TEST:	**Hepatitis B Surface Antigen**
Synonym:	HBsAg, Hepatitis B surface Antigen Qualitative; HBsAg Qual.
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 B Screen; Hepatitis B Panel)**
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:** Hepatitis B surface Antigen not detected. **Positive:** Presumptive evidence of Hepatitis B surface Antigen
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:	HBsAg Qualitative assay is for the qualitative detection of hepatitis B surface antigen in human serum or plasma. The assay may also be used to screen for HBV infection in pregnant women to identify neonates who are at risk for acquiring hepatitis B during the perinatal period. Assay results in conjunction with other laboratory results and clinical information, may be used to provide presumptive evidence of infection with the hepatitis B virus (HBV) (state of infection or associated disease not determined) in persons with signs and symptoms of hepatitis and in persons at risk for hepatitis B infection. 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: The effectiveness of the HBsAg Qualitative assay for use in screening blood, plasma, or tissue donors has not been established. Assay performance characteristics have not been established when the HBsAg Qualitative assay is used in conjunction with other manufacturers' assays for specific HBV markers. Current methods for the detection of hepatitis B surface antigen may not detect all potentially infected individuals. A nonreactive test result does not exclude the possibility of exposure to or infection with hepatitis B virus. A nonreactive test result in individuals with prior exposure to hepatitis B may be due to antigen levels below the detection limit of this assay or lack of antigen reactivity to the antibodies in this assay. If the HBsAg Qualitative results are inconsistent with clinical evidence, additional testing is suggested to confirm the result for diagnostic purposes. Results should be used in conjunction with patient history and other hepatitis markers for diagnosis of acute and chronic 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 results may be observed. Additional information may be required for diagnosis. Specimens from patients who have received preparations of mouse monoclonal antibodies for diagnosis or therapy may contain human anti-mouse antibodies (HAMA). Specimens containing HAMA may produce anomalous values when tested with assay kits such as HBsAg Qualitative that employ mouse monoclonal antibodies. A reactive HBsAg result does not exclude co-infection by another hepatitis virus.

TEST:	**Hepatitis B surface Antibody**
Synonym:	HBsAb, Hepatitis B surface Antibody, AUSAB.
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 B Panel, Hepatitis B post vaccine)**
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:** < 8.00 mIU/mL Individual is considered not immune to HBV infection. **Equivocal/Grayzone:** ≥ 8.00 mIU/mL to < 12.00 mIU/mL The immune status of the individual should be further assessed by considering other factors, such as clinical status, follow-up testing, associated risk factors, and the use of additional diagnostic information. **Positive:** ≥12.00 mIU/mL. Individual is considered immune to HBV infection.
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:	AUSAB assay is for the quantitative determination of antibody to hepatitis B surface antigen in human serum or plasma. It is intended for measurement of antibody response following hepatitis B virus (HBV) vaccination, determination of HBV immune status, and for the laboratory diagnosis of HBV disease associated with HBV test results and clinical information. 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: For diagnostic purposes, results should be used in conjunction with patient history and other hepatitis markers for diagnosis of acute and chronic infection. A non-reactive test result does not exclude the possibility of exposure to hepatitis B virus. Results obtained with the AUSAB assay may not be used interchangeably with values obtained with different manufacturers' assay methods. Assay does not differentiate between vaccines and natural infection. Results from immune suppressed patients should be interpreted with caution. Performance characteristics have not been established for therapeutic monitoring. A reactive anti-HBs result does not exclude co-infection by another hepatitis virus.

TEST:	**Hepatitis B Total Core Antibody**
Synonym:	HBc Total Ab; CORE, anti-HBcAb.
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:	**Test cannot be requested it is a reflex test for Hepatitis B Panel (Hepatitis B surface antibody negative specimens).**
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. Refer to serology guideline.
Availability:	Monday to Friday.
Results and Interpretation:	**Negative:** Hepatitis B core antibodies not detected. **Positive:** Hepatitis B core antibodies were detected. The presence of anti-HBc antibodies does not differentiate between acute or chronic hepatitis B 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:	The CORE assay is for the qualitative detection of antibodies to hepatitis B core antigen in human serum or plasma. It is intended as an aid in the diagnosis of acute, chronic, or resolved hepatitis B virus (HBV) infection in conjunction with other laboratory results and clinical information. 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**:** A nonreactive test result does not exclude the possibility of exposure to or infection with HBV. 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 CORE) that employ mouse monoclonal antibodies. 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.

