



## HCV Antibody Tests

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### FORWARD

When a person is infected with the hepatitis C virus (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 those who are HIV-positive) 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 coinfecting 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 test is the enzyme immunoassay (EIA and Elisa) – (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, the signal-to-cut-off (s/co) ratio or a viral load test will be performed.

### 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.

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### HCSP FACT SHEET

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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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Studies to determine the accuracy of the antibody tests were conducted using the EIA and confirming it with a RIBA test (highly accurate in all populations). 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 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.

Currently, an HCV antibody requires a blood sample through a fingerstick or blood draw. OraSure Technologies’ OraQuick HCV Rapid Antibody Test using blood draw and finger prick has been approved and CLIA waived by the Food and Drug Administration (FDA). The OraQuick HCV Antibody Test will allow for results to be given after 20 minutes.

It is important to remember that an HCV RNA (viral load) test will need to be performed to confirm active HCV infection. Up to 45% of people who are initially infected with HCV will naturally clear it from the body.

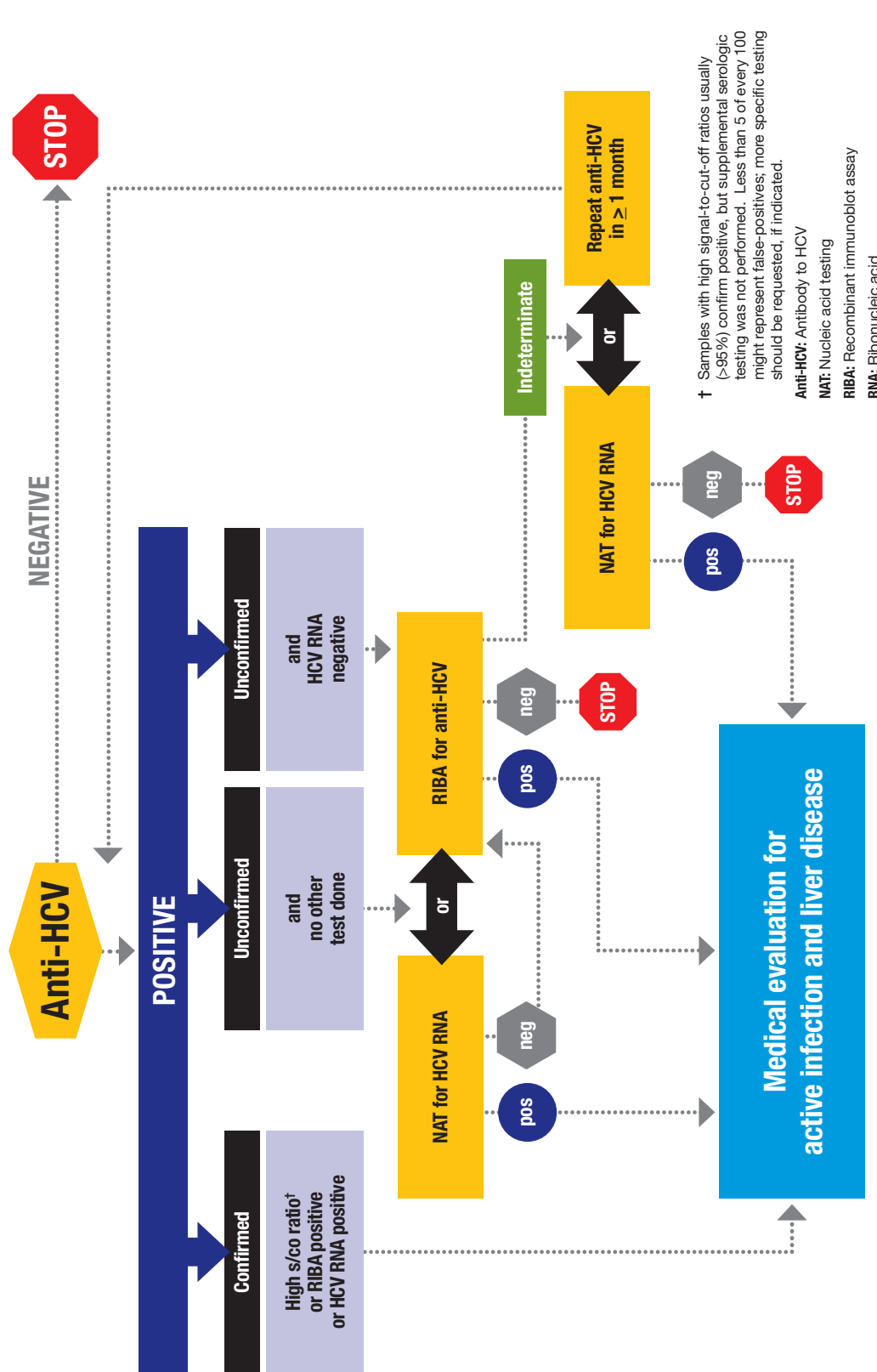
Once a person is infected with hepatitis C he or she will retain HCV antibodies for life even if the body is able to eliminate the hepatitis C virus from the body naturally or through medical treatment. It is important to note that HCV antibodies do not protect people from infection or re-infection by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

