



The importance of EN ISO 15189 accreditation of allergen-specific IgE determination for reliable in vitro allergy diagnosis

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BACKGROUND: Allergen-specific serum immunoglobulin E detection and quantification have become an important step in allergy diagnosis and follow-up. In line with the current trend of laboratory test accreditation to international standards, we set out to design and assess an accreditation procedure for allergen-specific serum IgE.

METHODS: Method validation according to the accreditation procedure under the EN ISO 15189 standard was carried out for allergen-specific immunoglobulin E determination using the fluoroimmunoenzymatic method ImmunoCAP(®) (ThermoFisher). Data were produced by 25 hospital laboratories in France. A total of 29 allergen specificities including mixes, extracts, and molecular allergens were assayed. Allergen-specific serum immunoglobulin E concentrations ranged from 0.1 to 100 kUA /l.

RESULTS: Repeatability, reproducibility, and accuracy results fulfilled method validation criteria for automated laboratory tests and proved similar irrespective of the allergen specificity, allergen-specific serum immunoglobulin E concentration, or individual laboratory.

CONCLUSION: Allergen-specific serum immunoglobulin E determination with the fluoroimmunoenzymatic method ImmunoCAP(®) is a highly repeatable, reproducible, and accurate method which may be considered as a single analyte assay in view of the EN ISO 15189 accreditation procedure.

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