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 result for hepatitis B surface antigen (HBsAg) prenatal is reactive, then HBsAg confirmation prenatal testing will be performed at an additional charge. If the HBsAg confirmation 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
Chemiluminescence Immunoassay (CIA)

NY State Available
Yes

Specimen

Specimen Type
Serum SST

Necessary Information
Date of collection is required.

Specimen Required
Patient Preparation: For 24 hours before specimen collection do not take multivitamins or dietary supplements containing biotin (vitamin B7), which is commonly found in hair, skin, and nail supplements and multivitamins.
Collection Container/Tube: Serum gel
Submission Container/Tube: Plastic vial
Specimen Volume: 2.5 mL
Collection Instructions: Centrifuge and aliquot serum into plastic vial within 24 hours.

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

Specimen Minimum Volume
2 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)	28 days	
	Refrigerated	7 days	
	Ambient	24 hours	

Clinical & Interpretive

Clinical Information

Hepatitis B virus (HBV) is a DNA virus that is endemic throughout the world. 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.

HBV is spread primarily through percutaneous contact with infected blood products (ie, blood transfusion, sharing of needles by 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.

Hepatitis C virus (HCV) is 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 2.4 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 SURFACE ANTIGEN
Negative

HEPATITIS C ANTIBODY
Negative

See Viral Hepatitis Serologic Profiles

Interpretation

Hepatitis B surface antigen (HBsAg) is the first serologic marker appearing in the serum 6 to 16 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.

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 signal-to-cutoff (S/Co) ratios of below 8.0 are not predictive of the true HCV antibody status; additional testing is recommended to confirm HCV antibody status.

Reactive results with S/Co ratios of 8.0 or greater 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 signal-to-cutoff ratio of 8.0 or greater 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.

Assay performance characteristics have not been established for the following specimen characteristics:
-Grossly icteric (total bilirubin level of >20 mg/dL)
-Grossly lipemic (triolein level of >3000 mg/dL)
-Grossly hemolyzed (hemoglobin level of >61 mg/dL)
-Contain particulate matter
-Cadaveric specimens

Clinical Reference

1. Bonino F, Piratvisuth T, Brunetto MR, Liaw Y: Diagnostic markers of chronic hepatitis B infection and disease. Antivir Ther. 2010;15(3):35-44
2. Jackson K, Locarnini S, Gish R: Diagnostics of hepatitis B virus: Standard of care and investigational. Clin Liver Dis. 2018 Aug 22;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 Jan;156(2):355-368. doi: 10.1053/j.gastro.2018.11.037
4. WHO Guidelines Development Group: World Health Organization guidelines on hepatitis B and C testing. Geneva: World Health Organization; 2017. Accessed November 4, 2022. Available at www.who.int/publications/i/item/9789241549981
5. Centers for Disease Control and Prevention. Testing and public health management of persons with chronic hepatitis B virus infection. Updated March 28, 2022. Accessed November 4, 2022. Available at www.cdc.gov/hepatitis/hbv/testingchronic.htm
6. 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 October 24, 2022. Accessed November 4, 2022. Available at www.hcvguidelines.org/contents
7. US Preventive Services Task Force, Owens DK, Davidson KW, et al: Screening for hepatitis C virus infection in adolescents and adults: US Preventive Services Task Force Recommendation Statement. JAMA. 2020 Mar 10;323(10):970-975. doi: 10.1001/jama.2020.1123
8. Society for Maternal-Fetal Medicine (SMFM), Hughes BL, Page CM, Kuller JA: Hepatitis C in pregnancy: screening, treatment, and management. Am J Obstet Gynecol. 2017 Nov;217(5):B2-B12
9. National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention: Pregnancy and HIV, viral hepatitis STD and TB prevention: HCV infection challenges. CDC; Update August 11, 2022. Accessed November 4, 2022. Available at www.cdc.gov/nchhstp/pregnancy/challenges/hcv.html
10. Schillie S, Wester C, Osborne M, Wesolowski L, Ryerson AB: CDC recommendations for hepatitis C screening among adults-United States, 2020. MMWR Morb Mortal Wkly Rep. 2020 Apr 10;69(2):1-17

Performance

Method Description

Specimens are first tested by the VITROS hepatitis B surface antigen (HBsAg) assay. Per assay manufacturer's recommendation, all HBsAg-reactive specimens (signal-to-cutoff ratios > or =1.00) in prenatal screening should be confirmed by the VITROS HBsAg Confirmatory assay.

HBsAg Screening:
This immunometric technique involves the simultaneous reaction of HBsAg in the sample with mouse-monoclonal HBs antibody (anti-HBs) coated onto the wells, and a horseradish peroxidase (HRP)-labeled mouse monoclonal anti-HBs in the conjugate. Unbound conjugate is removed by washing. A reagent containing luminogenic substrates (a luminol derivative and a peracid salt) and an electron transfer agent is added to the wells. The HRP in the bound conjugate catalyzes the oxidation of the luminol derivative, producing light. The electron transfer agent increases the level and duration of the light produced. The light signals are read by the system. The amount of HRP conjugate bound is indicative of the level of HBsAg present in the sample.(Package insert: VITROS HBsAg assay, GEM1201. Ortho-Clinical Diagnostics, Inc; version 13.1, 09/2019)

HBsAg Confirmation:
The VITROS HBsAg Confirmatory kit uses the principle of specific antibody neutralization to confirm the presence of HBsAg. The sample is tested twice: 1 aliquot is incubated with a neutralizing reagent containing high-titer anti-HBs (the confirmatory antibody); the second aliquot is incubated with a non-neutralizing control reagent (the sample diluent). The confirmatory antibody binds to HBsAg in the sample, inhibiting its reaction in the VITROS HBsAg assay. This leads to a reduced result compared to that for the non-neutralized control sample.(Package insert: VITROS HBsAg Confirmation assay, GEM4201. Ortho-Clinical Diagnostics, Inc; version 13.1, 09/2019)

Hepatitis C virus
The VITROS anti-hepatitis C virus (HCV) assay is performed using the VITROS Anti-HCV Reagent Pack and VITROS Immunodiagnostic Products Anti-HCV Calibrator on the VITROS Immunodiagnostic System. An immunometric technique is used, involving a 2-stage reaction. In the first stage, HCV antibody present in the sample binds to HCV recombinant antigens coated on the reaction wells, and unbound sample is removed by washing. In the second stage, HRP-labeled antibody conjugate (mouse monoclonal antihuman IgG) binds to human IgG captured on the well in the first stage. Unbound conjugate is removed by washing. A reagent containing luminogenic substrates (a luminal derivative and a peracid salt) and an electron transfer agent is added to the wells. The HRP in the bound conjugate catalyzes the oxidation of the luminal derivative, producing light. The electron transfer agent increases the level and duration of the light produced. The emitted light signals are detected and measured by the system. The amount of HRP conjugate bound is directly proportional to the level of anti-HCV antibodies present in a given sample.(Ismail N, Fish GE, Smith MN: Laboratory evaluation of a fully automated chemiluminescence immunoassay for rapid detection of HBsAg, antibodies to HBsAg, and antibodies to hepatitis C virus. J Clin Microbiol. 2004 Feb;42(2):610-617; package insert: VITROS Anti-HCV Assay, GEM 1243. Ortho-Clinical Diagnostics; version 14.1, 09/2019)

PDF Report
No

Day(s) Performed
Monday through Saturday

Report Available
Same day/1 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 Regional Manager. 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	In Process

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