

Orange Roughy IgE

Test Code: 32310A

Clinical and Procedure

Clinical Utility

This assay is used to detect allergen specific-IgE using the ImmunoCAP® FEIA method. In vitro allergy testing is the primary testing mode for allergy diagnosis.

Procedure

The ImmunoCAP® FEIA method uses as the solid phase a flexible, hydrophobic cellulosic 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. Viracor Eurofins provides an optional low range calibrator at 0.1 kU/L and a 0/1 class. This test has not been cleared or approved for diagnostic use by the U.S. Food and Drug Administration.

Turnaround Time

1-2 business days from receipt of specimen

Specimen Information

Specimen Type	Order Code	CPT Code	NY Approved	Volume	Assay Range
Serum	32310A	86003	Yes	0.5 mL (min. 340uL)	See Scoring Guide

Special Instructions

- Collect 1-2 mL whole blood in red top tube.
- Centrifuge and transfer 0.5 mL serum into a transfer tube.
- Ship at ambient or frozen temperature Monday through Friday.
- Specimens are stable for 4 weeks refrigerated or ambient; freeze for longer storage.

ImmunoCAP® Quantitative Scoring Guide:

Class	IgE (kU/L)	Comment
0	<0.10	Negative
0/1	0.10-0.34	Equivocal/Borderline
1	0.35-0.69	Low Positive
2	0.70-3.49	Moderate Positive
3	3.50-17.49	High Positive
4	17.50-49.99	Very High Positive
5	50.00-99.99	Very High Positive
6	>99.99	Very High Positive

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

Causes for Rejection

Lipemic samples may lead to rejection

Disclaimer

Specimens are approved for testing in New York only when indicated in the Specimen Information field above.

The CPT codes provided are based on Viracor Eurofins' interpretation of the American Medical Association's Current Procedural Terminology (CPT) codes and are provided for general informational purposes only. CPT coding is the sole responsibility of the billing party. Questions regarding coding should be addressed to your local Medicare carrier. Viracor Eurofins assumes no responsibility for billing errors due to reliance on the CPT codes illustrated in this material.

References

Position Statement 12 April 1990 published in Immunology and Allergy Practice.

Project Hope, Center for Health Affairs: "The Cost Implication and Cost Effectiveness of Allergy In Vitro Diagnostic Testing.", October 1988.

Hamilton, R and Adkinson, NF. Quantitation of allergen-specific IgE in serum using the RAST. Clin Immunoassay 1983; 6: 147-154.

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.

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.

Selner JC et al. Current issues relating to in vitro testing for allergen-specific IgE: a workshop report. Annals of Allergy 1999; 82:407 - 412.

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.

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.

Williams PB et al. Analytical precision and accuracy of commercial immunoassays for specific IgE: establishing a standard. J Allergy Clin Immunol 2000; 105:1221 - 1230.

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.

Valcour A. Allergy testing for the 21st century. Advance/Laboratory 2003; 12: 68 - 75.