

## Overview

### Useful For

Evaluation of individuals with suspected mast cell activation, which may occur as a result of anaphylaxis or allergen challenge

Evaluation of patients with suspected cutaneous or systemic mastocytosis

### Testing Algorithm

For more information, see [Mast Cell Disorder: Diagnostic Algorithm, Bone Marrow](#)

### Special Instructions

- [Mast Cell Disorder: Diagnostic Algorithm, Bone Marrow](#)

### Method Name

Fluorescence Enzyme Immunoassay (FEIA)

### NY State Available

Yes

## Specimen

### Specimen Type

Serum

### Specimen Required

#### Collection Container/Tube:

**Preferred:** Serum gel

**Acceptable:** Red top

**Submission Container/Tube:** Plastic vial

**Specimen Volume:** 0.5 mL

**Collection Instructions:** Centrifuge and aliquot serum into plastic vial

**Additional Information:** Tryptase degenerates very quickly when left in the presence of red blood cells.

### Forms

If not ordering electronically, complete, print, and send a [General Request](#) (T239) with the specimen.

### Specimen Minimum Volume

0.2 mL

### Reject Due To

Gross hemolysis	OK
Gross lipemia	OK
Gross icterus	OK

**Specimen Stability Information**

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

**Clinical & Interpretive**
**Clinical Information**

Tryptase, a neutral protease, is a dominant protein component of the secretory granules of human mast cells. There are 2 forms of tryptase, designated as alpha and beta, which are encoded by 2 separate genes.(1) Both are expressed as inactive proenzymes. Alpha-protryptase and beta-protryptase are spontaneously released from resting mast cells. The levels of the protryptases reflect the total number of mass cells within the body but are not an indication of mast cell activation. Beta-protryptase is processed to a mature form, which is stored in granules and released as an active tetramer that is bound to heparan or chondroitin sulfate proteoglycans. In contrast, an amino acid change in alpha-protryptase prevents processing to a mature form. Upon mast cell activation, degranulation releases mature tryptase, which is almost exclusively in the form of beta-tryptase.

During an anaphylactic episode, mast cell granules release tryptase; measurable amounts are found in blood, generally within 30 to 60 minutes.(2) The levels decline under first-order kinetics with half-life of approximately 2 hours. Measurement of tryptase 1 to 6 hours and at least 24 hours after the anaphylactic episode may be useful in demonstrating a return to baseline concentrations and evaluating the kinetics of the response. Tryptase concentrations may also be increased for a period of time following allergen challenge.

Mastocytosis occurs when there is clonal mast-cell proliferation, which leads to tissue accumulation.(3) Mastocytosis can be categorized as cutaneous and systemic. Cutaneous mastocytosis is generally associated with normal or slightly elevated (11.5-20.0 ng/mL) concentrations of tryptase. In systemic mastocytosis, high concentrations may be observed, with greater than 20 ng/mL being a minor criterion for the diagnosis of this condition.

**Reference Values**

<11.5 ng/mL

**Interpretation**

Transient tryptase concentrations greater than or equal to 11.5 ng/mL may be consistent with mast cell activation in the context of anaphylaxis or allergen challenge; measurement of tryptase in specimens obtained 1 to 6 hours and at least 24 hours after the episode may be useful in demonstrating a return to baseline concentrations.

Basal tryptase concentrations greater than or equal to 11.5 mg/mL may be consistent with cutaneous mastocytosis.

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Basal tryptase concentrations greater than or equal to 20 ng/mL may be consistent with systemic mastocytosis.

**Cautions**

Normal tryptase concentrations may be observed in some patients with acute mast cell activation if specimens are obtained greater than 12 hours after an anaphylactic episode or allergen challenge.

Some individuals may demonstrate an increase in tryptase concentrations above baseline after anaphylaxis or allergen challenge while remaining below 11.5 ng/mL; measurement of tryptase in specimens obtained 1 to 6 hours and at least 24 hours after the episode may be useful in demonstrating a transient increase in concentrations.

**Clinical Reference**

1. Lyons JJ, Yi T: Mast cell tryptases in allergic inflammation and immediate hypersensitivity. *Curr Opin Immunol.* 2021 Oct;72:94-106. doi: 10.1016/j.coi.2021.04.001
2. Platzgummer S, Bizzaro N, Bilo MB, et al: Recommendations for the use of tryptase in the diagnosis of anaphylaxis and clonal mastcell disorders. *Eur Ann Allergy Clin Immunol.* 2020 Mar;52(2):51-61. doi: 10.23822/EurAnnACI.1764-1489.133
3. Theoharides TC, Valent P, Akin C: Mast cells, mastocytosis, and related disorders. *N Engl J Med.* 2015 Jul 9;373(2):163-172. doi: 10.1056/NEJMra1409760

**Performance****Method Description**

Anti-tryptase, covalently coupled to ImmunoCAP, reacts with tryptase in the patient serum specimen. After washing, enzyme-labeled antibodies against tryptase are added to form a complex. After incubation, unbound enzyme-labeled antibodies are washed away, and the bound complex is incubated with a developing agent. After stopping the reaction, the fluorescence in the eluate is measured. The fluorescence is directly proportional to the concentration of tryptase in the serum specimen. (Package insert: ImmunoCAP Tryptase. Phadia AB; 10/2019)

**PDF Report**

No

**Day(s) Performed**

Monday through Friday

**Report Available**

2 to 5 days

**Specimen Retention Time**

14 days

**Performing Laboratory Location**

Rochester

**Fees & Codes**

**Fees**

- Authorized users can sign in to [Test Prices](#) for detailed fee information.
- Clients without access to Test Prices can contact [Customer Service](#) 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact [Customer Service](#).

**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**

83520

**LOINC® Information**

Test ID	Test Order Name	Order LOINC® Value
TRYPT	Tryptase, S	21582-2

Result ID	Test Result Name	Result LOINC® Value
TRYPT	Tryptase, S	21582-2