

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

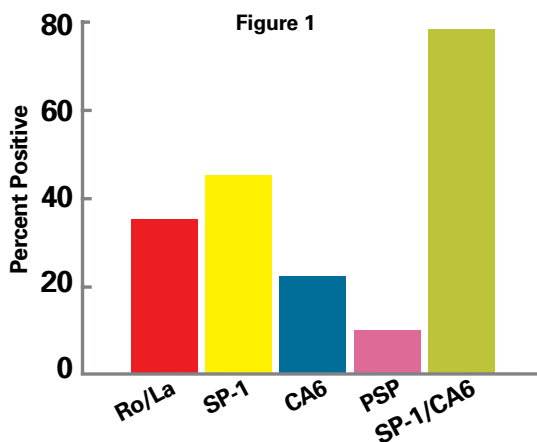
- Multiple tests need to be carried out including serology, imaging and biopsy
- No early markers available
- Delay in diagnosis of up to 6 years
- Most salivary and lachrymal glands are completely destroyed by the time diagnosis is established

Novel Markers for Early Diagnosis

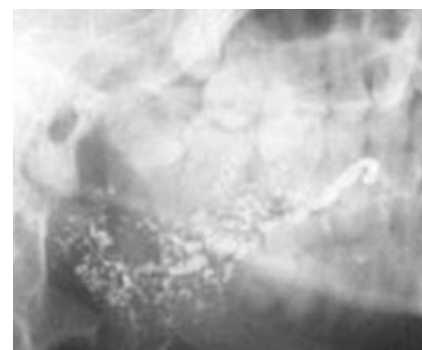
- Proprietary and new markers SP-1, CA6 and PSP
- Increases the sensitivity to over 80%
- Enables diagnosis early before the traditional markers (Ro/La) appear
- Early diagnosis leads to better disease management when glands are still functional

Immco Sjögren's Panel

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



Patients with SS produced antibodies to SP-1, CA6 and PSP in addition to Ro and La. These novel antibodies were found in 45% of patients meeting criteria for SS who lacked antibodies for Ro or La. In patients with idiopathic xerostomia and xerophthalmia for less than 2 years duration, 76% had antibodies to SP-1 and/or CA6 while only 31% had antibodies to Ro or La.



Sialographic image of the parotid gland in SS

Immco Tests

Code Description

076 Sjogren Syndrome Profile (includes all tests below)

001	ANA Titer and Pattern (HEp2/Mouse kidney)
011	Rheumatoid Factor levels (IgG, IgA, IgM)
045	SS-A (Ro)
046	SS-B (La)
094	Salivary Protein-I (SP-1) (IgG, IgA, IgM)
095	Carbonic Anhydrase – 6 (CA6) (IgG, IgA, IgM)
096	Parotid Specific Protein (PSP) (IgG, IgA, IgM)

093 Early Sjogren Syndrome Profile (includes all tests below)

094	Salivary Protein-I (SP-1) (IgG, IgA, IgM)
095	Carbonic Anhydrase – 6 (CA6) (IgG, IgA, IgM)
096	Parotid Specific Protein (PSP) (IgG, IgA, IgM)

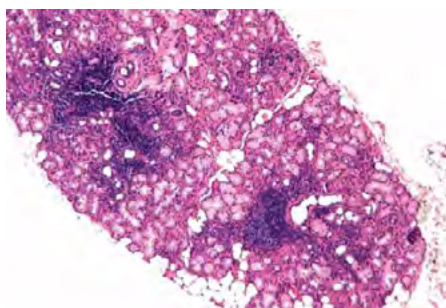
097 Comprehensive Sjogren Profile (includes all tests below)

001	ANA Titer and Pattern (HEp2/Mouse kidney)
011	Rheumatoid Factor levels (IgG, IgA, IgM)
045	SS-A (Ro)
046	SS-B (La)
094	Salivary Protein-I (SP-1) (IgG, IgA, IgM)
095	Carbonic Anhydrase – 6 (CA6) (IgG, IgA, IgM)
096	Parotid Specific Protein (PSP) (IgG, IgA, IgM)
511	H&E studies of minor salivary gland biopsies with Focus Scores

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 collection 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 Orange FedEx Clinical Pak.
4. Place Pre-paid FedEx return airbill on the outside of Clinical Pak and call FedEx for a pick up at 1-800-463-3339.

Overnight Courier Service: Please follow instructions contained in the Specimen Collection Kit and send to: Immco Diagnostics, Inc.
640 Ellicott Street, Buffalo, NY 14203

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

Selected References

- Delaleu, N., R. Jonsson, and M. M. Koller. 2005. Sjogren's syndrome. *Eur J Oral Sci* 113:101-113.
- Fox, R. I. 2005. Sjogren's syndrome. *Lancet* 366:321-331.
- Shen, L., C. Zhang, T. Wang, S. Brooks, R. J. Ford, Y. C. Lin-Lee, A. Kasianowicz, V. Kumar, L. Martin, P. Liang, J. Cowell, and J. Ambrus, JL. 2006. Development of Autoimmunity in Interleukin-14alpha Transgenic Mice. *Journal of Immunology* 177:5676-5686.
- Shen, L., L. Suresh, H. Li, C. Zhang, V. Kumar, O. Pankevycz, and J. J. Ambrus. 2009. IL-14alpha, the Nexus for Primary Sjogren's Disease in Mice and Humans. *Clinical Immunology* 130:304-312.
- Sjögren's Syndrome Foundation. "About Sjögren's." Available at <http://www.sjogrens.org/home/about-sjogrens-syndrome>.
- Suresh, L., Shen, L., and J. J. Ambrus. Stages of Sjogren's Syndrome Defined by Immune Mediators, 2012 ACR/ARHP Annual Meeting, to be held in Washington, D.C., November 9-14, 2012.
- Suresh, L., Shen, L., and J. J. Ambrus. M. Lindemann, P. Przemek Kowal K Malyavantham. Identification of nove early marker for Sjogren's syndrome. 25th Annual Meeting of American Association of Medical laboratory Immunologists, Minneapolis, MN, August 2012.
- Suresh, L., Shen, L., and J. J. Ambrus. M. Lindemann, P. Przemek Kowal K Malyavantham. Novel Autoantibodies in Sjogren's syndrome. *Clinical Immunology* 2012;145:251-255
- Vitali C, Bombardieri S, Jonsson R, Moutsopoulos HM, Alexander EL, Carsons SE, Daniels TE, Fox PC, Fox RI, Kassan SS, Pillemer SR, Talal N, Weisman MH; European Study Group on Classification Criteria for Sjögren's Syndrome. Classification criteria for Sjögren's syndrome: a revised version of the European criteria proposed by the American-European Consensus Group. *Ann Rheum Dis*. 2002;61:554-8.



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