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ACAAI Annual Scientific Meeting

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Steve Rusckowski Chairman, Chief Executive Officer and President Quest Diagnostics 500 Plaza Drive Secaucus, NJ 07094

Via email: stephen.h.rusckowski@questdiagnostics.com

Dear Mr. Rusckowski:

I am writing on behalf of the American College of Allergy, Asthma and Immunology -- a professional association of 6,000 allergist/immunologists and allied health professionals -- regarding our concerns about the direct-toconsumer food allergy testing offered by Quest Direct.

It has come to our attention that Quest Direct is now offering various food allergy panel tests, including a "Food Allergy Test Panel," "Nut Allergy Test Panel" "Seafood Allergy Test Panel," and "Shellfish Allergy Test Panel" (https://questdirect.questdiagnostics.com/). While we commend Quest for seeking to aid both the clinician and patient in food allergy testing, we are very concerned that this form of direct-to-consumer testing provides more harm than benefit to individuals concerned about food allergy.

According to current food allergy diagnostic guidelines, serum IgE testing can aid in the diagnosis of IgE-mediated food allergies and is a valid diagnostic test.<sup>1-2</sup> However, all guidelines recommend that testing be used in conjunction with the patient's medical history. In fact, the medical history is the most important part of the evaluation and establishes the pre-test probability of the patient having a food allergy, which is required to interpret the serum IgE test.<sup>2</sup> This is paramount in IgE-mediated food allergy, as serum IgE testing can be overly sensitive for food allergy leading to many false positive and clinically irrelevant tests in up to 50% of cases.1-3 This can lead to serious consequences to both individual patients (unnecessary food avoidances, unfounded fears, and decreased quality of life) and to society as a whole (increased health care costs due to overdiagnosis of food allergy). Although not as common, false-negative test results can also occur in serum IgE testing leading to future allergic reactions that may be life-threatening. Encouraging patients to self-evaluate for a condition as complex and potentially life threatening as food allergies



through a direct-to-consumer marketing campaign may unintentionally cause undue harm to patients.

Based on the above, we urge Quest to reconsider its direct-to-consumer food allergy serum IgE testing and join ACAAI along with other national medical associations<sup>4</sup> in following best practices for food allergy evaluation.

Sincerely,

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Mark Corbett, MD ACAAI President

- 1. NIAID-Sponsored Expert Panel, Boyce JA, Assa'ad A, Burks AW, et al. Guidelines for the diagnosis and management of food allergy in the United States: report of the NIAID-sponsored expert panel. J Allergy Clin Immunol. 2010 Dec;126(6 Suppl):S1-58.
- 2. Greenhawt M, Shaker M, Wang J, et al. Peanut allergy diagnosis: A 2020 practice parameter update, systematic review, and GRADE analysis. J Allergy Clin Immunol. 2020 Dec;146(6):1302-1334.
- 3. Liu AH, Jaramillo R, Sicherer SH, et al. National prevalence and risk factors for food allergy and relationship to asthma: results from the National Health and Nutrition Examination Survey 2005-2006. J Allergy Clin Immunol. 2010 Oct;126(4):798-806.
- 4. Choosing Wisely (clinician recommendations for food allergy testing): <u>https://www.choosingwisely.org/clinician-lists/#keyword=food\_allergy</u>