

# Food Allergy Diagnostic

## A blood test to reduce the need for food challenges

### The opportunity

Food allergy is a growing public health concern that affects 8% of children in the United States. The overall economic cost of food allergy in the United States has been estimated at \$24.8 (95%CI, \$20.6-\$29.4) billion annually (\$4184 per year per child).

Currently, there is no simple, accurate blood test to determine whether a child has a food allergy. Diagnostic tests for food allergies suffer from poor specificity, and up to half of the patients who test positive are asymptomatic. Many children are being referred to hospitals for confirmatory diagnoses by the gold standard oral food challenge test.

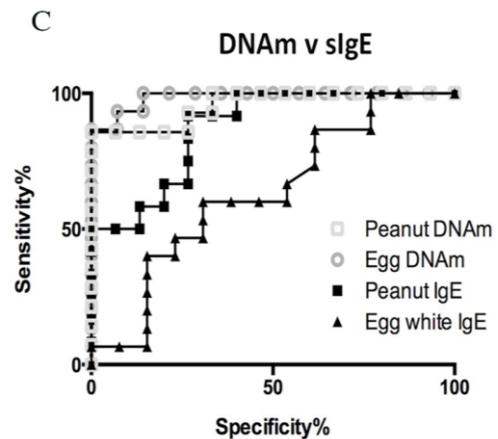
Food challenges are potentially dangerous, are time and labour intensive and costly to the health system. For these reasons they are often not performed, leading to misdiagnosis, unnecessary food avoidance diets, unreliable population prevalence estimates, and delays in therapeutic development.

Researchers at the Murdoch Childrens Research Institute have developed a methylation-based biomarker assay for diagnosing clinically relevant food allergy that is 2-3 times more sensitive than current diagnostics, and highly specific. This test will negate the need for an oral food challenge in a large number of children.

### The technology

The technology consists of a panel of 96 DNA methylation biomarkers discovered by high-throughput epigenetic screening of blood from patients undergoing oral food challenges.

The combined methylation profile of these biomarkers can be used to accurately diagnose patients with egg or peanut food allergies since patients with active allergy have higher methylation levels at these loci. Importantly, the approach was reproducible in an independent patient group yielding accurate diagnostic scores in two separate populations to date.



**Figure:** Area under the curve analysis of DNA methylation (DNAm) scores against serum IgE measures in peanut and egg allergic children.

### Opportunity for partnership

The discovery DNA methylation profiling was performed using the Illumina Infinium Human Methylation 450 bead array platform.

The Murdoch Childrens Research Institute is seeking a partner to validate and develop the technology on a clinically-relevant platform.

### Intellectual Property

The Murdoch Childrens Research Institute has filed an international PCT application (PCT/AU2015/050813) that broadly captures the use of 4,500 CpG probes identified as predictive of food allergy. MCRI is the sole owner of this IP.

### Key publications

Martino D, Dang T, Sexton-Oates A, Prescott S, Tang MLK, Dharmage S, et al. Blood DNA methylation biomarkers predict clinical reactivity in food-sensitised infants. *J Allergy Clin Immunol.* 2015 May;135(5):1319-1328.e12.