GENETRACK Diagnostics

Hepatitis B

WHAT IS HEPATITIS B?

Hepatitis refers to inflammation and damage to the liver. The most common causes of hepatitis are three viruses known as hepatitis A, B, and C. The hepatitis B virus (HBV) is a major global health problem that can cause both acute (short-term) and chronic (long-term) disease (1).

TRANSMISSION

In regions of the world with the highest rates of hepatitis B, perinatal transmission (mother to child at birth) is the most common way that HBV is spread. Horizontal transmission (exposure to infected blood), especially from an infected child to an uninfected child under the age of five years is also common (1).

HBV can also spread through needle stick injury, tattooing, piercing, sharing drug needles and syringes, and other exposures to infected blood, saliva, vaginal, and seminal fluids. Sexual transmission of HBV can occur, with more common occurrences in men who have sex with men, heterosexuals with multiple sex partners, and sex workers (and their clients) (1).

HBV can survive outside the body and remains infectious for at least seven days (2). This is why proper cleaning of environmental surfaces potentially contaminated with HBV is very important (3).

SYMPTOMS

Acute Infection

Many individuals with acute HBV infection remain asymptomatic and are unaware they are infected. However, it is still possible for viral transmission to occur even in the absence of symptoms. In symptomatic individuals, yellowing of the skin or eyes, nausea, vomiting, abdominal pain, dark urine, and fatigue can last several weeks or persist for up to six months (1, 4). The incubation period (from exposure to onset of symptoms) can vary from 30 to 180 days. In rare cases, acute liver failure and death can occur in conjunction with acute HBV infection (1).

Chronic Infection

In some individuals, hepatitis B can develop into a chronic infection. There is an 80-90% chance of chronic infection occurring in infants infected within their first year of life, and a 30-50% chance for children infected before the age of six years. The chance of a chronic infection in adults is much lower, as less than 5% of infected adults develop chronic infections, assuming there are no other health complications (1).

Chronic hepatitis B can develop into cirrhosis or liver cancer. Cirrhosis is when a build up of scar tissue inhibits the normal functioning of the liver. Initially there are no obvious symptoms, but as the disease progresses, signs can include fatigue, weakness, lower leg swelling, yellow skin, fluid accumulation in the abdomen, and the development of spider-like blood vessels on the skin (5). Liver cancer shares many of the same symptoms, as well as feeling nauseous, symptoms of indigestion, and pain at the top right of the abdomen or in the right shoulder (referred pain).

PREVALENCE

Hepatitis B is the most prevalent in the western Pacific region and in Africa, where at least 6% of the adult population is infected. In the United States, a total of 3,322 cases of acute hepatitis B were reported to CDC in 2018, but actual estimates were closer to 21,600 (6).

RISK POPULATIONS

Groups that have an increased risk of hepatitis B include children of hepatitis B-positive mothers, individuals who frequently require blood or blood products, dialysis patients, recipients of solid organ transplantations, incarcerated persons, injectable drug users, close contacts of hepatitis B-infected individuals, individuals with multiple sexual partners, and healthcare workers (1).

DIAGNOSIS

Clinical evaluations are unable to distinguish hepatitis B from hepatitis caused by other viruses (e.g. hepatitis A or C); hence laboratory analyses of blood samples are required for an accurate diagnosis. The most commonly detected component is the hepatitis B surface antigen (HBsAg). This is a part of the HBV, which can be detected within 30 to 60 days after infection, and remains detectable during both acute and chronic infections.

Other laboratory assays detect other components; including hepatitis B core antibody (detectable during an acute infection), hepatitis B e antigen (detectable during the initial phase of infection when there is high virus replication), and hepatitis B surface antibody (indicates past exposure to HBV through vaccination or past infection) (1).

TREATMENT AND PREVENTION

Acute Infection

There are no specific treatments for acute HBV infection. Maintaining an adequate nutritional and fluid intake is important, particularly as additional fluids may be lost through vomiting and diarrhea. Unnecessary medications should be avoided, including acetaminophen, as it can accelerate the liver damage (1).

Chronic Infection

Medications are available for chronic hepatitis B, but only 10% to 40% of individuals with chronic hepatitis B will require treatment. Oral treatments (tenofovir and entecavir) are the recommended medications, as they are the most potent drugs to suppress HBV, have few side effects, and only require a single pill per day. These medications supress the replication of HBV, thereby slowing progression of cirrhosis and reducing the risk of liver cancer, but they generally do not cure an HBV infection, so must continue for life (1).

