KBMO DIAGNOSTICS

THE ETIOLOGY OF FOOD SENSITIVITIES, INFLAMMATION AND INCREASED INTESTINAL PERMEABILITY.

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Introduction

Food sensitivities , Inflammation and Gut Permeability in one test!

- Overview of Food sensitivities
- KBMO Diagnostics
- Clinical Data
- New Products

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IFM Definitions

Food allergy: Immunologic IgE-mediated type 1 hypersensitivity

Food sensitivity: Immunologic reaction to food (IgA or IgG-mediated delayed hypersensitivity)

Food intolerance: Non-immunologic reaction to food (e.g. lactose intolerance)

Overview of Food Sensitivities

- Food Sensitivity and related diseases affect at least 100 million people worldwide.
- The prevalence of Food Sensitivities has increased > 50% in adults and children in the past few years.
- Symptoms include a variety of illnesses from skin rashes and headaches to chronic intestinal diseases.
- 90% of sensitivities are in eight food groups: Milk, Soy, Eggs, Wheat, Peanuts, Tree Nuts, Fish, Shellfish.
- One or all of the foods in a specific group may cause Food Sensitivity.
- Delayed Food sensitivities occur hours or days after food ingestion.
- Delayed Food sensitivities are caused by IgG 1-4 and Immune Complexes that activate Complement

When do Provider's use the FIT Test?

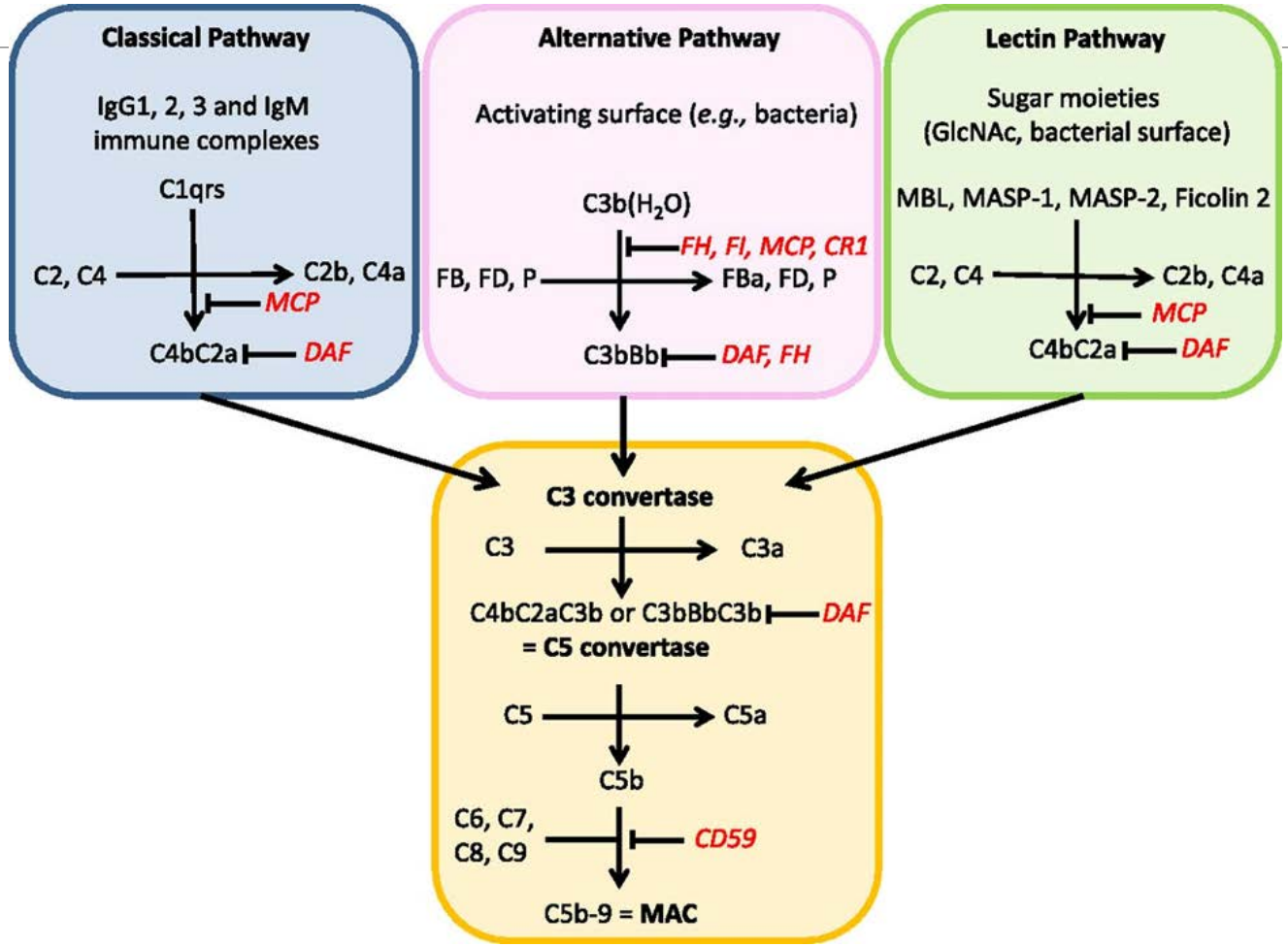
If a patient has:

- Autoimmune disease
- Thyroid Problems
- Arthritis
- Brain Fog
- Fatigue
- Digestive/Gut issues/Skin problems
- Fibroids, Endometriosis or Breast Cancer
- Other types of cancer

