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Tissue Specific Antibodies in Early Sjögren's Disease Diagnosis

Includes the Following Biomarkers:
Salivary protein 1 antibodies - IgG, IgA & IgM; Carbonic anhydrase VI antibodies - IgG, IgA & IgM, & Parotid specific/secretory protein antibodies - IgG, IgA, & IgM)

KSL Diagnostics Test Code:
308

Methodology:
Chemiluminescence

Units:
U/ml

Reference Range:
- <20 U/ml - Negative
- 20-25 U/ml - Borderline
- >25 U/ml- Positive

CPT Code:
83520 (x9)

Schedule/Turnaround Time:
Assay performed once weekly on Wednesday. Report availability is within one week from the time of specimen receipt.

Specimen Requirements:
Collect 5-10 ml of blood in a red top or serum separator tube. Separate serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to a Standard Transport Tube. Specimen need not be refrigerated or frozen.

Requested Specimen Volume:
2 mL

Absolute Minimum Volume:
0.5 mL

Cause for Rejection:
Specimens other than serum. Grossly hemolyzed, lipemic or icteric samples.

Sample Stability:
Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.

Clinical Relevance:
Sjogren's syndrome (SS) is a systemic autoimmune disease in which loss of salivary gland and lachrymal gland function is associated with hypergammaglobulinemia, autoantibody production, mild kidney, and lung disease and eventually lymphoma. SS involves dry eyes and dry mouth without systemic features that may be either primary or secondary to another autoimmune disease, such as SLE in patients with SS diagnosed at a late stage in their disease, after the salivary glands and lachrymal glands are already destroyed. Only symptomatic treatment can be offered for abnormal lachrymal and salivary gland function. The diagnosis for SS is currently at a crossroad with the American College of Rheumatology providing which requires characteristic autoantibodies (SS-A) or minor salivary gland biopsy. Since lip biopsies are not frequently performed in clinical practice, there is increased emphasis placed on autoantibodies in diagnosis. Novel antibodies specific to tissues in salivary and lacrimal glands were identified in 2012 by Shen et al., includes salivary gland protein 1 (SP-1), carbonic anhydrase VI (CA-VI) and parotid secretory protein (PSP). Further studies have shown that the isotype differentiation of the markers adds to the sensitivity of diagnosis of SS. These autoantibodies occurred earlier in the course of the disease than antibodies to Ro or La. In addition, antibodies to SP-1, CA-VI and PSP were found in patients meeting the criteria for SS who lacked antibodies to Ro or La. Furthermore, in patients with idiopathic xerostomia and xerophthalmia for less than 2 years, 76% had antibodies to SP-1 and/or CA6 while only 31% had antibodies to Ro or La. Antibodies to different isotypes (IgG, IgM & IgA) of SP-1, CA-VI and PSP are useful markers for identifying patients with SS at early stages of the disease or those that lack antibodies to either Ro or La.

Selected References:

- Fox, R (2005). Sjogren's syndrome. Lancet; 366: 321–331. 27
- Shen, L. et al., (2012). Novel autoantibodies in Sjogren's syndrome. Clinical Immunology;145, 251–255.