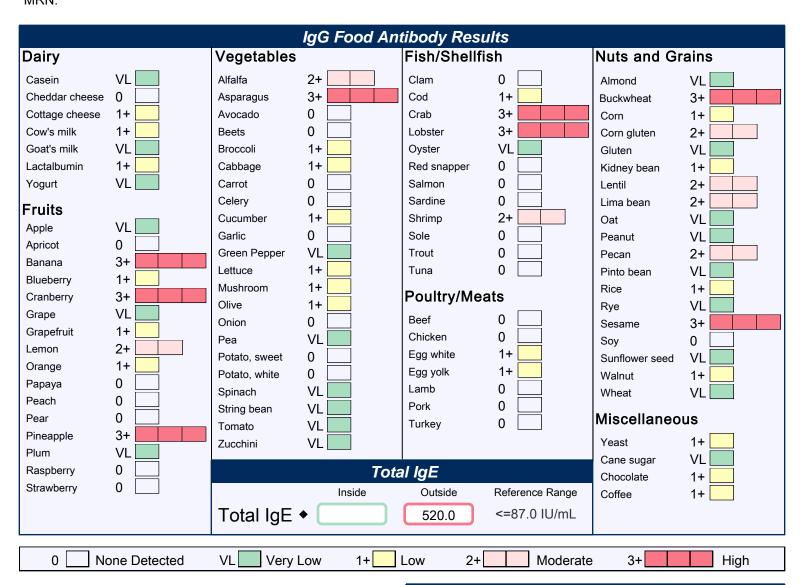


IgG Food Antibody Assessment (Serum)

63 Zillicoa Street Asheville, NC 28801 © Genova Diagnostics

GENOVA DIAGNOSTICS

Patient: SAMPLE PATIENT



- The performance characterisitcs of all assays have been verified by Genova Diagnostics, Inc. Unless otherwise noted with ◆, the assay has not been cleared by the U.S. Food and Drug Administration.
- Total IgE level may have clinical significance regardless of specific antibody levels.
- Increasing levels of antibody detected suggest an increasing probability of clinical reactivity to specific foods.
- The Elimination Diet commentary is specific to IgG results only. Allergens inducing an IgE response should be completely avoided.

Laboratory Comments					

Patient: ID: Page 2

Summary of IgG Test Results

Wild rice

Reactive / Non-Reactive Foods

3+ High

Asparagus Banana Buckwheat Coconut
Crab Cranberry Curry Garbanzo
Ginger Lobster Pineapple Sesame
Vanilla

2+ Moderate

Alfalfa Bean sprout Cashew Corn gluten
Fennel Lemon Lentil Lima bean
Oat bran Pecan Shrimp Watermelon

1+ Low

Blueberry Broccoli Cabbage Chocolate Cod Coffee Corn Cottage cheese Cow's milk Cucumber Cumin Egg white Egg yolk Grapefruit Kidney bean Lactalbumin Lettuce Marjoram Mushroom Olive Pistachio Rice Thyme Orange Walnut Wheat bran Yeast

VL Very Low

Allspice Almond Apple Basil **Black Pepper** Cane sugar Cantaloupe Casein Cavenne Cinnamon Cloves **Filbert** Flax seed Gluten Goat's milk Grape Green pepper Horseradish Millet Oat Oyster Paprika Parmesan cheese Pea Peanut Pinto bean Plum Rve

Sage Spinach String bean Sunflower seed Tomato Wheat Yogurt Zucchini

0 None Detected

Apricot Artichoke Avocado Bay leaf Beef Beets Carrot Celery Cheddar cheese Cherry Chicken Clam Dill Garlic Kamut Lamb Mung bean Mustard Navy bean Nutmea Onion Oregano Papaya Parsley **Peppermint** Peach Pear Pork Potato, white Potato, sweet Raspberry **Red Snapper** Rosemary Safflower Salmon Sardine Sole Strawberry Triticale Sov Trout Tuna Turkey

Commentary

Overview

Immunoglobulin G (IgG) antibodies that elicit an immune response to food are in a class distinct from Immunoglobulin E (IgE) food allergy reactions. IgG-mediated food responses are described as delayed hypersensitivity reactions and have been associated in the peer-reviewed literature with an array of common clinical conditions including migraine, obesity, asthma, autoimmune diseases, and irritable bowel syndrome.

