MAYO CLINIC LABORATORIES

Test Definition: PHEPU

Previous Viral Hepatitis (Unknown Type), Serum

Overview

Useful For

Determining if an individual has been infected following exposure to an unknown type of viral hepatitis virus

Obtaining baseline serologic markers of an individual exposed to a source with an unknown type of hepatitis

Determining immunity to hepatitis A and B viral infections

Profile Information

Test Id	Reporting Name	Available Separately	Always Performed
HAVTA	Hepatitis A Virus Total Ab, S	Yes	Yes
HBAG	HBs Antigen, S	Yes	Yes
HBAB	HBs Antibody, S	Yes	Yes
HBC	HBc Total 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
HBGNT	HBs Antigen Confirmation, S	No	No
HCVQN	HCV RNA Detect/Quant, S	Yes	No

Testing Algorithm

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

If hepatitis B virus surface antigen (HBsAg) is reactive, then HBsAg confirmation will be performed at an additional charge.

For more information see:
-Hepatitis B: Testing Algorithm for Screening, Diagnosis, and Management.
-Hepatitis C: Testing Algorithm for Screening and Diagnosis

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

HAVTA, HBAG, HBAB, HBC, 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: 2.6 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 1.8 mL serum into a plastic vial and ship frozen (preferred).

Forms

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

Specimen Minimum Volume

1.8 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 viral hepatitis in adults in the United States. HAV infection is spread by the oral/fecal route and produces acute hepatitis that 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 a DNA virus that is endemic 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 found in various human body fluids 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, while others develop chronic liver disease, including cirrhosis and hepatocellular carcinoma.

Hepatitis C:
Hepatitis C virus (HCV) is an RNA virus recognized as the cause of most cases of posttransfusion hepatitis that is a significant cause of morbidity and mortality worldwide. HCV is transmitted through contaminated blood or blood products or close, personal contact. HCV shows a high rate of progression (~75%) to chronic disease. In the United States, HCV infection is quite common, with an estimated 3.5 to 4 million chronic HCV carriers. Cirrhosis and hepatocellular carcinoma are sequelae of chronic HCV.

Reference Values

HEPATITIS B VIRUS SURFACE ANTIGEN
Negative

HEPATITIS B VIRUS SURFACE ANTIGEN CONFIRMATION
Negative

HEPATITIS B VIRUS SURFACE ANTIBODY, QUALITATIVE/QUANTITATIVE
Hepatitis B Surface Antibody
Unvaccinated: Negative
Vaccinated: Positive

HEPATITIS B VIRUS SURFACE ANTIBODY, QUANTITATIVE
Unvaccinated: <8.5 mIU/mL
Vaccinated: > or =11.5 mIU/mL

HEPATITIS B VIRUS CORE TOTAL ANTIBODIES
Negative

HEPATITIS A VIRUS TOTAL ANTIBODY
Unvaccinated: Negative
Vaccinated: Positive

HEPATITIS C VIRUS ANTIBODY
Negative

HEPATITIS C VIRUS RNA DETECTION and QUANTIFICATION by REAL-TIME RT-PCR
Undetected

Interpretation depends on clinical setting. For more information see Viral Hepatitis Serologic Profiles.

Interpretation

Interpretation depends on clinical setting. For more information see Viral Hepatitis Serologic Profiles.

Hepatitis A:
Hepatitis A virus (HAV)-specific total antibodies are almost always detectable by the onset of symptoms of acute hepatitis A (usually 15 to 45 days after exposure). The initial antibody consists almost entirely of the IgM subclass of antibody. Anti-HAV IgM usually falls to undetectable levels 3 to 6 months after infection. Anti-HAV IgG levels rise quickly once the virus is cleared and persist for many years.

Hepatitis B:
Hepatitis B virus surface antigen (HBsAg) is the first serologic marker appearing in the serum 6 to 8 weeks following hepatitis B virus (HBV) infection. A confirmed positive result for HBsAg is indicative of acute or chronic hepatitis B. 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 appears as the immune response following a course of inoculation with the hepatitis B vaccine.

Hepatitis B virus core antibody (anti-HBc) appears shortly after the onset of symptoms of HBV infection and may be the only serologic marker remaining years after exposure to hepatitis B.

Hepatitis C:
Hepatitis C virus-specific antibodies are usually not detectable during the first 2 months after exposure, but they are almost always detectable by the late convalescent stage of infection. HCV antibodies are not neutralizing and do not provide immunity.

Cautions

Positive hepatitis B surface antigen (HBsAg) results may need to be reported by the healthcare providers to their communicable disease surveillance units of state departments of health, as required by law in various states.

Type-specific tests should be used to evaluate individuals who have been exposed to a source with a known type of hepatitis (eg, hepatitis A, hepatitis B, hepatitis C).