TEST:	**Hepatitis B Core Antibody IgM**
Synonym:	HBc IgM Ab; anti-HBc IgM, CORE-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:	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:	**Test cannot be requested, it is a reflex test for Hepatitis B surface antigen POSITIVE specimens.**
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. Refer to serology guideline.
Availability:	Monday to Friday.
Results and Interpretation:	**Negative:** IgM anti-HBc not detected. Does not exclude the possibility of exposure to or infection with HBV. **Equivocal/Grayzone:** IgM anti-HBc may or may not be present. Patients with specimens exhibiting grayzone test results should be retested at approximately one-week intervals. Monitoring the level of IgM anti-HBc by retesting at approximately one week intervals will distinguish rapidly rising IgM anti-HBc levels associated with early acute hepatitis B infection from gradually decreasing or unchanging IgM anti-HBc levels often associated with late acute stage of HBV infection, six to nine months from the appearance of HBsAg. **Positive:** Presumptive evidence of IgM anti-HBc antibodies.
Reference Range:	Negative.
Additional Information:	For more information, see the CDC link at: http://www.cdc.gov/hepatitis/index.htm
Turnaround Time:	2-7 working days
Method:	Chemiluminescent microparticle immunoassay (CMIA)
Purpose of Test:	The CORE-M assay is for the qualitative detection of IgM antibody to hepatitis B core antigen in human serum or plasma. A test for IgM anti-HBc is indicated as an aid in the diagnosis of acute or recent hepatitis B virus (HBV) infection in conjunction with other laboratory results and clinical information. 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: Current methods for the detection of IgM anti-HBc may not detect all infected individuals. A non-reactive test result does not exclude the possibility of exposure to or infection with HBV. CORE-M assay is limited to the detection of IgM anti-HBc in human serum or plasma. It can be used to determine whether a patient has, or has recently had, acute or subclinical hepatitis B infection. Supportive clinical information, including other hepatitis B markers, should also be evaluated. The test cannot determine a patient's immune status to hepatitis B. Specimens from patients with high levels of IgM (*e.g.*, specimens from patients with multiple myeloma) may show depressed values when tested with assay kits (such as CORE-M) that use reagents containing anti-human IgM. 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 CORE-M) that employ mouse monoclonal antibodies. 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.

TEST:	**Hepatitis B Surface Antigen Confirmation**
Synonym:	HBsAg Qualitative Conformation; HBsAg Qualitative Neutralization assay
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:	**Test cannot be requested, it is a reflex test for Hepatitis B surface antigen POSITIVE specimens.**
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. Refer to serology guideline.
Availability:	Monday through Friday.
Results and Interpretation:	**Confirmed:** Presence of HBs Antigen confirmed. Confirmed result may indicate acute or chronic HBV infection, depending on presence of other HBV serological markers. **Not Confirmed:** Indicates the presence of HBsAg cannot be confirmed via neutralization. The repeatedly reactive result obtained with the HBsAg Qualitative assay may be the result of a nonspecific reaction (false reactive). As the presence of nonspecific binding may obscure low levels of HBsAg in the specimen due to early infection or early recovery, it is recommended that the patient be evaluated for other serologic markers of HBV infection (*i.e.*, total anti-HBc or IgM antiHBc) and that the patient be retested for HBsAg in 4 to 6 weeks.
Reference Range:	Not Applicable
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:	The HBsAg Qualitative confirmation assay is for the qualitative confirmation of the presence of hepatitis B surface antigen (HBsAg) in human serum or plasma by specific antibody neutralization. Assay results, in conjunction with other laboratory results and clinical information, may be used to provide presumptive evidence of infection with the hepatitis B virus (HBV) (state of infection or associated disease not determined) in persons with signs and symptoms of hepatitis and in persons at risk for hepatitis B infection. 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:	Limitation: The effectiveness of HBsAg Qualitative Confirmatory assay for use in screening blood, plasma, or tissue donors has not been established. Assay performance characteristics have not been established when HBsAg Qualitative Confirmatory assay is used in conjunction with other manufacturers' assays for specific HBV serological markers. If HBsAg Qualitative Confirmatory results are Inconsistent with clinical evidence, additional testing is suggested to confirm the result. For diagnostic purposes, results should be used in conjunction with patient history and other hepatitis markers for diagnosis of acute and Chronic 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 results may be observed. Additional information may be required for diagnosis. Specimens from patients who have received preparations of mouse monoclonal antibodies for diagnosis or therapy may contain human anti-mouse antibodies (HAMA). Specimens containing HAMA may produce anomalous values when tested with assay kits such as HBsAg Qualitative Confirmatory that employ mouse monoclonal antibodies. Although there is an association between the presence of HBsAg infectivity and a reactive result, it is recognized that presently available methods for HBsAg confirmation may not detect all possible cases of HBV infection.