TEST:	Hepatitis A IgM Antibody (Hepatitis A Screen)
Synonym:	HAV IgM, HAVAB-M.
Laboratory/Phone:	**Vaccine Preventable Disease/443-681-3889**
Specimen:	**Serum, plasma**
Specimen identification:	**Label container with patient's last name, first Name, DOB, specimen type, date and time of collection.**
Specimen Volume Required:	2-4 ml.
Specimen Volume Minimum:	2 ml.
Collect:	Venipuncture; Red top vacuum tube, transfer serum to sterile tube with leak-proof cap.
Form:	**DHMH 4677 (Hepatitis A Screen)**
Transport Conditions:	2-8°C-Refer to serology test guideline.
Packaging and Shipping:	Follow packaging and shipping instructions.
Specimen Rejection:	Discrepancy between name on tube and name on form, unlabeled; hemolytic; gross bacterial contamination. Specimens collected > 7 days prior to submission. Refer to serology guideline.
Availability:	**Monday to Friday. Call laboratory for prior approval.**
Results and Interpretation:	Assay results should be interpreted only in the context of other clinical laboratory findings and the total clinical status of the individual. It has been shown that a viremic window exists with individuals infected with HAV, where the individual may be symptomatic for hepatitis but IgM anti-HAV nonreactive. **Negative:** IgM anti-HAV not detected. Does not exclude the possibility of exposure to or infection with HAV. Levels of IgM anti-HAV may be below the cut-off in early infection. **Equivocal/Grayzone:** HAV IgM antibody may or may not be present. Patients exhibiting grayzone test results should be closely monitored by redrawing and retesting approximately one week intervals. Monitoring the level of IgM anti-HAV by redrawing and retesting at approximately one week intervals will distinguish rapidly rising IgM anti-HAV levels associated with early acute hepatitis A infection from gradually decreasing or unchanging IgM anti-HAV levels often associated with late acute stage of HAV infection. **Positive:** HAV IgM antibody detected. Presumptive evidence of HAV infection. A reactive IgM anti-HAV result does not rule out other hepatitis infections.
Reference Range:	Negative.
Additional Information:	For more information, see the CDC link at: http://www.cdc.gov/hepatitis/index.htm
Turnaround Time:	2-6 working days
Method:	Chemiluminescent microparticle immunoassay (CMIA)
Purpose of Test:	HAVAB-M assay is for the qualitative detection of IgM antibody to hepatitis A virus (IgM anti-HAV) in human serum or plasma. IgM anti-HAV is indicated for testing of specimens from individuals who have signs and symptoms consistent with acute hepatitis. Test results are used in conjunction with other laboratory results and clinical information as an aid in the diagnosis of acute or recent hepatitis A viral infection. During the acute phase of HAV infection, IgM anti-HAV appears in the patient's serum and is nearly always detectable at the onset of symptoms. In most cases, IgM anti-HAV response peaks within the first month of illness and can persist for up to six months. It is not intended for use in screening blood, plasma, or tissue donors.
Interfering Substances:	May not detect a recent infection, or infection in a person with severely compromised immune system.
Testing Site:	Central Laboratory 1770 Ashland Avenue, Baltimore, MD 21205.
Comment:	LIMITATIONS**:** Specimens from individuals who have received preparations of mouse monoclonal antibodies for diagnosis or therapy may contain human anti-mouse antibodies (HAMA). Such specimens may show either falsely elevated or depressed values when tested with assay kits (such as HA; HAVAB-M) reagents contain a component that reduces the effect of HAMA reactive specimens. Additional clinical or diagnostic information may be required to determine patient status. A reactive IgM anti-HAV result does not should be used and interpreted only in the context of the overall clinical picture. A negative test result does not exclude the possibility of exposure to hepatitis A virus. Levels of IgM anti-HAV may be below the cut-off in early infection and late acute infection. Heterophilic antibodies in human serum can react with reagent immunoglobulins, interfering with *in vitro* immunoassays. Patients routinely exposed to animals or to animal serum products can be prone to this interference and anomalous values may be observed. Additional information may be required for diagnosis. Specimens from **individuals with Non-Hodgkin's Lymphoma may cross-react with this assay.**

TEST:	**Hepatitis A IgG Antibody.**
Synonym:	HAV IgG, HAVAB-G
Laboratory/Phone:	**Vaccine Preventable Disease/443-681-3889**
Specimen:	**Serum, plasma**
Specimen identification:	**Label container with patient's last name, first Name, DOB, specimen type, date and time of collection.**
Specimen Volume Required:	Serum 2-4 ml.
Specimen Volume Minimum:	2 ml.
Collect:	Venipuncture; Red top vacuum tube, transfer serum to sterile tube with leak-proof cap.
Form:	**DHMH Form 4677 after obtaining prior approval**
Transport Conditions:	2-8°C-Refer to serology test guideline.
Packaging and Shipping:	Follow packaging and shipping instructions.
Specimen Rejection:	Discrepancy between name on tube and name on form, unlabeled hemolytic; gross bacterial contamination. Specimens collected > 7 days prior to submission. Refer to serology guideline.
Availability:	**Service available to government facilities Monday to Friday**
Results and Interpretation:	**Negative:** No detectable IgG antibody to hepatitis A virus. **Positive:** Presence of detectable IgG antibody to HAV. It indicates past HAV infection or confers immunity by HAV vaccination.
Reference Range:	Negative.
Additional Information:	For more information, see the CDC link at: http://www.cdc.gov/hepatitis/index.htm
Turnaround Time:	2-6 working days
Method:	Chemiluminescent microparticle immunoassay (CMIA)
Purpose of Test:	HAVAB-G assay is for the qualitative detection of IgG antibody to hepatitis A virus (IgG anti-HAV) in human serum or plasma. Detectable levels above the assay cut-off suggest immunity to HAV infections
Interfering Substances:	May not detect a recent infection, or infection in a person with severely compromised immune system.
Testing Site:	Central Laboratory 201 West Preston Street Baltimore, MD 21201.
Comment:	LIMITATIONS: If the Architect HAVAB-G results are inconsistent with clinical evidence, additional testing is suggested to confirm the results. Specimens from patients who have received preparations of mouse monoclonal antibodies for diagnosis or therapy may contain human anti-mouse antibodies (HAMA). Such specimens may show either falsely elevated or depressed values when tested with assay kits (such as ARCHITECT HAVAB-G) that employ mouse monoclonal antibodies. Specimens from individuals with **anti-E.coli, anti-CMV, or hemodialysis patients may cross react with this assay.** Heterophilic antibodies in human serum can react with reagent immunoglobulins, interfering with *in vitro* immunoassays. Patients routinely exposed to animals or to animal serum products can be prone to this interference and anomalous values may be observed. Additional information may be required for diagnosis. Specimens containing low antibody concentrations (near the cutoff) assayed after a freeze/thaw may exhibit elevated values that may be false positives.