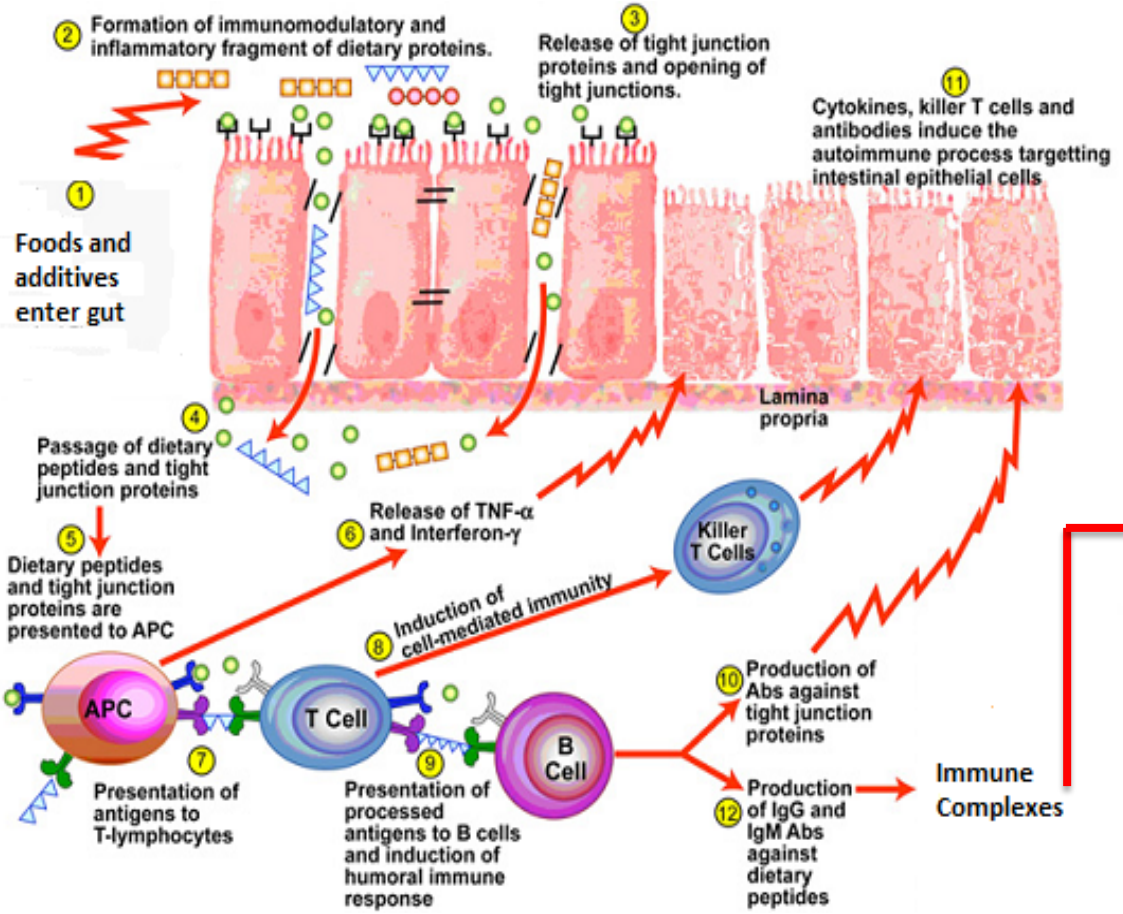
The FIT Test: Why Physician'sUse It

Immune Complexes and Inflammation can be associated with foods and are an underlying problem for many of the conditions doctors observe on a daily basis.

