

# Did You Know that 30-40% of Sjögren's Patients are Negative for Sjögren's Antibodies?

## The Difficult to Diagnose Patient

Sjögren's disease can be difficult to diagnose due to its systemic nature and lack of a single diagnostic test. No diagnostic criteria for Sjögren's exist for use in the clinical setting. Many patients also do not fulfill classification criteria that are very stringent and meant only for use in clinical trials—so when these criteria are used for everyone, a Sjögren's diagnosis is often missed.

There are two diagnostic tests for Sjögren's- a positive salivary gland biopsy and a positive test for a prominent antibody (anti-SSA/Ro)- as well as specific measures for dryness. However, some of these tests may be negative for a sizable portion of the Sjögren's population due to lack of testing accessibility, failure to obtain a good biopsy, and/or anti-SSA/SSB seronegativity. Approximately 30-40% of patients are negative for anti-SSA/Ro or anti-SSB/La antibodies and likely constitute a large portion of the undiagnosed and/or misdiagnosed patient population. Furthermore, patients with Sjögren's may also be positive for antinuclear antibodies (ANA) or rheumatoid factor (RF), contributing to differential diagnoses that can confound a Sjögren's diagnosis by mimicking serological results for other autoimmune disorders or result in comorbidity.

Classic symptoms for Sjögren's are dry eyes and dry mouth. However, many patients present with other clinical manifestations first, including pulmonary and neurological involvement, which may also delay Sjögren's diagnosis. Patients with more severe symptoms may have their history of dry eyes and dry mouth ignored, and patients with "mild" symptoms may receive no Sjögren's diagnosis or be dismissed. Sjögren's is a systemic disease that can have serious complications, so an early diagnosis is important.

To help confirm or rule out a Sjögren's diagnosis, it is important to implement a stepwise approach to patient assessment beginning with the least invasive and most accessible tests and then add additional testing where appropriate. While progress in reducing the time to diagnosis has been made, it still takes years on average to diagnose a patient with Sjögren's.

## How is Sjögren's diagnosed?

Unfortunately, there is no single test that will confirm the diagnosis of Sjögren's and thus physicians must conduct a series of tests and ask about symptoms the patient is experiencing.

Physicians will use a number of tests to determine a Sjögren's diagnosis.

### Objective tests used in diagnosis include:



#### Blood tests you may have include:

**SS-A (or Ro) and SS-B (or La):** Marker antibodies for Sjögren's. 70% of Sjögren's patients are positive for SS-A and 40% are positive for SS-B. Also found in lupus patients.



#### Eye tests most commonly used include:

**Schirmer test:** Measures tear production.

**Rose Bengal and Lissamine Green:** Use of dyes to examine the surface of the eye for dry spots.

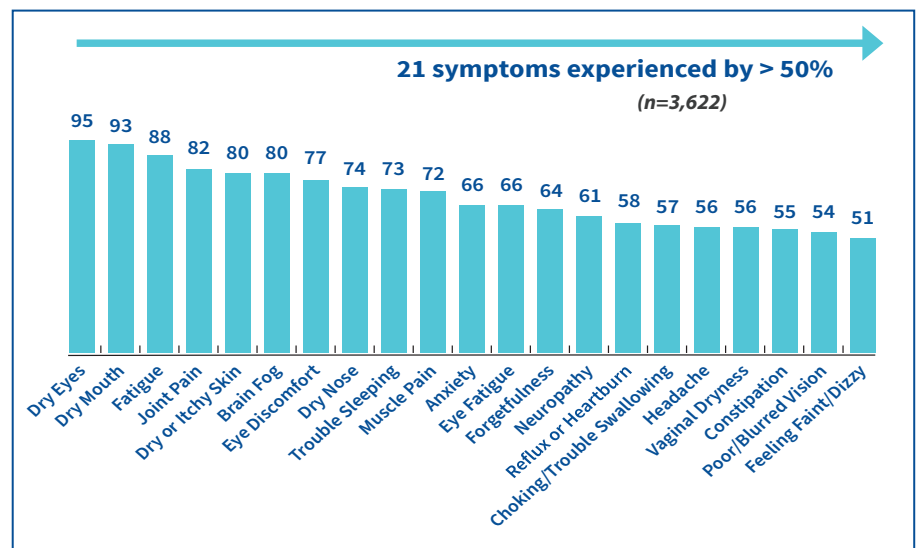


#### Dental tests most commonly used include:

**Salivary flow:** Measures the amount of saliva produced over a certain period of time.

**Salivary gland biopsy (usually in the lower lip):** Confirms lymphocytic infiltration of the minor salivary glands.

## Percentage of Respondents Experiencing Symptoms (Prior 12 Months)



Living with Sjögren's: Summary of Patient Survey. The Sjögren's Foundation; 2022. [www.sjogrens.org](http://www.sjogrens.org)

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**Thomas Grader-Beck, MD, PhD**

Associate Professor of Medicine  
Johns Hopkins University School of Medicine

#### **The Difficult-to-Diagnose Patient**

**Astrid Rasmussen, MD, PhD**

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