

ORTHO[®] HCV Version 3.0 ELISA Test System

**TODAY, OVER 4 MILLION PEOPLE
IN THE U.S. ARE INFECTED
WITH HEPATITIS C**



Shouldn't You Screen for HCV Using
the Most Specific Immunoassay Available?

ORTHO® Antibody to HCV Version 3.0 ELISA Test System

ENHANCED FEATURES

- Better Seroconversion Sensitivity when Compared to anti-HCV Version 2.0 EIA¹
- Best Specificity for Accuracy in Reporting, Providing Maximum Donor Retention when Compared to anti-HCV Version 2.0 EIA^{2,3}
- Proven to Detect anti-HCV in Low Level and Intermittently Viremic Samples⁴

“As you might expect, in those cases where there were discordant results, seroconversion with the 3.0 preceded seroconversion by 2.0 by a median of 17 days.”

Barbara Masecar, Bayer Corporation

“I want to note the difference in yield from the two different systems, really documenting the higher sensitivity of the EIA 3.0.”

Dr. Celso Bianco, America's Blood Centers

Quotes from the FDA NAT Workshop, December 2001

ORTHO® HCV 3.0 ELISA Test System has BETTER Sensitivity and Specificity when compared to the HCV Version 2.0 EIA, helping to ensure accuracy in result reporting.

U.S. Studies have shown:

- HCV 2.0 EIA false-negative rate of 1 in every 30,000 donors¹
- 21 out of 10,000 donors deferred with HCV Version 2.0 EIA²

¹REDS STUDY 1997

N=332,852 Donors

Of these 525 RR Positive Specimens using Ortho HCV and RIBA™ 3.0 SIA, 11 Specimens (21%) were false negatives when tested with Abbott HCV version 2.0 EIA

This translates into 1 in 30,000 HCV positive donors missed by HCV Version 2.0 EIA

²STUDY AT A MIDWEST U.S. DONOR CENTER 1997

N=3740 Donors

Number of False Positives, RIBA™ 3.0 SIA Negative Specimens:

Ortho HCV 3.0: 3/3740 = 0.08%

Abbott HCV 2.0: 8/3740 = 0.21%

This translates to 21 in 10,000 donors deferred with HCV Version 2.0 EIA

ORTHO® HCV Version 3.0 ELISA Test System has BETTER Specificity over the Competitor's Immunoassay.³

Published data from outside of the U.S. shows that the ORTHO® HCV Version 3.0 ELISA Test System has equivalent sensitivity and BETTER specificity when compared to the Abbott PRISM® HCV test. (Ex-USA data)

| | REPEAT REACTIVE RATES | |
|---------------------|-----------------------|-------------------|
| | ORTHO HCV 3.0* | ABBOTT PRISM™ HCV |
| La Gazette # 145 | 0.03% | 0.23% |
| La Gazette # 155 | 0.03% | 0.16% |
| Valencia | 0.16% | 0.30% |
| BPAC | NT | 0.29% |
| Average Performance | 0.07% | 0.25% |

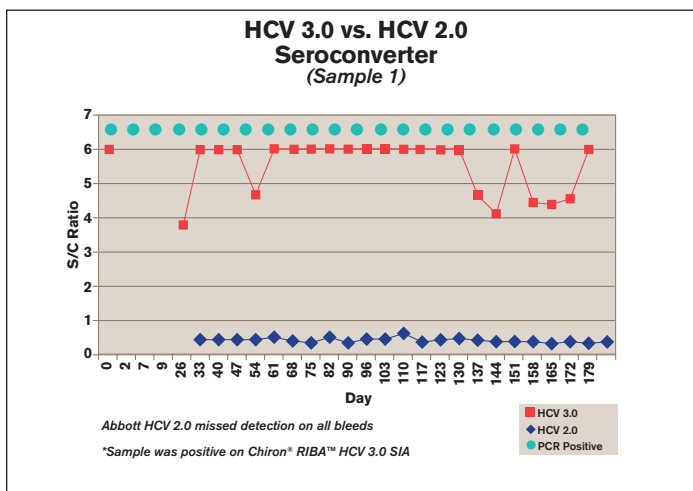
ORTHO® HCV Version 3.0 ELISA Test System is proven to detect samples with low level or intermittent viremia, not always detected by other test methods.⁴

Unlike HIV or HBV, intermittent viremia has been shown to occur. During stages of intermittent viremia, individuals carrying the antibody to HCV are still infectious.

