Docket #: S18-445

Stand-alone food allergy diagnostic test based on basophil activation

Stanford researchers have developed a rapid, accurate, and accessible method to test for food allergy and other types of allergy. This standalone diagnostic test can accurately predict the severity of an allergic reaction to allergens using a novel blood-based biomarker based on the activation of basophils.

The test analyzes blood after its collection and can deliver results in less than 3 hours at the point-of-care. Current allergy tests can take up to two weeks and faster methods such as the skin prick tests (SPT) can trigger allergic reactions. In contrast, this new test is fast, safe and convenient.

Patients who experience adverse reaction can obtain results quickly to avoid repeated exposure to the offending allergen. This rapid diagnostic test can also be used for monitoring treatment progress for patients undergoing allergy immunotherapy.

Stage of Development

- Research – in vitro
- Prototype in progress

Applications

- **Accurate, rapid, and early diagnosis** of allergies
- **Tracking the efficacy of food allergen immunotherapy** as a companion diagnostic
- Prototype to be a **standalone machine to be used by doctors/clinicians** as part of patient care to screen and manage allergens
- Ultimately, it could be a **consumer over-the-counter product** similar to the glucometers and heart rate monitors

Advantages

- **Accurate, rapid, and early diagnosis** of allergy (food, drug, insect, pollen, animal, other)
- **High predictive value based on accuracy**
- **Very fast compared to current standards** - 3 hours from fresh blood draw vs. 2 weeks in current assays
- **Point of-care** results
- **Does not trigger negative reaction** during the test, unlike skin prick tests (SPT)
- Can be combined with IgE levels in addition to activated basophil counts to improve allergy prediction

Publications

- Tsai, Mindy, Kaori Mukai, R. Sharon Chinthrajah, Kari C. Nadeau, and Stephen J. Galli. "Sustained successful peanut oral immunotherapy associated with low basophil activation and peanut-specific IgE." *Journal of Allergy and Clinical Immunology* (2019). doi: 10.1016/j.jaci.2019.10.038
- Moskal, Emily . In less than 10 minutes, Stanford researchers isolate the rarest white blood cells *Stanford Report* (2022).

Patents

- Published Application: WO2020102429
- Published Application: 20210394183
- Issued: 12,239,982 (USA)

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