



63 Zillicoa Street Asheville, NC 28801

Patient: SAMPLE **PATIENT**

DOB: Sex: MRN: © Genova Diagnostics

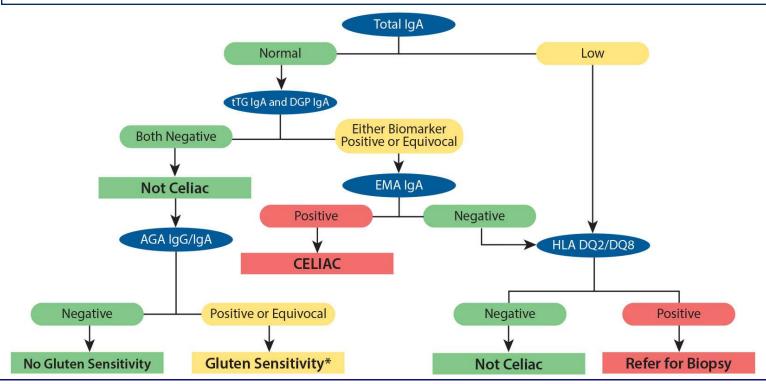
1006 Celiac & Gluten Sensitivities - Serum

Methodology: FEIA, Immunoturbidometric and IFA (when EMA IgA testing is performed)

Biomarker	Result		Reference Range
Total IgA	83	Insufficient	85-532 mg/dL
Anti-Tissue Transglutaminase IgA (tTG IgA)	51.0	Positive	<=6.9 U/ml
Anti-Deamidated Gliadin IgA (DGP IgA)	6.4	Negative	<=6.9 U/ml
Anti-Endomysial IgA (EMA IgA)	Not Detected		Not Detected
Anti-Gliadin IgA (AGA IgA)	2.7	Negative	<=6.9 U/ml
Anti-Gliadin IgG (AGA IgG)	6.4	Negative	<=6.9 U/ml

Interpretation

Patient results are consistent with Possible Celiac Disease.



Commentary

Total IgA result confirmed by repeat analysis.

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.

Commentary is provided to the practitioner for educational purposes, and should not be interpreted as diagnostic or as treatment recommendations. Diagnosis and treatment decisions are the practitioner's responsibility.

*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



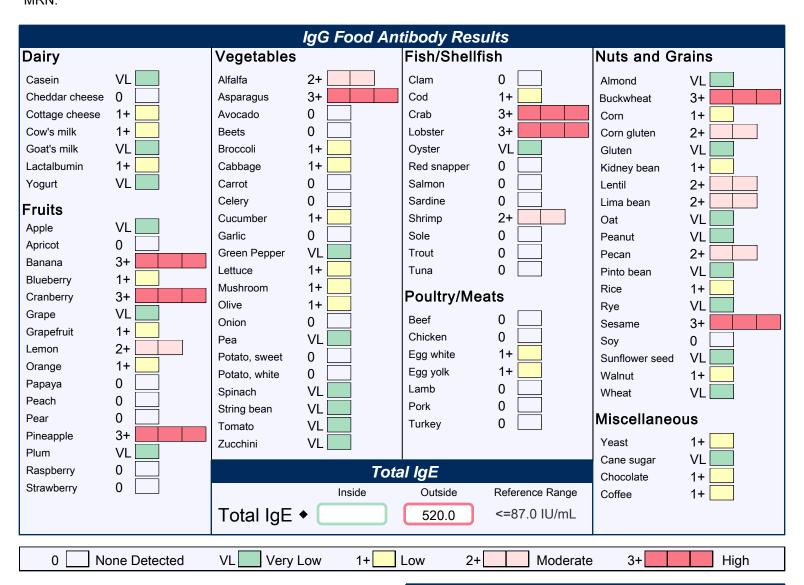
IgG Food Antibody Assessment (Serum)

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GENOVA DIAGNOSTICS

Patient: SAMPLE PATIENT

DOB: Sex: MRN:



- 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.

