thermoscientific

EliA™ SmD^P-S

Innovation, helping you get it right the first time
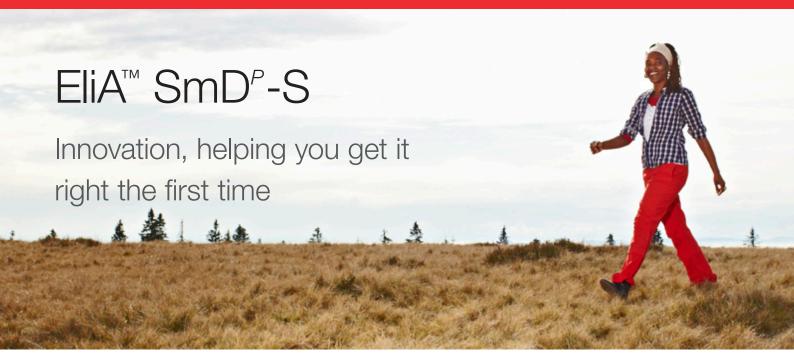
An integral part of your diagnostic algorithm for Systemic Lupus Erythematosus

Some facts about Sm antibodies

- Sm antibodies are **highly specific markers** for systemic lupus erythematosus (SLE).[1]

- The true antigen for SLE-specific Sm antibodies is SmD. Antibodies against SmB,B' or against purified Sm might occur in other connective tissue diseases[2,3]

- Sm antibodies **belong to the SLE classification criteria**.[4]

- Sm antibodies are found in 5–10% of Caucasian patients with SLE. The prevalence of Sm antibodies is much higher (30–40%) in Asian or Afro-American patients.[1]

- Sm antibodies are **early markers for SLE** and occur around one year before clinical onset.[1]

- Antibodies targeting the SmD_3 peptide are important, SLE-specific anti-Sm antibodies, and are particularly **useful for the differentiation of SLE and MCTD**.[3]

- SmD_3 is one of the main targets in SLE.[5] Antibodies targeting SmD_3 have a comparable sensitivity to those targeting purified Sm, but **the specificity is much better**.[3]

ThermoFisher
S C I E N T I F I C

State-of-the-art antigen SmD₃ combined with new innovative coating

In 2012 we launched the Thermo Scientific™ EliA™ SmD^P Well using the state-of-the-art antigen, synthetic SmD$_3$ peptide, reaching a very high test specificity. As positive anti-Sm results are often used as a deciding factor for SLE diagnosis we strove to develop a test with even higher specificity.

EliA SmD^P-S has been developed with a new innovative coating for our EliA well. This coating is a tailor made solution for binding the synthetic SmD$_3$ peptide antigen. While the sensitivity remained the same, this breakthrough meant an improvement of specificity from 97.2 % to 98.3 % (see table, Thermo Fisher Scientific, internal study)

Cohort n=733	EliA SmD^P-S	EliA SmD^P
Sensitivity	16.24%	16.24%
Specificity	98.3%	97.2%
Positive Likelihood Ratio	9.6	5.8
Negative Likelihood Ratio	0.85	0.86
Positive Predictive Value	77.8%	68.1%
Negative Predictive Value	76.2%	75.9%
Diagnostic Accuracy	76%	75%

Table 1: Comparison of EliA SmD^P with the new EliA SmD^P-S using 197 sera from SLE patients and 536 disease controls. (Thermo Fisher Scientific, internal data)

EliA SmD^P-S – best-in-class test performance

We compared EliA SmD^P-S with automated anti-Sm tests from three different suppliers, using a cohort of 633 patients (97 SLE patients and 536 disease controls). EliA SmD^P-S had the best specificity and the best sensitivity at stratified specificity. (Thermo Fisher Scientific, internal study)

Cohort n=633	EliA SmD^P	Supplier 1	Supplier 2	Supplier 3
Sensitivity	14.4%	19.6%	19.6%	16.5%
Specificity	98.3%	95.9%	96.1%	95.5%
Sensitivity at stratified specificity of 98%	14.4%	13.4%	11.3%	7.2%
Positive Likelihood Ratio	8.5	4.8	5.0	3.7
Positive Predictive Value	60.9%	46.3%	47.3%	40.0%

Table2: Performance data of EliA SmD^P-S compared with three automated tests for anti-Sm from other suppliers using 97 sera from SLE patients and 536 disease controls. (Thermo Fisher Scientific, internal data)

Technical data

Ordering information	Article No.	Package size	Cut-off			Short name
			negative	equivocal	positive	
EliA™ SmD^P-S Well	14-5672-01	4 x 16 wells	< 7 U/mL	7–10 U/mL	> 10 U/mL	sms

References

1. Conrad K, Schössler W, Hiepe F, Fritzler MJ. Autoantibodies in systemic autoimmune diseases: a diagnostic reference. Autoantigens, Autoantibodies, Autoimmunity Vol. 2, 3rd edn., 2015. **2.** Smolen JS, Hassfeld W, Graninger W, Steiner G. Antibodies to Antinuclear Subsets in Systemic Lupus- Erythematosus and Rheumatoid Arthritis. Clin Exp Rheumatol 1990;8(S5):41-44. **3.** Mahler M, Stinton LM, Fritzler MJ. Improved serological differentiation between systemic lupus erythematosus and mixed connective tissue disease by use of an SmD$_3$ peptide-based immunoassay. Clin Diagn Lab Immunol 2005;12:107-13. **4.** Petri M, Orbai AM, Alarcon GS et al. Derivation and Validation of the Systemic Lupus International Collaborating Clinics Classification Criteria for Systemic Lupus Erythematosus. Arthritis Rheum 2012;64:2677-86. **5.** Lemerle J, Renaudineau Y. Anti-Sm and Anti-U1-RNP Antibodies: An Update. Lupus Open Access 1(3) 1000e104.

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