Test Definition: PHSP

Prenatal Hepatitis Evaluation, Serum

Overview

Useful For

Screening pregnant women for chronic hepatitis B and hepatitis C in primary care settings, with or without risk factors for hepatitis C

Determining the level of infectivity of chronic hepatitis B in pregnant women

This test is **not useful for** diagnosis of hepatitis B during the "window period" of acute hepatitis B virus infection (ie, after disappearance of hepatitis B surface antigen and prior to appearance of hepatitis B surface antibody).

This test **should not be used** as a screening test for hepatitis C in blood or human cells/tissue donors.

This test profile is **not useful for** detection or diagnosis of acute hepatitis C virus (HCV) in pregnancy, since HCV antibodies may not be detectable until after 2 months following exposure, and HCV RNA testing is not performed on specimens with negative HCV antibody screening test results.

Profile Information

Test Id	Reporting Name	Available Separately	Always Performed
HBAGP	HBs Antigen Prenatal, S	Yes	Yes
HCVSP	HCV Ab Scrn Prenatal, S	Yes	Yes

Reflex Tests

Test Id	Reporting Name	Available Separately	Always Performed
EAG	Hepatitis Be Ag, S	Yes	No
HEAB	HBe Antibody, S	Yes	No
HBNTP	HBs Ag Confirmation Prenatal, S	No	No
HCVRP	HCV RNA Detect/Quant Prenatal, S	Yes	No

Testing Algorithm

If the hepatitis B virus surface antigen (HBsAg) result is reactive, then HBsAg confirmation testing will be performed at an additional charge. If the HBsAg confirmation result is positive, then HBe Ag and HBe antibody testing will be performed at an additional charge.

If the hepatitis C virus (HCV) antibody screen is reactive, then HCV RNA testing by reverse transcriptase-polymerase chain reaction will be performed at an additional charge.

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

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

Electrochemiluminescence Immunoassay (ECLIA)

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: 2.2 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 serum into a plastic vial 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

1.6 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject

Gross icterus	Reject

Specimen Stability Information

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

Clinical & Interpretive

Clinical Information

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 (ie, blood transfusion, sharing of needles among injection drug users). The virus is found in virtually every type of human body fluid and is 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. Infection of the infant can occur if the mother is a chronic hepatitis B surface antigen carrier or has an acute HBV infection at the time of delivery. Transmission is rare if an acute infection occurs in either the first or second trimester of pregnancy.

After a course of acute illness, HBV persists in about 10% of patients who were infected during adulthood. Some carriers are asymptomatic, while others may 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 and is a significant cause of morbidity and mortality worldwide. In the United States, HCV infection is quite common, with an estimated 3.5 to 4 million chronic HCV carriers.

Laboratory testing for HCV infection usually begins by screening for the presence of HCV-specific antibodies in serum, using an US Food and Drug Administration approved screening test. Specimens that are repeatedly reactive by screening tests should be confirmed with HCV tests with higher specificity, such as direct detection of HCV RNA by reverse transcriptase-polymerase chain reaction or HCV-specific antibody confirmatory tests.

HCV antibodies are usually not detectable during the first 2 months following infection but are usually detectable by the late convalescent stage (>6 months after onset) of infection. These antibodies neither neutralize the virus nor provide immunity against this viral infection. Decrease in the HCV antibody level in serum may occur following resolution of infection.

Current serologic screening tests to detect HCV antibodies include enzyme and chemiluminescence immunoassays. Despite the value of serologic tests to screen for HCV infection, several limitations of serologic testing exist:
-There may be a long delay (up to 6 months) between exposure to the virus and the development of detectable HCV-specific antibodies
-False-reactive screening test results can occur
-A reactive screening test result does not distinguish between past (resolved) and present HCV infection

-Serologic tests cannot provide information on clinical response to anti-HCV therapy

Reactive screening test results should be followed by a supplemental or confirmatory test, such as a nucleic acid test for HCV RNA or HCV antibody confirmatory test. Nucleic acid tests provide a very sensitive and specific approach for the direct detection of HCV RNA.

Reference Values

HEPATITIS B VIRUS SURFACE ANTIGEN
Negative

HEPATITIS C VIRUS ANTIBODY
Negative

See Viral Hepatitis Serologic Profiles

Interpretation

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. Persistence of HBsAg for more than 6 months indicates development of either a chronic carrier state or chronic liver disease. HBs antibody (anti-HBs) appears with the resolution of HBV infection after the disappearance of HBsAg.

