



HCSP FACT SHEET

HCV ADVOCATE

• HCV DIAGNOSTIC TOOLS •

Overview

HCV Diagnostic Tests

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A variety of different tests are used to diagnose hepatitis C.

These include:

- HCV Antibody Test
- HCV Viral Load Test or HCV RNA Test
- HCV Genotype/Subtype Test
- Liver Biopsy
- Fibroscan
- Non-Invasive Tests
- Staging Liver Disease

HCV Antibody Tests

When a person is exposed to HCV, the immune system produces proteins called antibodies against the virus. It usually takes the immune system a few weeks to develop enough antibodies to be detected by an antibody test, but it could take as long as six months. There are two commercial antibody tests used to detect HCV antibodies—HCV EIA (HCV ELISA) and CIA. The most common HCV antibody test is the HCV EIA or ELISA. A positive HCV antibody test will only confirm that someone has been infected with the hepatitis C virus at one time; an HCV RNA viral load test will need to be performed to find out if someone is actively infected with the hepatitis C virus.

In 2011 the FDA approved the OraQuick Rapid Antibody Test (finger prick and whole blood draw) that allows for test results to be given after 20 minutes. The FDA also approved the CLIA waiver that allows testing in non-traditional medical environments.

Once people are exposed to hepatitis C, they will retain HCV antibodies for life even if the body is able to eliminate the hepatitis C virus either naturally or if the person is cured by medical treatment. It is also important to remember that HCV antibodies do not protect people from infection or re-infection of hepatitis C.

HCV RNA (Viral Load) Tests

A viral load test measures the amount of HCV RNA (genetic material) in the blood. This test is used to confirm active HCV infection. There are two types of viral load tests:

- **Qualitative:** Measures the presence of the virus in the blood. This type of test is usually used to confirm initial and chronic infection with HCV. If HCV RNA is

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The information in this fact sheet is designed to help you understand and manage HCV and is not intended as medical advice. All persons with HCV should consult a medical practitioner for diagnosis and treatment of HCV.

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detected, a positive result is reported; if HCV RNA is not detected, the test result is negative

- **Quantitative:** Measures the amount of virus in the blood. This test generally is used for HCV treatment to determine if a patient is responding or has responded to treatment.

Scientific studies have not found any correlation between viral load and disease progression.

A viral load test requires a blood sample.

Genotype / Subtype Test

There are several strains of hepatitis C, called genotypes. These strains are very similar but have enough genetic diversity to classify them into seven major genotypes: 1, 2, 3, 4, 5, 6 and 7. Genotype 1 is the most common genotype (70-75%) in the United States, followed by genotypes 2 and 3 (25-30%). Genotypes 4, 5, 6 and 7 are less prevalent in the United States.

Additionally, a genotype may be further classified into subtypes, such as genotype 1a, 1b, etc. In a study published in 2010 it was found that the genotype distribution in the United States was 62.8% for genotype 1a; 12.4% genotype 3a; 10.9% genotype 1b, and 8.2% for genotype 2b. Other genotypes/subtypes were found, but the number of patients with the other genotypes was less than 6%.

A genotype/subtype test is generally given to someone who is considering HCV medical treatment and is only performed once since a person's genotype remains the same throughout the course of the disease unless they become re-infected with another genotype. Genotype and subtype tests require a blood sample

Liver Biopsy

Liver biopsies are used to measure the extent of liver damage, including the degree of inflammation, the extent of fibrosis (fibrous tissue), and the general health of the liver. The most common type of liver biopsy is the percutaneous biopsy (through the skin). An ultrasound

test might be performed before the procedure to locate the area where the needle is to be inserted and to look for any abnormalities. A medical professional will use a local anesthetic to numb the skin and muscle where the needle will be inserted. A tiny piece of the liver is drawn out through the needle.

The actual procedure to extract the liver specimen only takes a few seconds. After the procedure a patient will be required to lie on their right side (where the needle was inserted) for a few hours so that they can be monitored. About 30-50% of people experience mild to moderate pain. Complications from a liver biopsy rarely occur (1 in 1,000 biopsies or less). If necessary, people can ask their medical professional for a mild tranquilizer before a biopsy and for pain medication after the procedure.

The liver biopsy is generally only performed once, but it may be performed every 5-7 years to gauge disease progression. To view a percutaneous liver procedure go to: <https://youtu.be/ug3n7bvq2Wg>

Due to the cost and the potential health risks the alternatives listed below are replacing the percutaneous liver biopsy.

Fibroscan

The Fibroscan is an approved painless imaging test that is used to evaluate the amount of scarring (if any) of the liver. While the Fibroscan isn't 100% accurate, it has been shown to have a very high degree of accuracy for predicting mild fibrosis, severe fibrosis and cirrhosis. It is less likely to distinguish between no or minimal fibrosis. Furthermore, although not 100% accurate there have been studies that have found that combining the Fibroscan and Fibrometer—a blood test that measures certain blood markers—can provide an 87% accuracy. The Fibroscan is approved by the Food and Drug Administration. To view a Fibroscan procedure go to: <https://www.youtube.com/watch?v=kwUihV5bAdQ>

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Non-Invasive Liver Tests

There are other non-invasive tests used to stage the level of damage in the liver including the MP3, Fibrotest, Hepascore, Forns score, and APRI that combine a variety of blood tests to ascertain the level of damage in the liver.

Staging Liver Disease

Metavir

There are various models used to grade and stage the degree of liver damage. The most common one used for hepatitis C is the Metavir that grades fibrosis on a 5-point scale from 0-5. There is also a 4-point scale for inflammation 0 - 3.

Fibrosis Scale:

- Stage F0 = no fibrosis
- Stage F1 = mild fibrosis
- Stage F2 = moderate fibrosis
- Stage F3 = bridging fibrosis
- Stage F4 = cirrhosis

Inflammation Scale:

- A0 = no activity
- A1 = mild activity
- A2 = moderate activity
- A3 = severe activity

It is important to know that within each stage and level of activity there can be a wide variance of inflammation and disease. The Medivir is widely used because it is simple, and easy to use and understand. There are, however, other scoring systems available such as the Knodell that are much more complex.

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