a series of fact sheets written by experts in the field of liver disease

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# An Overview of 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 test
- Liver biopsy

### HCV Antibody Tests

When a person is exposed to HCV, the immune system produces 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 three commercial antibody tests used to detect HCV antibodies – HCV EIA, (HCV ELISA), CIA and HCV RIBA. 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 order to tell if the antibody positive response is a true antibody response there are confirmatory HCV antibody tests, such as the HCV RIBA and the signal-to-cut-off (s/co) ratio.

The HCV RIBA test may be used to test for HCV antibodies, but it is generally only used to confirm a positive result from an HCV EIA in a person with no known risk factors or in people with an existing autoimmune disease. Another recommendation for confirmatory antibody testing is a screening test called the signal-to-cut-off (s/co) ratio.

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 with medical treatment. It is important to note that HCV antibodies do not protect people from infection or re-infection of hepatitis C. *An HCV antibody tests requires a blood sample. For more information about HCV antibody tests see the HCSP Fact Sheet:* HCV Antibody Tests.

### 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 and can also help predict whether treatment is likely to be effective, and show whether HCV medications are working. There are two types of viral load tests – qualitative (measures the presence of the virus) and quantitative (measures the amount of virus). Medical studies have not found any correlation between viral load and disease progression. In other words, the amount of HCV RNA in the blood does not mean a person will be healthier or sicker.

In the past, viral load tests that measured the amount of the hepatitis C virus were reported in copies. Now, viral load tests are reported in international units in an attempt to standardize measurement between different brands of tests. Viral load test results are expressed as low (under 800,000 IU/mL) or high (over 800,000 IU/mL). There is evidence that the current cut-off between low and high viral load may be set too high. The newer studies have shown that people with a viral load under 400,00 IU/mL respond better than those who have a viral load above 400,000 IU/mL.

*A viral load test requires a blood sample.*

## Glossary of Terms

ANTIBODY (IMMUNOGLOBULIN): a protein produced by plasma cells (a type of immune system white blood cell) when they encounter foreign invaders. Specific antibodies bind to specific invaders, or antigens, and target them for destruction. The presence of antibodies indicates current infection with or past exposure to a pathogen.

ANTIBODY POSITIVE (SEROPOSITIVE): the presence in the blood of antibodies against a specific pathogen such as HCV.

ANTIBODY TEST: an assay that detects the presence of antibodies in a blood sample; ELISA and RIBA tests are used to detect HCV antibodies.

BRANCHED-CHAIN DNA ASSAY (bDNA): a test that measures the amount of virus (viral load) in plasma or tissues using a chemical signal emitted by viral genetic material.

ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA, ELISA II): a laboratory test used to detect the presence of antibodies in the blood.

GENETIC MATERIAL: deoxyribonucleic acid (DNA) and ribonucleic acid (RNA), the molecules that carry hereditary information.

HCV RNA: the genetic material of the hepatitis C virus. A detectable level of HCV RNA on a viral load test indicates that HCV is actively replicating.

POLYMERASE CHAIN REACTION (PCR): a highly sensitive test that uses an amplification technique to detect small amounts of genetic material (DNA or RNA) in a blood or tissue sample.

RIBONUCLEIC ACID (RNA): a single-stranded nucleic acid that encodes genetic information. RNA is made up of sequences of four building blocks: adenine, cytosine, guanine, and uracil. The presence of viral RNA in the blood indicates that a virus is actively replicating.

WINDOW PERIOD: the time between exposure to a microorganism and the production of sufficient antibodies to be detected on a test.

### *Genotype Test*

There are several strains of hepatitis C, called genotypes. These strains are very similar but have enough genetic differences to classify them into six major genotypes: 1, 2, 3, 4, 5, and 6. Additionally, a genotype may be further classified into subtypes, such as genotype 1a, 1b, etc. Genotype 1 is the most common genotype (70-75%) in the United States, followed by genotypes 2 and 3 (25-30%). Genotype information is important when considering HCV treatment because it can help predict treatment response. For example, treatment with pegylated interferon plus ribavirin is predicted to work approximately 50% of the time for people with genotype 1 and about 70- to 90% of the time for people with genotypes 2 or 3.

A genotype 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.

*A genotype test requires 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 ultra sound 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 patients will be required to lay 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. Because the rate of disease progression is faster in someone who is co-infected with HIV and hepatitis C, a liver biopsy is generally recommended every 3-5 years for this population.

There is a lot of research into various blood tests or markers to replace the liver biopsy, but currently the liver biopsy is the best diagnostic tool for gauging the health of the liver.

## *Be Sure to Check Out the Other Factsheets in this Series – HCV Diagnostic Tools*

- *An Overview of HCV Diagnostic Tests*
- *Grading and Staging a Liver Biopsy*
- *HCV Antibody Tests*
- *HCV Genotype and Quasispecies*
- *HCV Viral Load Tests*
- *Liver Biopsy*
- *Non-Invasive Markers of Liver Fibrosis*
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A publication of the Hepatitis C Support Project

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