

## **New food allergy diagnostics company, AllerGenis, recently launched to deliver innovative diagnostic technology enabling more precise food allergy detection and patient management**

*Data-driven technology designed to improve patient outcomes, reduce misdiagnoses*

**[Hatfield, PA]** — New food allergy diagnostics company, AllerGenis, LLC., recently launched for the purpose of bringing innovative, precision diagnostic solutions to food allergy clinicians, with the goal of improving patient outcomes through highly accurate and safe diagnostic tools.

The market for food allergy diagnostics is substantial, with 15 million Americans reportedly having food allergies, including eight percent of all children. Moreover, one in 13 children in the U.S. are at risk for life-threatening anaphylaxis.

Yet, current food allergy diagnostics have very low accuracy, and as many as 60 percent of patients may be misdiagnosed. AllerGenis has developed its technology using data-driven machine learning and next-generation multiplex immunoassay technology to more precisely diagnose and monitor patients with food allergies. It will be one of the first non-oncologic, precision medicine tools to help providers better diagnose, assess, and manage patients with food allergies.

“We are excited to launch our technology as an alternative to current food allergy diagnostics, which haven’t improved in nearly thirty years,” said Jim Garner, CEO and board member of AllerGenis. “Our mission is to provide physicians with clinically actionable information utilizing up-to-date technology, allowing for a safer diagnosis of food allergy and disease severity, without exposing patients to test-inflicted health risks.”

AllerGenis’ diagnostics next-generation technology uses a proprietary epitope mapping platform developed by Hugh Sampson MD, of the Elliot and Roslyn Jaffe Food Allergy Institute of the Icahn School of Medicine at Mount Sinai. The platform is a high-throughput, peptide-bead assay, which subdivides allergenic proteins into smaller peptides — called epitopes — and measures the reactivity of a patient’s IgE/IgG4 levels to these epitopes. Each patient will have a reactivity profile, known as an epitope signature, guiding providers with information to better assess and manage patients’ food allergies. Dr. Sampson and his team have already created a database of nearly one thousand epitope signatures to refine the algorithms underlying the technology’s precision.

“In the near future, as we build our repository of epitope signatures and phenotypes into a larger epitome database — similar to the Human Genome Project — we’ll be able to better indicate likely allergy outcomes,” said Dr. Sampson. “Also, we’ll be able, over time, to get a much better

understanding of how the human immune system actually deals with different food proteins. Hopefully, that will inform us on potential therapeutic avenues to follow.”

The first product to be launched using this proprietary technology platform will be the company’s peanut allergy assay, which will be available in the fall of 2019. Moving forward, AllerGenis plans to develop a pipeline of assays across food allergens. In its full development, the goal of AllerGenis’ technology program will be the ability to:

- Diagnose patient food allergy and associated severity (including anaphylaxis) without the risks associated with direct exposure to the allergen
- Distinguish between sensitivity and allergic disease, and who will naturally outgrow
- Assess, manage and monitor progress of therapy (ex. desensitization)
- Determine therapeutic efficacy (ex. Tolerance threshold)

AllerGenis is interested in pursuing business development opportunities/partnerships which have a clear strategic fit with our portfolio and commercial capabilities. For more information visit [www.allergen.com](http://www.allergen.com).

### **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, a 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. It leverages Genisphere’s Luminex bead-based immunoassay technology, which is used to make life science and diagnostics tests more sensitive. AllerGenis’ proprietary epitope mapping technology is based on immunological research by Dr. Sampson. 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 [www.allergen.com](http://www.allergen.com).

### **About the Mount Sinai Health System**

The Mount Sinai Health System is New York City’s largest integrated delivery system encompassing seven hospital campuses, a leading medical school, and a vast network of ambulatory practices throughout the greater New York region. Mount Sinai’s vision is to produce the safest care, the highest quality, the highest satisfaction, the best access and the best value of any health system in the nation. The System includes approximately 6,600 primary and specialty care physicians; 11 joint-venture ambulatory surgery centers; more than 140 ambulatory practices throughout the five boroughs of New York City, Westchester, Long Island,

and Florida; and 31 affiliated community health centers. The Icahn School of Medicine is one of three medical schools that have earned distinction by multiple indicators: ranked in the top 20 by *U.S. News & World Report's* "Best Medical Schools," aligned with a *U.S. News & World Report's* "Honor Roll" Hospital, No. 13 in the nation for National Institutes of Health funding, and among the top 10 most innovative research institutions as ranked by the journal *Nature* in its Nature Innovation Index. This reflects a special level of excellence in education, clinical practice, and research. The Mount Sinai Hospital is ranked No. 18 on *U.S. News & World Report's* "Honor Roll" of top U.S. hospitals; it is one of the nation's top 20 hospitals in Cardiology/Heart Surgery, Gastroenterology/GI Surgery, Geriatrics, Nephrology, and Neurology/Neurosurgery, and in the top 50 in six other specialties in the 2018-2019 "Best Hospitals" issue. Mount Sinai's Kravis Children's Hospital also is ranked nationally in five out of ten pediatric specialties by *U.S. News & World Report*. The New York Eye and Ear Infirmary of Mount Sinai is ranked 11th nationally for Ophthalmology and 44th for Ear, Nose, and Throat, while Mount Sinai Beth Israel, Mount Sinai St. Luke's and Mount Sinai West are ranked regionally.

For more information, visit [www.mountsinai.org](http://www.mountsinai.org) or find Mount Sinai on [Facebook](#), [Twitter](#) and [YouTube](#).

#### **Media contact**

Joseph Salerno, MS  
312-506-5241  
HDMZ  
[joseph.salerno@hdmz.com](mailto:joseph.salerno@hdmz.com)

#### **Investment contact**

Russ Fein  
646-572-0421  
Corporate Fuel Partners  
[russ@corporatefuel.com](mailto:russ@corporatefuel.com)