

Dear Colleague,

15/08/2025

Suspension of dilution of tryptase samples (for known mast cell disorder patients with results >200µg/L)

Our mast cell tryptase assay is generally used for the investigation of a potential anaphylactic reaction (a series of samples) or as a single sample for the investigation / monitoring of systemic mastocytosis.

The mast cell tryptase assay has an analytical measuring range of 1 – 200µg/L. As part of our recent ISO 15189 laboratory inspection, it came to our attention that the dilution and then re-measurement of samples >200µg/L to obtain a quantitative tryptase value above 200µg/L is outwith the manufacturer's analytical range and therefore outside the scope of the assay.

Please note that where tryptase is being measured for a suspected anaphylactic reaction it has always been reported as either 1 - 200µg/L or >200µg/L; these samples have never been diluted.

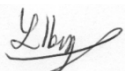
Historically, for known mast cell disorder patients, tryptase results have occasionally been diluted i.e. a systemic mastocytosis patient with a mast cell tryptase >200µg/L. However, this was done by the laboratory and not at the request of the clinical team. An audit has now been performed and identified that over the last 4 years the majority (77%) of all mast cell disorder patients with results above 200µg/L were reported as >200µg/L and never diluted further. On average only one sample per year was diluted to give a quantitative value above 200µg/L. Furthermore, no clinicians have contacted the laboratory to ask for their known mast cell disorder patient with results >200µg/L to be diluted and remeasured.

In terms of initial investigations for systemic mastocytosis the WHO guidelines indicate a baseline tryptase of ≥ 20 ng/mL (20µg/L) as a minor criterion for the diagnosis of systemic mastocytosis; this sits comfortably within the analytical range of 1-200µg/L.

Consequently, as we cannot guarantee the linearity of the assay outside the standard measuring range of 1 – 200 µg/L, we will no longer be able to offer this service. Going forward all mast cell tryptase results above the analytical range of 1 - 200µg/L will be reported as >200µg/L. We will no longer dilute and re-measure samples >200µg/L to obtain a quantitative tryptase value above 200µg/L.

We would be grateful if you could share this letter with colleagues and contact us if you have any further questions.

Best wishes,



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