Screening Test Kit Name	Manufacturer	Assay Format	Signal-to-cut-off ratio predictive of a true positive ≥ 95% of the time
Ortho HCV Version 3.0 ELISA Test System	Ortho	EIA (Enzyme Immunoassay)	≥ 3.8
Abbott HCV EIA 2.0	Abbott	EIA (Enzyme Immunoassay)	≥ 3.8
VITROS Anti-HCV	Ortho	CIA (Chemiluminescent Immunoassay)	≥ 8.0
AxSYM Anti-HCV	Abbott	MEIA (Microparticle Immunoassay)	≥ 10.0
Architect Anti-HCV	Abbott	CMIA (Chemiluminescent Microparticle Immunoassay)	≥ 5.0
Advia Centaur HCV	Bayer	CIA (Chemiluminescent Immunoassay)	≥ 11.0

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**Hepatitis C Virus (HCV) Infection Testing for Diagnosis**



† Samples with high signal-to-cut-off ratios usually (>95%) confirm positive, but supplemental serologic testing was not performed. Less than 5 of every 100 might represent false-positives; more specific testing should be requested, if indicated.  
 Anti-HCV: Antibody to HCV  
 NAT: Nucleic acid testing  
 RIBA: Recombinant immunoblot assay  
 RNA: Ribonucleic acid



DEPARTMENT OF HEALTH & HUMAN SERVICES  
 Centers for Disease Control and Prevention  
 Division of Viral Hepatitis



www.cdc.gov/hepatitis

# Glossary of Terms

*The glossary below lists some of the terms most commonly used in diagnostic tests*

**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.

**FIBROSCAN:**

A machine that sends vibration waves through the liver to detect and analyze liver scarring.

**GENETIC MATERIAL:**

Deoxyribonucleic acid (DNA) and ribonucleic acid (RNA), the molecules that carry hereditary information.

**LIVER BIOPSY:**

A needle procedure that measures the degree of damage (if any) of the liver.

**NON-INVASIVE LIVER TESTS:**

Tests that combine a variety of blood tests to ascertain the level of damage to the liver.

**RAPID HCV ANTIBODY TEST:**

A point-of-care test that collects and processes a sample and gives results after 20 minutes.

**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.

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**Related publications:**

**An Overview of HCV Diagnostic Tests**

[www.hcvadvocate.org/hepatitis/factsheets\\_pdf/diagnostic.pdf](http://www.hcvadvocate.org/hepatitis/factsheets_pdf/diagnostic.pdf)

**HCV Viral Load Tests**

[http://hcvadvocate.org/hepatitis/factsheets\\_pdf/viralload.pdf](http://hcvadvocate.org/hepatitis/factsheets_pdf/viralload.pdf)

**Fibroscan**

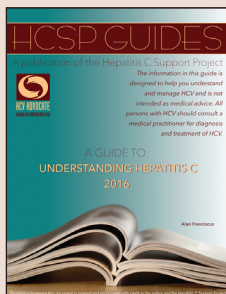
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**Reading a Lab Report: A Basic Primer**

[www.hcvadvocate.org/hepatitis/factsheets\\_pdf/Reading\\_a\\_Lab\\_Report.pdf](http://www.hcvadvocate.org/hepatitis/factsheets_pdf/Reading_a_Lab_Report.pdf)

**For more information**

- **Centers for Disease Control and Prevention**  
[www.cdc.gov/Hepatitis](http://www.cdc.gov/Hepatitis)
- **Mayo Clinic:**  
[www.mayoclinic.com/health/liver-biopsy/MY00949](http://www.mayoclinic.com/health/liver-biopsy/MY00949)
- **MedlinePlus:**  
[www.nlm.nih.gov/medlineplus/ency/article/003895.htm](http://www.nlm.nih.gov/medlineplus/ency/article/003895.htm)
- **National Digestive Diseases Information Clearinghouse (NDDIC)**  
<http://digestive.niddk.nih.gov/ddiseases/pubs/liverbiopsy/>



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