Labo	oratory Co	omments	

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



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Patient: **SAMPLE PATIENT**

DOB: Sex: MRN:

lgE Food Antibody Results					
	RESULT CLASS INDICATOR kU/L		RESULT CLASS INDICATO	OR	
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	
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	

Laboratory Comments					

IgG Vegetarian Food Profile



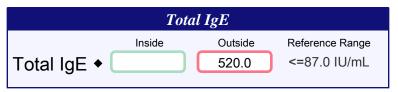
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Patient: SAMPLE **PATIENT**

DOB: Sex:

MRN:

	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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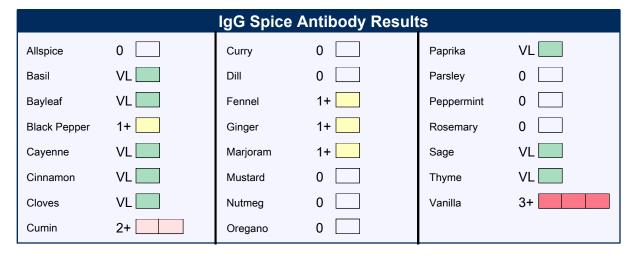
Patient: SAMPLE PATIENT

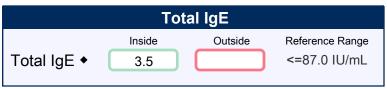
DOB: Sex: MRN:

1005 IgG Spice Profile - Serum

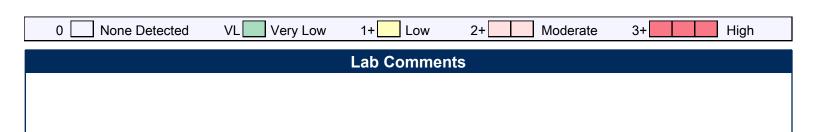
Methodology: EIA and Chemiluminescent







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IgE Inhalants Profile

Texas +

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Patient: SAMPLE PATIENT

DOB: Sex: MRN:

Trees	IgE .	Antibody l	Levels	
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		RESULT		INDICATOR
Grasses Bermuda Grass 0.67 II June Grass (Kentucky Blue) 2.87 III Perennial Rye Grass 3.57 III Weeds Image: Comparison of the c	Trees			
Grasses Bermuda Grass 0.67 II	Maple	<0.24	0/1	
Description	Mountain Cedar	3.27	III	
June Grass (Kentucky Blue) 2.87 III Perennial Rye Grass 3.57 III Weeds Lamb's quarters <0.24	Grasses			
Weeds Lamb's quarters <0.24	Bermuda Grass	0.67	II	
Weeds Lamb's quarters <0.24	June Grass (Kentucky Blue)	2.87	III	
Lamb's quarters <0.24	Perennial Rye Grass	3.57	III	
English Plantain	Weeds			
Rough Marsh Elder <0.24	Lamb's quarters	<0.24	0/1	
Giant Ragweed <0.24	English Plantain	<0.24	0/1	
Molds Misc. Cat dander <0.24	Rough Marsh Elder	<0.24	0/1	
Misc. Cat dander <0.24	Giant Ragweed	<0.24	0/1	
Misc. Cat dander <0.24	Molds			
Cat dander <0.24	Mold Generic	0.89	II	
Cockroach <0.24	Misc.			
Dog dander <0.24	Cat dander	<0.24	0/1	
Mite - D. farinae 0.57 II	Cockroach	<0.24	0/1	
Mite - D. microceras 0.77 II	Dog dander	<0.24	0/1	
	Mite - D. farinae	0.57	II	
Mite - D. pteronyssinus 0.41 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 lgE				
	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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Patient: **SAMPLE PATIENT**

DOB: Sex: MRN:

lgE Mold Ar	ntibody l	Result	s
INHALANT	RESULT kU/L	CLASS	INDICATOR
Aspergillus fumigatus	<0.24	0/1	
Alternaria tenuis (Alternaria alternata)	3.12	Ш	
Candida albicans	<0.24	0/1	
Cladosporium herbarum	<0.24	0/1	
Curvularia lunata	0.36	I	
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	П	
Pityrosporum orbiculare	0.42	П	
Rhizopus nigricans	0.53	П	
Stemphylium botryosum	0.81	П	
Trichoderma viride	0.25	1	

		Key	
Class	kU/L	Levels of Specific IgE Undetectable	Indicator
0/1	<=0.24	or Equivocal	
1	0.25 - 0.39	Low	
11	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

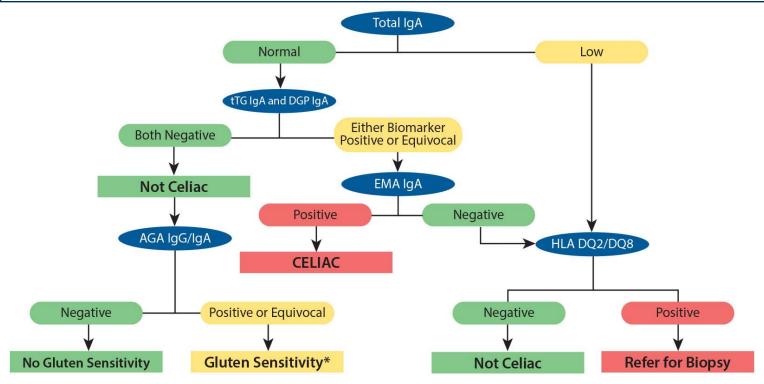
DOB: Sex: MRN:

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)	
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*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	

Step 3:

Ship the specimen to the lab

Specimen must be returned in the Genova Diagnostics kit box for correct delivery to the lab. Not following these instructions may result in a shipping charge.

