



State of the Art Diagnostics for Sjögren's Syndrome

Sjögren's Syndrome (SS) is one of the common autoimmune disorders affecting over 4 million Americans of which 90% are women. It is often seen in association with other autoimmune diseases, especially systemic lupus erythematosus and rheumatoid arthritis. The hallmark symptoms are severe dry mouth and/or eyes, due to destruction of the salivary and lachrymal glands. Almost 4% of patients with SS will develop lymphoma, predominantly B cell non-Hodgkin lymphomas.

Traditional Disease Diagnosis

- Multiple tests need to be carried out including serology, imaging and biopsy
- No early markers available
- Delay in diagnosis of up to 6 years
- Most salivary and lachrymal glands are completely destroyed by the time diagnosis is established

Novel Markers for Early Diagnosis

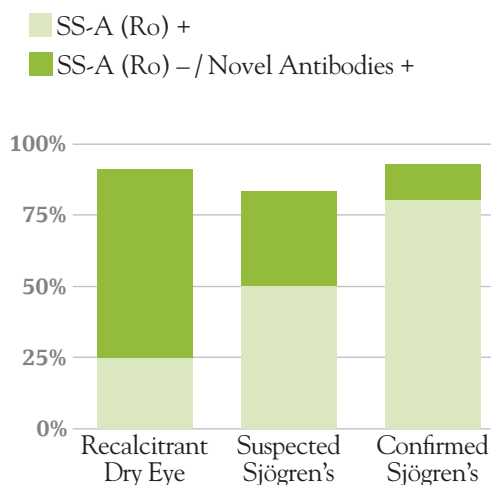
- Proprietary and new markers SP-1, CA-6 and PSP
- Increases the sensitivity to over 80%
- Enables diagnosis early before the traditional markers SS-A (Ro) and SS-B (La) appear
- Early diagnosis leads to better disease management when glands are still functional



Sjö from Immco Diagnostics

- Combines novel and traditional markers for early diagnosis with higher sensitivity and specificity

Sensitivity of Autoantibodies



Prevalence of autoantibodies in pSS^{1,2,3}

n	SS-A (Ro) +	SS-A (Ro) -	SS-A (Ro) + / Novel Ab +	SS-A (Ro) + / Novel Ab -	SS-A (Ro) - / Novel Ab +	SS-A (Ro) - / Novel Ab -	Combined Sensitivity (SS-A (Ro) + and/or Novel Ab +)
314	235 (74.8%)	79 (25.2%)	97 (30.9%)	138 (43.9%)	50 (15.9%)	29 (9.2%)	285 (90.8%)

1. Shen L. 2014. 2. Xuan J. 2018. 3. He J. In press.

Immco Tests

Code Description

076 Sjögren's Syndrome Profile includes all tests listed below:

001	ANA titer and pattern on HEp-2 & Mouse kidney
011	Rheumatoid Factor (RF); IgG, IgA & IgM
045	SS-A (Ro)
046	SS-B (La)
094	Salivary Protein-1 (SP-1) (IgG, IgA, IgM)
095	Carbonic Anhydrase (CA-6) (IgG, IgA, IgM)
096	Parotid Specific Protein (PSP) (IgG, IgA, IgM)

093 Early Sjögren's Syndrome Profile includes all tests listed below:

094	Salivary Protein-1 (SP-1) (IgG, IgA, IgM)
095	Carbonic Anhydrase (CA-6) (IgG, IgA, IgM)
096	Parotid Specific Protein (PSP) (IgG, IgA, IgM)

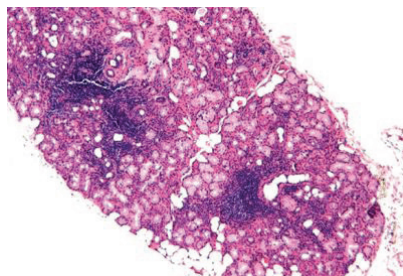
097 Comprehensive Sjögren's Syndrome Profile includes all tests listed below:

001	ANA titer and pattern on HEp-2 & Mouse kidney
011	Rheumatoid Factor (RF); IgG, IgA & IgM
045	SS-A (Ro)
046	SS-B (La)
094	Salivary Protein-1 (SP-1) (IgG, IgA, IgM)
095	Carbonic Anhydrase (CA-6) (IgG, IgA, IgM)
096	Parotid Specific Protein (PSP) (IgG, IgA, IgM)
511	Light Microscopy (H&E) of minor salivary glands (min. 6 minor salivary lobules required)

Sample Submission

Collect 5-10 ml of blood in red top or serum separator tube. If possible, separate serum from clot and place serum in orange or clear tube provided. Do not puncture top of tube. If separation facilities are not available, the blood can be sent in the collection tube.

