

Allergen-Specific IgE Testing By Conventional RAST

CPT Code: 86003 for each allergen

Background. Soon after the identification of IgE as the reagent or the antibody involved in Type I (or immediate-type) hypersensitivities, a semi-quantitative radioimmunoassay was developed for the detection of specific IgE in serum. Since then, *in vitro* IgE testing (i.e. "RAST") has gained an important role worldwide and a number of technical and procedural modifications have been introduced. The clinical utility and appropriate use of this testing was outlined in a Position Statement from the American Academy of Allergy and Immunology (AAAAI) in 1983⁽¹⁾

Worldwide Acceptance. *In vitro* allergy testing is the primary testing mode for allergy diagnosis throughout the world, especially in Europe and Asia, and its use has also grown over the years in the U.S., although skin testing is still the most common test format with board-certified allergists in the U.S.⁽²⁻⁷⁾ However, physicians who prefer to use *in vitro* tests will point to the following advantages when compared to skin testing:

- Patient convenience
- Useful with skin disease
- More quantitative
- No drug interference
- Stability of reagents
- Fewer false positives

Recent reports have also shown that an *in vitro* method is especially useful in the diagnosis of food allergy⁽⁸⁾. For certain esoteric allergens that are not available by the ImmunoCAP method, IBT Reference Lab offers the Conventional RAST test method.

Method. The test method is a radioimmunoassay (RIA). Allergens are covalently coupled to the cellulose paper discs via the APT method. ¹²⁵I-labelled anti-IgE is used to quantify the patient's specific IgE.

Calibration. The assay uses a five-point calibration curve and the system was standardized vs the Pharmacia ImmunoCAP and provides units similar to the Pharmacia ImmunoCAP RAST. The results are reported in kU/L of specific IgE.

Tests Available. The test system is only used for those allergens that are not available from Pharmacia Diagnostics (Refer to the Directory of Services.) The individual tests have not been cleared or approved by the FDA. Their validation and performance has been determined by IBT Reference Laboratory. However, according to CLIA regulations, such tests can be used for diagnostic purposes.

Scoring System for the Conventional RAST.

Class	IgE (kU/L)	Comment
0	< 0.1	Below Detection
0/1	0.1 - 0.34	Equivocal/Borderline
1	0.35 - 0.69	Low Positive
2	0.7 - 3.4	Moderate Positive
3	3.5 - 17.4	Positive
4	>17.4	Strong Positive

Specimen Requirements. 0.5 mL of serum should be provided for each allergen tested. The serum may be shipped at ambient temperatures.

References:

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- (2) Project Hope, Center for Health Affairs: "The Cost Implication and Cost Effectiveness of Allergy *In Vitro* Diagnostic Testing.", October 1988.
- (3) Hamilton, R and Adkinson, NF. Quantitation of allergen-specific IgE in serum using the RAST. *Clin Immunoassay* 1983; 6: 147-154.
- (4) Kelso, JM, Sodhi, N, Gosselin, VA and Yunginger, JW. Diagnostic performance characteristics of the standard Phadebas RAST, modified RAST, and Pharmacia CAP system vs skin testing. *Annals of Allergy* 67:511-514, 1991.
- (5) Williams, PB, Dolen, WK, Koepke, JW and Selner, JC. Comparison of skin testing and three *in vitro* assays for specific IgE in the clinical evaluation of immediate hypersensitivity. *Annals of Allergy* 69:48-52, 1992.
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- (7) Poon, AW, Goodman, CS, Rubin, RJ. *In vitro* and skin testing for allergy: comparable clinical utility and costs. *American Journal of Managed Care* 1998; 4: 969 - 985.
- (8) Sampson, HA et al. Clinical aspects of allergic disease: relationship between food-specific IgE concentration and the risk of positive food challenges. *J Allergy Clin Immunol* 1997; 100:444-451.
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- (10) Szeinbach, S et al. Precision and accuracy of commercial laboratories ability to classify positive and/or negative allergen-specific IgE results. *Ann Allergy, Asthma & Immunol* 2001; 86: 373 - 381.

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