

Improving People's Lives Through Innovations in Personalized Health Care

### 2021 10 Tests I Wish You'd Never Ordered Allergy Immunology Edition

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## Disclosures

- Dr. Martin has no relevant financial relationships to disclose.
- This presentation will not include any non-FDA approved or investigational uses of products or medical devices.





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## **Objectives**

- Understand the food allergies are due to IgE to a specific food, and there are limitations to allergy testing to food
- Understand tolerance and the fact that Patients may have positive reactions to food testing that are not clinically significant
- Understand that appropriate testing for food allergies is based on a careful history.



## The Problem

\*Food allergy is common and affects up to 10% of the population

\*Lopes JP & Sicherer, Current Opinions in Immunology (2020) 66:57-64





# Patient #1: Mr. Smith

- Mr. Smith is a 35 year old IT worker
- CC: GI irritability: worse after meals
- Bloating
- Fatigue
- Malaise
- Some diarrhea
- He brings with him his food allergy testing from Everlywell.



# Check in with Dr. Google

#### After listening to a add on MSNBC he went to...

At-Home Food Sensitivity Test   E × +			0	-	٥	×
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	Test a larger variety of foods					
	\$159 1 ~ Add to Cart Free Shipping • FSA / HSA accepted					

## You Learn more!

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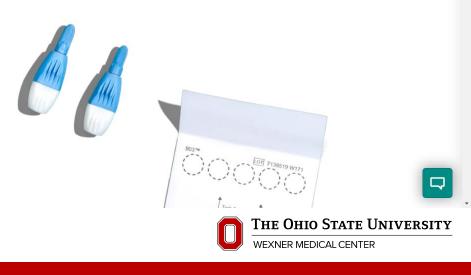
#### A lab built around you

As Everlywell grows, we are constantly improving and finding solutions to best serve our customers. That's why we decided to open our own flagship lab, Everlywell Diagnostics, located in Dallas, Texas. Incorporating Everlywell Diagnostics, a CLIA-certified and CAP-accredited laboratory, into our network of labs allows us to provide a superior experience for our customers while continuing to maintain the highest standards of accuracy, quality, and reliability. Everlywell Diagnostics' clinical validation and correlation studies found our athome collection methods to be comparable with traditional collection methods like venipuncture.

#### COLLECTION METHODS

#### At-home self-collected samples that are validated against traditional methods

Our at-home sample collection methods have been clinically validated against traditional methods to meet rigorous standards for test accuracy and reliability. Dried blood spot testing and many other collection methods we offer, like saliva and urine, have been trusted sample collection methods for over 30 years. We offer established collection methods. carefullu and optimallu



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#### Food Sensitivity Test

Learn your reactivity to 96 common foods that may be causing discomfort

Physician-reviewed
CLM-certified



### Learn How Your Body Responds to 96 Different Foods

Food Sensitivity Test

**★ ★ ★ ★ 5**598

This at-home test measures your body's immune response to 96 foods to help guide you on what types of food may be the best to choose for an elimination diet.

IgG Reactivity to **96 Foods** 

Finger prick sample collection

Test a larger variety of foods

\$159

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#### REVIEW



**Open Access** 

# CSACI Position statement on the testing of food-specific IgG

Stuart Carr<sup>1\*</sup>, Edmond Chan<sup>2</sup>, Elana Lavine<sup>3</sup> and William Moote<sup>4</sup>

The Canadian Society of Allergy and Clinical Immunology (CSACI) is very concerned about the increased marketing of food-specific immunoglobulin G (IgG) testing towards the general public over the past few years, supposedly as a simple means by which to identify "food sensitivity", food intolerance or food allergies. In the past, this unvalidated

the opinions expressed by the American Academy of Allergy Asthma and Immunology (AAAAI) [1], and by the European Academy of Allergy and Clinical Immunology (EAACI) [2]. Both of these organizations warn about the inappropriate measurement of food-specific IgG or IgG4 to suggest the presence or potential of adverse reactions

 The Canadian Society of Allergy and Clinical Immunology strongly discourages the practice of food specific IgG testing for the purposes of identifying or predicting adverse reactions to food.

# In the USA: Choosing Wisely

- Five things Physicians and Patients Should Question
- American Academy of Allergy, Asthma and Immunology
  - 2012: Released 1-5
  - 2014: Released 6-10





An initiative of the ABIM Foundation

Our Mission Clinician Lists For Patients

American Academy of Allergy, Asthma &

### American Academy of Allergy, Asthma & Immunology

Search Recommendations

Ten Things Physicians and Patients Should Question

Lists

Released April 4, 2012 (1-5) and March 3, 2014 (6-10); Last reviewed 2021

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Getting Started



# Don't perform unproven diagnostic tests, such as immunoglobulin G(lgG) testing or an indiscriminate battery of immunoglobulin E(lgE) tests, in the evaluation of allergy.

Appropriate diagnosis and treatment of allergies requires specific IgE testing (either skin or blood tests) based on the patient's clinical history. The use of other tests or methods to diagnose allergies is unproven and can lead to inappropriate diagnosis and treatment. Appropriate diagnosis and treatment is both cost effective and essential for optimal patient care.

#### JIVERSITY



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## How do you explain this?

- You explain to Mr. Smith that even though he has positive testing to the IgG food panel, that data is nonspecific, not helpful and potentially misleading.
- Mr. Smith now has to choose between you and Dr. Google. What is your next step?
  - Get an appropriate IgE food screening test?
  - Take a great history?
  - Send the patient to GI?
  - Sent the patient to Allergy for a food challenge?



