IgE assay design guidance, 7/17

July 2017—To define the current state of reagents and serological assay technology used to measure total human immunoglobulin E and IgE antibodies of defined allergen specificities in human blood, the Clinical and Laboratory Standards Institute published a revised document that focuses on IgE assay design and calibration, validation methods, quality assurance of assay reagents, quality control strategies, and clinical applications.

The report, “Analytical Performance Characteristics, Quality Assurance, and Clinical Utility of Immunological Assays for Human Immunoglobulin E Antibodies of Defined Allergen Specificities (I/LA20-Ed3),” includes guidance on specifications for assay design to fulfill FDA 510(k) requirements; an overview of the 10 cross-reactive allergen families and the rationale for IgE anti-allergen component analysis in diagnostic allergy testing; detailed guidance on IgE antibody assay QC strategies; and enhanced guidance for clinicians who utilize IgE antibody results to assess allergic sensitization in their patients. The novel database supplement, “Supplemental Data for Allergen Specificity of IgE Antibody Autoanalyzers (I/LA37),” lists allergen codes currently used by immunoglobulin E antibody assay manufacturers along with their common name, Latin name, and allergen grouping.

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