

## **AllerGenis' Food Allergy Diagnostic Assay Demonstrates Significant Accuracy for Predicting Patient Outcomes in Milk Oral Immunotherapy**

***Using a growing database of patient reactivity signatures can better predict milk-allergic patient outcomes compared to traditional methods, AllerGenis' researchers report today in JACI***

**[Hatfield, PA]** — AllerGenis, a data-driven precision diagnostics company focused on food allergies, today reported research results in *The Journal of Allergy and Clinical Immunology* (JACI) that demonstrate its ability to predict, with significant accuracy, milk allergy patients' outcomes before milk oral immunotherapy treatment (Milk-OIT) is administered, using the company's novel milk allergy diagnostic assay. This publication is part of the company's broader effort to create a food allergy diagnostics platform.

Cow's milk allergy (CMA) is one of the most common food allergies in children under the age of 5.<sup>1</sup> Milk-OIT has emerged in the past decade as a potential relief to CMA patients; however, for many, the desensitization to milk is not sustained once the therapy is completed. Moreover, Milk-OIT carries significant risks, including anaphylaxis. For these reasons, the ability to stratify patients according to their predicted response to therapy would represent a significant boon for patient safety.

In this study, CMA patient blood samples were taken before Milk-OIT and analyzed to predict the patient's probability for sustained desensitization to milk allergens after the completion of the treatment. Comparing the results to patient samples taken after Milk-OIT revealed that AllerGenis' assay was able to predict patients' desensitization outcomes with 87 percent accuracy, more than what is possible with models based on standard serum component protein assays.

"Our [previously validated research](#)<sup>2</sup> demonstrated that our diagnostic assay is very accurate at diagnosing milk allergy," said lead author Hugh A. Sampson, M.D., of the Elliot and Roslyn Jaffe Food Allergy Institute of the Icahn School of Medicine at Mount Sinai. "We thought it was possible to use this tool to provide predictive data to clinicians treating milk allergic patients with Milk-OIT. Based on these results, we have a new and powerful tool for clinicians to improve safety and quality of life for their patients."

Dr. Sampson, Mayte Suárez-Fariñas, PhD., and their team used a next-generation peptide-based immunoassay to subdivide allergenic milk proteins into smaller peptide fragments — called epitopes — and measured the reactivity of the epitopes to a patient's IgE/IgG4 antibodies, creating a distinct antibody-epitope reactivity profile for each patient. Because the peptide assay measures reactivity to each of the epitopes, instead of the whole protein allergen,

the assay results are able to provide information about a patient's food allergy sensitivity with more than double the accuracy of current diagnostic methods.

Next, the research team produced antibody-epitope reactivity signatures for each patient sample, and then used those data and machine learning to build a predictive algorithm. In this case, the algorithm was also applied to predict patients' sustained unresponsiveness to milk allergens following Milk-OIT.

"We often hear from clinicians that improved precision in food diagnostics is long overdue," said Bob Getts, PhD., co-author and Chief Science Officer at AllerGenis. "We've been confident for some time now that high-throughput, next-generation technologies could dramatically improve food allergy diagnostic, prognostic and predictive precision. These results demonstrate that. Our goal is to get this technology and approach into the hands of clinicians."

The research results, authored by Dr. Sampson and Dr. Suárez-Fariñas, et al., are available in the December 3rd issue of *JACI*. AllerGenis is using these and previous research data to bring new food allergy diagnostic assays to clinicians — the company's peanut allergy assay, launching in late 2019, will be the first product released using this technology platform.

### **About AllerGenis**

Established in 2017 and located in Hatfield, PA, AllerGenis develops precision, data-driven diagnostics to help healthcare providers more accurately and safely diagnose, assess and monitor patients with food allergies. The company was founded out of a collaboration between Genisphere, provider of the 3DNA® platform for targeted drug delivery, and Hugh Sampson MD, of the Elliot and Roslyn Jaffe Food Allergy Institute of the Icahn School of Medicine at Mount Sinai. AllerGenis' proprietary epitope mapping technology is based on immunological research by Dr. Sampson and leverages Genisphere's expertise in improving sensitivity of diagnostic tests. AllerGenis is creating the largest food allergy knowledge base populated by individual patient epitope signatures derived from epitope mapping, clinical history, and patient-reported outcomes to gain clinical insights.

For more information, visit <https://www.allergenis.com>.

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