

Overview**Useful For**

Establishing the diagnosis of primary biliary cirrhosis

Method Name

EnzymeImmunoassay(EIA)

NY State Available

Yes

Specimen**Specimen Type**

Serum

Specimen Required**Container/Tube:**

Preferred: Serum gel

Acceptable: Red top

Specimen Volume:0.5 mL

Forms

If not ordering electronically, complete, print, and send 1 of the following forms with the specimen:

[-General Request](#) (T239)

[-Gastroenterology and Hepatology Client Test Request](#) (T728)

Specimen Minimum Volume

0.4 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject
Gross icterus	OK

Specimen Stability Information

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

Clinical and Interpretive

Clinical Information

Antimitochondrial antibodies (AMA) are detectable by indirect immunofluorescence in more than 90% of patients with primary biliary cirrhosis (PBC), but this method also detects AMA of differing specificities in other diseases. The mitochondrial antigens recognized by AMA in patients' sera have been classified numerically as M1 through M9, with the M2 antigen complex recognized by AMA in sera from patients with PBC. M2 antigen is comprised of enzyme proteins of the 2-oxoacid dehydrogenase complex that are located on inner mitochondrial membranes. Included in this group of autoantigens are the pyruvate dehydrogenase complex, and 2-oxoglutarate dehydrogenase complex.

Reference Values

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.

Interpretation

Positive results for antimitochondrial antibody (AMA) of M2 specificity are highly specific for primary biliary cirrhosis (PBC), and false-negative results are rare.

A positive result for AMA of M2 specificity in a patient with clinical features of PBC is virtually diagnostic for this disease.

Cautions

The level of antimitochondrial antibody (AMA) is not useful to indicate the stage or prognosis of the disease or for monitoring the course of disease. Positive results are found (infrequently) in patients with CREST (calcinosis, Raynaud's phenomenon, esophageal hypomotility, sclerodactyly, and telangiectasia) syndrome, relatives of patients with primary biliary cirrhosis and other autoimmune diseases.

Supportive Data

Testing performed in the Immunology Antibody Laboratory of the antimitochondrial antibody (AMA)-M2 by EIA revealed a false-positive rate of less than 2% in normals and overall concordance compared with indirect immunofluorescence of 90% on sera from the Mayo primary biliary cirrhosis (PBC) Serum Bank. Ten discordant results were obtained (negative by EIA and positive by immunofluorescence assay). Seven of the 10 patients had no histologic evidence of PBC on liver biopsy.

Clinical Reference

1. Rich R, Fleisher T, Shearer W, et al: Inflammatory hepatobiliary cirrhosis. In *Clinical Immunology Principles and Practice*. Third edition. Philadelphia, Elsevier 2008 April 15
2. Muratori L, Granito A, Muratori P, et al: Antimitochondrial antibodies and other antibodies in primary biliary cirrhosis: diagnostic and prognostic value. *Clin Liver Dis* 2008;12:261-276
3. Kaplan MM, Gershwin ME: Primary biliary cirrhosis. *N Engl J Med* 2005;353(12):1261-1273

4. Van Norstrand MD, Malinchoc M, Lindor KD, et al: Quantitative measurement of autoantibodies to recombinant mitochondrial antigens in patients with primary biliary cirrhosis: relationship to levels of autoantibodies to disease progression. Hepatology 1997;25(1):6-11

Performance

Method Description

Enzyme immunosorbent assay with purified M2 antigens. This method detects both IgG and IgM antibodies to M2 antigens. Testing is performed on the Agility instrument by Dynex. (Package insert: Bio-Rad, Kallestad Anti-Mitochondrial Kit, Distributed by Bio-Rad Laboratories, Inc., Hercules, CA 04/14)

PDF Report

No

Day(s) and Time(s) Test Performed

Monday through Saturday; 11 a.m.

Analytic Time

1 day

Maximum Laboratory Time

1 day

Specimen Retention Time

14 days

Performing Laboratory Location

Rochester

Fees and Codes

Fees

- Authorized users can sign in to [Test Prices](#) for detailed fee information.
- Clients without access to Test Prices can contact [Customer Service](#) 24 hours a day, seven days a week.
- Prospective clients should contact their Regional Manager. For assistance, contact [Customer Service](#).

Test Classification

This test has been cleared, approved or is exempt by the U.S. Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information

83516

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
AMA	Mitochondrial Ab, M2, S	51715-1

Result ID	Test Result Name	Result LOINC Value
AMA	Mitochondrial Ab, M2, S	51715-1