

Mast Cell Tryptase

Test Name: Tryptase Assay
Test Code: 44
CPT Code: 83516 or 86849

Description: Tryptase is a neutral protease of molecular weight 134,000 that is found almost exclusively in mast cells^{1,2}. This enzyme exists in two structural forms (α & β) that can now be distinguished by monoclonal antibodies.

The β -tryptase is the storage form concentrated in mast cell granules. When mast cells are activated they secrete this β -tryptase with other mediators, including histamine. Note that the previously available tryptase RIA only measured this β form.

Mast cells constitutively produce the α form of tryptase^{3,4}. The new tryptase assay, based on the B12 monoclonal antibody, measures both forms of tryptase (α & β) and thus can be used as a specific marker for the total mast cell burden (α -tryptase) and for systemic mast cell degranulation (primarily β -tryptase).

Method: Enzyme Immunoassay (FEIA). It is manufactured by Phadia for the UniCAP instrument.

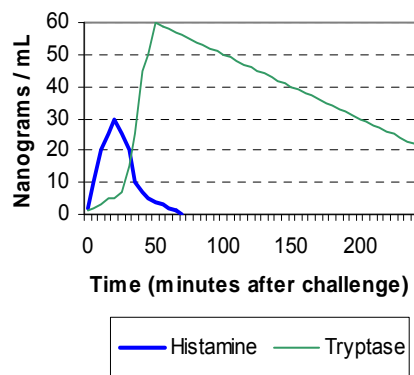
Normal Range Reported: < 11.4 ng/mL. The α -tryptase in a normal reference population was determined to be 4.5 ± 2.3 in a recent study⁷.

Specimen Requirements: 1 mL serum or plasma. Tryptase is stable for three weeks frozen and at 4 - 25° C. The specimen may be shipped frozen or at ambient temperatures. In the summer months it is recommended that specimens be shipped via overnight courier with ice packs or dry ice.

Indications/Use of the Test:

1. Post-mortem Analysis: This test can be utilized to identify anaphylaxis as a cause of death.
2. Research and non-diagnostic investigations:
 - (a) Differential Diagnosis of Anaphylaxis Unlike histamine, tryptase remains elevated in the blood for several hours following an anaphylactic reaction (see graph). The finding of an elevated tryptase, which subsequently decays to background levels, is convincing evidence that the patient had experienced a systemic mast cell event⁵. However, it should be noted that β -tryptase levels may sometimes be elevated in postmortem sera in the absence of documented anaphylaxis^{6,10}.

Mediator Release During Anaphylaxis
 Plasma Tryptase and Histamine



(b) Diagnosis of Mastocytosis The new assay using the B12 monoclonal measures both forms of tryptase and has greatly increased sensitivity for mastocytosis⁷. These patients may have greatly elevated values (e.g 30 - 700 ng/mL).

(c) Monitoring Allergen Challenges The assay has applications in various research projects where mast cell activity needs to be measured^{8,9}.

References:

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