



## HCV Viral Load Tests

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### FORWARD

Viral load tests are blood tests that measure HCV ribonucleic acid (RNA, or genetic material) in the blood. The presence of viral RNA indicates that the virus is actively replicating (reproducing and infecting new cells). A viral load test is usually first done after a person has tested positive for exposure to HCV based on an antibody test. A blood sample is taken and the amount of HCV RNA in a milliliter of blood is measured. Viral load tests confirm whether an individual is actively infected with HCV. Viral load test results are reported in terms of International Units per milliliter (IU/mL).

### Types of HCV Viral Load Tests

*There are two categories of HCV viral load tests:*

- **Qualitative viral load tests** — These tests determine the presence of HCV RNA in the blood. This type of test is usually used to confirm chronic infection with HCV. If viral RNA is detected, a positive result is reported; if viral RNA is not detected, the test result is negative.
- **Quantitative viral load tests** — These tests measure the amount of virus in one milliliter of blood. In the past the level of the viral load was correlated with the chances of responding to HCV treatment, but it is less important with the HCV direct-acting antiviral medications.

*There are currently three tests commonly used for HCV viral load testing:*

- **Polymerase chain reaction (PCR)** — PCR tests detect HCV RNA in the

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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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blood, which indicates current active infection. This type of quantitative PCR test is very sensitive, and can measure as few as 5-10 IU/mL.

- **Branched-chain DNA (bDNA)** — The bDNA method quantitative viral load testing is easier (and cheaper) to use for a large number of samples, but only measures viral loads greater than 615 IU/mL. This means that if a person has a viral load below 615 IU/mL, HCV could be present in the blood but not be detected by the test. However, the test will detect higher viral load ranges so it is useful when beginning HCV therapy.

**Transcription-mediated amplification (TMA)**

— TMA technology allows for the amplification and detection of nucleic acids (components of genetic material) in the blood. This test can measure as few as 5-10 IU/mL. This newer test appears easier and cheaper to use, streamlining test processing and producing consistent, reliable, and more rapid results.

**Interpreting Viral Load Test Results**

HCV viral load is often reported as low or high.

Expressed as International Units (IU/mL):

- Low: less than 800,000 IU/mL
- High: more than 800,000 IU/mL

If no HCV RNA is found by a test, a person's viral load is said to be undetectable. Note that whether viral load is undetectable depends on which test is used. PCR and TMA tests can measure viral loads much lower than a bDNA test can detect. Importantly, the blood of an individual with a very low viral load may still contain HCV even though the current tests cannot

measure it; that is, the virus may not have been truly eradicated from the body.

Viral load test results can vary depending on how a blood sample is handled and stored. Furthermore, results may vary from lab to lab. For this reason, most experts recommend that people should get their viral load testing done by the same laboratory each time, so that results are more comparable.

Changes in viral load are sometimes expressed in terms of logs. A log change is a 10-fold increase or decrease.

***Note:** A log drop in viral load is measured by decreasing the number by one zero. For instance, a one log drop in a viral load of 1,000,000 International Units is 100,000 International Units; a two log drop in a viral load of 1,000,000 International Units is 10,000 International Units*

**Uses of Viral Load Test Results**

Viral load test results have many uses, such as confirming active HCV infection, and measuring HCV treatment response before, during, and after therapy.

**Confirming active HCV infection**

— After a person has tested positive for HCV antibodies, an HCV viral load test is usually performed to confirm active HCV infection. This test is necessary because in 25-45% of people exposed to HCV, the body's immune system can naturally clear the virus out of the body.

The body's immune system can completely resolve an acute infection in some cases. If HCV antiviral treatment results in a undetectable HCV RNA or viral load 12 weeks post treatment it is called a sustained virological response, commonly referred to as a viral cure.

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**Before treatment** — A viral load test will be performed to establish a baseline measurement.

**During treatment** — Viral load measurements are taken at certain time points during treatment to make sure that the medications are working.

**After treatment** — Viral load measurements can be used after cessation of therapy to monitor for relapse — that is, to see if the virus becomes detectable again after being undetectable when treatment was completed. If the viral load is undetectable 12 weeks post treatment is it considered a sustained virological response (SVR) or commonly referred to as a viral cure.

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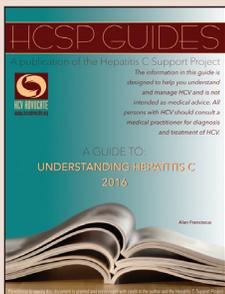
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