

**ImmunoCAP®**  
Is it allergy?



# **ImmunoCAP® Tryptase**

**Product information**

**Phadia**

## ***Clinical utility of ImmunoCAP® Tryptase***

### ***Risk marker for severe reactions***

- ◆ elevated baseline levels indicate increased risk for severe reactions (1-3)
  - in insect and drug allergy
  - before and during venom SIT (Specific ImmunoTherapy)

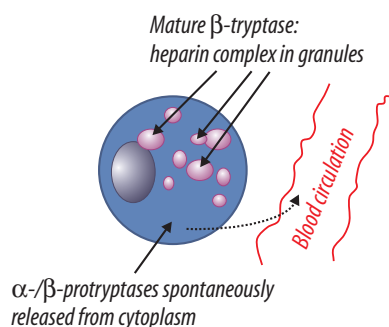
### ***Anaphylactic reactions***

- ◆ transient elevated levels
  - confirming mast cell activation (4, 5)
  - post mortem diagnosis (6, 7)

### ***Marker for haematological neoplastic disorders and mastocytosis***

- ◆ persistent elevated / increasing tryptase levels indicate haematological malignances
  - diagnosis and prognosis
  - follow up of therapy

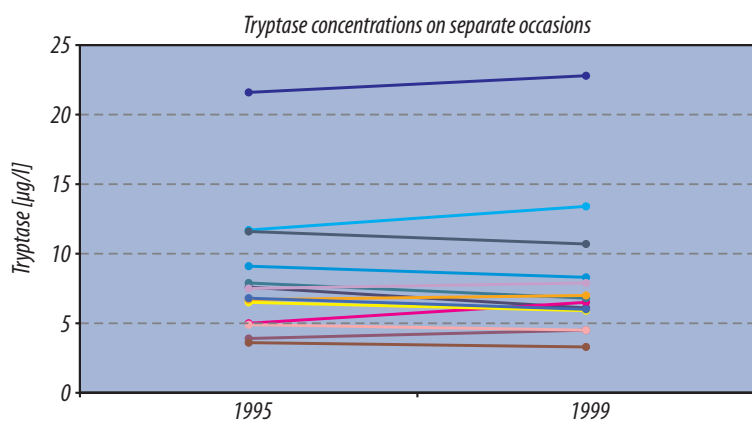
# What is Tryptase



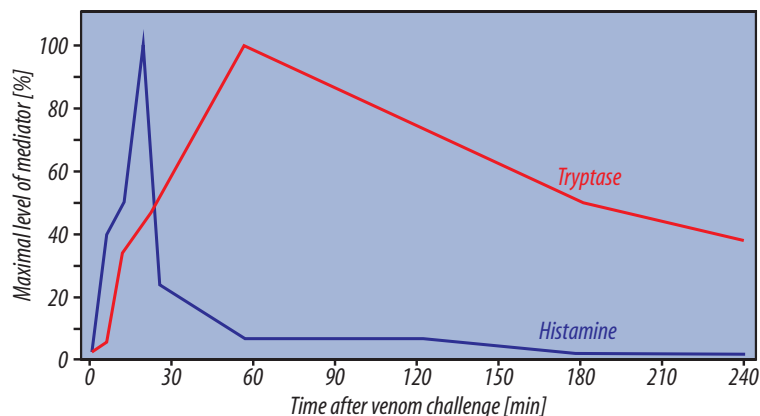
Tryptase is the most abundant protein in mast cells.

- Baseline level; Concentration of proforms of tryptase reflects the number of mast cells
- Increased levels of mature  $\beta$ -tryptase indicates mast cell activation

ImmunoCAP Tryptase measures the total tryptase, i.e. all proforms of  $\alpha$ -tryptase and  $\beta$ -tryptase as well as mature  $\beta$ -tryptase (4, 10).



Each individual has its own unique baseline level, which is rather stable over time under normal conditions.

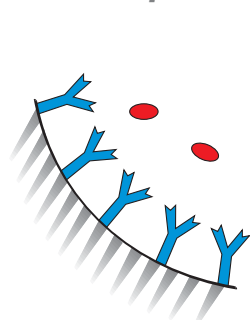


Mature  $\beta$ -tryptase is transiently elevated in most cases of anaphylactic reactions. The peak level is usually reached 15-120 minutes after onset of the reaction, then the tryptase level declines slowly within the next 3-6 hours. The return to baseline level can generally be verified approximately 24 hours after the reaction (1, 5).

