



Primary Biliary Cholangitis Antibody Panel, Serum

Test ID: PBCPN

Useful for:

Evaluation of at-risk or previously diagnosed primary biliary cholangitis patients with new features of other liver diseases or systemic autoimmune diseases

Profile Information:

Test ID	Reporting Name	Available Separately	Always Performed
NAIFA	Antinuclear Ab, HEp-2 Substrate, S	Yes	Yes
SP100	SP100 Antibody, IgG, S	Yes	Yes
GP210	GP210 Antibody, IgG, S	Yes	Yes
AMA	Mitochondrial Ab, M2, S	Yes	Yes

Highlights:

This is the recommended first-line autoantibody panel for the evaluation of at-risk individuals under investigation for primary biliary cholangitis with new features of other liver diseases or overlapping connective tissue disease.

Methods:

GP210, SP100: Enzyme-Linked Immunosorbent Assay (ELISA)

AMA: Enzyme Immunoassay (EIA)

NAIFA: Indirect Immunofluorescence

Reference Values:

MITOCHONDRIAL AB, M2

Negative: <0.1 Units

Borderline: 0.1-0.3 Units

Weakly positive: 0.4-0.9 Units

Positive: > or =1.0 Units

Reference values apply to all ages.

SP100 Antibody, IgG

Negative: < or =20.0 Units

Equivocal: 20.1-24.9 Units

Positive: > or =25.0 Units

GP210 Antibody, IgG

Negative: < or =20.0 Units

Equivocal: 20.1-24.9 Units

Positive: > or =25.0 Units

ANTINUCLEAR AB, HEP-2 SUBSTRATE

Negative: <1:80

Specimen Requirements:

- Supplies:** Sarstedt Aliquot Tube, 5 mL (T914)
- Container/Tube:**
- Preferred:** Serum gel
- Acceptable:** Red top
- Submission Container:** Plastic vial
- Specimen Volume:** 1.5 mL
- Collection Instructions:** Centrifuge and aliquot serum into a plastic vial.
- Minimum Volume:** 1.1 mL

Specimen Stability Information:

Specimen Type	Temperature	Time
Serum	Refrigerated (preferred)	21 days
	Frozen	21 days

Cautions:

Serologic tests for autoantibodies, including anti-gp210 and anti-Sp100, should not be relied upon exclusively to determine the etiology or prognosis of patients with primary biliary cholangitis (PBC). Correlations between anti-mitochondrial (AMA), anti-Sp100, or anti-gp210 antibodies for specific HEp-2 IFA patterns (AMA, multiple nuclear dots, or nuclear punctate envelope) are variable. Positive correlation between PBC-specific autoantibody and their corresponding HEp-2 IFA pattern is likely to increase the likelihood for PBC.

A negative result for anti-gp210 antibodies and/or anti-Sp100 antibodies does not exclude a diagnosis of PBC.

Positive results for antimitochondrial antibodies of M2 specificity are found (infrequently) in patients with systemic sclerosis, relatives of patient with PBC, systemic lupus erythematosus, Sjogren syndrome, idiopathic inflammatory myopathies, as well as individuals who may appear healthy.

Some patients without clinical evidence of systemic autoimmune rheumatic disease (SARD) may be positive for anti-cellular antibody. This occurs at variable prevalence depending on the patient demographics. A positive result may also precede clinical manifestation of SARD or be associated with some viral or chronic infections, cancers, or use of certain medications. All results must be reported in the appropriate clinical context as the performance of the test can be variable.

CPT Code:

86039

83516 x2

86381

Day(s) Performed: Tuesday

Report Available: 2-8 days

Questions

Contact Amy Ennis, Laboratory Resource Coordinator at 800-533-1710.