Minor salivary glands need to be collected from normal appearing mucosal site. At least 6-7 minor salivary gland lobules need to be collected and placed in 10% Formalin and transported.



Foci of lymphocytic infiltrate in minor salivary gland lobule in SS. (H & E, Original magnification x40)

Ship to Immco Diagnostics

Pack Specimen Collection Kit following these simple steps:

1. Place tube(s) into specimen bag.
2. Place test requisition and a copy of the patient's medical insurance information and any other pertinent paperwork into the outside pocket of specimen bag.
3. Fold and roll specimen bag and contents into white mailer box and place in the enclosed poly courier bag.
4. Place pre-paid return airbill on outside of poly courier bag and call the number on the bag for a pick up.

Questions? Call 1.800.537.TEST for Immco Customer Service or visit us online at www.immco.com.

For details about our products and services, please contact laboratoryservices@immco.com.

Selected References

- Shen, L. and L. Suresh (2017). "Autoantibodies, detection methods and panels for diagnosis of Sjogren's syndrome." *Clin Immunol*. In press
- De Langhe, E., et al. (2017). "Evaluation of Autoantibodies in Patients with Primary and Secondary Sjogren's Syndrome." *Open Rheumatol J* 11: 10-15.
- Everett, S., et al. (2017). "Analysis of novel Sjogren's syndrome autoantibodies in patients with dry eyes." *BMC Ophthalmol* 17(1): 20.
- Sandhu P, Ambrus JL Jr (2017) Novel Autoantibodies in Sjogren's Syndrome. *J Immunol Clin Res* 4(1): 1034-1037
- Beckman, K. A., et al. (2017). "The Potential Role for Early Biomarker Testing as Part of a Modern, Multidisciplinary Approach to Sjogren's Syndrome Diagnosis." *Adv Ther* 34(4): 799-812
- Lichtbroun, A. S. (2016). "Positive Findings on an Early Autoantibody Panel in Sjogren's Syndrome Often Predate Positive Findings on Classic Tests: Comment on the Article by Theander et al." *Arthritis Rheumatol* 68(8): 2054-2055
- Matossian, C. and J. Micucci (2016). "Characterization of the serological biomarkers associated with Sjogren's syndrome in patients with recalcitrant dry eye disease." *Clin Ophthalmol* 10: 1329-1334.
- Beckman, K. A., et al. (2016). "Making the diagnosis of Sjogren's syndrome in patients with dry eye." *Clin Ophthalmol* 10: 43-53.
- Suresh, L., et al. (2015). "Investigation of novel autoantibodies in Sjogren's syndrome utilizing Sera from the Sjogren's international collaborative clinical alliance cohort." *BMC Ophthalmol* 15: 38.
- Beckman, K. A. (2014). "Detection of early markers for Sjogren syndrome in dry eye patients." *Cornea* 33(12): 1262-1264.
- Vishwanath, S., et al. (2014). "Xerophthalmia of Sjogren's Syndrome Diagnosed with Anti-Salivary Gland Protein 1 Antibodies." *Case Rep Ophthalmol* 5(2): 186-189.
- Vishwanath, S., et al. (2014). "Anti-salivary gland protein 1 antibodies in two patients with Sjogren's syndrome: two case reports." *J Med Case Rep* 8: 145.
- Shen, L., et al. (2012). "Novel autoantibodies in Sjogren's syndrome." *Clin Immunol* 145(3): 251-255.
- Shen, L., et al. (2014). "Evaluation of salivary gland protein 1 antibodies in patients with primary and secondary Sjogren's syndrome." *Clin Immunol* 155(1):42-6.
- Xuan, J., et al. (2017). "Investigation of autoantibodies to SP-1 in Chinese patients with primary Sjogren's syndrome." *Clin Immunol* 188:58-63.

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