

Sjögren's Syndrome Classification Criteria

Inclusion/exclusion criteria and the weighted 5-item scoring system for classification of primary Sjögren's syndrome.

2016 ACR/EULAR Criteria
Classification Criteria for Primary
Sjögren's Syndrome
Shiboski CH, et al. • Ann Rheum Dis
2017;76:9–16

NOTE Classification (not diagnostic) criteria — apply once inclusion criteria are met and exclusion criteria are absent.

1 Inclusion Criteria

Applies to any patient with **≥1 symptom of ocular or oral dryness** — daily troublesome dry eyes >3 months, sand/gravel sensation, tear substitute use >3×/day, daily dry mouth >3 months, or frequent liquids to aid swallowing dry food.

Or **suspicion of Sjögren's** based on ESSDAI systemic features, with ≥1 positive domain.

2 Exclusion Criteria

Prior history of: head/neck radiation treatment, active hepatitis C (PCR-confirmed), AIDS, sarcoidosis, amyloidosis, graft-versus-host disease, or IgG4-related disease.

3 Weighted Classification Items

ITEM	WEIGHT
Labial salivary gland biopsy — focal lymphocytic sialadenitis, focus score ≥1/4mm ²	3 pts
Serology — anti-SSA/Ro positive	3 pts
Ocular staining — OSS ≥5 (or van Bijsterveld ≥4) in ≥1 eye	1 pt
Schirmer's test — ≤5 mm/5 min in ≥1 eye	1 pt
Salivary flow — unstimulated whole saliva ≤0.1 mL/min	1 pt

4 Scoring & Test Performance

Threshold: classify as primary Sjögren's syndrome if total weighted score ≥4, inclusion criteria are met, and no exclusions are present.

Performance: sensitivity 96% (95% CI 92–98%), specificity 95% (95% CI 92–97%) in the validation cohort.

Technical notes: hold anticholinergic drugs before ocular/salivary testing when feasible; **biopsy** should be interpreted by a pathologist experienced in focus-score counting.