Complications

Cirrhosis and liver cancer are potential long-term complications of chronic hepatitis B. Cirrhosis treatments include treatment for the underlying hepatitis infection, as well as actions to prevent the disease progressing, such as abstaining from alcohol, avoiding medications that harm the liver, and following a healthy, low-fat diet. Treatment options for liver cancer are limited and it can progress quickly, so disease outcome is generally poor, with most individuals in low-income countries dying within a few months of diagnosis. Where available, surgery and chemotherapy may prolong life for a few years. Liver transplantation has varying success (1).

Prevention

A very effective and safe vaccination for hepatitis B is available. This vaccine induces protective antibody levels in more than 95% of individuals, with protection lasting for at least 20 years and probably lifelong. World Health Organization (WHO) recommendations are for hepatitis B vaccination in all children and adolescents younger than 18 years of age, as well as unvaccinated individuals in high-risk groups,

such as injectable drug users and healthcare workers who may be exposed (1).

Antiviral prophylaxis is also recommended to prevent HBV transmission from mother to child, and should be provided to pregnant women with high levels of HBV nucleic acid (high viral load) (1).

Safe injection practices, quality-assured screening of all donated blood and blood products, and condom use all help protect against HBV transmission (1).

TESTING RECOMMENDATIONS

The CDC recommends HBV screening of individuals born in countries with high HBV prevalence (≥2%), as well as unvaccinated US-born children of parents born in countries with high HBV prevalence. HBV screening should occur in pregnant women, HIV-positive individuals, injectable drug users, men who have sex with men, close contacts of HBV-infected individuals, blood and tissue donors, individuals with end-stage renal disease and those requiring immunosuppressive therapy. Infants born to HBV-infected mothers should also be tested (7).

TEST PROCEDURE

Correct specimen collection and handling is required for optimal assay performance.

This test requires a blood sample from a finger prick. All supplies for sample collection are provided in this kit. First wash and dry hands. Warm hands aid in blood collection. Clean the finger prick site with the alcohol swab and allow to air dry. Use the provided lancet to puncture the skin in one quick, continuous and deliberate stroke. Wipe away the first drop of blood (as it may be contaminated with tissue fluid or skin debris). Massage finger to increase blood flow at the puncture site and hold in a position that gravity facilitates the collection of blood on the fingertip. Transfer the blood to the blood collection card or blood collection tube (microtainer).

Avoid squeezing or 'milking' the finger excessively. If blood flow stops, perform a second skin puncture on another finger if more blood is required.

Dispose of all sharps safely and return sample to the laboratory in the provided prepaid return shipping envelope.

Upon receipt at the laboratory, the blood sample is analyzed by the fully automated Alinity i HBsAg Qualitative II chemiluminescent microparticle immunoassay on the Alinity ci series analyzer. This assay detects hepatitis B surface antigen (HBsAg) in the blood sample. The amount of HBsAg in the blood sample is measured in relative light units by a chemiluminescent reaction.

SPECIAL INSTRUCTIONS

Hepatitis B surface antigen (HBsAg) is usually detectable within 30 to 60 days post exposure (3). A false negative result may occur for specimens collected before HBsAg has reached detectable levels.

TEST INTERPRETATION

A reactive result indicates that HBsAg was detected in the specimen tested. This result is consistent with a current HCV infection, either acute or chronic. Follow up testing is required to distinguish acute and chronic, and evaluate liver damage, carrier status etc.

A negative result indicates that no HBsAg was detected in the specimen tested, and indicates that the individual who supplied the tested sample does not have an active infection. However, it is possible that an acute infection that is resolving will also return a negative result.

An indeterminate result indicates that a new specimen should be tested.

DISCLAIMERS/LIMITATIONS

This report is not intended for use in medico-legal applications. These results are intended for screening for hepatitis B and should be interpreted in conjunction with other laboratory and clinical information.

This test detects active infections (both acute and chronic), but does not detect past exposure to hepatitis B through vaccination or past infection.

Correct specimen collection and handling is required for optimal assay performance.

A false negative result may occur for specimens collected before HBsAg has reached detectable levels. HBsAg is usually detectable within 30 to 60 days post exposure (3).

A false negative result may occur for an acute infection that is resolving. Additional testing is required to confirm this scenario.

A reactive result may occur in the period after hepatitis B vaccination. Usually this is only within 14 days of vaccination (9) but may occur for up to 52 days after vaccination (10).

False results may occur in specimens from individuals that have received preparations of mouse monoclonal antibodies for diagnosis or therapy. Additional clinical or diagnostic information may be required for these specimens.

Assay interference may occur in specimens from individuals routinely exposed to animals or to animal serum products. Additional clinical or diagnostic information may be required for these specimens.

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