The FIT Test: Immune Complex Formation



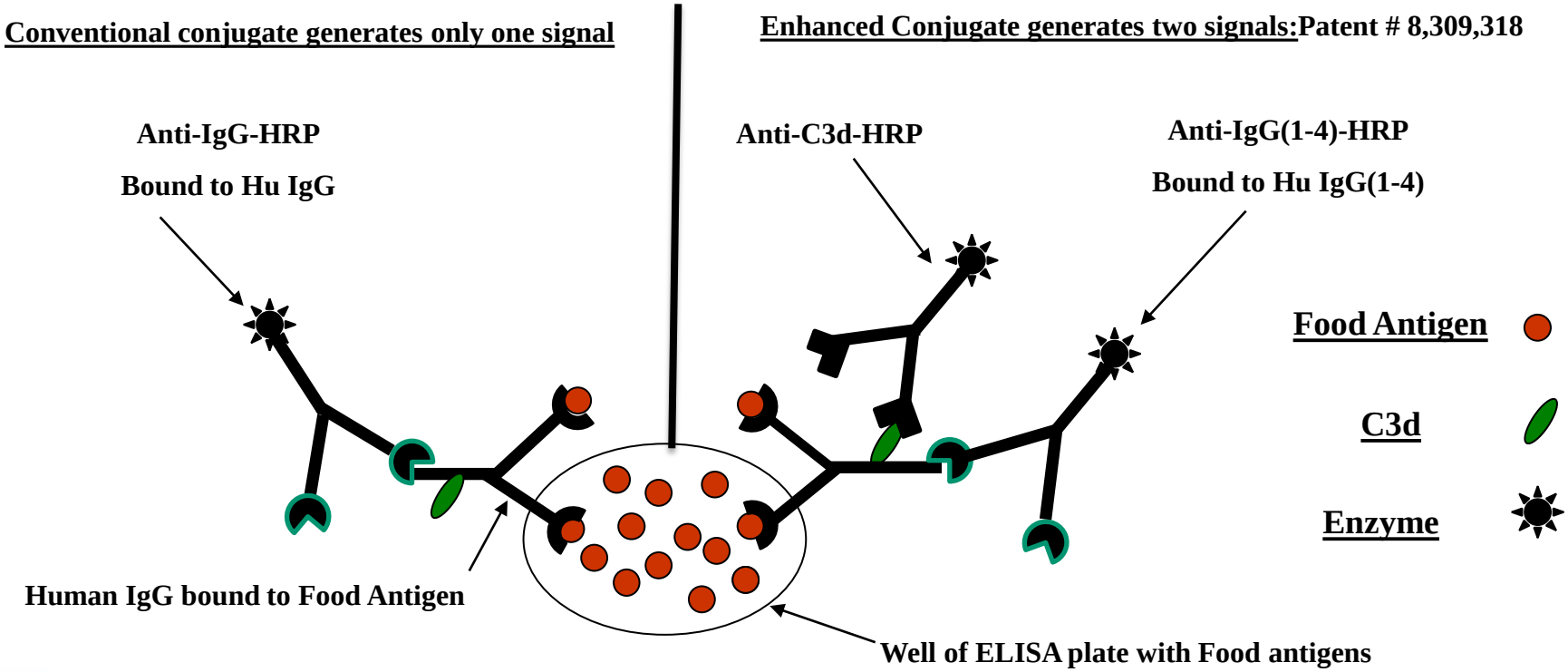
The FIT Test: Immune Complex Activation



Why KBMO’s approach is different

The FIT Test:Format and Technology Showing Enhanced Sensitivity

Comparison of conventional conjugate: anti-IgG with enhanced conjugate: anti-IgG(1-4)and anti-C3d



The FIT Test: KBMO Diagnostics

- Founded in 2004 by Dr Brent Dorval MIT Founder of Rapid HIV Diagnostic
- 20,000 sq ft of buildings on a campus outside of Boston MA
- ISO 13485 certified quality and FDA registered Manufacturing Facility and CLIA High Complexity Labs
- Patent Granted October 2012: Detection of Antigen Specific Immune Complexes: #8,309,318
- Owner of the C3d Cell Line and lyophilization technology to ensure quality and consistent results traceability of the foods
- First company to achieve COFEPRIS and AMVISA certification and growing internationally

The FIT Test: Overview

- The FIT Test measures 132 Foods, Colorings and Additives
- Finger stick enables is a quick and easy way to obtain a sample
- The Patient Report measures leaky gut
- Best in Class Patient Compliance tools

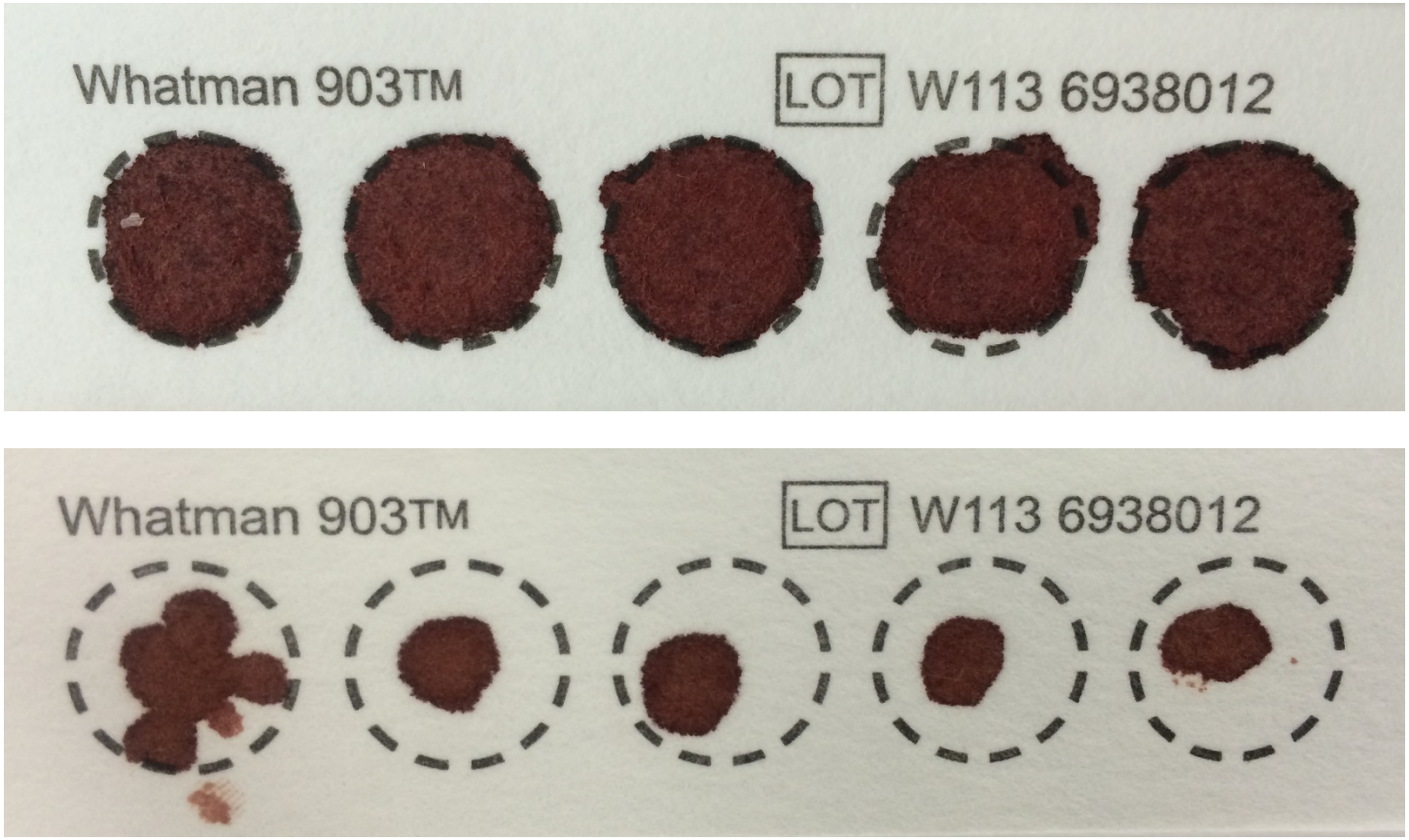
Additives	Plant Foods: Beans	Plant Foods: Berries
Aspartame	Cocao	Avocado
Benzoic Acid	Coffee	Blueberry
BHA	Green,string	Cranberry
MSG	Kidney	Grape, White seedless
Polysorbate 80	Lima	Raspberry
Red #2	Navy	Strawberry
Red #3	Pinto	Extracts/Misc.
Red #40	Soy	Canola Oil
Saccharin	Wax	Gelatin
Yellow #6	Plant Foods: Fruits	Sugar,cane
Dairy	Apple	Tea
Casein	Apricot	Mushroom
Milk, Cow	Banana	Microbial
Egg,white,chick.	Cantaloupe	Yeast,baker's
Fish	Cherry	Yeast,brewer's
Catfish	Grapefruit	Poultry
Codfish	Honeydew Melon	Chicken
Flounder	Lemon	Duck
Grouper	Lime	Turkey
Halibut	Olive,green	Seeds
Orange Roughy	Onion,white	Cotton
Salmon	Orange	Dill
Snapper	Peach	Safflower
Sole	Pear	Sesame
Swordfish	Pineapple	Sunflower
Trout	Plum	Shellfish
Tuna	Watermelon	Clam
Grains	Plant Foods: Vegetable	Crab
Barley	Artichoke	Lobster
Buckwheat	Asparagus	Scallops
Millet	Broccoli	Shrimp
Oat	Beets	Spice
Rice	Cabbage	Basil
Rye	Carob	Cinnamon
Wheat,gulten	Lettuce	Garlic
Wheat,whole	Carrot	Ginger
Meats	Cauliflower	Hops
Beef	Celery	Mustard
Lamb	Corn,sweet	Oregano
Pork	Cucumber	Paprika
Nuts	Pea,green	Pepper,Black
Almond	Potato,sweet	Pepper,Chili
Cashew	Potato,white	Pepper,Green
Coconut	Pumpkin	Pepper,Red Cayenne
Colanut	Spinach	Peppermint
Walnut,English	Squash Mix	Rosemary
Hazelnut	Tomato	Tumeric
Peanut	Zucchini	Vanilla
Pecan		

