MAYO CLINIC LABORATORIES

Test Definition: AHEP

Acute Viral Hepatitis Profile, Serum

Overview

Useful For

Differential diagnosis of recent acute viral hepatitis

Profile Information

Test Id	Reporting Name	Available Separately	Always Performed
HAIGM	Hepatitis A IgM Ab, S	Yes	Yes
HBAG	HBs Antigen, S	Yes	Yes
HBIM	HBc IgM Ab, S	Yes	Yes
HCVDX	HCV Ab w/Reflex to HCV PCR, S	Yes	Yes

Reflex Tests

Test Id	Reporting Name	Available Separately	Always Performed
HCVQN	HCV RNA Detect/Quant, S	Yes	No
HBGNT	HBs Antigen Confirmation, S	Yes	No

Testing Algorithm

If the hepatitis C virus (HCV) antibody result is reactive, then HCV RNA detection and quantification by real-time reverse transcription-polymerase chain reaction will be performed at an additional charge.

If the hepatitis B surface antigen result is reactive, then confirmation will be performed at an additional charge.

The following algorithms are available:
-Hepatitis B: Testing Algorithm for Screening, Diagnosis, and Management
-Hepatitis C: Testing Algorithm for Screening and Diagnosis
-Viral Hepatitis Serologic Profiles

Special Instructions

- Viral Hepatitis Serologic Profiles
- Hepatitis B: Testing Algorithm for Screening, Diagnosis, and Management
- Hepatitis C: Testing Algorithm for Screening and Diagnosis

Method Name

HAIGM, HBAG, HBIM, HCVDX, HBGNT: Electrochemiluminescence Immunoassay (ECLIA)
HCVQN: Real-Time Reverse Transcription-Polymerase Chain Reaction (RT-PCR)

NY State Available

No

Specimen

Specimen Type
Serum SST

Necessary Information
Date of collection is required.

Specimen Required
Patient Preparation: For 24 hours before specimen collection, patient should **not** take multivitamins or dietary supplements (eg, hair, skin, and nail supplements) containing biotin (vitamin B7).
Supplies: Sarstedt Aliquot Tube 5 mL (T914)
Collection Container/Tube: Serum gel (red-top tubes are **not acceptable**)
Submission Container/Tube: Plastic vial
Specimen Volume: 2.7 mL
Collection Instructions:
1. Centrifuge blood collection tube per manufacturer's instructions (eg, centrifuge and aliquot within 2 hours of collection for BD Vacutainer tubes).
2. Aliquot 2 mL serum into a plastic vial labeled as SST Serum, and ship frozen (preferred).

Forms
If not ordering electronically, complete, print, and send 1 of the following:
-Gastroenterology and Hepatology Test Request (T728)
-Infectious Disease Serology Test Request (T916)

Specimen Minimum Volume
1.9 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject
Gross icterus	Reject
Heat-inactivated specimen	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum SST	Frozen (preferred)	84 days	
	Refrigerated	6 days	

Clinical & Interpretive

Clinical Information

Hepatitis A:
Hepatitis A virus (HAV) is an RNA virus that accounts for 20% to 25% of acute viral hepatitis in adults in the United States. Hepatitis A is spread by the oral/fecal route and produces acute hepatitis, which follows a benign, self-limited course. Spread of the disease is usually associated with contaminated food or water caused by poor sanitary conditions. Outbreaks frequently occur in overcrowded situations and institutions or high-density centers such as prisons and healthcare centers. Epidemics may occur following floods or other disaster situations. Chronic carriers of HAV have never been observed.

Hepatitis B:
Hepatitis B virus (HBV) is an endemic DNA virus throughout the world. The infection is spread primarily through percutaneous contact with infected blood products (eg, blood transfusion, sharing of needles among injection drug users). The virus is also found in virtually every human body fluid and is known to be spread through oral and genital contact. HBV can be transmitted from mother to child during delivery through contact with blood and vaginal secretions; it is not commonly transmitted transplacentally. After a course of acute illness, HBV persists in approximately 10% of patients. Some chronic carriers are asymptomatic; others develop chronic liver disease, including cirrhosis and hepatocellular carcinoma.

