

63 Zillicoa Street Asheville, NC 28801 © Genova Diagnostics

Patient:	SAMPLE
	PATIENT
DOB:	

Sex:

MRN:

1003 IgE Inhalant Profile - Serum

Methodology: Chemiluminescent

IgE Antibody Levels **Inhalant Region** RESULT CLASS INDICATOR INHALANT kU/L **Mid-Atlantic:** DE, MD, VA, Trees DC, NC Elm <0.24 0/1 <0.24 Maple 0/1 Oak 1.0 Ш Grasses - The performance characteristics of all assays have been Bermuda Grass <0.24 0/1 verified by Genova Diagnostics, Inc. All assays are cleared by the U.S. Food and Drug Administration. Johnson Grass <0.24 0/1 - Total IgE level may have clinical significance regardless of June Grass (Kentucky Blue) <0.24 0/1 specific antibody levels. - IgE levels must be used in conjunction with the clinical picture Weeds and are not intended to be independently diagnostic. Common Ragweed <0.24 0/1 **Total IgE** Cocklebur < 0.24 0/1 Rough Pigweed < 0.24 0/1 Inside Outside **Reference Range** Total IgE 140.2 <=87.0 IU/mL Molds Key Mold Generic <0.24 0/1 Levels of Class kU/L Specific IgE Indicator Misc. Undetectable Cat dander 100.0 VI 0/1 <=0.24 or Equivocal Cockroach <0.24 0/10.25 - 0.39 Low П 0.4 - 1.29 Dog dander 8.83 IV Moderate Ш 1.3 - 3.89 Mite - D. farinae High 0.24 0/1IV 3.9 - 14.99 Very High 0.24 Mite - D. microceras 0/1v 15 - 24.99 Very High Mite - D. pteronyssinus 0.56 Ш

Lab Comments

VI

>=25

Very High

IgG Food Antibody Assessment (Serum)



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Patient:	SAMPLE
	PATIENT

DOB:

Sex:

MRN:

IgG Food Antibody Results							
Dairy		Vegetables		Fish/Shellfis	sh	Nuts and Gr	ains
Casein Cheddar cheese Cottage cheese Cow's milk Goat's milk Lactalbumin Yogurt Fruits Apple Apricot Banana Blueberry Cranberry Grape Grapefruit	VL 0 1+ 1+ VL 1+ VL VL 0 3+ 1+ 3+ VL 1+ 1+ 1+ 1+ 1+ 1+ 1+ 1+ 1+ 1+		2+ 3+ 0 1+ 1+ 0 0 1+ 0 0 1+ 0 0 1+ 0 0 1+ 0 1+ 1+ 1+ 1+ 1+ 1+ 0 VL 1+ 0 VL		0	Nuts and Gr Almond Buckwheat Corn Corn gluten Gluten Kidney bean Lentil Lima bean Oat Peanut Pecan Pinto bean Rice Rye Sesame Soy	ains VL 3+ 1+ 2+ VL 1+ 2+ VL 2+ VL 2+ VL 2+ VL 2+ VL 2+ VL 3+ 0
Lemon Orange Papaya Peach Pear Pineapple Plum Raspberry Strawberry	2+ 1+ 0 0 3+ VL 0 0 0	Pea Potato, sweet Potato, white Spinach String bean Tomato Zucchini	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	Egg white Egg yolk Lamb Pork Turkey	0	Soy Sunflower seed Walnut Wheat Miscellaneo Yeast Cane sugar Chocolate Coffee	VL 1+ VL
0 🗌 No	one Detected	VL Very L	_ow 1+	Low 2+	Moderate	3+	High

- 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.

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Laboratory Comments

Patient: ID: Summarv of IaG Test Results

Summary (or igg i	est Results	
	Reactive /	Non-Reactive Foods	
	3+	- High	
Asparagus Crab Ginger Vanilla	Banana Cranberry Lobster	Buckwheat Curry Pineapple	Coconut Garbanzo Sesame
	2+	- Moderate	
Alfalfa Fennel Oat bran Wild rice	Bean sprout Lemon Pecan	Cashew Lentil Shrimp	Corn gluten Lima bean Watermelon
	1+	- Low	
Blueberry Cod Cow's milk Egg yolk Lettuce Orange Walnut	Broccoli Coffee Cucumber Grapefruit Marjoram Pistachio Wheat bran	Cabbage Corn Cumin Kidney bean Mushroom Rice Yeast	Chocolate Cottage cheese Egg white Lactalbumin Olive Thyme
	VL	_ Very Low	
Allspice Black Pepper Cayenne Flax seed Green pepper Oyster Peanut Sage Tomato	Almond Cane sugar Cinnamon Gluten Horseradish Paprika Pinto bean Spinach Wheat	Apple Cantaloupe Cloves Goat's milk Millet Parmesan cheese Plum String bean Yogurt	Basil Casein Filbert Grape Oat Pea Rye Sunflower seed Zucchini
	0	None Detected	
Apricot Beef Cheddar cheese Dill Mung bean Onion Peach Potato, sweet Rosemary Sole Trout	Artichoke Beets Cherry Garlic Mustard Oregano Pear Potato, white Safflower Soy Tuna	Avocado Carrot Chicken Kamut Navy bean Papaya Peppermint Raspberry Salmon Strawberry Turkey	Bay leaf Celery Clam Lamb Nutmeg Parsley Pork Red Snapper Sardine Triticale

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:	

IgE Food Antibody Results					
	RESULT kU/L	CLASS INDICATOR		RESULT kU/L	CLASS INDICATOR
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	
I	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	

Laboratory Comments

IgG Vegetarian Food Profile

G	E١	J(N	VΑ
				ICS

PATIENT

Patient: SAMPLE

DOB: Sex: MRN: 63 Zillicoa Street Asheville, NC 28801 © Genova Diagnostics

	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+		

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

- The performance characteristics of all assays have been verified by Genova

Diagnostics, Inc. Unless otherwise noted with \bullet , the assays have not been cleared by the U.S. Food and Drug Administration.

