

New Research Demonstrates Clinical Viability of Epitope Mapping Technology Platform for Food Allergy Diagnosis

Newly published peer-reviewed paper in Scientific Reports from Nature demonstrates concordance between epitope mapping and oral food challenge for diagnosing peanut and milk allergies

HATFIELD, Penn. – December 20, 2019 – [AllerGenis](#), a data-driven precision diagnostics company focused on food allergies, this week reported [research results](#) in *Scientific Reports from Nature*, in preparation for the clinical launch of its bead-based epitope mapping diagnostic platform. The study quantified and validated the performance of the platform against the widely used peptide microarray assays in clinical patient populations.

AllerGenis' diagnostic platform analyzes the reactivity and binding of patients' IgE antibodies to epitopes of allergenic proteins, enabling a molecular level of resolution not available in current food allergy diagnostics and revealing actionable data about food allergies — diagnostic and prognostic assessment, level of allergen sensitivity, patient suitability for immunotherapy, and allergy subtypes.

[“Previous literature](#) has established epitope binding as a high-precision method to characterize food allergies,” said lead author Mayte Suárez-Fariñas, Ph.D., Senior Faculty in Population Health Science and Policy, and Genetics and Genomic Sciences, of the Icahn School of Medicine at Mount Sinai. “Other methods, such as peptide microarrays, tried to make use of epitope mapping. However, they were labor intensive, required large serum samples, and had a limited detection frequency. With advances in data science and high-throughput instrumentation, we are now able to take full advantage of epitope analyses.”

The newly published study followed AllerGenis' standard protocol, where the allergenic epitopes are coupled to beads before incubation with serum or plasma samples and secondary fluorophore antibodies. The fluorescence signals are quantified by a Luminex reader, which are then converted to epitope-binding values to be used for diagnosis. Ultimately, the study revealed four key pieces of information:

1. Although IgE antibodies are not abundant in blood, AllerGenis' diagnostic was able to detect their epitope binding patterns with a detection frequency of 98 to 100 percent. In comparison, peptide microarrays had a detection frequency of 17 to 21 percent.
2. AllerGenis' diagnostic acquired raw data from samples in 4 to 5 hours versus nearly two days for peptide microarrays. Moreover, the AllerGenis diagnostic is high-throughput and multiplexed, allowing for multiple measurements from a single sample in a short period of time.
3. The epitope mapping diagnostic produced consistent results across three independent laboratories for samples of varying allergic reactivity. This demonstrates its reliability and reproducibility, which is critical to ensure clinical readiness of the diagnostic platform.
4. Epitope-binding patterns of IgE antibodies are a clinically viable biomarker for food allergies with high concordance with oral food challenge, the gold standard of food allergy diagnosis. The study found that having a low or high IgE reactivity to allergenic epitopes had a correlation with

the patient's chances of passing an oral food challenge. Intermediate levels of IgE required an additional assessment of IgG4.

"There still remains a significant unmet need for improved food allergy diagnostics," said Bob Getts, PhD., Chief Science Officer at AllerGenis and co-author of the study. "These results demonstrate that AllerGenis' platform not only is orders of magnitude more powerful based on throughput than conventional epitope analysis methods, but also is more sensitive and reliable than current food allergy tests and can be conducted at clinical scale. We're excited about the potential of empowering patients to find clarity about their food allergies through our platform."

The research results, authored by Dr. Suárez-Fariñas, et al., are available in *Scientific Reports*. AllerGenis is using these and previous research data to bring new food allergy diagnostic assays to clinicians. Its peanut allergy diagnostic assay, launching in a limited capacity in early 2020, 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.allergen.com>.

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Study

Suprun, M, et al. Novel Bead-Based Epitope Assay is a sensitive and reliable tool for profiling epitope-specific antibody repertoire in food allergy. *Sci Rep.* 2019; 9, 18425.

Reference

Sampson HA. Utility of food-specific IgE concentrations in predicting symptomatic food allergy. *J Allergy Clin Immunol.* 2001;107(5):891–896.