Hepatitis C:
Hepatitis C virus (HCV) is an RNA virus that is a significant cause of morbidity and mortality worldwide. The infection is transmitted through contaminated blood or blood products or other close, personal contacts. It is recognized as the cause of most cases of posttransfusion hepatitis. Hepatitis C shows a high rate of progression (~75%) to chronic infection and disease and accounts for the majority of chronic viral hepatitis In the United States. Cirrhosis and hepatocellular carcinoma are sequelae of chronic infection with this virus.

Reference Values

HEPATITIS B SURFACE ANTIGEN
Negative

HEPATITIS B SURFACE ANTIGEN CONFIRMATION
Negative

HEPATITIS B CORE IgM ANTIBODY
Negative

HEPATITIS A IgM ANTIBODY
Negative

HEPATITIS C ANTIBODY
Negative

HEPATITIS C VIRUS RNA DETECTION AND QUANTIFICATION BY REAL-TIME RT-PCR

Undetected

Interpretation

Interpretation depends on clinical setting. See Viral Hepatitis Serologic Profiles

Hepatitis A Virus (HAV):
HAV-specific antibodies are usually detectable by the onset of symptoms (usually 15 to 45 days after exposure). The initial antibody consists almost entirely of IgM subclass antibody. Anti-HAV IgM usually falls to undetectable levels 3 to 6 months after infection.

Hepatitis B Virus (HBV):
HBsAg is the first serologic marker appearing in the serum 6 to 8 weeks following HBV infection. In acute cases, HBsAg usually disappears 1 to 2 months after the onset of symptoms. Anti-HBs appears with the resolution of HBV infection after the disappearance of HBsAg. Anti-HBs also appear as the immune response following a course of inoculation with the hepatitis B vaccine.

During acute hepatitis B in symptomatic individuals, detectable anti-HBc consists almost entirely of the IgM subclass. Anti-HBc IgM can be detected shortly after the onset of symptoms and usually remains detectable for 6 months. Anti-HBc IgM and Anti-HBc total may be the only serologic markers of a recent HBV infection detectable in the "window period", during which HBsAg has declined to become undetectable and anti-HBs has not yet become detectable.

Hepatitis C Virus (HCV):
In immunocompetent individuals, HCV-specific IgG and IgM antibodies are usually not detectable in the first 2 months after exposure to HCV, and this "window period: may be as long as 6 months in immunocompromised individuals. HCV antibodies are not neutralizing and does not provide immunity against subsequent HCV infection.

If HBsAg, anti-HAV IgM, and anti-HCV are negative and patient's condition warrants, consider testing for Epstein-Barr virus or cytomegalovirus.

The following algorithms are available:
-Hepatitis B: Testing Algorithm for Screening, Diagnosis, and Management
-Hepatitis C: Testing Algorithm for Screening and Diagnosis

Cautions

Consider administration of human immune globulin to individuals exposed to patients with hepatitis A.

Consider administration of hepatitis B immune globulin and/or hepatitis B vaccine to individuals exposed to hepatitis B patient's blood or body fluids.

Positive hepatitis B surface antigen (HBsAg) or positive anti-hepatitis A virus (HAV) IgM test results should be reported by the attending physician to the State Department of Health, as required by law in some states.

Serum specimens from individuals taking biotin supplements at 20 mg or more per day may have false-negative results for anti-HAV IgM, anti-HBc IgM, and anti-HCV Ab, due to interference of biotin with the assay. Such individuals should stop taking these biotin-containing dietary supplements for minimum 12 hours before blood collection for this test.

