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

Testing Algorithm
For information see First-Line Screening for Autoimmune Liver Disease Algorithm.

Special Instructions
- First-Line Screening for Autoimmune Liver Disease Algorithm

Method Name
Enzyme-Linked Immunosorbent Assay (ELISA)

NY State Available
Yes

Specimen

Specimen Type
Serum

Specimen Required
Supplies: Sarstedt Aliquot Tube, 5 mL (T914)
Collection Container/Tube:
Preferred: Serum gel
Acceptable: Red top
Submission Container/Tube: Plastic vial
Specimen Volume: 0.5 mL Serum
Collection Instructions: Centrifuge and aliquot serum into a plastic vial.

Forms
If not ordering electronically, complete, print, and send 1 of the following with the specimen:
-Gastroenterology and Hepatology Test Request (T728)
-General Request (T239)

Specimen Minimum Volume
Serum: 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 chronic liver disease characterized by immune-mediated destruction of hepatocytes, leading to inflammation and fibrosis.(1) The diagnosis of AIH in children and adults is based on a combination of clinical, laboratory, and histological findings in patients with unexplained acute or chronic hepatitis following the exclusion of the commonly encountered etiologies of hepatitis.(2,3) Based on these features and others, a revised diagnostic scoring system in AIH research studies was published in 2008.(2) AIH predominantly affects women with clinical presentation that varies significantly from asymptomatic liver dysfunction to acute liver failure. The laboratory profile for AIH is characterized by abnormalities of specific liver enzyme, diverse autoantibodies, and in some cases elevated total IgG levels.(1-3) Evidence of liver dysfunction includes elevated aspartate aminotransferase, alanine aminotransferase, and gamma glutaryl transferase in the context of normal alkaline phosphatase.(2,3) AIH can be stratified into two main subtypes based on the presence of specific autoantibodies and patient's age, these include AIH-type1 (AIH-1) or AIH-type 2 (AIH-2).(2-5) Patients with AIH-1 are positive for antinuclear autoantibodies, smooth muscles antibodies associated with anti-filamentous-actin IgG antibody, or both, while patients with AIH-2 have detectable anti-liver kidney microsomal type-1 (anti-LKM1), or rarely, anti–liver kidney microsomal type-3, or anti–liver cytosol type-1 antibodies. Antibodies against soluble liver antigens/liver pancreas autoantigen can also be detected in AIH-1 patients.(5) Compared to AIH-2, which generally occurs in children with a more moderate or severe disease course, AIH-1 occurs in all age groups, has a relatively mild course that is responsive to timely treatment with steroids and azathioprine.(3)

Anti-LKM-1 antibodies were originally described by immunofluorescence exhibiting a typical cytoplasmic staining of hepatocytes and proximal renal tubular epithelia, using rodent tissue.(6) Subsequently, Mann and colleagues identified the cytochrome P450 2D6 (CYP2D6) as the major target for anti-LKM-1 antibodies.(7) Following the identification of cytochrome CYP2D6 antigen, solid-phase immunoassays have been developed and implemented for use in the differential evaluation of autoimmune liver disease or AIH-2 in children and young adults.(2,3) Very limited clinical or laboratory studies have been performed to investigate the performance characteristics of anti-LKM-1 antibodies in unbiased patient cohorts. In a recent study using the line immunoassay and digital liquid chip method, in patients with autoimmune liver disease, the agreement both assays not optimal probably due to low prevalence.(8)

Reference Values

Negative: < or =20.0 Units
Equivocal: 20.1-24.9 Units
Positive: > or =25.0 Units
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 diagnose autoimmune hepatitis (AIH) or predict the development of disease.

Anti-LKM-1 antibodies are not the only serological marker for AIH and should be evaluated in the context of other AIH-associated autoantibodies, including antinuclear antibodies, smooth muscle antibodies, or filamentous-actin 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. Nat Rev Dis Primers. 2018;4:18017. doi:10.1038/nrdp.2018.17
2. Hennes EM, Zeniya M, Czaja AJ, et al. Simplified criteria for the diagnosis of autoimmune hepatitis. Hepatology. 2008;48(1):169-176
3. Mack CL, Adams D, Assis DN, et al. Diagnosis and management of autoimmune hepatitis in adults and children: 2019 Practice Guidance and Guidelines From the American Association for the Study of Liver Diseases. Hepatology. 2020;72(2):671-722
4. Beretta-Piccoli BT, Mieli-Vergani G, Vergani D. Serology in autoimmune hepatitis: A clinical-practice approach. Eur J Intern Med. 2018;48:35-43
5. Dalekos GN, Gatselis NK. Autoimmune serology testing in clinical practice: An updated roadmap for the diagnosis of autoimmune hepatitis. Eur J Intern Med. 2023;108:9-17
6. Rizzetto M, Swana G, Doniach D. Microsomal antibodies in active chronic hepatitis and other disorders. Clin Exp Immunol. 1973;15(3):331-344
7. Manns MP, Johnson EF, Griffin KJ, Tan EM, Sullivan KF. Major antigen of liver kidney microsomal autoantibodies in idiopathic autoimmune hepatitis is cytochrome P450db1. J Clin Invest. 1989;83(3):1066-1072
8. Lv H, Deng A, Chen Y, Su Z. Clinical performance of the line immunoassay and digital liquid chip method for detecting autoimmune liver disease autoantibodies. Arch Pathol Lab Med. 2025;149(3):271-275

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

Mayo Clinic Laboratories - Rochester Superior Drive

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

Test Definition: LKM

Liver/Kidney Microsome Type 1 Antibodies, Serum

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