# You take a good history

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- Your patient's history and physical are not very helpful
- You suspect food allergy, and ask questions about reactions to specific foods
- Answers are not helpful



# You Decide to do a screening IgE food panel



- The concern is due to the word "screening"
- + IgE testing to a food indicates a "sensitivity" but may not indicate a true allergy.



## Back to Choosing Wisely Issues #6 – 10 were released in 2014

#7: Don't perform food IgE testing without a history consistent with potential IgE-Mediated food allergy.



# Allergy Choosing Wisely statement #7a

False or clinically irrelevant positive allergy tests are frequent. In-discriminant screening results in inappropriate avoidance of foods and wastes healthcare resources. IgE testing for specific foods must be driven by a history of signs or symptoms consistent with an IgE-mediated reaction after eating a particular food. Ordering IgE testing in individuals who do not have a history consistent with or suggestive for food allergy based on history frequently reveals positive tests that are unlikely to be clinically relevant. Testing, when done, should be limited to suspect foods...."



# Allergy Choosing Wisely statement #7b

The diagnostic utility of IgE testing for specific foods is optimal when a history compatible with or suggestive for the diagnosis of food allergy is present. In the absence of a compatible or suggestive history, the pre-test probability for a diagnosis of food allergy is low and a positive skin test or in vitro IgE test does not establish a diagnosis of food allergy. Skin testing or serum testing for specific IgE to food antigens has excellent sensitivity and high negative predictive value, but has low specificity and low positive predictive value."



# Allergy Choosing Wisely statement #7c

Considering that 50 to 90% of presumed cases of food allergy do not reflect IgE mediated (allergic) pathogenesis and may instead reflect food intolerance or symptoms not causally associated with food consumption, ordering panels of food tests leads to many incorrectly identified food allergies and inappropriate recommendations to avoid foods that are positive on testing."



# Evaluation of the food allergic patient

- Food Allergy: A Practice Parameter update--2014
- The evaluation of the patient with suspected food allergy should include a <u>detailed medical history</u> that considers the symptoms indicative of various types of adverse reactions to foods, including other immunologic and nonimmunologic food reactions, the epidemiologic characteristics of potential triggers, and evaluation of the temporal relationship between food ingestion and onset of symptoms.

Sampson et al. J Allergy Clin Immunol. (2014) 134(5): 1016-1025



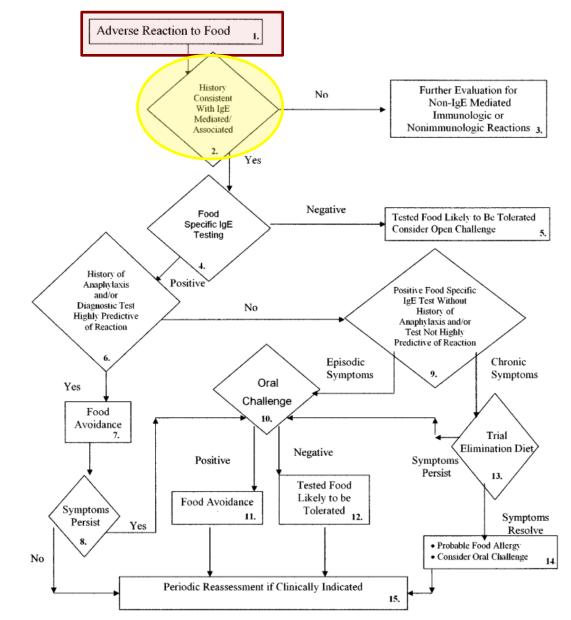
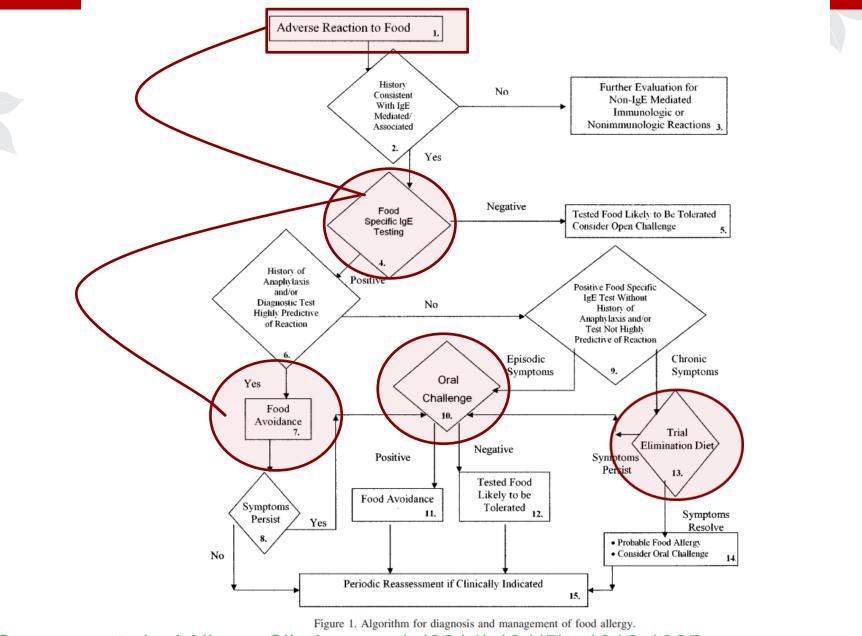


Figure 1. Algorithm for diagnosis and management of food allergy.

Sampson et al. J Allergy Clin Immunol. (2014) 134(5): 1016-1025

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Sampson et al. J Allergy Clin Immunol. (2014) 134(5): 1016-1025

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# **Thank You**



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