

Bio-Rad Laboratories
Improving healthcare with every test

Hepatitis C

Testing System

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Nearly four million Americans are infected with HCV. Of the 200,000 newly infected each year, a high percentage experience no acute symptoms.

The Hepatitis C Virus (HCV) is now known to be the causative agent for most, if not all, blood-borne non-A, non-B hepatitis (NANBH).²⁻⁷ Studies throughout the world indicate that HCV is transmitted through contaminated blood and blood products, through blood transfusions or through other close, personal contacts. Currently, in the United States, greater than 90% of transfusion-associated hepatitis infections are considered to be NANBH infections.^{8,9} Worldwide, other forms of NANBH are recognized.

Up to 85% of those infected with Hepatitis C will develop chronic infections, and 20% develop cirrhosis, possibly leading to cancer or liver failure. Treatments are currently available, yet only 5% of cases are diagnosed. The development of advanced generation ELISA diagnostic tests for HCV have proven to be remarkably effective at reducing the risk of HCV transmission.

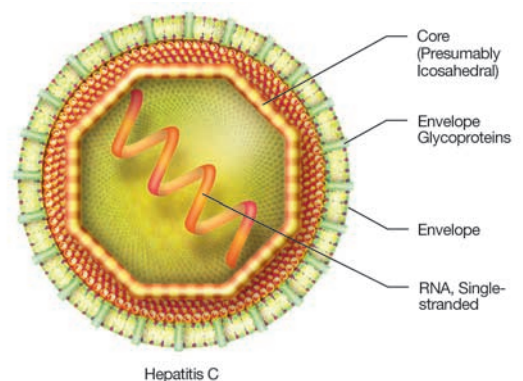
Confidence in Results

- Recombinant technology
- Reproducible results
- Specificity 99.5%*

Convenience

- Microwell technology
- 480 tests
- 1 year shelf life

* In a study of known positives.



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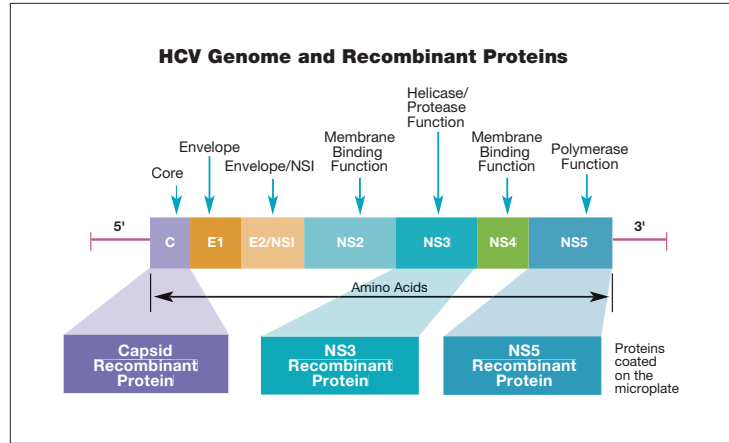
Hepatitis C Testing System

ORTHO® HCV v.3.0 ELISA Test System

The Ortho® HCV v.3.0 ELISA Test System uses three recombinant antigens developed by Chiron® Corporation to detect the antibody to HCV. These antigens, c22-3, c200 and NS5, cover 60% of the HCV genome, allowing for broader detection of HCV antibodies.

CHIRON® RIBA™ HCV 3.0 SIA

Chiron® RIBA™ HCV 3.0 SIA is intended to be used as a supplemental test for human serum or plasma specimens found to be repeatedly reactive in HCV antibody screening procedures.



Prevalence

| Prevalence of Anti-HCV in U.S. Donor Population | | | | |
|---|------------------|--------------|--------------------|---------------------|
| Number | Initially Tested | Non-Reactive | Initially Reactive | Repeatedly Reactive |
| Volunteers Blood Donors | 30,025 | 29,884 | 155 (0.52%) | 136 (0.45%) |
| Commercial Plasma Donors | 3,000 | 2,984 | 16 (0.53%) | 13 (0.43%) |

Field Performance data demonstrate excellent specificity of 99.95% in these low prevalence populations**

Correlation between initial and repeat reactive is 87.1%

Performance Data on HCV Seroconversion Panels

| Summary of Seroconversion Studies* | | | |
|------------------------------------|---|----------------------------|---------------|
| Disease | Number Detected Total Cases Version 3.0 | Earlier by HCV Improvement | Range of Days |
| Pt. NANBH | 21 | 5 (24%) | 20 to 34 |
| Pt. NANBH | 14 | 2 (14%) | 21 to 45 |
| Dialysis | 5 | 2 (40%) | 20 to 68 |
| Dialysis | 45 | 15 (24%) | 7 to 30 |
| Pt. NANBH | 16 | 4 (25%) | 7 to 84 |
| Pt. NANBH | 8 | 1 (13%) | 6 |
| TOTAL | 109 | 29 (27%) | |

* Data on file.

HCV Version 3.0 detected anti-HCV earlier in 27% of seroconversion cases.

Ordering Information

| Catalog No. | Description | |
|-------------|--|------------|
| 930740 | ORTHO® HCV, Version 3.0, ELISA Test System | 480 tests |
| 933040 | ORTHO® HCV, Version 3.0, ELISA Stop Solution | 2 x 500 mL |
| 933730 | ORTHO® HCV, Version 3.0, ELISA Wash Buffer | 6 x 150 mL |
| 930590 | RIBA™ HCV Starter Kit | 1 kit |
| 930600 | CHIRON® RIBA 3.0 SIA | 30 tests |



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For further information call us toll free at 1-800-2BIO-RAD or visit us on the worldwide web at www.bio-rad.com.

Clinical
Diagnostics Group

Website www.bio-rad.com U.S. 1-800-2-BIO-RAD Australia 61-2-9914-2800 Austria 43-1-877-8901 Belgium 32-9-385-5511 Brazil 5521-2507-6191 Canada 1-514-334-4372
Czech Republic 420-2-41430532 China 86-21-63052255 Denmark 45-4452-1000 Finland 358-9-804-22-00 France 33-1-4795-6000 Germany 49-89-31884-0 Hong Kong 852-2789-3300 India 91-124-6398112 Israel 972-3-9514127 Italy 39-02-216091 Japan 81-3-5811-6290 Korea 82-2-3473-4460 Latin America 305-894-5950 Mexico 5255-5534-2552
The Netherlands 31-318-540666 New Zealand 64-9-415-2280 Norway 47-23-38-41-30 Poland 48-22-815-39-51 Portugal 351-21-472-7700 Russia 7-095-721-14-00
Singapore 65-6272-9877 South Africa 27-11-442-85-08 Spain 34-91-590-5200 Sweden 46-8-555-127-00 Switzerland 41-61-717-95-55 Thailand 662-651-8311
United Kingdom 44-208-328-2000