Performance characteristics have not been established for the following specimen characteristics:
-Grossly icteric (total bilirubin level of >25 mg/dL)
-Grossly lipemic (intralipid level of >1000 mg/dL)
-Grossly hemolyzed (hemoglobin level of >1000 mg/dL)
-Containing particulate matter
-Cadaveric specimens

Clinical Reference

1. LeFevre ML, et al. Screening for hepatitis B virus infection in nonpregnant adolescents and adults: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med. 2014;161(1):58-66. doi:10.7326/M14-1018
2. Jackson K, Locarnini S, Gish R. Diagnostics of hepatitis B virus: Standard of care and investigational. Clin Liver Dis (Hoboken). 2018;12(1):5-11. doi:10.1002/cld.729
3. Coffin CS, Zhou K, Terrault NA. New and old biomarkers for diagnosis and management of chronic hepatitis B virus infection. Gastroenterology. 2019;156(2):355-368.e3. doi:10.1053/j.gastro.2018.11.037
4. World Health Organization. Guidelines on hepatitis B and C testing. World Health Organization; 2017. Accessed October 8, 2024. Available at www.who.int/hepatitis/publications/i/item/9789241549981
5. Conners EE, Panagiotakopoulos L, Hofmeister MG, et al. Screening and testing for hepatitis B virus infection: CDC Recommendations - United States, 2023. MMWR Recomm Rep. 2023;72(1):1-25. Published 2023 Mar 10. doi:10.15585/mmwr.rr7201a1

Performance

Method Description

Hepatitis B Surface Antigen Screen:
The Elecsys HBsAg (hepatitis B surface antigen) II assay is performed using an electrochemiluminescence immunoassay on the automated cobas e 801 immunochemistry analyzer. HBsAg present in the patient's sample reacts with two biotinylated monoclonal anti-HBs, and a mixture of monoclonal anti-HBs and polyclonal anti-HBsAg antibodies labeled with a ruthenium complex react to form a sandwich complex. After addition of streptavidin-coated microparticles, the complexes become bound to the solid phase via interaction of biotin and streptavidin. The reaction mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode, and unbound substances are washed away. Voltage is applied to the electrode that induces chemiluminescent emissions, which are measured by a photomultiplier. Test results for each patient's sample is determined by comparing the electrochemiluminescence signal generated from the reaction product to the cutoff index (COI) value set from reagent lot-specific assay calibrations.(Package insert: Elecsys HBsAG II. Roche Diagnostics; v3.0, 02/2022)

Hepatitis B Surface Antigen Confirmation:
The Elecsys HBsAg II Auto Confirm assay is performed using an electrochemiluminescence immunoassay on the automated cobas e 801 immunochemistry analyzer. This test is based on 2 parallel measurements. For the first measurement, the sample is treated with the control pretreatment reagent (PT2) prior to immunoreaction. This measurement serves as a reference. For the second measurement the sample is treated with the confirmatory pretreatment reagent (PT1) prior to immunoreaction. During incubation with confirmatory pretreatment, unlabeled polyclonal anti-HBsAg antibodies are bound to the sample HBsAg and thereby block the binding sites for the labeled antibodies used in the following immunoreaction. The confirmation result (%) is automatically assessed by determining

the ratio of both measurements.

During testing, the auto-diluted sample is incubated with control pretreatment and confirmatory pretreatment, followed by formation of sandwich complexes of biotinylated monoclonal anti-HBsAg antibodies and a mixture of monoclonal anti-HBsAg antibody and polyclonal anti-HBsAg antibodies labeled with a ruthenium complex. After addition of streptavidin-coated microparticles, the complexes become bound to the solid phase via interaction of biotin and streptavidin. The reaction mixture is then aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode, and unbound substances are then washed away. Voltage is applied to the electrode that induces chemiluminescent emissions, which are measured by a photomultiplier. Results are determined by comparing the electrochemiluminescence signal generated from the reaction product to the cutoff index value set from reagent lot-specific assay calibration. The confirmation result (%) is calculated from the ratio of the COI obtained for the measurement with confirmatory pretreatment to the COI obtained for the measurement with control pretreatment.(Package Insert: Elecsys HBsAg II Auto Confirm. Roche Diagnostics; v1.0, 12/2020)

