

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

HCV Diagnostic Tools: HCV Antibody Tests

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When a person is infected with 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. A person who has been recently infected with HCV may be in the window period – the time it takes between initial infection and the development of antibodies. The average time it takes for people to develop HCV antibodies is 2 months but can take as long as 6 months; however, this is uncommon.

In people with a compromised immune system (organ transplant recipients and HIV-positive patients) the body might not be able to develop enough antibodies to be detected by a test. Studies have found that anywhere between 8 and 10% of people with HIV and hepatitis C do not develop HCV antibodies. For this reason, it is recommended that persons with HIV who have a known risk factor for HCV, but who test antibody negative, get tested for HCV RNA (viral load) test.

The most common type of HCV antibody tests is the enzyme immunoassay (EIA) – (manufacturers–Abbott, Bio-Rad, Innogenetics, Ortho). In populations with a high risk for acquiring HCV, the accuracy of these tests

is up to about 99%. The HCV antibody tests are very sensitive so rarely will they be false-negative unless the person is in the window period.

If a person with little or no risk factors tests positive for the HCV antibody with the EIA test, a RIBA antibody test can be used to prove or disprove the EIA results.

Signal-to-cut-off (s/co) ratio

The method for determining a positive HCV antibody test is a complicated process that records how strongly a blood sample reacts during the HCV antibody test. In order to have confidence that the antibody is truly a positive test result, a system has been developed to retest a positive EIA result to predict the accuracy of the results.

Studies to determine the accuracy of the antibody tests were conducted using the EIA and confirming it with a RIBA test. It was found that if the “signal” or strength of the reaction was above a certain number (signal) then it was a true positive result. In the case of the s/co ratio, once the signal reaches a certain point, it was found that there was a 95% chance that the test provided a true positive HCV antibody result. This was verified by repeated testing of the original antibody blood sample.

The s/co ratio was developed because the RIBA and the HCV RNA (viral load) tests are expensive. Many private and public health organizations do not have the resources or money to spend on further testing; but since the s/co ratio has such a high accuracy rate, people can be identified and then referred to follow-up medical care. The Centers for Disease Control and Prevention recommend labs use s/co and consider a positive antibody test to be confirmed when it is used.

It is important to remember that an HCV RNA (viral load) test will need to be performed to confirm active HCV infection since about 25 to 45% of people will naturally clear HCV from the body.

Currently, an HCV antibody requires a blood sample through a fingerstick or blood draw. There will soon be a rapid HCV antibody test that can give results within 20 minutes.

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.

OraSure is currently developing and testing an oral fluid rapid HCV antibody test. OraSure is expected to seek FDA marketing approval for their oral antibody test in 2008.

Once a person is infected with hepatitis C he or she will retain HCV antibodies for life even if the body is able to eliminate the hepatitis C virus from the body naturally or with medical treatment. It is important to note that HCV antibodies do not protect people from infection or re-infection by hepatitis C

Be sure to check out the other Factsheets in the HCV Diagnostic Tools series

- Diagnostic Tests
- Genotype and Quasispecies
- Grading and Staging a Liver Biopsy
- Liver Biopsy
- Reading a Lab Report: A Basic Primer
- Viral Load Tests

For more information about hepatitis C, hepatitis B and HCV coinfections, please visit www.hcvadvocate.org.

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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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