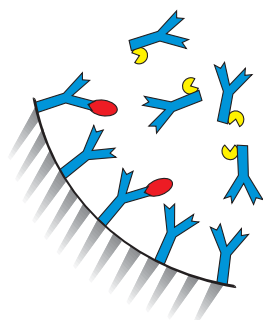
# ImmunoCAP® Tryptase

A fluoroenzymeimmunoassay, based on the ImmunoCAP technology.

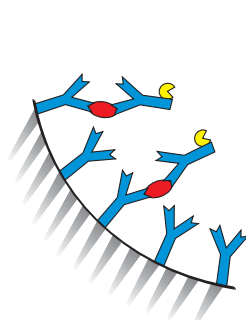
## Test Principle



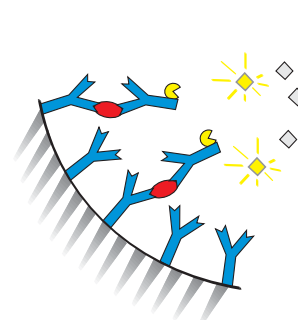
Anti-tryptase, covalently coupled to ImmunoCAP, reacts with the tryptase in the patient serum sample.



After washing, enzyme-labeled antibodies against tryptase are added to form a complex.



After incubation, unbound enzyme-anti-tryptase is washed away, and the bound complex is then incubated with a developing agent.



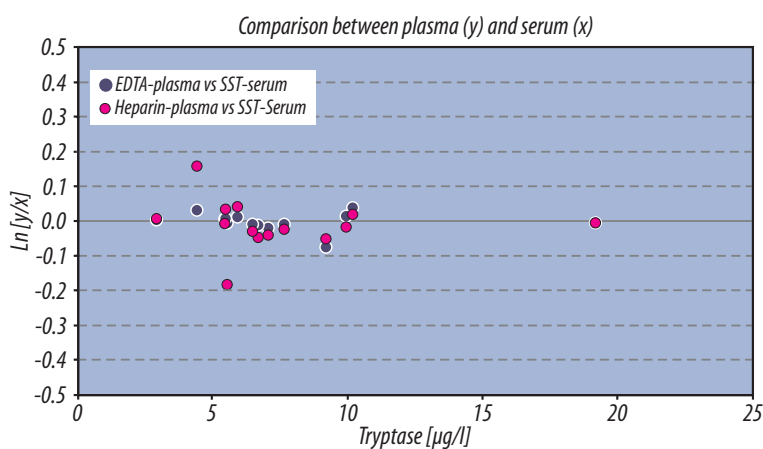
After stopping the reaction, the fluorescence of the eluate is measured. The fluorescence is directly proportional to the concentration of tryptase in the serum sample.

ImmunoCAP Tryptase measuring range: 1 - 200 µg/l (undiluted samples)

Serum level (µg/l)	Coefficient of variation (%)	
	Within assay	Between assay
5 - 20	3	4
20 - 100	3	5
100 - 200	2	6

## Precision

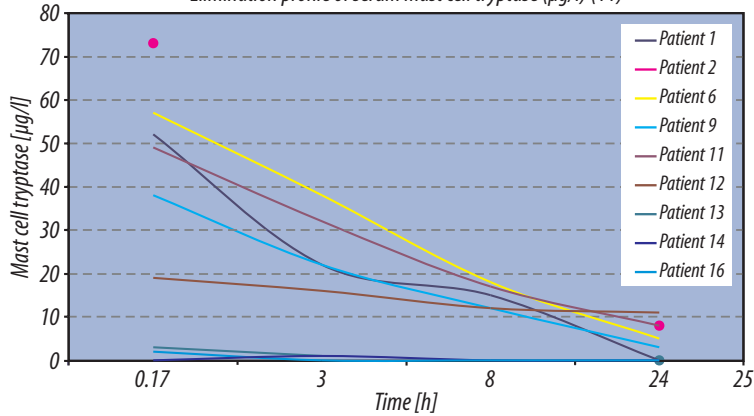
Seven samples with different concentration of tryptase were assayed in 4 replicates on 18 different occasions using the same lots of reagents. The coefficients of variation are shown in the table below.



## Sample collection

Serum and plasma (EDTA or heparin) samples from venous blood can be used(a).

