

Latex RIA

Test Name: Latex RIA Panel
Test Code: 401468
CPT Code: 86003 x 3

Description: This panel of latex specific IgE tests relies on the following three latex antigen preparations to aid in the identification of patients sensitive to natural rubber products:

- 1. Ammoniated Latex.** Proteins were isolated from Malaysian *H. brasiliensis* latex collected in ammonia, the form usually used to manufacture dipped products.
- 2. Non-Ammoniated Latex (NAL) or Buffered Latex.** To preserve the antigenic integrity of all proteins, latex was collected in a neutral pH buffer using the method developed by the FDA to prepare reference extracts.
- 3. Glove Latex.** An aqueous extract was prepared from a commercial latex exam glove.

Method: Radioimmunoassay ⁽¹⁾. The analytical specificity of test has been documented by inhibition studies with soluble latex antigen ⁽²⁾.

Units Reported: U/mL (The units are arbitrary and cannot be used to calculate IU of IgE). A class score is provided as an estimate of relative IgE dose.

Normal Range and Guidelines for Interpretation:

U/mL	Class	Interpretation
< 5	0	Negative (or Normal)
≥ 5 to < 25	1	Equivocal/Low Positive
≥ 25 to < 50	2	Positive
≥ 50 to < 200	3	"
≥ 200	4	"

If any of the individual antigens are positive ^(3 5), then the test is considered positive and the patient is potentially at risk if exposed via a parenteral or mucosal route to any natural rubber product. As with any allergy test (skin test or *in vitro*), positive test results are sometimes observed in patients with no clear history of an adverse reaction. In addition, patients with disease may not always test positive with one of the latex allergy tests ⁽³⁾. The Latex RIA was compared to the FDA cleared ImmunoCAP latex allergy test kit from Pharmacia Diagnostics with 138 sera ⁽²⁾. Using this test as the reference or standard the Latex RIA demonstrated 98.4 % sensitivity and 90.8 % specificity (see following data).

Latex RIA Result

		Neg	Pos
Pharmacia ImmunoCAP Result	Neg	69	7
	Pos	1	61

Specimen Requirement: 2 mL serum. The sera can be shipped at ambient temperature.

Comments/Background: Natural rubber products are made from latex from the *Hevae brasiliensis* tree. The crude latex, usually collected in ammoniated solution to prevent microbial growth, contains an array of cellular proteins, lipids, amino acids, nucleotides and large quantities of cis-1,4-poly-isoprene. The cross-linking of the poly-isoprene in the presence of sulfur and other chemical additives gives latex its unique physical properties. Without special processing, the finished products may contain as much as 1 to 3% by weight protein. These are the allergens that sensitize and pose a risk for health care workers, rubber industry workers, spina bifida patients and others who have had multiple surgeries. There are several excellent reviews on the natural history of latex allergy ^(4,5). The prevalence of latex allergy has been estimated to vary for different populations ⁽⁴⁾. Although less than 1% in the general population, it is 3% in atopics, 8% in health care workers and 41% in spina bifida patients.

Delayed hypersensitivity reactions (allergic contact dermatitis) to rubber products are well known. These reactions are thought to be T cell-mediated responses to the chemical additives used in manufacturing and may be negative with tests for latex specific IgE.

References:

- Halsey JF, et al. Evaluation of a sensitive latex-specific IgE RIA panel. International Latex Conference: Sensitivity to Latex in Medical Devices [Abstract]. 1992:27.
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- Hamilton RG. Diagnosis of natural rubber latex allergy: multicenter latex skin testing efficacy study. *J Allergy Clin Immunol* 1998; 102:482-490.
- Turjanmaa k et al. Natural rubber latex allergy. *Allergy* 1996; 51:593-602.
- Slater J. Latex allergy. *J Allergy Clin Immunol* 1994; 94:139 –149.

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