

## Allergen-Specific IgE Testing ImmunoCAP®

**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 radio-immunoassay 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, especially the ImmunoCAP®. These changes, in conjunction with improved reagents have increased the sensitivity of the test, without a significant decrease in specificity. The clinical utility and appropriate use of this testing was outlined in a Position Statement from the American Academy of Allergy and Immunology (AAAI) in 1983 and recently reviewed<sup>(1,11)</sup>

**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.<sup>(2-7)</sup> However, physicians who prefer to use *in vitro* tests will point to the following advantages when compared to skin testing:

- Patient convenience
- More quantitative
- No drug interference
- Fewer false positives
- Lack of patient risk
- International standards
- Stability of reagents
- Useful with skin disease

Recent reports have also shown that an *in vitro* method is especially useful in the diagnosis of food allergy<sup>(8)</sup>.

**Method:** The Pharmacia ImmunoCAP® FEIA. This method uses as the solid phase a flexible, hydrophobic cellulose polymer to which allergen has been covalently linked. The advantage of this system is that it has a very high antigen binding capacity when compared to other systems and it has minimal non-specific binding with high total IgE.

**Calibration:** The ImmunoCAP assay uses total IgE standards from WHO Reference 75/502 to generate results in kilounits of IgE. The ImmunoCAP specific IgE blood test was the first test cleared by the FDA for the quantitative measurement of specific IgE.

**Tests Available:** Over 500 different allergens are available by ImmunoCAP. In addition, several hundred esoteric allergens are available from IBT using the paper disc RAST method. It should be noted that this RAST incorporates a different calibration and scoring system. Refer to a sample report.

### ImmunoCAP® Quantitative Scoring Guide:

Class	IgE( kU/L)	Comment
0	< 0.10	Negative
0/1	0.10-0.34	Equivocal
1	0.35-0.69	Low Positive
2	0.70-3.4	Moderate Positive
3	3.5-17.4	High Positive
4	17.5-49.9	Very High Positive
5	50.0 -99.9	"
6	≥ 100	"

Note that IBT includes an extra calibrator at 0.10 kU/L and uses it to define an optional equivocal class.

**Specimen Requirements:** 0.5 mL of serum for each allergen. Sera may be shipped at ambient temp.

### References:

- (1) Position Statement 12 April 1990 published in *Immunology and Allergy Practice*.
- (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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- (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.
- (11) Valcour, A. Allergy testing for the 21<sup>st</sup> century. *Advance/Laboratory 2003*; 12: 68 - 75.

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