Study Proves:

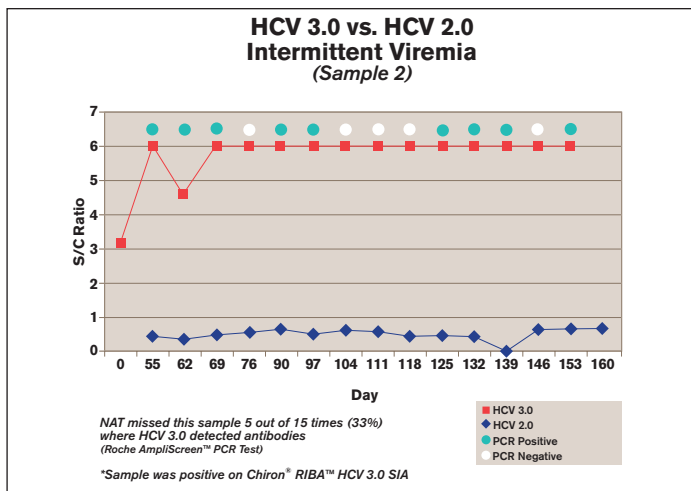
Seroconversion Sample 1

ORTHO® HCV Version 3.0 ELISA Test System detected antibody that was missed on the anti-HCV Version 2.0 EIA in ALL BLEEDS.



Seroconversion Sample 2

This sample showed intermittent viremia was detected ONLY by the ORTHO® HCV Version 3.0 ELISA Test System on 5 bleeds that were below the detection limits of HCV RNA PCR.



Overview of Study Objective:

Compare performance of Abbott HCV 2.0 EIA and ORTHO® HCV Version 3.0 ELISA serology for detection of HCV antibodies in viremic seroconversion panels identified during plasma donor NAT screening.

- In 42 (59%) of the 71 panels found negative on Abbott HCV 2.0 seroconversion occurred earlier with ORTHO® HCV Version 3.0.
- In all 42 cases, seroconversion by HCV 3.0 EIA preceded seroconversion by HCV 2.0 EIA.
- Of these 42 cases, two were followed for 160 – 180 days using HCV 2.0 EIA and never seroconverted with the 2.0 EIA. Both panels were always positive with the ORTHO® HCV Version 3.0 ELISA Test System and always (false) negative with the HCV 2.0 EIA. The second of these two panels was intermittently positive for RNA and always positive using the ORTHO® HCV Version 3.0 ELISA*.

*Roche AmpliScreen™ PCR tested both of these panels for RNA. In one panel (sample 1), all panel members were positive for RNA as well as HCV core antigen, meaning that this sample was viremic.

Study References:

LH Tobler¹, B Masecar², EA Davis², W Andrews², B Phelps³ and MP Busch^{1,4}

- 1) Blood Centers of the Pacific, San Francisco, CA
- 2) Bayer Corporation, Raleigh, NC
- 3) Chiron Corporation, Emeryville, CA
- 4) University of California, San Francisco, CA

ORTHO® HCV Version 3.0 ELISA Test System

| Description | Product Code |
|--------------------|---------------------|
| 480 Test Kit Size | 930740 |
| 2400 Test Kit Size | 930750 |

Chiron® RIBA™ HCV 3.0 SIA is also available for supplemental testing

| Description | Product Code |
|--------------------|---------------------|
| 30 Test Kit Size | 930600 |

To place an order, please contact Customer Service at 1-800-828-6316 or order online at www.orthoclinical.com

www.orthoclinical.com

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Roche AmpliScreen™ PCR is a trademark of Roche Molecular Diagnostics.
Chiron® RIBA™ HCV 3.0 SIA is a registered trademark of Chiron Corporation.
Abbott PRISM® HCV is a registered trademark of Abbott Laboratories, Diagnostic Division. (This assay is not currently available in the U.S.)

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