- Plan to ship the specimen Monday Friday overnight delivery only.
- Call 1.800.GoFedEx (1.800.463.3339) to schedule shipping. When the automated system asks "How may I help you?" say "Return a Package." Tell the FedEx representative "I am using a billable stamp" and they will walk you through the process and make it easy.
- Seal all frozen serum tubes and the absorbent pad in the biohazard bag. Remove foam box from kit box. Place frozen freezer brick in bottom of foam box. Lay biohazard bag with specimens inside, on top of the freezer brick. Replace lid on foam box. Place rubber band around foam box to secure lid.
- Slide foam box back inside kit box and place your completed and signed requisition form on top before closing. Do NOT staple or tape box.
- Print your name and address in the section marked "From" on the prepaid shipping envelope label. DO NOT mark or write in any other sections.
- Put the kit box into the prepaid mailing envelope and seal the envelope.
- Keep your shipment and tracking numbers for future reference and tracking purposes.





Antibody Assessments & Celiac Profile

Clinician Instructions

15-285









Check Your Kit

- A 4 SST serum collection tubes
- **B** 4 Transfer tubes
- C 1 Pipette
- D 1 Biohazard bag and absorbent pad
- E 1 Freezer brick

- F 1 Foam insulator box
- G 1 Rubber band
- H 1 Requisition (to be completed and signed)
- I 1 Prepaid mailing envelope



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63 Zillicoa Street

call Client Services at 800.522.4762 and press "1".

If any items are missing or expired,

Step 1:

Important things to know and consider

- At least 8 hours prior to collection: Freezer brick must be frozen a minimum of 8 hours before shipping.
- Specimens must be received in the laboratory within 24 hours of collection. To ensure the accuracy of test results, please observe the following:
 - If testing for food antibodies, it is suggested that the patient eat a variety of foods for 2-3 weeks prior to food antibody testing (except for foods that are known to cause severe reactions). Doing so will help to ensure the presence of antibodies to allergenic foods.
 - The following medications may impact the antibody test: Glucocorticosteroids (e.g., oral prednisone and/or steroid metered-dose inhaler), chemotherapy, immunosuppressive agents (e.g., Humira, Rituxan) and NSAIDS (e.g., Ibuprofen, Naproxen, Tylenol, Aspirin).
- Non-interfering factors to the antibody test: antibiotics, antihistamines, and antidepressants.
- Test may be inaccurate if the patient has liver damage or HIV infection.
- The following table lists minimum specimen requirements necessary to provide results.

# profiles	ml Serum	# SST tubes
1	3 ml	1 tube
2	6 ml	2 tubes
3	9 ml	3 tubes
4 or more	12 ml	4 tubes

Schedule & Prepare for Serum Collection

- Plan for Monday-Friday collection only: Specimens must be received in the laboratory within 24 hours of collection.
- Contact FedEx and schedule to ship the specimen overnight delivery Monday - Friday. Sample MUST be stored frozen at least 2 hours before shipping.
- Freeze the enclosed freezer brick a minimum of 8 hours before shipping.
- Samples must be frozen a minimum of 2 hours prior to shipping. Keep samples frozen until ready to ship.
- Complete the Requisition Form with all patient and billing information. Be sure it is signed by the Patient/Responsible Party and the healthcare provider.

Step 2

Blood Draw & Serum Preparation

Not following these instructions may affect the test results.



Write the patient's name and the time and date of collection on each collection tube and transfer tube.



new blood to fill the SST tubes.



Allow the blood in the SST tubes to **clot for 15 minutes** while standing in a rack. Then centrifuge the tubes for 15 minutes at 3000 RPM.



Using the pipette, **transfer all of the serum** from all SST tubes into the transfer tubes. Screw the tops on the tubes tightly to avoid leakage. Discard the SST tubes.



Wrap the absorbent pad around the transfer tubes and put them into the biohazard bag, making sure that the bag is securely sealed; freeze immediately. Samples must be frozen a minimum of 2 hours prior to shipping. Keep samples frozen until ready to ship.



When ready to ship, make sure all the tubes in the Biohazard bag are tightly closed and are identified with completed information.