Serum specimens from individuals taking biotin supplements at 20 mg or more per day may have **false-positive** results for HAV total antibody and HBc total antibody, as well as **false-negative** results for HBsAg and HCV total antibody, 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 >500 mg/dL)
-Containing particulate matter
-Cadaveric specimens
-Immunocompromised or immunosuppressed specimens

Clinical Reference

1. De Paula VS. Laboratory diagnosis of hepatitis A. Future Virology. 2012;7(5):461-472
2. American Association for the Study of Liver Diseases (AASLD) and Infectious Diseases Society of America (IDSA): HCV guidance: Recommendations for testing, managing, and treating hepatitis C. AASLD, IDSA; Updated December 19, 2023. Accessed October 7, 2024. Available at www.hcvguidelines.org/contents
3. World Health Organization. Guidelines on hepatitis B and C testing. World Health Organization; 2017. Accessed October 7, 2024. Available at www.who.int/publications/i/item/9789241549981
4. 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

Performance

Method Description

Hepatitis A Virus Total Antibody:
The Elecsys Anti-HAV (hepatitis A virus) II assay is performed using an electrochemiluminescence immunoassay on the automated cobas e 801 immunochemistry analyzer. Hepatitis A virus (HAV)-specific antibodies in the patient's serum binds with added HAV antigen in the reaction. After addition of biotinylated monoclonal anti-HAV and

streptavidin-coated microparticles, patient's anti-HAV 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 that induces chemiluminescent emissions, which are measured by a photomultiplier. Test result is determined automatically with the assay-specific software in comparing the electrochemiluminescence signal generated in the patient's sample to the signal cutoff index (COI) value set from reagent lot-specific assay calibration.(Package insert: Elecsys Anti-HAV II. Roche Diagnostics; v3.0, 11/2022)

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 analzyer. 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 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 which induces chemiluminescent emissions that are measured by a photomultiplier. Results are determined by comparing the electrochemiluminescence signal generated from the reaction product to the COI 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 B Virus Surface Antibody:

The Elecsys Anti-HBs (hepatitis B virus surface) quantitative assay is performed using an electrochemiluminescent immunoassay on the automated cobas e 801 immunochemistry analyzer. Anti-HBs present in patient's serum sample reacts with the biotinylated HBsAg (ad and ay subtypes) and HBsAg (ad/ay) labeled with a ruthenium complex to form a sandwich complex. After the addition of streptavidin-coated microparticles, the complexes bind to a solid phase via interaction of biotin and streptavidin. The reaction mixture is aspirated into the measuring cell where microparticles are magnetically captured onto the surface of the electrode, and unbound substances are washed away. Voltage is applied to the electrode which induces chemiluminescent emissions that are measured by a photomultiplier. The emission signal generated is directly proportional to the concentration of anti-HBs present in the patient's serum sample.(Package insert: Elecsys Anti-HBs. Roche Diagnostics; v1.0, 2019)

Hepatitis B Virus Core Total Antibody:
The Elecsys Anti-HBc (hepatitis B viral core) II assay is performed using an electrochemiluminescence immunoassay on the automated cobas e 801 analyzer. Anti-HBc present in the patient's sample are pretreated first with a reducing reagent, and after the addition of hepatitis B virus core antigen (HBcAg), complexes are formed with anti-HBc in the sample. The remaining unbound sites on the HBcAg become occupied after addition of biotinylated antibodies and ruthenium complex-labeled antibodies specific for HBcAg, together with streptavidin-coated microparticles. The entire complex 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. After unbound substances are washed away, voltage is applied to the electrode which induces chemiluminescent emissions that are measured by a photomultiplier. Results are determined by comparing the electrochemiluminescence signal generated from the reaction product of the sample to the COI value set from assay reagent lot-specific assay calibration.(Package insert: Elecsys Anti-HBc II. Roche Diagnostics; v1.0, 04/2022)

Hepatitis C Virus Antibody:
The Elecsys Anti-HCV (hepatitis C virus) II assay will be performed on the fully automated cobas e 801 electrochemiluminescence immunoassay analyzer. During the first incubation, antibodies to 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
Profile tests: Monday through Sunday; Reflex tests: Varies

Report Available
Same day/1 to 2 days

Specimen Retention Time
14 days

Performing Laboratory Location
Jacksonville

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
86704
86706
86708
86803
87340
87341 (if appropriate)
87522 (if appropriate)

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
PHEPU	Previous Hepatitis Profile	92890-3

Result ID	Test Result Name	Result LOINC® Value
HBC	HBc Total Ab, S	13952-7
HB_AB	HBs Antibody, S	10900-9
HBSQN	HBs Antibody, Quantitative, S	5193-8
H_BAG	HBs Antigen, S	5196-1
HCVA4	HCV Ab, S	40726-2
HAVT	Hepatitis A Virus Total Ab, S	13951-9