Overview

Useful For
Assessing mast cell activation, which may occur as a result of anaphylaxis or allergen challenge
Assessing patients with systemic mastocytosis or mast cell activation syndrome

Method Name
FluorescenceEnzymelImmunoassay(FEIA)

NY State Available
Yes

Specimen

Specimen Type
Serum

Specimen Required
Container/Tube:

Preferred: Serum gel
Acceptable: Red top

Specimen Volume: 0.5 mL

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

<table>
<thead>
<tr>
<th>Gross hemolysis</th>
<th>OK</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gross lipemia</td>
<td>OK</td>
</tr>
<tr>
<td>Gross icterus</td>
<td>OK</td>
</tr>
</tbody>
</table>

Specimen Stability Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum</td>
<td>Frozen (preferred)</td>
<td>14 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Refrigerated</td>
<td>7 days</td>
<td></td>
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</tbody>
</table>
Clinical and 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. 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 heparin 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.

After anaphylaxis, mast cell granules release tryptase; measurable amounts are found in blood, generally within 30 to 60 minutes. The levels decline under first-order kinetics with half-life of approximately 2 hours. By comparison, histamine (another immunologic mediator released by activated mast cells) is cleared from blood within minutes. Increased serum levels may also occur after allergen challenge or in patients with systemic mastocytosis or mast cell activation syndrome.

Reference Values
<11.5 ng/mL

Interpretation
Levels of total tryptase in serum greater than or equal to 11.5 ng/mL may indicate mast cell activation occurring as a result of anaphylaxis or allergen challenge, or it may indicate increased number of mast cells as seen in patients with mastocytosis.

Cautions
Tryptase may be undetectable or not elevated in some patients with acute mast cell activation if specimens are obtained greater than 12 hours after an anaphylactic episode.

Clinical Reference

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, Uppsala, Sweden, 10/2018)

PDF Report
No
Day(s) and Time(s) Test Performed
Monday through Friday; 9 a.m. and 1 p.m.

Analytic Time
1 day

Maximum Laboratory Time
5 days

Specimen Retention Time
14 days

Performing Laboratory Location
Rochester

Fees and 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 Regional Manager. 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 U.S. Food and Drug Administration.

CPT Code Information
83520

LOINC® Information

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<th>Order LOINC Value</th>
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<td>Tryptase, S</td>
<td>21582-2</td>
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<table>
<thead>
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