Anaphylactic shock during general anaesthesia  
Elimination profile of serum mast cell tryptase ( $\mu\text{g/l}$ ) (11)



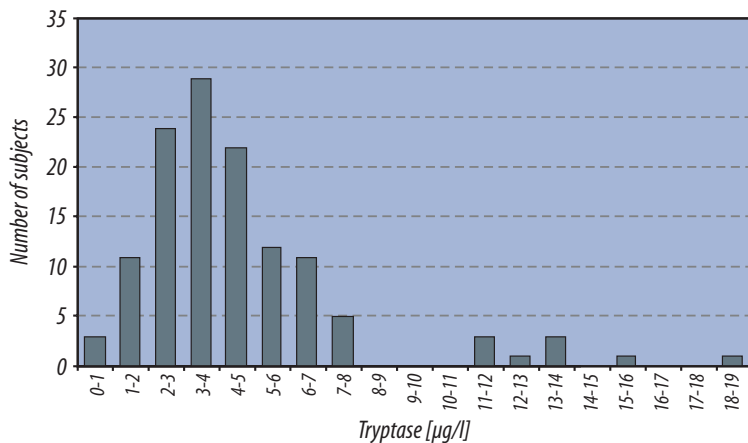
### Timing of blood samples (5, 11-13)

- ◆ 1st sample within 15 minutes up to 3 hours after the onset of the symptoms
- ◆ 2nd sample after 24-48 hours to confirm the return to baseline levels
- ◆ 3rd sample after 1-2 weeks if incidences of mastocytosis or other causes to elevated basal levels are suspected

Post mortem samples should be taken within 48 hours from time of death.

Other suggested sampling schemes may be recommended in local guidelines in different countries.

The time between the reaction and sample collection should be noted.



### Tryptase levels

Tryptase in healthy individuals

A study(a) with 126 apparently healthy individuals (61 males and 65 females), without evidence of mast cell stimulation, was performed.

The age range was: 12-61 years

Geometric mean: 3.8  $\mu\text{g/l}$

95 upper percentile: 11.4  $\mu\text{g/l}$

### Tryptase in disease

Baseline tryptase levels in the range of approximately 10-20  $\mu\text{g/l}$  reflect an increased mast cell burden indicating an increased risk in patients with history of severe anaphylactic reaction (4, 14).

Individuals with increased baseline levels are at higher risk for severe reaction during venom SIT (1-3).

Sudden increase in Tryptase levels which then return to baseline within ~48 hours indicate Mast cell activation and is a tool to confirm an anaphylactic reaction. Peak levels may range from 20  $\mu\text{g/l}$  to more than 200  $\mu\text{g/l}$  (4, 5).

In patients with systemic mastocytosis levels of tryptase are, in general, persistently elevated above 20  $\mu\text{g/l}$  and may range up to more than 1000  $\mu\text{g/l}$  (8).

In anaphylaxis the triggering agent should be identified. Common allergens implicated in anaphylaxis are insect venoms, drugs, latex and foods.

## ***Summary Tryptase***

- ◆ A specific marker for mast cells
- ◆ There are two main forms,  $\alpha$ - and  $\beta$ -tryptase, measurable in the circulation
- ◆ Low levels of  $\alpha$ -/ $\beta$ -protryptases are normally measured in circulation
- ◆ Increased baseline levels of  $\alpha$ -/ $\beta$ -protryptases might be a risk factor for severe allergic reaction
- ◆ Serum levels of  $\alpha$ -/ $\beta$ -protryptases are consistently increased in systemic mastocytosis
- ◆  $\beta$ -tryptase is actively released from granules on mast cell activation
- ◆ Serum (and local) levels of tryptase are transiently increased after mast cell activation, e.g. in anaphylaxis

***Increased baseline levels of tryptase ➡ Increased risk for severe reactions***

## *ImmunoCAP® Tryptase products*

### **ImmunoCAP® 250 Tryptase**

<b>Product</b>	<b>Size</b>	<b>Art. No.</b>
Tryptase conjugate 50	2 x 50	10-9329-xx
Tryptase Calibrator Strip	1 curve	10-9330-xx
Tryptase Curve Control Strip	6 x 1 CC1	10-9351-xx
Tryptase Anti-Tryptase	16	14-4518-xx
<b>Control</b>		
ImmunoCAP Tryptase Control	6 x 0.5 ml	10-9370-01

### **ImmunoCAP® 100<sup>€</sup> Tryptase**

<b>Product</b>	<b>Size</b>	<b>Art. No.</b>
Tryptase	48	10-9303-xx
Tryptase Calibrators	1 curve	10-9302-xx
Tryptase Curve Control	6 vials	10-9341-xx
IgE/ECP/Tryptase Sample Diluent	6 x 3.0 ml	10-9256-01
<b>Control</b>		
ImmunoCAP Tryptase Control	6 x 0.5 ml	10-9370-xx

The -xx indicates country-specific products.

## References

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## Read more:

52-5108-33 Clinical Utility of ImmunoCAP® Tryptase.

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