- 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.

0 None Detecte	ed VL Very Low	1+ Low	2+ Moderate	3+ High
		Laboratory Com	ments	



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Patient: SAMPLE PATIENT

DOB:

Sex:

MRN:

1005 IgG Spice Profile - Serum *Methodology: EIA and Chemiluminescent*

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

IgG Spice

IMMUNOLOGY

	Tot	al IgE	
	Inside	Outside	Reference Range
Total IgE ◆	3.5		<=87.0 IU/mL

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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.

0 None Detected	VL Very Low	1+ Low	2+ Moderate	3+ High
		Lab Commer	nts	
	Dagag Denvior Deb D(ADMLI) Lak Direct			

IgE Inhalants Profile

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Patient: SAMPLE PATIENT

DOB:

Sex:

MRN:

lgE	Antibody L	evels			l	nhalant Regi	ion
INHALANT	RESULT kU/L	CLASS	INDICATOR	Texa			
Trees				 ,			L_
Maple	<0.24	0/1					
Mountain Cedar	3.27	111				\sim	Ĺ
Grasses							
Bermuda Grass	0.67	II					
June Grass (Kentucky Blue)	2.87	III -				aracteristics of all a	
Perennial Rye Grass	3.57	111		the U.S.	Food and D	Diagnostics, Inc. All Drug Administration.	
Weeds					intibody lev	have clinical signific els.	ance
Lamb's quarters	<0.24	0/1		- IgE level	s must be u	used in conjunction	
English Plantain	<0.24	0/1		and are r	not intended	to be independent	ly dia
Rough Marsh Elder	<0.24	0/1					
Giant Ragweed	<0.24	0/1					
Molds							
Mold Generic	0.89	II					
Misc.						Total IgE	
Cat dander	<0.24	0/1			Insic	le Outside	Re
Cockroach	<0.24	0/1		Total IgE		520.0	<
Dog dander	<0.24	0/1					
Mite - D. farinae	0.57	II [Key	
Mite - D. microceras	0.77	II [Levels of	
Mite - D. pteronyssinus	0.41	II [Class	kU/L	Specific IgE Undetectable	In
				0/1	<=0.24	or Equivocal	
	Lab Comme	nts		1	0.25 - 0.3	9 Low	
				п	0.4 - 1.29		
				ш	1.3 - 3.89	-	
					3.9 - 14.9		
					15 - 24.9		
				VI	>=25	Very High	

stics of all assays have been tics, Inc. All assays are cleared by ninistration. nical significance regardless of conjunction with the clinical picture ndependently diagnostic.

	7	otal 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	
1	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	

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IgE Molds Profile

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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	Ш	
Pityrosporum orbiculare	0.42	Ш	
Rhizopus nigricans	0.53	Ш	
Stemphylium botryosum	0.81	II	

0.25

Lab Comments

kU/L

<0.24

3.12

<0.24

<0.24

RESULT CLASS INDICATOR

0/1

0/1

0/1

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

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

- 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 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.



INHALANT

Aspergillus fumigatus

Cladosporium herbarum

Candida albicans

Trichoderma viride

Alternaria tenuis (Alternaria alternata)



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Celiac & Gluten Sensitivities



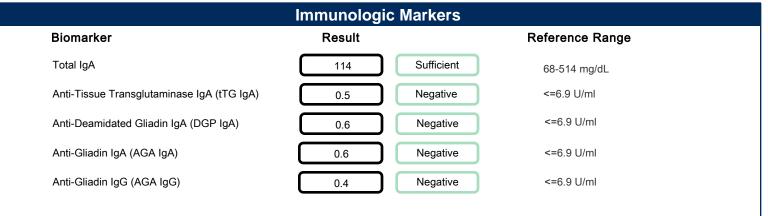
Patient: SAMPLE PATIENT

DOB:

Sex:

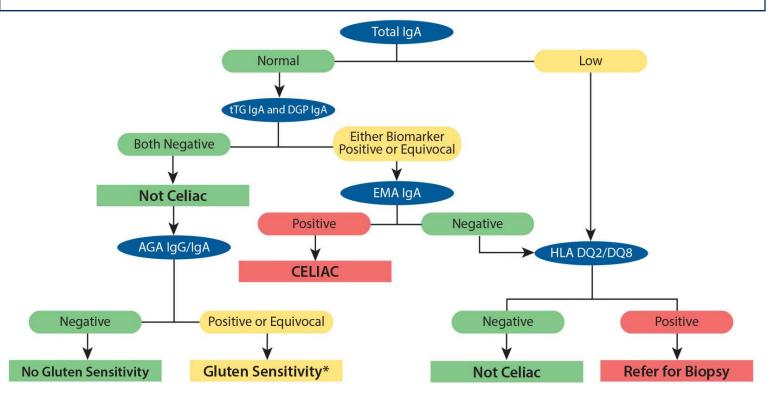
MRN:

1006 Celiac & Gluten Sensitivities-Serum



Interpretation

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



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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

Ship the specimen to the lab

Step 3

DIAGNO

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





Keep the kit box for shipping your specimen to the lab.

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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

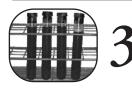
Not following these instructions may affect the test results.



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



Draw 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.