AllerGenis Begins Testing Patient Samples for Peanut Allergy Using Proprietary Epitope Mapping Technology

HATFIELD, Pa.—June 24, 2020— [AllerGenis](#) LLC, a data-driven precision diagnostics company focused on food allergies, today announced the onset of operations at its Hatfield facility to test patient samples using its VeriMAP^{TM} Peanut Diagnostic, a diagnostic solution for patients with peanut allergies.

AllerGenis received full certification under Clinical Laboratory Improvement Amendments of 1988 (CLIA) to perform its high complexity clinical laboratory testing. This is a crucial step for the company as it begins offering VeriMAP Peanut Diagnostic to Centers of Excellence and community allergists over the next few months, with plans to expand into additional allergy centers in early 2021.

"Many food allergy sufferers have lived with great uncertainty throughout their lives as they navigate the realities of living with their condition," said Jim Garner, CEO of AllerGenis. "With VeriMAP Peanut Diagnostic, we have a chance to dramatically reduce that uncertainty for hundreds of thousands of patients through a highly accurate diagnosis. It has been decades since the last technological breakthrough in food allergy diagnosis. We are extremely excited to bring 21st century solutions to bear on this tremendous healthcare challenge."

Current skin or serologic testing for allergen-specific IgE has low specificity and low positive predictive value, often resulting in false positive rates of up to 60 percent, which can lead to inconclusive test results and overdiagnosis. Oral food challenge (OFC), the clinical gold standard for food allergy diagnosis, is inherently risky to patients and can have months-long testing backlogs, which may be even longer due to the strain on the healthcare system from COVID-19. VeriMAP Peanut Diagnostic has a 93 percent concordance with OFC results and is available to patients with a simple blood draw — providing food allergy patients a diagnosis with greater certainty.

"What started out 20 years ago as a desire to understand how the immune system processes and 'sees' food allergens, has now evolved into a serologic test for peanut allergy that can replace the need for OFC in most cases," said Hugh Sampson, MD, former director of the Elliot and Roslyn Jaffe Food Allergy Institute and Kurt Hirschhorn Professor of Pediatrics at the Icahn School of Medicine at Mount Sinai. "This test should largely eliminate the uncertainty of current laboratory-based tests for peanut allergy and allow for more timely discussions related to treatment decisions. I look forward to continued collaborations with AllerGenis and top researchers around the world to further revolutionize the diagnosis and management of food allergies."

"VeriMAP is an exciting advancement in the accurate diagnosis of peanut allergies, and provides clinicians and peanut allergy sufferers an alternative to food challenges," said William McCann, MD, Chief Medical Officer of Allergy Partners — one of the testing centers participating in the initial limited launch of VeriMAP Peanut Diagnostic. "We are

excited to explore this technology's application in the clinical setting."

To demonstrate the utility of VeriMAP Peanut Diagnostic, AllerGenis collaborated with top food allergy experts from Stanford University and King's College London, in addition to Dr. Sampson. The results from the research were recently reported in the preprint server medRxiv (available at this link), which validate the performance of the bead-based epitope mapping diagnostic platform that is the technological foundation of VeriMAP Peanut Diagnostic.

The study presents discovery data for VeriMAP Peanut Diagnostic on the LEAP cohort and validates its performance on two independent cohorts, POISED and CoFAR2. The study included a comparison of the VeriMAP Peanut Diagnostic to commonly used food allergy tests: skin prick, allergen-specific IgE, and Ara h2. The bead-based VeriMAP Peanut Diagnostic assay demonstrated high accuracy and a false positive rate significantly lower than other diagnostic tests assessed.

Aside from VeriMAP Peanut Diagnostic, AllerGenis is also developing diagnostic tests for dairy, egg, shellfish, tree nut and other food allergies.

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 Icahn School of Medicine at Mount Sinai.

AllerGenis' technology platform is based on immunological research by Dr. Sampson, and leverages Genisphere's expertise in improving sensitivity of diagnostic tests. Mount Sinai Health System has licensed its proprietary epitope mapping platform to AllerGenis, which the company is using to create 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.allergenis.com.

Contacts

Media Contact
Azeem Zeekrya
312-506-5244
azeem.zeekrya@hdmz.com

Investment Contact
Jim Garner, CEO
401-965-2499
jim.garner@allergenis.com