

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).<sup>2-7</sup> 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.<sup>8,9</sup> 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.

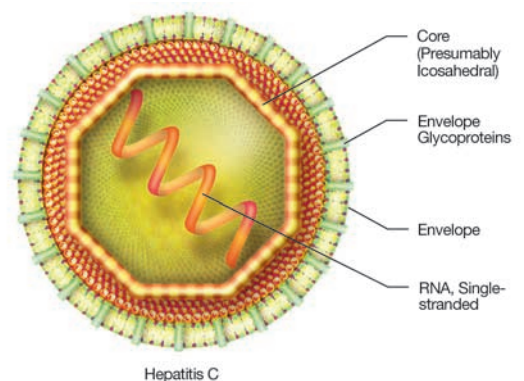
### Confidence in Results

- Recombinant technology
- Reproducible results
- Specificity 99.5%\*

### Convenience

- Microwell technology
- 480 tests
- 1 year shelf life

\* In a study of known positives.



**BIO-RAD**



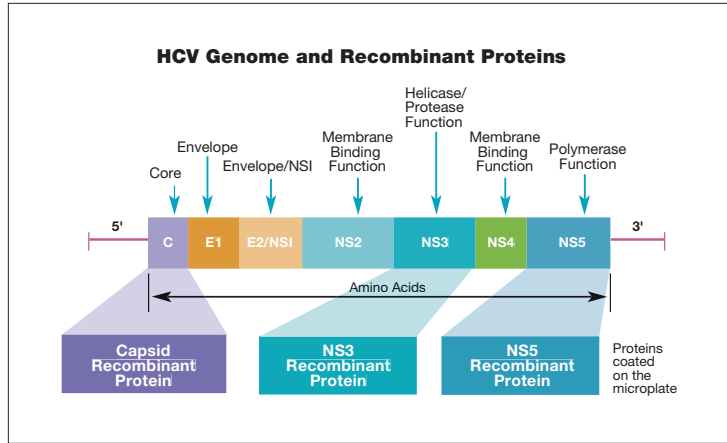
# Hepatitis C Testing System

## 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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Clinical  
Diagnostics Group

Website [www.bio-rad.com](http://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