

Category

Best Startup

Product/Solution Name

Allergenis

Date of Approval

N/A

Indications

Diagnosis of food allergy, Tolerance Levels, and Severity

Therapeutic Categories

Allergy and Immunology

Background information and need for solution/product

Over 32 million Americans have food allergies, including 1 in every 13 children or approximately 2 in every classroom. As many as 60% are over-diagnosed with current blood and skin testing, causing a mental, emotional, and financial toll on individuals, caregivers, and their families. The gold standard in diagnosing food allergies is an oral food challenge (OFC) which is anxiety-inducing, time and resource-intensive, may incur a risk of anaphylactic reactions, and is not widely available in clinical practice. The OFC is also often required by therapeutic products during clinical trials which can inhibit trial enrollment and slow time-to-market for treatment solutions. Allergenis' revolutionizing technology was developed by a world leader in Food Allergy diagnosis and management, Hugh A. Sampson, M.D. and validated by innovation focused institutions including Mount Sinai, and Stanford University, amongst others. Dr. Sampson has spent over 20 years developing the technology and is cited in hundreds of publications on the use of epitopes in food allergy diagnosis, phenotype prediction, and treatment outcomes. Working with Dr. Sampson, Allergenis has commercialized the first assay for peanuts, with multiple allergens (milk, egg, wheat, and tree nuts) in the pipeline. Unique in the space, Allergenis uses only oral food challenged (OFC) confirmed food allergic patients to develop the testing which has allowed the platform to achieve over 93% accuracy with OFC outcomes. Individuals need a comprehensive road map to understand if they are allergic, how allergic they are, what their threshold levels are, and whether they are at increased risk of experiencing a life-threatening reaction. The Allergenis diagnostic offers a safe, easy-to-access, alternative to an OFC with up to 93% accuracy, far superior to currently available blood or skin tests, that helps individuals get clarity on these questions. The Allergenis patent-protected platform has 190 times the resolution available in existing tests and is the only assay able to predict tolerance level, form, and reaction type.

Allergenis also collaborates with therapeutic companies pursuing regulatory approvals in the field of food allergies, integrating our biomarkers into the development and clinical use of their products to advance the acceptance of reliable biomarkers as safe and effective alternatives to oral food challenges.

This partnership is mutually beneficial, as it increases trial enrollment and accelerates time-to-market

for treatment solutions. We provide our proprietary epitope mapping platform technology to therapeutic companies and partner with them to use our biomarkers for clinical patient selection and to evaluate the effectiveness of their therapeutic products. Our tests may also be used to track treatment response once products become FDA-approved and available, further securing our position as a global leader in this burgeoning therapeutic field, while generating additional revenue.

<https://www.foodallergy.org/resources/blood-tests>

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6135119/>

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5770894/>

<https://onlinelibrary.wiley.com/doi/10.1111/all.14905>

<https://pubmed.ncbi.nlm.nih.gov/35960650/>

History of the development of the solution/product

Hugh A. Sampson, M.D., the founder of the bead-based epitope technology, is the Kurt Hirschhorn Professor of Pediatrics and the Director Emeritus of the Jaffe Food Allergy Institute at the Icahn School of Medicine in New York and has over 40 years' experience in clinical and basic research focusing on food allergic disorders and basic immunologic mechanisms responsible for these disorders. His research has been funded continuously by grants from the NIH, including the Principal Investigator for the Consortium for Food Allergy Research, has authored/co-authored over 550 original articles and 90 book chapters primarily on various aspects of food allergic disorders, and has chaired working groups that produced standardized criteria for diagnosing anaphylaxis and conducting double-blind placebo-controlled oral food challenges (Practall Guidelines).

Allergenis has commercialized the epitope technology in the food allergy market offering precision molecular diagnostics with a machine-learning, AI approach to predictive analytics. Additionally, Allergenis is the first food allergy test which can be initiated by a caregiver and/or individual via a partner telemedicine channel, all while receiving the necessary and medical support from an allergist with expertise in managing food allergy.

Why this solution/product is innovative, the broad implications for future research, and/or how it will improve the human condition

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Please provide appropriate references (ie Pubmed links)

<https://pubmed.ncbi.nlm.nih.gov/15536426/>

<https://pubmed.ncbi.nlm.nih.gov/35730331/>

<https://pubmed.ncbi.nlm.nih.gov/33991353/>

<https://pubmed.ncbi.nlm.nih.gov/35960650/>