The FIT (Food Inflammation Test) Fingerstick Shipping and Reporting:

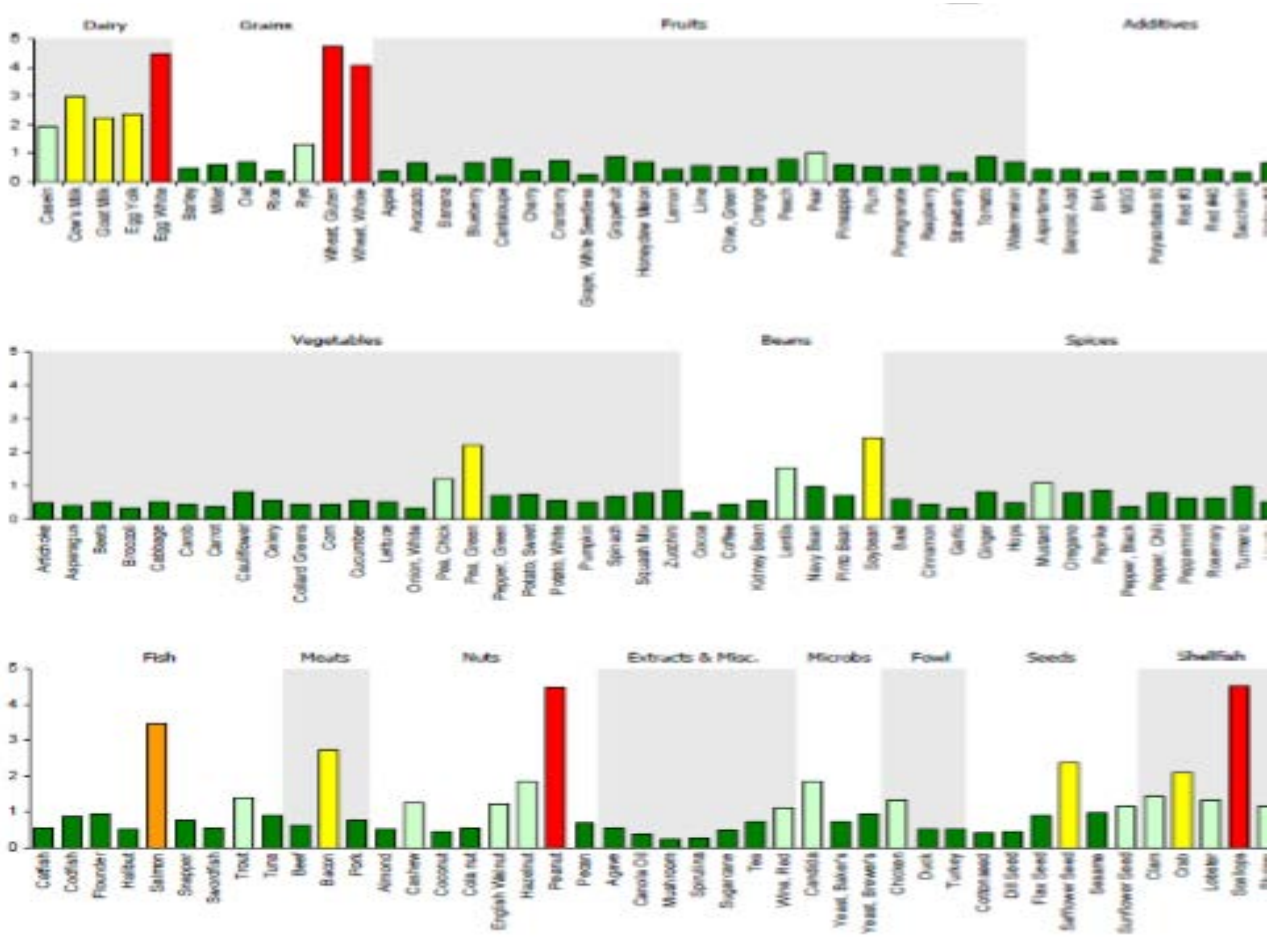
Instructions:	
1	Use the side of the fingertip on either the middle or ring finger for the finger stick. Do not use the center pad of the finger it is the most sensitive area.
2	Warming your finger may be necessary to acquire the correct amount of blood. Simply run warm to hot water over it for a few minutes and dry it well before gently massaging the finger from the base to the tip until the finger turns red.
3	Clean the site you will use the finger stick with the provided alcohol swab and allow to air dry.
4	Position the lancet provided over the area you just cleaned and press lancet firmly against puncture site. Once the site has b[illegible] the lancet aside. Gently massage from the hand toward the puncture site to obtain required volume. Do not squeeze or apply strong repetitive pressure to the site as it may damage the sample.
5	Fill each circle on the provided collection card with blood. It is important to fill each circle to ensure enough sample can be obtained [illegible]ister the test. At least three circles must be filled, but if possible please fill all five.
6	Following collection, clean the area with the second provided alcohol wipe and press clean gauze or cotton on the area until bleeding has stopped.
	Label the collection card with name and date the sample was collected. Wait a few minutes until the blood has dried completely on the card before placing it inside the provided biohazard bag, sealing it and placing it inside the provided return envelope.
7	Ship the envelope in the mail to: KBMO Diagnostics 4 Business Way Hopedale MA, 01747
8	KBMO Diagnostics will analyze the sample and e-mail a complete report in 5-7 days.

