

# 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

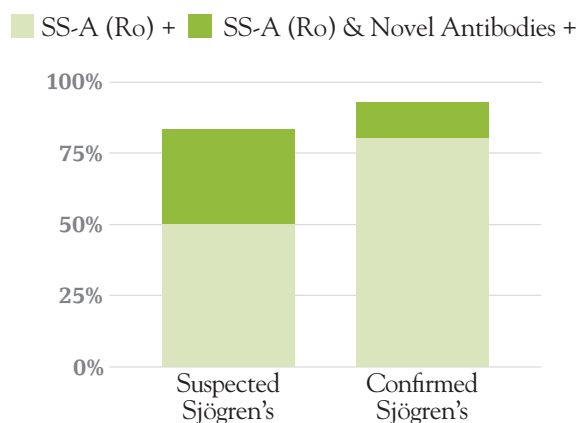
## Novel Markers for Early Diagnosis

- 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

## Immco Sjögren's Panel

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

Sensitivity of Autoantibodies



Prevalence of autoantibodies in pSS at different disease duration

Disease Duration	Number of Pts	Anti-SSA +	Anti-SSA – and Novel Antibodies +	Anti-SSA – and Novel Antibodies –
<5 yrs	19	13 (68.4%)	5 (26.4%)	1 (5.2%)
5-10 yrs	20	16 (80%)	2 (10%)	2 (10%)
>10 yrs	22	20 (90.9%)	1 (4.5%)	1 (4.5%)

## 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)

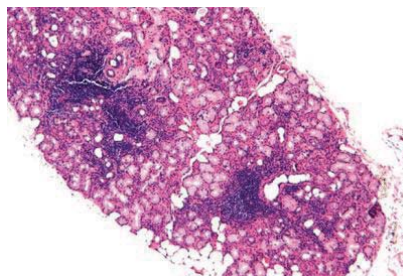
#### 097 Comprehensive Sjögren's Syndrome Profile includes all tests listed below:

- 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](http://www.immco.com).

**For details about our products and services, please contact [laboratoryservices@immco.com](mailto:laboratoryservices@immco.com).**

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