TEST:	**Hepatitis C Antibody (Hepatitis C Screen)**
Synonym:	HCV Ab; anti-HCV; Hepatitis C Screen
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 4677 (Hepatitis C 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.
Results and Interpretation:	**Negative:** Antibodies to HCV not detected; does not exclude the possibility of exposure to HCV. **Equivocal/Grayzone:** Antibodies to HCV may or may not be present; another specimen should be obtained from the individual for further testing or follow CDC recommendations for supplemental testing. **Positive:** Presumptive evidence of antibodies to HCV; follow CDC recommendations for supplemental testing.
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:	**Anti-HCV assay is for the qualitative detection of antibody to Hepatitis C Virus in human serum or plasma. Assay results, in conjunction with other laboratory results and clinical information, may be used to provide presumptive evidence of infection with HCV (state of infection or associated disease not determined) in persons with signs and symptoms of hepatitis and in persons at risk for hepatitis C infection. It is not intended for use in screening blood, plasma, or tissue donors.**
Interfering Substances:	Test results in an immune compromised patients should be interpreted with caution.
Testing Site:	Central Laboratory 1770 Ashland Avenue, Baltimore, MD 21205.
Comment:	LIMITATIONS: For diagnostic purposes, results should be used in conjunction with patient history and other hepatitis markers for diagnosis of acute and chronic infection. Current methods for the detection of antibodies to HCV may not detect all infected individuals. A nonreactive test result does not exclude the possibility of exposure to HCV. Nonreactive test results in individuals with prior exposure to HCV may be due to antibody levels being below the detection limit of this assay or to lack of antibody reactivity to the recombinant antigens used in this assay. Immunocompromised patients who have HCV may produce levels of antibody below the sensitivity of this assay and may not be detected as positive. The affinity or avidity differences of anti-human IgG/IgM for anti-HCV have not been determined with this assay. Therefore, there may not be a demonstration of a significant increase in antibody level between acute and convalescent specimens for a patient in the late acute stage of infection when IgM antibodies are decreasing. Results obtained with Anti-HCV assay may not be used interchangeably with values obtained with different manufacturers' assay methods. Assay performance characteristics have not been established for newborns, infants, children, or populations of immunocompromised or immunosuppressed patients. 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. A reactive anti-HCV result does not exclude co-infection by another hepatitis virus. The magnitude of an Anti-HCV assay result cannot be correlated to an end point titer.