IgG Testing: Factors to Consider

IgG testing can be very useful in screening foods that a person is eating on a regular basis and which may be causing adverse reactions. However, it is possible to have adverse reactions to foods with low or non-detected levels of IgG. Because the IgG profile measures exposure of the immune system to food antigens, performing this test on a patient who is not consuming a particular food or who is taking a drug with known ability to suppress immune function (i.e. steroids) may result in the test not showing a positive reaction, potentially leading to a false negative result for the particular food. Be advised that if the patient is already on an elimination diet due to known food reactions, a negative result on an IgG food antibody profile does not necessarily mean that they can freely eat the food without experiencing symptoms.

IgG Results Interpretation

The amount of IgG antibodies is measured using a semi-quantitative ELISA assay procedure. The relative degrees of IgG present for each food are reported using a semi-quantitative level; None Detected (0), VL (very low), Low (1+), Moderate (2+) or High (3+). The degree of reactivity may not correlate with the severity of patient's response, therefore clinical correlation is advised as it can help direct treatment.

Clinical Management of Reactive IgG Foods: Elimination Diet

The purpose of an elimination diet is to pinpoint symptom-triggering foods that may be the root cause of and/or perpetuating chronic health issues. This diet is specific to food sensitivities that elicit an Immunoglobulin G (IgG) response and not those defined as classic (IgE-mediated) food allergy reactions. An elimination diet is a strategic process which depends on the oversight of the healthcare provider to ensure that a patient's nutritional requirements - macronutrient, micronutrient, and caloric needs - are adequate.

Four-Phases of an Elimination Diet



PHASE 1 – PREPARATION

A patient's clinical presentation and the IgG Food Antibody Assessment results typically determine which food(s) to temporarily remove from the diet. The average time frame for an elimination diet is 1 to 3 months. It is optimal to work with the patient to determine a start and end date for the elimination diet. Patient guidance around preparation ahead of the start date is important to ensure success. These include: (1) encouraging the patient to remove offending foods from the home and adjust grocery shopping accordingly; (2) providing the patient with resources that advance meal preparation, such as recipe books or reputable websites. Directing the patient to record foods consumed, date of consumption/elimination, and any notable changes in symptoms in a food journal can help track the progress of the diet.

Commentary



PHASE 2 – ELIMINATION

It is important to ensure the patient avoids those foods which resulted in a demonstrable reaction, either in whole food forms or as ingredients in other prepared foods to gain the greatest benefit. For patients unable to eliminate all reactive foods from their diet, focusing on the foods that elicited a stronger reaction (i.e.: 2+ and 3+) may be considered for an elimination diet. Practitioners may also encourage elimination of a complete food group when the patient shows reactivity to all foods tested within that group.



PHASE 3 – REINTRODUCTION

The reintroduction of eliminated foods is done one food at a time while monitoring for any adverse reaction. The patient should consume the test food several times throughout the day for several days. If symptoms occur with reintroduction, the patient should be instructed to remove that food once again and to evaluate whether the symptoms diminish over the next few days following elimination. Signs which may indicate an IgG food reaction include the following: headache, itching, bloating, fatigue, diarrhea or constipation, and indigestion. If the food does not cause symptoms during the reintroduction phase, it can be added back into the diet. The patient should continue this process with each food eliminated.

CAUTION: All patients warrant counseling related to signs and management of immediate hypersensitivity reactions prior to food reintroduction following an elimination diet. If reintroduction of a food causes an immediate allergic reaction (i.e. swelling of face, mouth, tongue, etc.; wheezing, rash/hives, or other allergic symptoms), it is imperative that the patient be treated as soon as possible. Following resolution of the immediate hypersensitivity reaction, the patient should be instructed to completely avoid consumption of that food.



