MAYO CLINIC LABORATORIES

Test Definition: PHEP

Previous Hepatitis (Unknown Type), Serum

Overview

Useful For

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

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
HAIGG	Hepatitis A IgG 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 surface antigen (HBsAg) is reactive, then HBsAg confirmation will be performed at an additional charge.

See the following:
-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

HAIGG: Chemiluminescent Microparticle Immunoassay (CMIA)
HBAG, HBAB, HBC, HCVDX, HBGNT: Chemiluminescence Immunoassay (CIA)

NY State Available
Yes

Specimen

Specimen Type
Serum
Serum SST

Necessary Information
Date of draw is required.

Specimen Required
Two aliquots of serum are required for testing: 0.5 mL of refrigerated serum and 2.5 mL of frozen serum.

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: 3 mL
Collection Instructions:
1. Centrifuge blood collection tube per collection tube manufacturer's instructions (eg, centrifuge and aliquot within 2 hours of collection for BD Vacutainer tubes).
2. Aliquot 0.5 mL serum into a plastic vial labeled as HAIGG, and ship refrigerate (required)
3. Aliquot remaining 2.5 mL serum into a second 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 Client Test Request (T728)
-Infectious Disease Serology Test Request (T916)

Specimen Minimum Volume
2.5 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject
Gross icterus	Reject
Heat-inactivate	Reject

d specimen	

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated	5 days	
Serum SST	Frozen (preferred)	28 days	
	Refrigerated	5 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 by drug users). The virus is 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, while 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. HCV is transmitted through contaminated blood or blood products or close, personal contact. It is recognized as the cause of most cases of posttransfusion hepatitis. HCV shows a high rate of progression (>50%) 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 SURFACE ANTIGEN
Negative

HEPATITIS B SURFACE ANTIGEN CONFIRMATION
Negative

HEPATITIS B SURFACE ANTIBODY, QUALITATIVE/QUANTITATIVE

Hepatitis B Surface Antibody
Unvaccinated: negative
Vaccinated: positive

Hepatitis B Surface Antibody, Quantitative
Unvaccinated: <5.0 mIU/mL
Vaccinated: > or =12.0 mIU/mL

HEPATITIS B CORE TOTAL ANTIBODIES
Negative

HEPATITIS A IgG ANTIBODY
Unvaccinated: negative
Vaccinated: positive

HEPATITIS C ANTIBODY
Negative

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

Interpretation depends on clinical setting. See Viral Hepatitis Serologic Profiles.

Interpretation

Hepatitis A:
Antibody against hepatitis A antigen (anti-HAV) is almost always detectable by the onset of symptoms (usually 15-45 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 surface antigen (HBsAg) is the first serologic marker appearing in the serum 6 to 16 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 appears as the immune response following a course of inoculation with the hepatitis B vaccine.

Hepatitis B 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:
Anti-HCV is usually not detectable during the early months following infection but is almost always detectable by the late convalescent stage of infection. Anti-HCV is not neutralizing and does not provide immunity.

Interpretation depends on clinical setting. See Viral Hepatitis Serologic Profiles.

Cautions

Consider administration of immune globulin to the individual exposed to hepatitis A.

Consider administration of hepatitis B immune globulin and/or hepatitis B vaccine to the individual exposed to hepatitis B.

Positive hepatitis B surface antigen test results should be reported by the attending physician to the State Department of Health, as required by law in some 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).

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 >500 mg/dL)
-Containing particulate matter
-Cadaveric specimens
-Immunocompromised or immunosuppressed specimens

Clinical Reference

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2. de Paula VS: Laboratory diagnosis of hepatitis A. Future Virology. 2012 May;7(5):461-472
3. Bonino F, Piratvisuth T, Brunetto MR, Liaw YF Diagnostic markers of chronic hepatitis B infection and disease. Antivir Ther. 2010;15(Suppl 3):35-44
4. Wasley A, Fiore A, Bell BP: Hepatitis A in the era of vaccination. Epidemiol Rev. 2006;28:101-111
5. American Association for the Study of Liver Diseases and Infectious Diseases Society of America: HCV guidance: Recommendations for testing, managing, and treating hepatitis C. Accessed October 7, 2022. Available at www.hcvguidelines.org/contents
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7. Jackson K, Locarnini S, Gish R: Diagnostics of hepatitis B virus: Standard of care and investigational. Clin Liver Dis (Hoboken). 2018 Aug;12(1):5-11. doi: 10.1002/cld.729
8. 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.e3. doi: 10.1053/j.gastro.2018.11.037
9. World Health Organization: WHO guidelines on hepatitis B and C testing. 2017. Accessed October 7, 2022. Available at www.who.int/hepatitis/publications/HEP17001_WEB11.pdf?ua=1
10. Division of Viral Hepatitis, National Center for HIV, Viral Hepatitis, STD, and TB Prevention: Testing and public health management of persons with chronic hepatitis B virus infection. Centers for Disease Control and Prevention. Updated March 28, 2022. Accessed October 7, 2022. Available at www.cdc.gov/hepatitis/hbv/testingchronic.htm