For Further Information and more Draw Kits Contact: INFO@KBMODiagnostics.com
Call with any questions Tel: 1-617-933-8130

FIT Test:
Good Spot vs a Rejected One



The FIT Test: Patient Report



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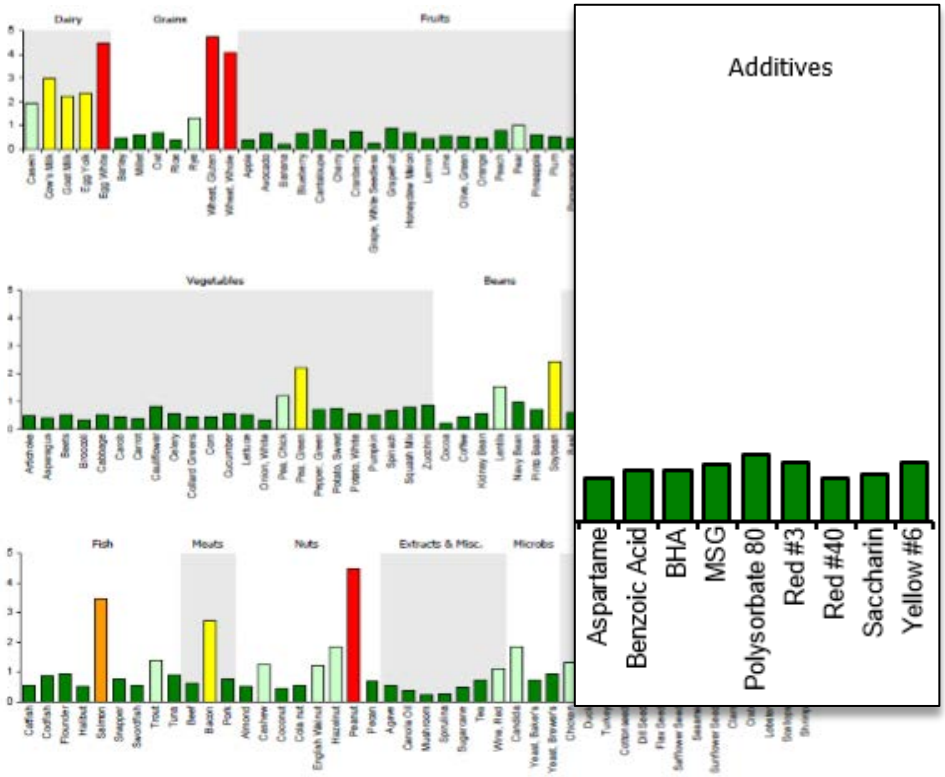


Why do we care about chemical additives?

