

Overview
Useful For

Evaluation of patients with liver disease of unknown etiology

Evaluation of patients with suspected autoimmune hepatitis

Method Name

Enzyme-Linked Immunosorbent Assay (ELISA)

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 a [Gastroenterology and Hepatology Client Test Request \(T728\)](#) with the specimen.

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

Autoimmune liver disease (eg, autoimmune hepatitis and primary biliary cirrhosis) is characterized by the presence of autoantibodies including smooth muscle antibodies (SMA), antimitochondrial antibodies (AMA), and anti-liver/kidney microsomal antibodies type 1 (anti-LKM-1).(1) Subtypes of autoimmune hepatitis (AIH) are based on autoantibody reactivity patterns.

Anti-LKM-1 antibodies serve as a serologic marker for AIH type 2 and typically occur in the absence of SMA and antinuclear antibodies. These antibodies react with a short linear sequence of the recombinant antigen cytochrome monooxygenase P450 2D6.(2) Patients with AIH type 2 more often tend to be young, female, and have severe disease that responds well to immunosuppressive therapy.

Reference Values

< or =20.0 Units (negative)

20.1-24.9 Units (equivocal)

> or =25.0 Units (positive)

Reference values apply to all ages.

Interpretation

Seropositivity for anti-liver/kidney microsomal antibodies type 1 (anti-LKM-1) antibodies is consistent with a diagnosis of autoimmune hepatitis (AIH) type 2.

Cautions

Serologic tests for autoantibodies, including anti-liver/kidney microsomal antibodies type 1 (anti-LKM-1), should not be relied upon exclusively to determine the etiology or prognosis of patients with liver disease.

Anti-LKM-1 antibodies may occur in some patients with chronic hepatitis caused by hepatitis C virus infection. Although the epitopes recognized by anti-LKM-1 antibodies in hepatitis C virus infection are different than in patients with autoimmune hepatitis (AIH) type 2, physicians must use caution in interpreting the results of tests for anti-LKM-1 antibodies in such patients.

Clinical Reference

1. Clinical Immunology Principles and Practice. Third edition. Edited by RR Rich, TA Fliasher, WT Shearer, et al: Philadelphia, PA, Mosby Elsevier, 2008
2. Czaja AJ, Homburger HA: Autoantibodies in liver disease. Gastroenterology. January 2001;120(1):239-249

Performance

Method Description

Enzyme-linked immunosorbent assay (ELISA) for the semi-quantitative detection of liver/kidney microsomal antibodies type 1 (LKM-1) antibodies in human serum.(Package insert: INOVA Diagnostics, Inc. San Diego, Revision 1, March 2000)

PDF Report

No

Day(s) and Time(s) Test Performed

Monday, Wednesday, Friday

Analytic Time

1 day

Maximum Laboratory Time

4 days

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

86376

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
LKM	Liver/Kidney Microsome Type 1 Ab, S	32220-6

Result ID	Test Result Name	Result LOINC Value
LKM	Liver/Kidney Microsome Type 1 Ab, S	32220-6