

## Overview

### Useful For

Evaluation of autopsy cases in which anaphylaxis in the context of allergen exposure or mast cell activation is a suspected cause of death

### Method Name

Fluorescence Enzyme Immunoassay (FEIA)

### NY State Available

Yes

## Specimen

### Specimen Type

Serum

### Specimen Required

**Supplies:** Sarstedt Aliquot Tube, 5 mL (T914)

**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.

### 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	Refrigerated	7 days	

	Frozen (preferred)	14 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 a half-life of approximately 2 hours. Severe anaphylactic reactions can lead to fatal airway, respiratory, and circulatory compromise. Anaphylaxis as a cause of death may be suspected in individuals with a known history of allergy, previous anaphylactic episodes, or based on autopsy evidence including mucous plugging, hyperinflated lungs, and petechial hemorrhages.(3) Measurement of tryptase in postmortem serum samples may be useful in investigating deaths in which anaphylaxis is suspected. However, interpretation of results can be difficult, as the reference value for routine diagnostic testing is not applicable to postmortem samples. A recent study identified a concentration of 53.8 mcg/L for postmortem tryptase, which resulted in a sensitivity of 89% and a specificity of 93% for the identification of anaphylaxis as the cause of death.(4) However, it is unclear how widely applicable this cutoff value is, given the complexities of postmortem specimen collection and biological processes.

### Reference Values

No established reference values

### Interpretation

Increased concentrations of total tryptase may indicate mast cell activation occurring as a result of anaphylaxis or allergen challenge, or it may indicate an increased number of mast cells as seen in patients with mastocytosis. However, no specific cutoff value has been widely validated for autopsy specimens.

### Cautions

Tryptase may be low or undetectable in individuals with acute mast cell activation if specimens are obtained greater than 12 hours after an anaphylactic episode.

It is recommended that postmortem tryptase be measured in serum obtained from peripheral blood sources, such as the femoral vessels.

Postmortem tryptase concentrations may be affected by specimen collection technique and length of postmortem interval prior to specimen collection

### Clinical Reference

1. Lyons JJ, Yi T. Mast cell tryptases in allergic inflammation and immediate hypersensitivity. *Curr Opin Immunol.* 2021;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 mast cell disorders. *Eur Ann Allergy Clin Immunol.* 2020;52(2):51-61. doi:10.23822/EurAnnACI.1764-1489.133
3. Garland J, Ondruschka B, Broi UD, et al. Post mortem tryptase: a review of literature on its use, sampling and interpretation in the investigation of fatal anaphylaxis. *Forensic Sci Int.* 2020;314:110415. doi:10.1016/j.forsciint.2020.110415
4. Tse R, Wong CX, Kesha K, et al. Post mortem tryptase cut-off level for anaphylactic death. *Foresnic Sci Int.* 2018;284:5-8. doi:10.1016/j.forsciint.2017.12.035

## Performance

### Method Description

Antitryptase, 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 modified from the manufacturer's instructions. Its performance characteristics were determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the US Food and Drug Administration.

**CPT Code Information**

83520

**LOINC® Information**

Test ID	Test Order Name	Order LOINC® Value
TRYPA	Tryptase, Autopsy	21582-2

Result ID	Test Result Name	Result LOINC® Value
TRYPA	Tryptase, Autopsy	21582-2