GENETRACK Diagnostics

Hepatitis C

WHAT IS HEPATITIS C?

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 C virus (HCV) causes acute (short-term) infections in some individuals, but in most individuals, the virus remains in the body causing serious chronic (long-term) infection.

TRANSMISSION

HCV is usually transmitted through exposure to blood from an infected individual. The most common way that HCV is transmitted is through sharing needles. Other potential sources of infection include at birth (~6% of infants of infected mothers), sexual intercourse (rare but more common in men who have sex with men), healthcare exposures, blood transfusions, and organ transplants (now very uncommon), unregulated tattoos or body piercings, and sharing personal items that have been in contact with infected blood (e.g. glucose monitors, razors) (1).

SYMPTOMS

Many individuals with acute HCV 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, lack of appetite, diarrhea, vomiting, fever, dark urine, joint pain, and fatigue can occur between two and twelve weeks post-exposure (1).

More than 50% of individuals infected with HCV develop a chronic infection (2). Most individuals with chronic HCV also remain asymptomatic or only show general symptoms such as fatigue or depression. Over several decades, mild to severe liver disease develops in most affected individuals, including cirrhosis (5-25% of cases) and liver cancer (3). Several factors increase the risk of the development of cirrhosis in HCV infected individuals, including being male, >50 years, increased alcohol consumption, hepatitis B or HIV coinfection, and immunosuppressive therapy (3). Chronic HCV infection is a common reason for a liver transplant in the United States (4). Due to a general lack of symptoms, often individuals infected with HCV are only diagnosed through screening for blood donation or during a routine health check up (1).

PREVALENCE

In 2018, there were 3,621 new cases of HCV reported to CDC. However, actual estimates are closer to 50,300 new cases during 2018 (5). During 2013-2016, there were an estimated 2.4 million individuals in the United States with chronic HCV (6). In 2018, there were 15,713 US death certificates with HCV recorded as an underlying or contributing cause of death (5), but actual numbers are estimated to be considerably higher (7).

RISK POPULATIONS

Individuals who have an increased risk of HCV include individuals with HIV infection, current or former injectable drug users, individuals on hemodialysis, individuals who have received blood or organ donations prior to July 1992 or clotting factors before 1987, health care personnel who may be exposed to blood from HCV individuals, and children born to HCV-positive mothers (1).

DIAGNOSIS

HCV diagnosis is by laboratory analyses of a blood sample. The initial test detects HCV antibodies that are produced by the immune system of an infected individual in response to the HCV infection. The presence of HCV antibodies indicates that an individual has either a current or past HCV infection. Additional testing to detect HCV RNA is required to diagnose an active infection and determine the viral load.

TREATMENT

Individuals who are diagnosed with HCV should be provided with a medical evaluation for liver disease, vaccinations for hepatitis A and B, HIV testing, and advice regarding reduced alcohol consumption and weight management for overweight and obese individuals. Affected individuals should not donate blood, tissue, or semen, and refrain from sharing items that may come into contact with blood (e.g. razors, glucose meters, toothbrushes). Any cuts or sores on the skin should be covered to reduce the risk of HCV transmission.

There is currently no available vaccine for HCV, because there are seven HCV genotypes and 67 subtypes (8) and the virus mutates rapidly (9). Treatment options for HCV vary depending on HCV genotype, viral load, stage of infection, liver damage, and any other health complications. Most individuals with an acute infection are unaware of the HCV infection so the majority of newly diagnosed individuals are already in the chronic stage of HCV. Spontaneous clearance of HCV from an acute infection is also possible, and is more common in younger females, individuals infected with HCV genotype 1, and individuals with certain genetic polymorphisms, particularly near the IL28B gene (2). Despite the chance of spontaneous clearance from acute HCV, treatment should still begin for most affected individuals (10).

HCV is treated with antiviral medications to eliminate HCV from the body. Newly developed “direct-acting” antivirals have improved HCV treatment considerably with fewer side effects and shorter treatment periods. Nowadays, over 90% of individuals infected with HCV can be cured with 8-12 weeks of oral therapy (11). Effective treatment slows down the progression of inflammation and scarring of the liver and reduces the chances of liver cancer. However, antivirals do not help repair any tissue damage that has already occurred. Serious complications from HCV may result in a necessary liver transplant (10).

TESTING RECOMMENDATIONS

The CDC recommends universal HCV screening at least once in a lifetime for all adults and for all pregnant women during each pregnancy, except in populations where the prevalence of HCV is less than 0.1%. HCV testing should occur in HIV-positive individuals, anyone who has ever injected drugs, individuals with abnormal liver tests and/or liver disease, and in anyone who received donated blood or organs before July 1992 or clotting factor concentrates before 1987. Anyone who has been potentially exposed to the blood of an infected individual should get tested. Regular testing is recommended for individuals who currently use injectable drugs or are on hemodialysis (12).

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 Anti-HCV chemiluminescent microparticle immunoassay on the Alinity ci series analyzer. This assay detects antibodies to recombinant HCr43 and c100-3 antigens representing core, NS3, and NS4 regions of the HCV genome. The amount of anti-HCV in the blood sample is measured in relative light units by a chemiluminescent reaction.

SPECIAL INSTRUCTIONS

HCV antibodies may be detected 1-2 weeks after exposure (14), but are generally not detected until 8-11 weeks post-exposure, and can be longer in individuals that lack an adequate immune response (15). A false negative result may occur for specimens collected before antibodies have reached detectable levels.

Reactive results from this HCV antibody test should be followed up with additional laboratory testing.

TEST INTERPRETATION

A reactive result indicates that HCV antibodies were detected in the specimen tested. This result is consistent with a current HCV infection, or a past infection that has resolved, or a biologic false positivity for HCV antibody. Follow up testing for HCV nucleic acid (RNA) is required to identify a current infection.

A negative result indicates that no HCV antibodies were detected in the specimen tested. If recent exposure to HCV is suspected, testing for HCV nucleic acid (RNA) is recommended.

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 HCV and should be interpreted in conjunction with other laboratory and clinical information.

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

A negative result does not exclude the possibility of infection. False-negative test results may occur due to improper specimen collection, or HCV antibody levels below the sensitivity of this assay. Antibodies may be detected as early as two weeks post-exposure, but are generally not detected until 8-11 weeks post-exposure, and can be longer in individuals that lack an adequate immune response (15).

A reactive result does not confirm a current HCV infection, as both resolved infections and current infections would return a positive result. False-positive results are rare. Follow up testing for HCV nucleic acid (RNA) is required to identify a current infection.

If an individual is undergoing heparin therapy, the specimen for testing should be collected prior to heparin therapy to prevent erroneous results from partial coagulation.

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