

FDA Clears Thermo Scientific EliA SmD^P-S Test For Use In U.S.

New blood test is designed to reduce the number of false positive results and provide improved diagnostic guidance in Systemic Lupus Erythematosus

PORTAGE, Mich., Aug. 26, 2021 /PRNewswire/ -- Thermo Scientific EliA SmD^P-S test has been cleared by the U.S. Food & Drug Administration (FDA) for aiding the diagnosis of Systemic Lupus Erythematosus (SLE), the most common type of lupus. This new test enhances specificity without sacrificing sensitivity, leading to a more precise diagnosis while also reducing the number of false positives¹.

"Diagnosing autoimmune diseases is often challenging," said Dr. Henry Homburger, Professor Emeritus of Laboratory Medicine at Mayo Clinic College of Medicine. "Existing serologic tests have less than ideal diagnostic specificity for SLE. With the new EliA SmD^P-S assay, clinicians can have greater confidence for differentiating SLE from mixed connective tissue disease, because of the improved immuno-chemical specificity. This innovative test in turn, has the potential to improve treatment and outcomes for patients with SLE."

The EliA SmD^P-S utilizes an advanced coating technique optimized for binding the synthetic SmD₃ peptide antigen, which contains the most specific epitope for Sm peptide antibodies. Antibodies that react with SmD₃ peptide do not cross react with other Sm peptides, which improves the specificity of this test for distinguishing SLE from MCTD².

"The new EliA SmD^P-S replaces the former SmDP test to become a best-in-class test for the detection of Sm antibodies, providing clinicians with a higher degree of diagnostic confidence," said Dr. Homburger. "With its improved specificity, EliA SmD^P-S could be used to further evaluate potential associations with systemic complications, including nephritis."

For more information on the Thermo Scientific EliA SmD^P-S test, please visit <https://www.thermofisher.com/phadia>

About Thermo Fisher Scientific

Thermo Fisher Scientific Inc. is the world leader in serving science, with annual revenue exceeding \$30 billion. Our Mission is to enable our customers to make the world healthier, cleaner and safer. Whether our customers are accelerating life sciences research, solving complex analytical challenges, improving patient diagnostics and therapies or increasing productivity in their laboratories, we are here to support them. Our global team of more than 80,000 colleagues delivers an unrivaled combination of innovative technologies, purchasing convenience and pharmaceutical services through our industry-leading brands, including Thermo Scientific, Applied Biosystems, Invitrogen, Fisher Scientific, Unity Lab Services and Patheon. For more information, please visit www.thermofisher.com.

1. Mahler M et al. Improved Serological Differentiation between Systemic Lupus Erythematosus and Mixed Connective Tissue Disease by Use of an SmD₃ Peptide-Based Immunoassay. *Clin and Diag Lab Immunol*. Jan. 2005, p. 107-113. ([LINK](#))
2. Mahler M et al. Identification of a SmD₃ epitope with a single symmetrical dimethylation of an arginine residue as a specific target of a subpopulation of anti-Sm antibodies. *Arthritis Res Ther* 2005, 7:R19-R29. ([LINK](#))

Media Contact Information
Angela Christoforos
Greenough (for Thermo Fisher)
508-801-2391
achristoforos@greenough.biz

SOURCE Thermo Fisher Scientific

<https://india.newsroom.thermofisher.com/2021-08-26-FDA-Clears-Thermo-Scientific-EliA-SmD-P-S-Test-For-Use-In-U-S>