PHASE 4 - LONG TERM MANAGEMENT

An elimination diet based on food sensitivity testing is part of a comprehensive approach to overall gastrointestinal health. Based on the test results and the complete clinical presentation of the patient, a long-term plan is usually developed utilizing the results of the reintroduction phase. Clinicians may also consider assessing and treating intestinal permeability, as gut barrier integrity is important for proper immune responses to foods. Nutrients that have been found to support intestinal barrier and decrease potential inflammation are glutamine, vitamin A, vitamin D, essential fatty acids (Omega-3), probiotics, and butyrate. Botanicals that can also be considered to assist with intestinal health are slippery elm, deglycyrrhizinated licorice (DGL), Aloe vera extract, and marshmallow root.



IgE Food Antibody Assessment

63 Zillicoa Street
Asheville, NC 28801
© Genova Diagnostics



Patient: SAMPLE PATIENT

IgE Food Antibody Results					
	RESULT CLASS INDICATOR kU/L	RESULT CLASS INDICATOR kU/L			
Grains		Nuts			
Buckwheat	<0.24 0/1	Almond <0.24 0/1			
Corn	<0.24 0/1	Brazil nut <0.24 0/1			
Oat	<0.24 0/1	Coconut <0.24 0/1			
Rice	<0.24 0/1	Hazelnut <0.24 0/1			
Sesame	<0.24 0/1	Peanut <0.24 0/1			
Soybean	<0.24 0/1	Seafood			
Wheat	<0.24 0/1	Blue mussel <0.24 0/1			
Dairy		Codfish <0.24 0/1			
Egg white	<0.24 0/1	Salmon <0.24 0/1			
Cow's milk	<0.24 0/1	Shrimp <0.24 0/1			
		Tuna <0.24 0/1			

Total IgE					
	Inside	Outside	Reference Range		
Total IgE		520.0	<=87.0 IU/mL		

- IgE levels must be used in conjunction with the clinical picture and are not intended to be independently diagnostic.
- The performance characteristics of all assays have been verified by Genova Diagnostics, Inc. All assays are cleared by the U.S. Food and Drug Administration.
- Total IgE level may have clinical significance regardless of specific antibody levels.
- Increasing levels of antibody detected suggest an increasing clinical reactivity to specific foods.

		Key	
Class	kU/L	Levels of Specific IgE Undetectable	Indicator
0/1	<=0.24	or Equivocal	
1	0.25 - 0.39	Low	
Ш	0.4 - 1.29	Moderate	
III	1.3 - 3.89	High	
IV	3.9 - 14.99	Very High	
V	15 - 24.99	Very High	
VI	>=25	Very High	

	Laboratory Comments
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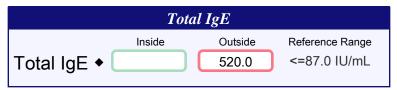
IgG Vegetarian Food Profile

63 Zillicoa Street Asheville, NC 28801 © Genova Diagnostics



Patient: SAMPLE PATIENT

	IgG Vegetable Food Results						
Artichoke	0	Garbanzo	3+	Parmesan cheese	VL		
Bean sprout	2+	Filbert	VL	Pistachio	1+		
Cantaloupe	VL	Kamut	0	Safflower	0		
Cashew	2+	Millet	VL	Triticale	0		
Cherry	0	Mung bean	0	Watermelon	2+		
Coconut	3+	Navy bean	0	Wheat bran	1+		
Flax seed	VL	Oat bran	2+	Wild rice	2+		



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- Increasing levels of antibody detected suggest an increasing probability of clinical reactivity to specific foods.
- Total IgE level may have clinical significance regardless of specific antibody levels.





