

# FDA clears test for mastocytosis diagnosis

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The Food and Drug Administration has approved a new test to help physicians diagnose a group of rare cell disorders. The test, or assay, was developed by an expert at Virginia Commonwealth University in the field of mast cells.

Lawrence Schwartz, M.D., Ph.D., chair of the Division of Rheumatology, Allergy and Immunology and the Charles and Evelyn Thomas Professor of Medicine at VCU, has spent more than 30 years researching mast cells. These cells are vital to the [inflammatory process](#) within the body and may play protective roles in wound healing and fighting infections.

"When a mast cell is triggered, it releases several strong chemicals into the body, including histamine and tryptase. [Histamine](#) causes itching, swelling, wheezing and sneezing and other signs and symptoms of allergic reactions," said Schwartz.

Mastocytosis, a group of rare chronic disorders found in both children and adults, is caused by the presence of too many of these mast cells in the body. If there are too many mast cells, the increased burden of chemicals released from these cells can cause several symptoms that range in intensity from mild to severe.

Because [mast cells](#) play a role in allergic reactions, the symptoms of mastocytosis are often similar to an allergic reaction. However, mastocytosis may occur spontaneously rather than be triggered by an allergen.

The FDA has cleared ImmunoCAP Tryptase, a new diagnostic assay, to measure the level of tryptase in the blood as an aid in the diagnosis of systematic mastocytosis. A persistently elevated baseline level of tryptase is an indication of possible mastocytosis.

"A physician cannot diagnose systematic mastocytosis based only on a physical examination. The [FDA approval](#) of the tryptase assay will provide doctors with an additional [diagnostic tool](#)," said Schwartz.

VCU first licensed the assay in 1993 to Pharmacia, now named Thermo Fisher Scientific Inc. The assay has one FDA-approved application – helping to diagnose mastocytosis – and several potential applications, including the diagnosis of systemic anaphylaxis, the prediction of increased risk for future episodes of severe anaphylaxis and use by medical examiners to evaluate cause of death.

"When somebody dies without a clear cause, by measuring postmortem tryptase levels, an increased level of tryptase provides support for an anaphylactic event near the time of death," said Schwartz.

Provided by Virginia Commonwealth University

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