IBT Laboratories

Specializing in molecular & cellular immunology

ImmunoCAP™ Latex Allergy Test

Test Name: ImmunoCAP™ Latex Allergy Test
Test Code: 84010
CPT Code: 86003

Background: Type I hypersensitivities or IgE-mediated allergies to latex-derived products have become a significant medical problem throughout the world [(1)] . The prevalence of this type of latex allergy is particularly high in certain high risk populations. For health care workers the prevalence is estimated to be in the 4 - 10% range whereas it may be greater than 50% in spina bifida patients [(2)] .

Method: ImmunoCAP™, the EIA with fluorescent substrate (FEIA) from Pharmacia Diagnostics. The test uses a non-ammoniated latex allergen preparation with at least 10 different protein components.

Units Reported: IgE concentration in kU/L and a class score. The IgE concentration is estimated from a total IgE standard curve and is referenced to an international standard for total IgE.

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: 1.0 mL serum. (0.3 mL Minimum volume). The sera can be shipped at ambient temperatures.

Indications for use: The test is useful to confirm the diagnosis of Type I latex allergy. The identified risk groups for this disease include: health care workers, rubber industry workers and patients with spina bifida and others with multiple surgeries. The test would be appropriate for those in these risk groups who have symptoms such as rhinitis, asthma, conjunctivitis and anaphylaxis. It is not useful in most patients with contact dermatitis (i.e. Type IV hypersensitivity) to the chemicals used in the manufacture of latex products.

Performance: The ImmunoCAP™ latex test has been cleared by the FDA for marketing in the US. The ImmunoCAP™ was evaluated in parallel with a previously cleared latex allergy test (DPC AlaSTAT) and the two exhibited an overall agreement of 90% [(3)] . Further, in 11 published clinical studies, mostly from Europe, the sensitivity of the assay was 91.7% and the specificity was reported to be 92% [(4)] . The overall agreement with the clinical judgements in these 11 studies was 483/524 (92.2%).

References:

(1) Slater J. Latex allergy. *J Allergy Clin Immunol 1994*; 94: 139 - 149.
(2) Turjanmaa K, et al. Natural rubber latex allergy. *Allergy 1996*;51: 593- 602.
(3) Williams PB, et al. Comparing two methods for assessing specific IgE to latex. *Eur J Allergy & Clin Immunol 1997*; abstract
(4) List of references available from Pharmacia Diagnostics.

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