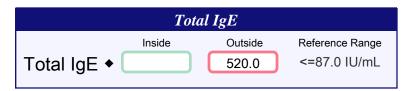




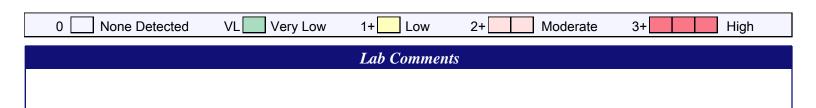
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Patient: SAMPLE PATIENT

IgG Spice Antibody Results					
Allspice	VL	Curry	3+	Oregano	0
Basil	VL	Dill	0	Paprika	VL
Bayleaf	0	Fennel	2+	Parsley	0
Black Pepper	VL	Ginger	3+	Peppermint	0
Cayenne	VL	Horseradish	VL	Rosemary	0
Cinnamon	VL	Marjoram	1+	Sage	VL
Cloves	VL	Mustard	0	Thyme	1+
Cumin	1+	Nutmeg	0	Vanilla	3+



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- Increasing levels of antibody detected suggest an increasing probability of clinical reactivity to specific foods.
- $\hbox{-} \ \text{Total IgE level may have clinical significance regardless of specific antibody levels}.$





IgE Inhalants Profile

Texas +

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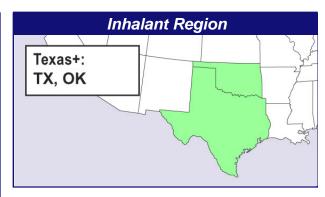


Patient: SAMPLE PATIENT

DOB: Sex: MRN:

lg E	E Antibody Levels
INHALANT	RESULT CLASS INDICATOR kU/L
Trees	
Maple	<0.24 0/1
Mountain Cedar	3.27 III
Grasses	
Bermuda Grass	0.67 II
June Grass (Kentucky Blue)	2.87 III
Perennial Rye Grass	3.57 III
Weeds	
Lamb's quarters	<0.24 0/1
English Plantain	<0.24 0/1
Rough Marsh Elder	<0.24 0/1
Giant Ragweed	<0.24 0/1
Molds	
Mold Generic	0.89 II
Misc.	
Cat dander	<0.24 0/1
Cockroach	<0.24 0/1
Dog dander	<0.24 0/1
Mite - D. farinae	0.57 II
Mite - D. microceras	0.77 II
Mite - D. pteronyssinus	0.41 II

Lab Comments



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- Total IgE level may have clinical significance regardless of specific antibody levels.
- IgE levels must be used in conjunction with the clinical picture and are not intended to be independently diagnostic.

Total IgE					
	Inside	Outside	Reference Range		
Total IgE		520.0	<=87.0 IU/mL		

		Key	
Class	kU/L	Levels of Specific IgE Undetectable	Indicator ——
0/1	<=0.24	or Equivocal	
ı	0.25 - 0.39	Low	
П	0.4 - 1.29	Moderate	
Ш	1.3 - 3.89	High	
IV	3.9 - 14.99	Very High	
V	15 - 24.99	Very High	
VI	>=25	Very High	



IgE Molds Profile

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GENOVA DIAGNOSTICS

Patient: SAMPLE PATIENT

DOB: Sex:

MRN:

IgE Mold Ar	tibody l	Result	S
INHALANT	RESULT kU/L	CLASS	INDICATOR
Aspergillus fumigatus	<0.24	0/1	
Alternaria tenuis (Alternaria alternata)	3.12	III	
Candida albicans	<0.24	0/1	
Cladosporium herbarum	<0.24	0/1	
Curvularia lunata	0.36	1	
Epicoccum purpurascens	<0.24	0/1	
Fusarium moniliforme	<0.24	0/1	
Helminthosporium halodes	<0.24	0/1	
Mucor racemosus	<0.24	0/1	
Penicillium notatum	<0.24	0/1	
Phoma betae	0.4	II	
Pityrosporum orbiculare	0.42	II	
Rhizopus nigricans	0.53	II	
Stemphylium botryosum	0.81	II	
Trichoderma viride	0.25	I	

		Key	
Class	kU/L	Levels of Specific IgE Undetectable	Indicator
0/1	<=0.24	or Equivocal	
ı	0.25 - 0.39	Low	
П	0.4 - 1.29	Moderate	
III	1.3 - 3.89	High	
IV	3.9 - 14.99	Very High	
V	15 - 24.99	Very High	
VI	>=25	Very High	

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- Total IgE load may have clinical significance regardless of specific antibody levels.
- IgE levels must be used in conjunction with the clinical picture and are not intended to be independently diagnostic.