Performance

Method Description

Hepatitis A IgG Antibody:
The ARCHITECT HAVAB-G assay is an automated immunoassay designed for the qualitative detection of hepatitis A virus (HAV)-specific IgG antibody in human serum using chemiluminescent microparticle immunoassay method. Patient's sample, assay diluent, and HAV-coated paramagnetic microparticles are combined first in a reaction well. Anti-HAV IgG present in the patient sample binds to the HAV-coated microparticles. After washing, the acridinium-labeled antihuman IgG conjugate is added to bind to anti-HAV IgG. Following another wash cycle, pre-trigger and trigger solutions are added to the reaction mixture. The resulting chemiluminescent reaction is measured as relative light units. The presence or absence of anti-HAV IgG in the patient sample is determined by comparing the chemiluminescent signal in the reaction to the cutoff signal determined from an ARCHITECT HAVAB-G calibration. Specimens with signal to cutoff (S/Co) values at or above 1.00 are considered positive for anti-HAV IgG. Specimens with S/Co values below 1.00 are considered negative.(Package insert: HAVAB-G. Abbott Laboratories; 04/2020)

Hepatitis B Surface Antigen:
Specimens are first tested by the VITROS hepatitis B surface antigen (HBsAg) assay. With modification to the assay manufacturer's instructions for use, specimens yielding S/Co from 1.00 to 100.0 will be confirmed by the VITROS HBsAg Confirmatory assay. Specimens that are strongly positive (ie, S/Co >100.0) do not require this confirmation.

This immunometric technique involves the simultaneous reaction of HBsAg in the sample with mouse monoclonal 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 are 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, no. GEM1201. Ortho-Clinical Diagnostics, Inc; V13.1, 09/06/2019)

Hepatitis Bs Antigen 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, no. GEM4201_EN_US. Ortho-Clinical Diagnostics, Inc; version 13.1, 09/06/2019)

Hepatitis Bs Antibody:
The VITROS anti-HBs quantitative assay is a chemiluminescent immunoassay based on an immunometric technique in which the anti-HBs present in the clinical serum sample reacts with HBsAg (ad and ay subtypes) coated onto the assay reaction wells. An HRP-labeled HBsAg conjugate (ad and ay subtypes) then complexes with the bound anti-HBs forming an "antigen sandwich." Unbound materials are removed by washing.

A reagent containing luminogenic substrates (a luminol derivative and a peracid salt) and an electron transfer agent are added to the wells. HRP in the bound conjugate catalyzes the oxidation of the luminol derivative to produce light. The electron transfer agent increases the level and duration of the light produced. The light signals are detected by the system. The amount of HRP conjugate bound is directly proportional to the concentration of anti-HBs antibody

present.(Package insert: VITROS Anti-HBs Quantitative Assay, no. GEM1208_US_EN. Ortho-Clinical Diagnostics, Inc; Version 14.004/08/2020)

Hepatitis B Core Total Antibody:
The VITROS anti-hepatitis B core (anti-HBc) assay is a competitive immunoassay method based on the reaction of anti-HBc in the sample with hepatitis B core antigen (HBcAg)-coated wells. Unbound sample is removed by washing. HRP-labeled antibody conjugate (mouse monoclonal anti-HBc) is then allowed to react with the remaining exposed HBcAg on the well surface. Unbound conjugate is removed by washing.

The bound HRP conjugate is measured by a luminescent reaction. A reagent containing luminogenic substrates (a luminol derivative and a peracid salt) and an electron transfer agent are 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 concentration of anti-HBc present in the sample.(Package insert: VITROS Anti-HBc Assay, no. GEM1208_EN_US. Ortho-Clinical Diagnostics, Inc; Version 14.1, 09/06/2019)

Hepatitis C Virus Antibody:
The VITROS anti-HCV assay is performed using an immunometric technique 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 are 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.(Package insert: VITROS Anti-HCV Assay, no. GEM1243_EN_US. Ortho-Clinical Diagnostics, Inc; Version 14.1, 09/06/2019)

PDF Report
No

Day(s) Performed
Profile tests: Monday through Friday; Reflex tests: Varies

Report Available
Same day/1 to 2 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 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
PHEP	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
HAIGG	Hepatitis A IgG Ab, S	40724-7
HCVA4	HCV Ab, S	40726-2