Contents lists available at ScienceDirect

Food and Chemical Toxicology

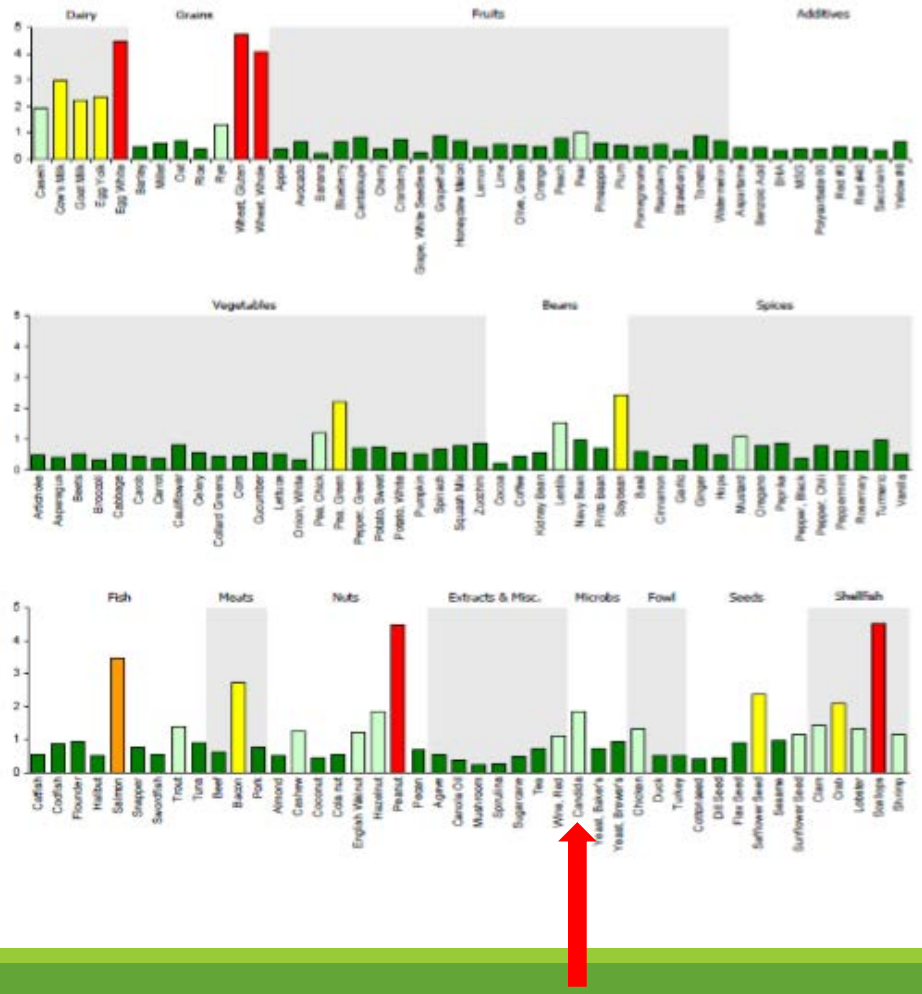
journal homepage: www.elsevier.com/locate/foodchemtox

Review

Food contact materials and gut health: Implications for toxicity assessment and relevance of high molecular weight migrants

Gut health is determined by an intact epithelial barrier and balanced gut microbiota,
Studies suggest that some direct food additives, but also some food contaminants, such as pesticide residues and substances migrating from food contact materials (FCMs), may adversely affect the gut barrier or gut microbiota.

