

## Overview

### Useful For

- Establishing a diagnosis of an allergy to peanut
- Defining the allergen responsible for eliciting signs and symptoms
- Identifying allergens:
  - Responsible for allergic disease and/or anaphylactic episode
  - To confirm sensitization prior to beginning immunotherapy
  - To investigate the specificity of allergic reactions to insect venom allergens, drugs, or chemical allergens

### Special Instructions

- [Allergens - Immunoglobulin E \(IgE\) Antibodies](#)

### Highlights

Immunoglobulin E antibody to total peanut extract will be tested.  
In vitro serum testing for IgE antibodies to total peanut extract provides an indication of potential immune response to peanut related allergens that may be associated with allergic disease.

### Method Name

FluorescenceEnzymelImmunoassay(FEIA)

### NY State Available

Yes

## Specimen

### Specimen Type

Serum

### Ordering Guidance

For a listing of allergens available for testing, see [Allergens - Immunoglobulin E \(IgE\) Antibodies](#) in Special Instructions

### Specimen Required

#### Container/Tube:

**Preferred:** Red top

**Acceptable:** Serum gel

**Specimen Volume:** 0.5 mL for every 5 allergens requested

### Forms

[If not ordering electronically, complete, print, and send an Allergen Test Request](#) (T236) with the specimen.

### Reject Due To

Gross hemolysis    OK  
Gross lipemia        OK

Gross icterus      OK

### Specimen Minimum Volume

For 1 allergen: 0.3 mL

For more than 1 allergen: (0.05 mL x number of allergens) + 0.25 mL deadspace

### Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	14 days	
	Frozen	90 days	
	Ambient	7 days	

## Clinical & Interpretive

### Clinical Information

Peanut allergy is one of the most common food allergies in the United States, with an estimated prevalence of approximately 1% to 2%.<sup>(1)</sup> The clinical symptoms of peanut allergy may range from relatively mild, such as rhinorrhea, pruritus, or nausea, to a systemic and potentially life-threatening anaphylactic reaction. The diagnosis of peanut allergy is based upon the presence of compatible clinical symptoms in the context of peanut exposure, with support from identification of potential peanut-specific IgE allergen antibodies, either by skin testing or in vitro serology testing. In vitro serology testing has generally focused on assessing for the presence of total peanut IgE antibodies. These antibodies are identified by immunoassay in which the capture allergen is an extract prepared from natural peanut raw material. Most studies have demonstrated a correlation between the amount of total peanut IgE allergen antibody present and an increased likelihood of a clinical allergic response.

Clinical manifestations of immediate hypersensitivity (allergic) diseases are caused by the release of proinflammatory mediators (histamine, leukotrienes, and prostaglandins) from IgE-sensitized effector cells (mast cells and basophils) when cell-bound IgE antibodies interact with allergen.

Once an elevated antibody response to total peanut IgE extract is established, assessment for the presence of specific IgE antibodies to the most common individual peanut allergenic components may be considered.

### Reference Values

Class	IgE kU/L	Interpretation
0	<0.10	Negative
0/1	0.10-0.34	Borderline/Equivocal
1	0.35-0.69	Equivocal
2	0.70-3.49	Positive
3	3.50-17.4	Positive
4	17.5-49.9	Strongly positive
5	50.0-99.9	Strongly positive
6	> or =100	Strongly positive

### Interpretation

Detection of IgE antibodies in serum (Class 1 or greater) indicates an increased likelihood of allergic disease as opposed

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to other etiologies and defines the allergens that may be responsible for eliciting signs and symptoms.

**Cautions**

Results from peanut specific IgE antibody testing must be interpreted in the context of patient's clinical evaluation and history of allergen exposures.

Negative results for IgE to total peanut and any peanut components do not completely exclude the possibility of clinically relevant allergic responses upon exposure to peanut. Clinical correlation of results from in vitro IgE testing with patient history of allergic or anaphylactic responses to peanut is recommended.

Positive results for IgE to total peanut or any peanut components are not diagnostic for peanut allergy, and only indicate patient may be sensitized to peanut or a cross-reactive allergen. Recommend correlation of results from in vitro IgE testing with patient history of allergic or anaphylactic responses to peanut.

Testing for IgE antibodies may not be useful in patients previously treated with immunotherapy to determine if residual clinical sensitivity exists, or in patients in whom the medical management does not depend upon identification of allergen specificity.

Some patients with significantly elevated concentrations of total peanut IgE antibodies do not have any reaction when administered a peanut oral food challenge. This may be due to the presence of an IgE antibody specific for a nonallergenic protein present within the peanut extract.

Furthermore, some individuals with clinically insignificant or no sensitivity to allergens may have detectable levels of IgE antibodies in serum; therefore results must be interpreted in the clinical context. False-positive results for IgE antibodies may occur in patients with markedly elevated serum IgE (>2,500 kU/L) due to nonspecific binding to allergen solid phases.

**Clinical Reference**

1. Sicherer SH, Wood RA: Advances in diagnosing peanut allergy. *J Allergy Clin Immunol Pract.* 2013 Jan;1(1):1-13. doi: 10.1016/j.jaip.2012.10.004
2. Eller E, Bindslev-Jensen C: Clinical value of component-resolved diagnostics in peanut-allergic patients. *Allergy.* 2013 Feb;68(2):190-194. doi: 10.1111/all.12075
3. Homburger HA, Hamilton RG: Allergic diseases. In: McPherson RA, Pincus MR, eds. *Henry's Clinical Diagnosis and Management by Laboratory Methods.* 23rd ed. Elsevier; 2017:1057-1070
4. Klemans RJ, van Os-Medendorp H, Blankestijn M, Bruijzeel-Koomen CA, Knol EF, Knulst AC: Diagnostic accuracy of specific IgE to components in diagnosing peanut allergy: a systematic review. *Clin Exp Allergy.* 2015 Apr;45(4):720-730. doi: 10.1111/cea.12412

**Performance****Method Description**

Specific IgE from the patient's serum reacts with the allergen of interest, which is covalently coupled to an ImmunoCAP. After washing away nonspecific IgE, enzyme-labeled anti-IgE antibody is added to form a complex. After incubation, unbound anti-IgE is washed away and the bound complex is then incubated with a developing agent. After stopping the reaction, the fluorescence of the eluate is measured. Fluorescence is proportional to the amount of specific IgE present in the patient's sample (ie, the higher the fluorescence value, the more IgE antibody is present).(Package insert: ImmunoCAP System Specific IgE FEIA. Rev 06/2019)

**PDF Report**

No

**Specimen Retention Time**

14 days

**Performing Laboratory Location**

Rochester

**Fees & Codes****Test Classification**

This test has been cleared, approved, or is exempt by the US Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

**CPT Code Information**

86003