Validation of the new microarray platform ALEX for specific IgE detection of respiratory and plant-food allergens

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Abstract

Background: As the use of multiplex specific IgE (sIgE) detection methods becomes increasingly widespread, proper comparative validation assessments of emerging new platforms are vital. The objective of this study was to assess the clinical and technical performance of the ALEX platform (MacroArray Diagnostics), in comparison to the ImmunoCAP ISAC 112 microarray and the ImmunoCAP singleplex method (ThermoFisher Scientific) in the diagnosis of pollen (cypress, grass, olive), dust mite Dermatophagoides pteronyssinus, Alternaria alternata, fruit (apple, peach) and nut (walnut, hazelnut and peanut) allergy. Methods: We enrolled 153 allergic patients and 16 non-atopic controls. sIgE assays were conducted using ISAC112, ALEX version 2 (ALEX2), and ImmunoCAP for whole extracts and major components. Technical validation of ALEX2 was performed by measuring repeatability and inter-assay, inter-batch and inter-lab reproducibility. Results: When measured globally (detection by one or more allergen components), ALEX2 showed adequate sensitivity and specificity for most of the allergens studied, comparable in general to that of ISAC112 (except for olive pollen and walnut) and similar to that of ImmunoCAP whole extract measurements. Component-by-component analysis showed comparable results for all techniques, except for Ole e 1 and Jug r 3 in both ISAC112 and ImmunoCAP comparisons, and Alt a 1, when compared with ISAC112. Continuous sIgE levels correlate with sIgE by ImmunoCAP. Good reproducibility and repeatability were observed for ALEX2. Conclusions: ALEX2 shows sound technical performance, and adequate diagnostic capacity, comparable in general to that of ISAC112 and ImmunoCAP for some aeroallergens and plant-food allergies in Mediterranean patients.

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