The FIT Test: Patient Report

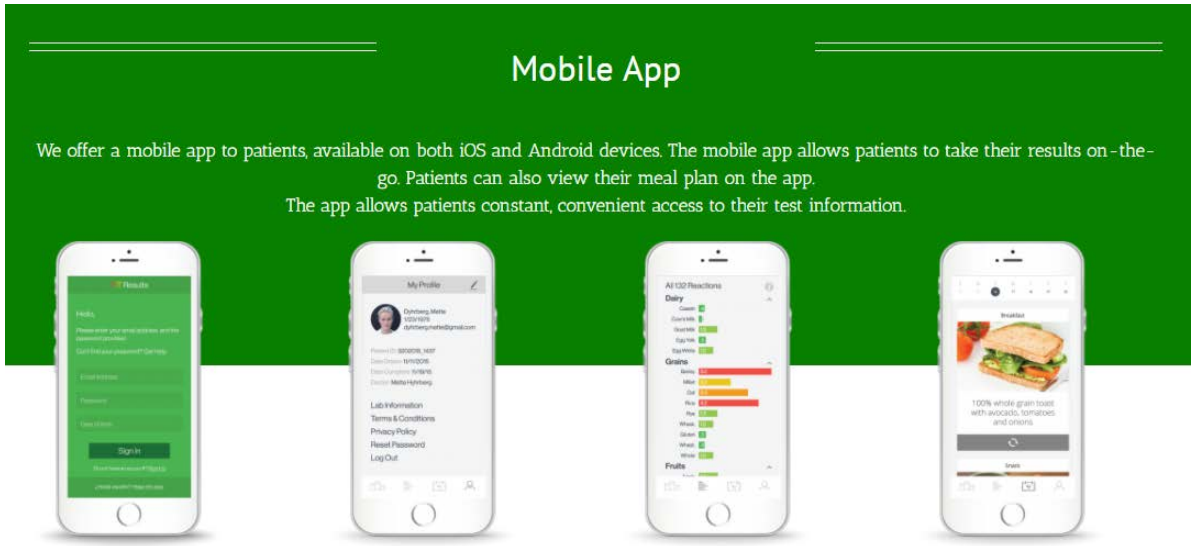


The FIT Test: Meal Plan

Day	Breakfast	Snack	Lunch	Snack	Dinner
Sunday	Cashew Nut Milk; Almonds; Cinnamon; Oatmeal	Hazelnuts	Grilled Shrimp; Salad greens; Cucumbers; Tomatoes; Celery; Beets; Onions; Olives; Sunflower Seeds	Guacamole; Zucchini Spears	Grass fed beef; Mashed sweet potato; Cauliflower
Monday	Smoothie; Almond Milk; Avocado; Blueberries; Pea, Green; Flax Seeds	Cashews	Grilled Chicken; Onions; Ginger; Cucumber; Cabbage leaf wrap	Salsa; Zucchini Spears	Flounder; Asparagus; Broccoli
Tuesday	Yeast Free Whole Grain Toast; Sunflower Seed Butter; Cinnamon	Celery; Hummus	Lettuce Wrap; Turkey; Avocado; Cucumbers; Hummus; Olives	Almonds	Ground Chicken; Sesame; Asparagus; Zucchini noodles; Collard Greens
Wednesday	Plain Coconut Milk Yogurt; Cinnamon; Pecans; Vanilla	Hazelnuts	Turkey Soup; Zucchini noodles	Avocado; Olive oil, Sea salt	Stir Fry; Organic tofu; Garlic; Sesame; Ginger; Broccoli; Cashews; Shredded Cabbage
Thursday	Rice Milk; Cinnamon; Sunflower Seeds; Vanilla; Oatmeal	Broccoli; Hummus	Chick Peas; Tuna; Onions; Garlic; Tomatoes; Cucumbers; Sunflower Seeds	Celery; Cashew Nut Butter	Ground turkey meatballs; Tomato Sauce; Pinto beans; Side salad of greens with slivered almonds
Friday	Avocado; Tomatoes; Yeast Free Whole Grain Toast	Cashews	Steak Tips; Salad greens; Beets; Artichoke Hearts; Sesame seeds	Hazelnuts	Cauliflower; Collard Greens; Salmon
Saturday	Hazelnut Butter; Cinnamon; Coconut, Shredded; Almond Flour Pancakes	Almonds	Clams with garlic and olive oil; Tomatoes; Kidney Beans; Stew	Cucumber Slices; Hummus	Pork Tenderloin; Lentil salad: tomato, cucumber & lentils; Zucchini; Onions

Health warning: Please know that this example for your personalized healthy meal plan was created based on the FIT test results ONLY. No further medical information has been available to our team. Please contact your physician before implementing any new dietary regiment.

The FIT Test: Phone App



Available on the App Store

Get it on Google play

Provider Resources

Direct access to KBMO for provider consults

Access to Provider's Guide

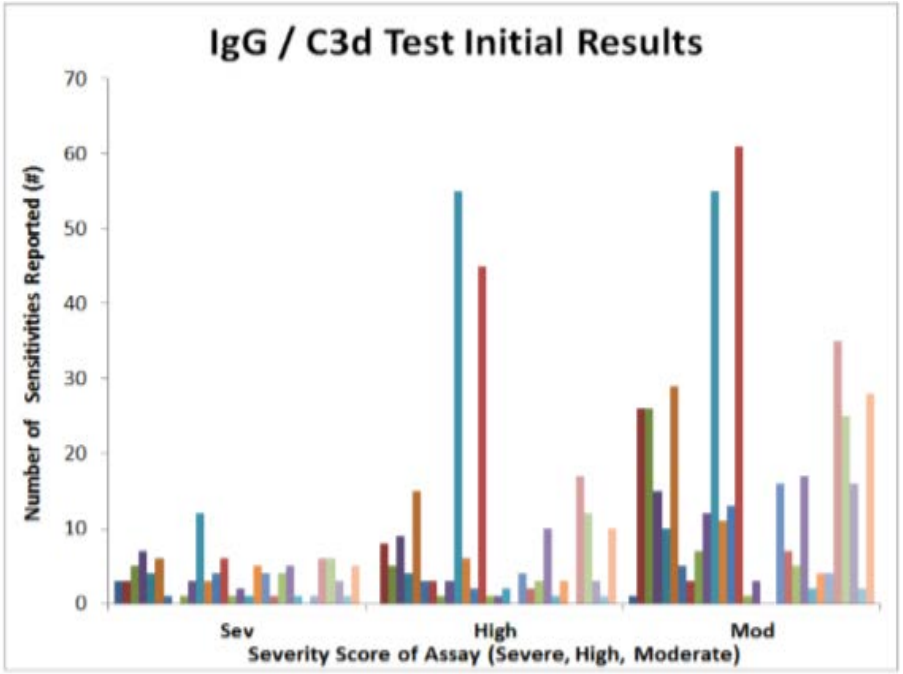
Social Media and Waiting Room content

Discounted Kit to try the FIT test

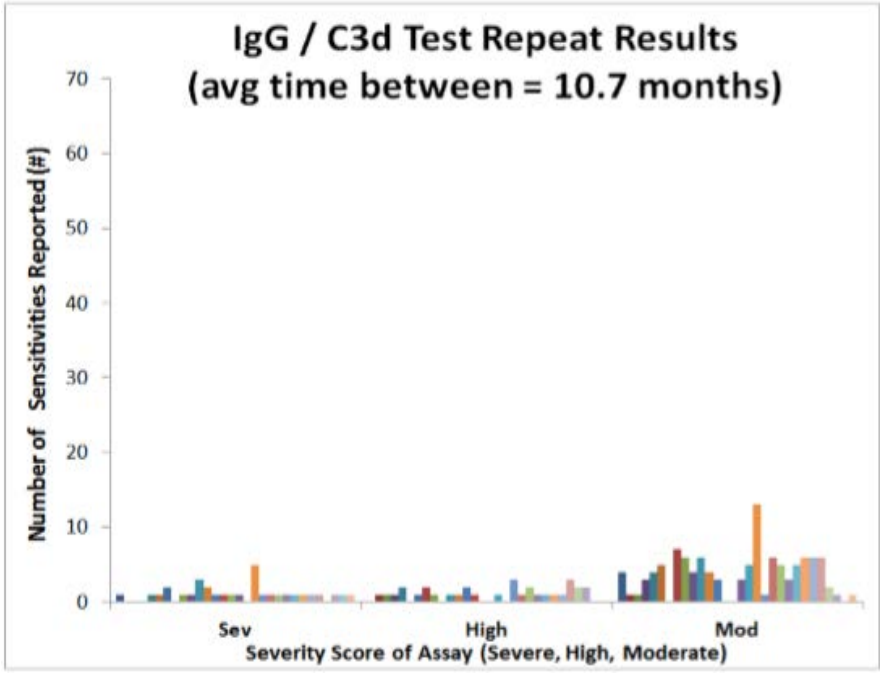
The Clinical Studies

The FIT Test: Clinical

TEST BEFORE ELIMINATION DIET



TEST AFTER ELIMINATION DIET



Data was analyzed for 30 patients tested before and after the elimination diet. There was a significant reduction in number of sensitivities reported after the elimination diet, which indicates the FIT Test could predict specific food sensitivities.