Total IgE					
	Inside	Outside	Reference Range		
Total IgE		520.0	<=87.0 IU/mL		
_					

Lab Comments



Celiac & Gluten Sensitivities

IMMUNOLOGY



63 Zillicoa Street Asheville, NC 28801 © Genova Diagnostics

Patient: **SAMPLE**

PATIENT

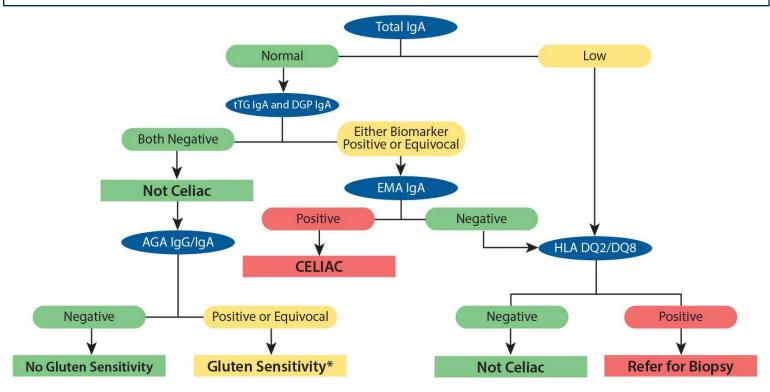
DOB: Sex: MRN:

1006 Celiac & Gluten Sensitivities-Serum

Immunologic Markers				
Biomarker	Result	Reference Range		
Total IgA	114	Sufficient 68-514 mg/dL		
Anti-Tissue Transglutaminase IgA (tTG IgA)	0.5	Negative <=6.9 U/ml		
Anti-Deamidated Gliadin IgA (DGP IgA)	0.6	Negative <=6.9 U/ml		
Anti-Gliadin IgA (AGA IgA)	0.6	Negative <=6.9 U/ml		
Anti-Gliadin IgG (AGA IgG)	0.4	Negative <=6.9 U/ml		

Interpretation

Patient results are normal. Clinical Correlation advised. A trial of a Gluten Free Diet may be required to exclude Gluten Sensitivity.



Patient: ID:	Page 11
Commentary	
Methodology: FEIA, Immunoturbidometric and IFA (when EMA IgA testing is performed)	
The performance characteristics of all assays have been verified by Genova Diagnostics, Inc. Unless otherwise noted with •, the assay has been cleared by the U.S. Food and Drug Administration.	
*AGA IgG/IgA is positive in only about 50% of patients with Gluten Sensitivity. Therefore, clinical correlation is required and a trial of a Gluten Free Diet may be indicated to confirm diagnosis. Volta U, De Giorgio R. New understanding of gluten sensitivity. Nat Rev Gastroenterol Hepatol. 2012 Feb 28;9(5):295-9	

Patient: ID: Page 12

Methodology: ELISA - enzyme-linked immunosorbent assay

Zonulin Family Peptide, Serum

Result

65.2

Н

Zonulin Family Peptide
Reference Range

25.5-56.1 ng/mL

Zonulin Family Peptide

This test is for research use only. Genova will not provide support on interpreting the test results. This test does not detect zonulin. The Scheffler paper suggests that the IDK kit may detect a zonulin family peptide, such as properdin.¹

The performance characteristics of Zonulin Family Peptide have been verified by Genova Diagnostics, Inc. The assay has not been cleared by the U.S. Food and Drug Administration.

References

1. Scheffler L, et al. Widely Used Commercial ELISA Does Not Detect Precursor of Haptoglobin2, but Recognizes Properdin as a Potential Second Member of the Zonulin Family. *Front Endocrinol.* 2018;9:22.