MAYO CLINIC LABORATORIES

Test Definition: LKM

Liver/Kidney Microsome Type 1 Antibodies, Serum

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
Collection Container/Tube:
Preferred: Serum gel
Acceptable: Red top
Submission Container/Tube: Plastic vial
Specimen Volume: 0.5 mL
Collection Instructions: Centrifuge and aliquot serum into a plastic vial.

Forms
If not ordering electronically, complete, print, and send Gastroenterology and Hepatology Test Request (T728) with the specimen:

Specimen Minimum Volume
0.4 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject
Gross icterus	OK
Heat treated	Reject

Specimen Stability Information

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

Clinical & Interpretive

Clinical Information

Autoimmune hepatitis (AIH) is a form of chronic liver disease that results from a loss of immune system tolerance and recognition of self-antigens.(1) AIH occurs in children and adults, with a significant female predominance. The clinical presentation of AIH varies significantly from asymptomatic liver dysfunction to acute liver failure. Evidence of liver dysfunction manifests as elevated aspartate aminotransferase, alanine aminotransferase, and gamma glutaryl transferase in the context of normal alkaline phosphatase. In addition, most individuals with AIH display increased concentrations of total IgG.

AIH is associated with the production of autoantibodies, which also serves to subcategorize patients.(2) AIH type I is characterized by the presence of antinuclear antibodies (ANA) and smooth muscle antibodies (SMA). AIH type I is associated with anti-liver/kidney microsomal-1 (LKM-1) and anti-liver cytosol-1 antibodies. AIH type I occurs in children and adults and usually has a relatively mild course that is responsive to steroids and azathioprine. In contrast, AIH type 2 occurs predominantly in children, with a more moderate/severe disease course.

Most of the autoantibodies associated with AIH were originally detected and characterized by indirect immunofluorescence (IIF).(3) Anti-LKM-1 antibodies can be detected by IIF using rodent stomach/liver/kidney composite tissue; anti-LKM-1 antibodies display staining of the proximal tubules in the kidney and cytoplasmic staining of the hepatocytes, with no reactivity on the stomach tissue. The antigen for anti-LKM-1 antibodies has been identified as cytochrome P450 2D6, which has led to the development of solid-phase and bead-based immunoassays.

Although not diagnostic in isolation, the various autoantibodies play an important part in establishing the diagnosis of AIH. Simplified diagnostic criteria for AIH include autoantibodies (ANA, SMA, anti-LKM-1, and anti-SLA), IgG concentrations, histopathology, and evaluation for viral hepatitis, with a scoring system to define probable or definite AIH.(4)

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 antibodies is consistent with a diagnosis of autoimmune hepatitis type 2, in patients with compatible clinical symptoms and histopathology.

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 are not the only serological marker for autoimmune hepatitis (AIH) and should be evaluated in the context of other AIH-associated autoantibodies, including antinuclear antibodies and smooth muscle antibodies.

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

Clinical Reference

1. Mieli-Vergani G, Vergani D, Czaja AJ, et al: Autoimmune hepatitis. Primer. 2018 Apr 12;4:18017. doi: 10.1038/nrdp.2018.17
2. Beretta-Piccoli BT, Mieli-Vergani G, Vergani D: Serology in autoimmune hepatitis: A clinical-practice approach. Eur J Intern Med. 2018 Feb;48:35-43. doi: 10.1016/j.ejim.2017.10.006
3. Liberal R, Mieli-Vergani G, Vergani D: Clinical significance of autoantibodies in autoimmune hepatitis. J Autoimmun. 2013 Oct;46:17-24. doi: 10.1016/j.jaut.2013.08.001
4. Hennes EM, Zeniya M, Czaja AJ, et. al: Simplified criteria for the diagnosis of autoimmune hepatitis. Hepatology. 2008 Jul;48(1):169-76. doi: 10.1002/hep.22322

Performance

Method Description

Purified full-length recombinant human cytochrome P450 2D6 antigen is bound to the wells of a polystyrene microwell plate under conditions that will preserve the antigen in its native state. Pre-diluted controls and diluted patient sera are added to separate wells, allowing any liver/kidney microsomal antibodies type 1 present to bind to the immobilized antigen. Unbound sample is washed away, and an enzyme labeled anti-human IgG antibody (conjugate) is added to each well. A second incubation allows the enzyme labeled anti-human IgG antibody to bind any patient antibodies, which have become attached to the microwells. After washing away any unbound enzyme labeled anti-human IgG antibody, the remaining enzyme activity is measured by adding a chromogenic substrate and measuring the intensity of the color that develops. The assay is evaluated by spectrophotometrically measuring and comparing the color intensity that develops in the patient wells with the color in the calibrator wells. (Package insert: INOVA Diagnostics, Inc.; Revision 13; 10/2018)

PDF Report

No

Day(s) Performed

Monday, Wednesday, Friday

Report Available

2 to 4 days

Specimen Retention Time
14 days

Performing Laboratory Location
Rochester

Fees & 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 account representative. For assistance, contact Customer Service.

Test Classification
This test has been cleared, approved, or is exempt by the US 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