The FIT Test: Clinical Testing Results.

Significant improvement in symptoms was observed

Complaint/Symptom	Number of Patients Reporting on Initial Test	Number of Patients Reporting on Second Test
Memory/Concentration	*22*	*3*
Anxiety/Mood/Depression	*20*	*3*
Bloating/Stomach Pain	*18*	*2*
Fatigue	*18*	*4*
Sleeplessness/Insomnia	*15*	*3*
Joint Pain / Stiffness / Swelling	*13*	*1*
Muscle Aches	*13*	*1*
Craving Sugar	*12*	*2*
Sleeplessness/Insomnia	*12*	0
Lightheaded/Dizzy	*11*	*2*
Allergies/Sinus	*9*	*2*
Cold Intolerance	*9*	*3*
Inability to lose weight	*9*	*2*
Libido/Impotence	*9*	0
Constipation	*8*	*2*
Diarrhea	*7*	*1*
Halitosis	*7*	*1*
Tearing Eyes	*6*	*1*
Brittle Nails/Dry Skin/Dry Mouth	*5*	0
Bruising	*5*	*1*
Headaches	*5*	*3*
Irregular Heart Beat	*5*	*1*
Numbness Hands/Feet	*5*	*1*
Sinus Problems	*5*	0
Thyroid	*5*	*1*
Eczema	*4*	0
Drowsiness	*3*	0
PMS	*3*	*1*

IBS Clinical Study

Study Title: Evaluating the Health Benefits and Outcomes of IBS and Food Sensitivity, using the FIT Test IgG1-4+C3d Immune Complexes

Principle Investigator is William Essilfie, MD

Results

IBS Severity Score Day 1 to EOS:

Intervention Group: Avg 126.89 points decrease in IBS severity score

Control Group: Avg 46 points decrease in IBS severity score

Homocysteine Day 1 to EOS:

Intervention Group: Avg decrease .05

Control Group: : Avg increase .64

CRP Day 1 to EOS:

Intervention Group: Avg decrease of .47

Control Group: Avg decrease of .10

Clinical Outcomes greatly improved compared with IgG Only Tests or ALCAT

- KBMO saw TWICE the IBS Severity Score reduction compared with ALCAT

- A 50% improvement in IBS Severity Score compared with IgG only tests

New Products

- New FIT 132
- FIT 176
- Zonulin
- FAST Test

New FIT 132

Removals:

Safflower Seed
Cotton Seed
Squash Mix
Kola Nut
Catfish

Additions:

Butternut Squash
Sea Bass
Quinoa
Lamb
Whey

The Zonulin Test

ZONULIN
TEST

Overview of Zonulin

- Protein that is synthesized in intestinal and liver cells
- Key biomarker for intestinal permeability
- Only reversible regulator of intestinal permeability
- Elevated levels of Zonulin are associated with:

Autoimmune Diseases	Celiac Disease	Non-Celiac Gluten Sensitivity	Rheumatoid Arthritis	Type I Diabetes
Adult Glucose Intolerance	Inflammatory Bowel Disease	Asthma	Multiple Sclerosis	Juvenile Nonalcoholic Fatty Liver Disease

Published in final edited form as:
Ann N Y Acad Sci. 2012 July ; 1258(1): 25–33. doi:10.1111/j.1749-6632.2012.06538.x.

Zonulin, regulation of tight junctions, and autoimmune diseases

Zonulin is the only human protein discovered to date that is known to reversibly regulate intestinal permeability by modulating intercellular TJs. Zonulin expression is augmented in autoimmune conditions associated with TJ dysfunction, including celiac disease (CD) and T1D.

ultrastructure, relatively little is known about their physiological and pathophysiological regulation. Our discovery of zonulin, the only known physiologic modulator of intercellular TJ described so far, increased understanding of the intricate mechanisms that regulate the intestinal epithelial paracellular pathway and led us appreciate that its up-regulation in genetically susceptible individuals leads to autoimmune diseases.

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Zonulin, regulation of tight junctions, and autoimmune diseases

Zonulin is integrally involved in the pathogenesis of autoimmune diseases. Zonulin can be used as a biomarker of impaired gut barrier function for several autoimmune, neurodegenerative, and tumoral diseases, and can be a potential therapeutic target for the treatment of these devastating conditions.

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NEXT Gen Zonulin..

Launch First Quarter of 2020: Exclusive to KBMO

Zonulin: Measuring Zonulin Protein not antibodies and not Properdin!

Test Format: Blood Spot or Serum

Dream Development Team

Dr Alessio Fasano: Discovered Zonulin and partnering with KBMO

Dr Brent Dorval: Developer of the first rapid HIV Diagnostic

ALL FIT TESTS WILL INCLUDE ZONULIN AS SOON AS WE LAUNCH

FAST Test: IN OFFICE

- Dr Brent Dorval invented the first rapid HIV Diagnostics and has been working for the last 10 years on the FAST Test which measures Wheat, Eggs and Dairy in 4 minutes IN OFFICE

- Concept ideal screen for ALL patients and if any of the “big Three” come up then reflex them on to one of the larger panels

- DTC? With an APP in a couple of years which directs patients back to Providers

The FIT Test: Conclusions

- Patented Multi pathway detection technology broadly adapted
- Best in Class patient compliance tools
- Excellent clinical outcomes backed by IRB Approved clinical study
- New Products Developed by World Class Scientists and Physicians