Hepatitis A IgM Antibody:
The Elecsys Anti-HAV (hepatitis A virus) IgM assay is performed using an electrochemiluminescence immunoassay on the automated cobas e 801 immunochemistry analyzer. Hepatitis A virus-specific IgM antibody (anti-HAV IgM) in the patient's serum sample is pretreated with anti-Fdy reagent to block specific IgG in the presence of monoclonal anti-HAV antibodies labeled with ruthenium complex. After addition of biotinylated monoclonal h-IgM-specific antibodies, HAV antigen, and streptavidin-coated microparticles, patient's anti-HAV IgM form a sandwich complex with the HAV antigen and the ruthenium-labeled anti-HAV antibody which becomes bound to the solid phase via interaction of biotin and streptavidin. The reaction mixture is then aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode, and unbound substances are washed away. Voltage is applied to the electrode and induces chemiluminescent emissions that are measured by a photomultiplier. Test result for each patient's sample is determined automatically by the assay-specific software program by comparing the electrochemiluminescence signal generated from the patient's sample to the COI value set from reagent lot-specific assay calibrations.(Package insert: Elecsys Anti-HAV IgM. Roche Diagnostics; v5.0, 11/2022)

Hepatitis B Core IgM Antibody:
The Elecsys Anti-HBc IgM assay is performed with an electrochemiluminescence immunoassay on the automated cobas e 801 immunochemistry analyzer. Hepatitis B virus core IgM antibody (anti-HBc IgM) present in patient's sample is pretreated with anti-Fdy reagent to block specific IgG. After addition of biotinylated monoclonal human IgM-specific antibodies, the complexes formed from reaction of ruthenium-labeled HBc antigen, streptavidin-coated microparticles, anti-HBc IgM present in the sample, and the biotinylated anti-human IgM become bound to the solid phase via interaction of biotin and streptavidin. The reaction mixture is then aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode, and unbound substances are washed away. Voltage is applied to the electrode that induces chemiluminescent emissions, which are measured by a photomultiplier. Test result is determined by comparing the electrochemiluminescence signal generated from the sample to the COI value set from reagent lot-specific assay calibration.(Package insert: Elecsys Anti-HBc IgM. Roche Diagnostics; v1.0, 09/2020)

Hepatitis C Virus Antibody:
The Elecsys Anti-HCV II assay will be performed on the fully automated cobas e 801 electrochemiluminescence immunoassay analyzer. During the first incubation, antibodies to hepatitis C virus (HCV) in the patient's sample, biotinylated HCV-specific antigens and a reagent containing HCV-specific antigens labeled with a ruthenium complex to

form a sandwich complex. In the second incubation, after addition of streptavidin-coated microparticles, the complex becomes bound to the solid phase via interaction of biotin and streptavidin. The reaction mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then washed away, and application of a voltage to the electrode then induces chemiluminescent emissions, which are measured by a photomultiplier. Test result for each patient's sample is determined automatically by the assay-specific software program by comparing the electrochemiluminescence signal obtained from the sample with the COI value set from reagent lot-specific assay calibrations.(Package insert: Elecsys Anti-HCV II. Roche Diagnostics; v1.0, 03/2023)

PDF Report
No

Day(s) Performed
Monday through Sunday

Report Available
1 to 3 days

Specimen Retention Time
14 days

Performing Laboratory Location
Mayo Clinic Jacksonville Clinical Lab

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
80074 (if all 4 initial tests are performed)
86709 (if all 4 are not performed)
86705 (if all 4 are not performed)
87340 (if all 4 are not performed)
86803 (if all 4 are not performed)
87522 (if appropriate)
87341 (if appropriate)

Test Definition: AHEP

Acute Viral Hepatitis Profile, Serum

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
AHEP	Acute Hepatitis Profile	24363-4

Result ID	Test Result Name	Result LOINC® Value
HBIM	HBc IgM Ab, S	24113-3
H_BAG	HBs Antigen, S	5196-1
HAIGM	Hepatitis A IgM Ab, S	13950-1
HCVA4	HCV Ab, S	40726-2