Hepatitis B e antigen (HBeAg) appears at approximately the same time as HBsAg and indicates that the virus is replicating and the individual is infectious. Appearance of anti-HBe after the disappearance of HBsAg and HBeAg usually indicates recovery and loss of infectivity.

Reactive hepatitis C virus (HCV) antibody screening results with cutoff index (COI) at or below 20.0 are not predictive of the true HCV antibody status; additional testing is recommended to confirm HCV antibody status.

Reactive results with COI greater than 20.0 are highly predictive (95% or greater probability) of the true HCV antibody status, but additional testing is needed to differentiate between past (resolved) and chronic hepatitis C.

A negative screening test result does not exclude the possibility of exposure to, or infection with, HCV. Negative screening test results in individuals with prior exposure to HCV may be due to low antibody levels that are below the limit of detection of this assay or lack of reactivity to the HCV antigens used in this assay. Patients with acute or recent HCV infections (<3 months from time of exposure) may have false-negative HCV antibody results due to the time needed for seroconversion (average of 8 to 9 weeks). Testing for HCV RNA using HCVRP / Hepatitis C Virus (HCV) RNA Detection and Quantification, Real-Time Reverse Transcription-PCR, Prenatal, Serum is recommended for detection of HCV infection in such patients.

Cautions

Positive hepatitis B surface antigen (HBsAg) test results should be reported by the patient care provider to the State Department of Health as required by law in some states.

Individuals, especially neonates and children, who recently received hepatitis B vaccination may have transient positive HBsAg test results because of the large dose of HBsAg used in the vaccine relative to the individual's body mass.

A single negative hepatitis C virus (HCV) RNA test result together with a reactive HCV antibody screen result with a cutoff index greater than 20.0 do not rule out the possibility of chronic HCV infection. Repeat testing for HCV RNA in 1 to 2 months is recommended in patient at risk for chronic hepatitis C.

Serum specimens from individuals taking biotin supplements at 20 mg or more per day may have **false-positive** results for anti-hepatitis B e antigen (HBeAg) antibody and **false-negative** results for HBeAg, HBsAg, and anti-HCV 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.

Assay performance characteristics have not been established for the following specimen characteristics:
-Grossly icteric (total bilirubin level of >40 mg/dL)
-Grossly lipemic (intralipid level of >2000 mg/dL)
-Grossly hemolyzed (hemoglobin level of >1000 mg/dL)
-Contain particulate matter
-Cadaveric specimens

Clinical Reference

1. 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
2. Society for Maternal-Fetal Medicine. Hepatitis C in pregnancy: screening, treatment, and management. Am J Obstet Gynecol. 2017; 217(5):B2-B12
3. 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
4. US Preventive Services Task Force. Screening for hepatitis C virus infection in adolescents and adults: US Preventive Services Task Force Recommendation Statement. JAMA. 2020;323(10):970-975. doi:10.1001/jama.2020.1123
5. Centers for Disease Control and Prevention. Screening and Testing for HIV, Viral Hepatitis, STD and Tuberculosis in Pregnancy. CDC; Updated January 25, 2024. Accessed October 8, 2024. Available at www.cdc.gov/pregnancy-hiv-std-tb-hepatitis/php/screening/?CDC_AAref_Val
6. Centers for Disease Control and Prevention. Screening and testing for hepatitis B virus infection: CDC Recommendations – United States, 2023. MMWR Recomm Rep 2023;72(No. RR-1):1-25. Available at www.cdc.gov/mmwr/volumes/72/rr/rr7201a1.htm?s_cid=rr7201a1_w

Performance

Method Description

Hepatitis B Surface Antigen Screening:
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:
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, Doc. 08741034501, v1.0; 12/2020)

Hepatitis C virus
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 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. Doc. 08837058190, v1.0; 03/2023)

PDF Report
No

Day(s) Performed
Monday through Sunday

Report Available
Same day/1 to 4 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
87340
86803
G0472 (if appropriate for government payers)
87522 (if appropriate)
86707 (if appropriate)
87341 (if appropriate)
87350 (if appropriate)

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
PHSP	Prenatal Hepatitis Evaluation	101653-4

Result ID	Test Result Name	Result LOINC® Value
HBSAP	HBs Antigen Prenatal, S	5196-1
HCVA6	HCV Ab Prenatal, S	40726-2