



hepatitis C BASICS

•••• **HCV Viral Load Tests** ••••

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Viral load tests are blood tests that indicate the presence and measure the amount of hepatitis C virus (HCV) in the blood. HCV contains RNA, which is the genetic material that helps it replicate, i.e., make more copies of itself. Finding HCV RNA in the blood tells us that the virus is making more copies of itself and infecting new liver cells. After a person tests positive for HCV antibodies, the viral load test is performed to confirm the presence of HCV RNA. To do this, a blood sample is taken and the amount of HCV RNA in the blood is measured. This test is important because about 15 to 45% of people who get HCV will be able to fight off the virus naturally by using the body's immune system.

The more virus someone has (HCV viral load) the easier it may be to pass HCV from a mother to her infant during pregnancy or birth – although this information needs to be studied more and confirmed. HCV is not spread from daily contact with someone. It also is not very common to spread HCV by having sex if someone is in a long-term monogamous relationship. HCV

spreads through contact with blood. HCV is not spread from daily contact with someone.

Having a lot of virus (high viral load) does not mean that you will get sicker more quickly, but it does predict how well the medicines will work.

••••• **Uses of Test Results** •••••

••••• Viral load test results have many uses. You may be tested ••••• for your viral load:

••••• **Before you start taking medicine** — A viral load test ••••• can help tell if someone has hepatitis C and how well ••••• treatment is predicted to work. People with low viral ••••• loads before treatment are more likely to get rid of the ••••• virus.

••••• **During treatment** — A decrease in viral load while on ••••• treatment usually means that treatment is working. The ••••• phrase “complete virological response” means that the ••••• viral load can’t be detected anymore. After 12 weeks of ••••• treatment, an early virological response – “2-log drop ••••• (from 1,000,000 to 10,000)” or “undetectable” viral load ••••• – means the medications are working. If someone does ••••• not have either of these happen, he or she will probably ••••• not be able to get rid of HCV from his or her body. Most ••••• people would stop treatment at this point.

••••• **After treatment** — Viral load tests can be used after ••••• finishing treatment to see if the virus “comes back,” or ••••• becomes detectable again in the blood. This is called ••••• “viral breakthrough.” This happens when viral load goes ••••• so low that tests can’t find it, and then, after treatment, ••••• comes back. Testing can help a doctor make sure this ••••• has not happened. If the viral load test comes back as ••••• negative six months after stopping treatment then the ••••• term used is “sustained virological response” (SVR). ••••• Some experts call this a ‘cure.’

Understanding Test Results

After taking one of these tests, HCV viral load is usually reported as either “low” or “high.” Viral load test results used to be measured by “number of copies” of the virus, but are now usually reported in terms of “International Units per milliliter.”

| | <u>Copies</u> | <u>International Units (IU/mL)</u> |
|---------|---------------------|------------------------------------|
| • Low: | less than 2 million | less than 800,00 |
| • High: | more than 2 million | more than 800,000 |

Some recent studies have suggested that the cut-off between low and high viral load may be set too high. These studies have shown that people with a viral load under 400,000 IU/mL respond better to current medications compared to those who have a viral load above 400,000 IU/mL. In addition the studies did not find that having a higher viral load above 400,000 IU/mL lowered the chances of responding to current HCV treatment. In other words people who had a viral load of 1,000,000 IU/mL responded about the same as people with 400,000 IU/ml. More studies are needed to confirm this.

If the test does not find the virus, a person’s viral load is said to be “undetectable.” It is important to remember that if one test cannot find any virus, a different test might find “low” amounts. The blood of a person with a very low viral load still has a small amount of HCV. This can happen even if the tests cannot measure it. It is important to continue treatment to get rid of all of the virus from the body.

Test results can change depending on how a blood sample is handled and stored. Also, results may be different from one lab to another. This is why most doctors say that people should get their testing done by the same lab each time. It helps to make sure that the test results can be compared over time.

Changes in viral load are sometimes expressed in terms of “logs.” A “log drop” is a 10-fold change in viral load. (Take one zero off the end of the starting number for each “log drop”)

| Example: | |
|---------------------|-----------|
| Starting viral load | 1,000,000 |
| one-log drop | 100,000 |
| two-log drop | 10,000 |

Types of Tests

Qualitative (Quality) viral load tests – This type of test tells us **if** there is any HCV RNA in the blood, but **it does not tell us how much** is present. If HCV is detected, a positive result is reported; if HCV is not detected, the test result is negative.

Quantitative (Quantity or number) viral load tests – These tests measure **how much** of the virus is in your blood. They are often used to predict how well treatment will work. If treatment has already been started, they can also be used to find out if treatment is working.

There are 3 types of technology that are used to perform a viral load test:

■ **PCR** (Polymerase chain reaction) – PCR tests measure HCV RNA in the blood to tell if there is an active infection. They can measure small amounts of virus [5-10 IU/mL].

■ **bDNA** (Branched-chain DNA) – The bDNA test only measures medium to high viral loads above 50 IU/mL. This means that if a person has a viral load below 50 IU/mL, this test may not be able to detect the virus.

■ **TMA** (Transcription-mediated amplification) – The TMA test is also a test that measures the HCV RNA in a blood sample. This test can measure very small amounts of virus (as few as 5-10 IU/mL).

Changing “copies per milliliter” to “International Units”

There is no set way to change the amount of HCV RNA from “copies per milliliter” to “International Units (IU).” Your lab report will often list both. Table 1 lists examples of how they compare, depending on the test used.

Test Type (Assay) Conversion Factor

| | |
|--------------------------------------|-------------------------|
| Amplicor HCV Monitor v2.0 | 1 IU/mL = 0.9 copies/mL |
| Cobas Amplicor HCV Monitor v2.0 ... | 1 IU/mL = 2.7 copies/mL |
| Versant HCV RNA 3.0 Quantitative ... | 1 IU/mL = 5.2 copies/mL |
| Cx HCV RNA Quantitative | 1 IU/mL = 3.8 copies/mL |
| SuperQuant | 1 IU/mL = 3.4 copies/mL |

Understanding viral load and how it is used in the treatment of hepatitis C will help you see how well your treatment is working. It will also help you talk to your doctor about your own test results.

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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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