Docket #: S16-414

ISAP- a PCR-based method for isotype-specific antibody detection

Stanford researchers have developed a PCR-based method that detects disease-relevant, isotype-specific antibodies and can be used to diagnose allergy. Allergy is a prevalent immune hypersensitivity disease that affects more than 20% of the US population. Current methods for diagnosing and monitoring allergy patients may be inappropriate for children, require large amounts of sample and/or are expensive. To overcome these limitations and provide a sensitive, specific, and cost-efficient diagnostic tool the inventors have developed the ISAP (Isotype-Specific Agglutination-PCR) assay.

ISAP is a PCR-based method for detecting antigen-binding antibodies of a specific isotype. Using only a small amount of sample, the assay can detect the isotype of antibodies against a particular allergen to allow deep investigation of the immunoglobulin response. ISAP can be coupled with other PCR-based methods into a single multiplexed assay to detect total IgE, specific IgE, specific IgG4 and total anti-allergen antibodies providing a comprehensive picture of the immune response. This technique offers a more sensitive, specific and cost-effective method for better allergy testing in labs and clinics.

Stage of research
Using mouse models of peanut allergy, the inventors have shown this method is more sensitive than ELISA-based methods and at least as effective as the gold standard ImmunoCAP platform, while having key advantages including cost-effectiveness and reduced sample consumption. Optimization of the method for clinical use is ongoing.

Applications

- Allergy diagnostic- including peanut allergy

- Monitor disease-relevant antibodies associated with autoimmune diseases, infection or inflammation for better disease management

Advantages

- PCR-based allergy detection assay
- Enhanced sensitivity and specificity- more sensitive than ELISA-based methods
- Low sample consumption- uses small amount of sample as compared to ImmunoCAP assays
    - Better for pediatric patients
- Low assay cost
- Simple work flow
- Does not require specialized equipment- uses standard qPCR instruments
- Establishes a complete view of the allergic response- allows multiplex detection of diverse allergic information
- Compatible with serum or whole blood samples

Publications

- Mukai K, Chinthrajah R.S, Nadeau KC, Tsai M, Gaudenzio N, Galli SJ, "A new fluorescent-avidin-based method for quantifying basophil activation in whole blood" *The Journal of Allergy and Clinical Immunology*Article in Press (as of 28092017).
- C-t Tsai, P.V. Robinson, F.d J.Cortez, M. L.B. Elma, D. Seftel, N. Pourmandi, M.W. Pandori and C.R. Bertozzi, Antibody detection by agglutination-PCR (ADAP) enables early diagnosis of HIV infection by oral fluid analysis. PNAS 2018 : 1711004115v1-201711004.

Patents

- Published Application: 20200309784
- Published Application: 20230333116
- Issued: 11,656,233 (USA)
- Issued: 12,546,784 (USA)

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