

## Allergen-Specific IgG4 Testing

**CPT Code:** 86849 or 86001

**Background:**

The IgG4 subclass is present in the lowest concentration in serum with an approximate range in adults of 0.2 to 1.0 g/L (or 200 to 1000 mcg/mL). It has a biological half-life of 21 – 24 days. It does not activate complement via the classical pathway.

**Method:** Fluorescence-based enzyme immunoassay (FEIA). A six point standard curve is used to calculate the specific IgG4 concentrations. The calibrators are referenced to the International Reference Preparation for serum immunoglobulins (WHO 67/97). This test was developed and its performance characteristics determined by IBT Reference Laboratory. It has not been cleared or approved by the U.S. Food and Drug Administration.

**Specimen Requirements:** 1 mL serum minimum is requested. Up to 20 allergens can be tested with one mL of serum. Ship at ambient temperature.

**Units & Reportable Range:**

	<u>mcg/mL of IgG4</u>
Lower Limit of Quantitation	0.15
Upper Limit of Quantitation	30.0

**Normal Ranges Reported:** Varies by allergen (Refer to report)

**Allergens Available:** Request most current list from client services.

**General Notes on Use:** Although there have been many publications concerning the measurement of allergen-specific IgG4, the clinical utility of such tests has not been established except in special situations. Thus, the quantitative IgG4 test should only be ordered by specialists who recognize the limitations of the test. The normal reference ranges reported represent the expected results for individuals who have no unusual exposure and have not been immunized with the indicated allergen. The ranges reported have no disease-associated significance.

Pollens and other Inhalants. Physicians sometimes use allergen-specific IgG or IgG4 to monitor patients undergoing immunotherapy. Increasing IgG and IgG4 responses following the administration of immunotherapy generally correlate with a positive treatment outcome.

Venoms. Venom-specific IgG & IgG4 have been reported to be helpful in evaluating and optimizing therapy in patients with venom hypersensitivity. Low levels of so-called “IgG blocking antibody” are associated with the more serious reactions to challenge.

Fungal Allergens. Immunologic responses to fungi may be useful in the evaluation of patients with hypersensitivity pneumonitis and fungal sinusitis because the antibodies indicate exposure and immunologic sensitization. However, there is no established immuno-pathological threshold for these IgG4 responses.

Other Allergens. The application to other antigens such as occupational allergens and drugs and biological allergens has not been established.

General Reference on IgG Subclasses:

Hamilton RG. Assessment of human allergic disease. In: Rich RR, Fleisher TA, Shearer WT, Kotzin BL and Schroeder HW (eds). Clinical Immunology, Principles & Practice, 2<sup>nd</sup> Ed., Chapter 124, Mosby, New York.

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