

# **Hepatitis C Seroconversion Panel PHV915**

## **HCV Genotype 2b**

### **INTENDED USE**

This panel is a group of serial bleeds from an individual plasma donor during a period of HCV antibody seroconversion. This panel is intended for use by manufacturers and other laboratories for evaluation of their HCV detection assays with well characterized specimens, and with comprehensive data for comparative analysis. For Research Use Only. Not for use in diagnostic procedures.

### **PRODUCT DESCRIPTION**

SeraCare Life Sciences has assembled these plasma samples from a group of serial bleeds from a single plasma donor collected during a period of HCV antibody seroconversion. All units were maintained in a frozen state, except for the interval of dispensing into vials. No preservatives were added. This panel is configured as 4 members, 1.0mL per vial.

### **REAGENTS**

Cat No. PHV915-1.0 1 vial per member  
4 members, 1.0 mL per vial

### **INTERPRETATION OF RESULTS**

The attached data sheet provides the results of anti-HCV from U.S. FDA licensed and international screening and diagnostic tests in addition to various supplemental methods. Also included are results for HCV RNA and genotype by commercial methods. Tests were performed at SeraCare Life Sciences, by the manufacturer, or at internationally recognized reference laboratories by individuals who routinely use these test procedures. Numeric results of EIA tests are means of duplicates, expressed as specimen absorbance to cutoff ratios (s/co). Specimens with s/co of  $\geq 1.0$  are considered reactive. Results of supplemental tests are presented and interpreted as indicated by the manufacturer's package insert. The specific HCV structural and nonstructural proteins are indicated by both their generic name and by the designation of the manufacturer. The genotype 2b was determined by Innogenetics using the line probe assay, INNO-LIPA

HCV II, which uses the reverse hybridization principle to distinguish the 6 major types of HCV and their subtypes. HCV RNA results are expressed as I/U mL or S/CO according to the manufacture's instructions

### **PRECAUTIONS**

These materials have not been inactivated and should be considered biohazardous. Use the Centers for Disease Control (CDC) recommended universal precautions for handling this product.<sup>1</sup>

The units that make up this panel were found to be negative for anti-HIV-1/2 and HBsAg.

Do not pipette by mouth.

Do not smoke, eat or drink in areas where specimens are handled. These materials should be disposed of in a manner that will inactivate pathogenic agents.

### **STORAGE**

Panel members should be stored frozen at -70°C or colder to preserve RNA or -10°C or colder to preserve antibody. SeraCare Life Sciences recommends dividing the samples into smaller aliquots if necessary to avoid repeated freeze-thaw cycles.

### **LIMITATIONS**

PHV915 is offered for research use only. Not for use in diagnostic procedures. Data are provided for informational purposes. Seracare Life Sciences does not claim that others can duplicate test results exactly.

### **REFERENCES**

1. CDC recommendations for prevention of HIV transmission in health care settings. MMWR 36(supp.2) 1987.

**For assistance, contact SeraCare Life Sciences Technical Support**

Phone (508) 244-6400 or US Toll Free (800) 676-1881

Visit our website at [www.seracare.com](http://www.seracare.com)



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**SeraCare Life Sciences**  
**Hepatitis C Seroconversion Panel (HCV Genotype 2b)**  
**PHV915**

----- HCV RNA, results expressed as IU/mL and s/co-----

Member <u>I.D. #</u>	Bleed <u>Dates</u>	Days Since <u>1st Bleed</u>	Roche Real-Time	Abbott Real Time	Bayer Versant	Gen-Probe PROCLEIX®
			HCV Taqman RT-PCR SeraCare <u>IU/mL</u>	m2000 HCV RNA Assay RL39 <u>IU/mL</u>	HCV RNA bDNA 3.0 RL40 <u>IU/mL</u>	HCV RNA Assay RL52 <u>s/co</u>
PHV915-01	04-Apr-97	0	2.1 x 10 <sup>2</sup>	1.8 x 10 <sup>2</sup>	BLD	15.2
PHV915-02	09-Apr-97	5	BLD	2.9 x 10 <sup>1</sup>	BLD	13.0
PHV915-03	16-Apr-97	12	8.5 x 10 <sup>2</sup>	3.3 x 10 <sup>2</sup>	BLD	17.6
PHV915-04	18-Apr-97	14	3.4 x 10 <sup>2</sup>	3.1 x 10 <sup>2</sup>	BLD	17.2
<b>Run Date:</b>			24-Feb-10	9-Feb-10	10-Feb-10	10-Feb-10
<b>Kit Lot #:</b>			M11351	420179	C038	413561
<b>Exp. Date:</b>			31-Mar-10	29-Jan-11	20-May-10	15-Aug-10
<b>Product #:</b>			03568555 190	08L50-60	02553870/02554338	301030

**BIOHAZARD CAUTION: Potentially infectious materials. Follow Universal Precautions. Panel members were tested and found negative for anti-HIV-1/2 and HBsAg.**

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BLD = Below the limit of Detection; NA = Not available

**SeraCare Life Sciences**  
**Hepatitis C Seroconversion Panel (HCV Genotype 2b)**  
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**Data Sheet**

----HCV Ab, results expressed as s/co----

Member I.D. #	Days Since 1st Bleed	Abbott HCV	Ortho HCV	Ortho Anti-HCV RIBA 3.0					Abbott Architect	Abbott AXSYM	Ortho HCV	
		EIA 2.0	EIA 3.0	MFG					HCV Assay	HCV Assay	EIA 3.0	
		SeraCare	SeraCare	c100(p)	c33c	c22(p)	NS4	SOD	Result	RL53	SeraCare	SeraCare
		<u>s/co</u>	<u>s/co</u>	<u>(NS4)</u>	<u>(NS3)</u>	<u>(CORE)</u>	<u>(NS5)</u>			<u>s/co</u>	<u>s/co</u>	<u>s/co</u>
PHV915-01	0	0.2	0.0	-	+/-	-	-	-	NEG	0.2	0.3	0
PHV915-02	5	0.3	0.4	-	1+	-	-	-	IND	0.7	0.5	0.4
PHV915-03	12	0.4	1.3	-	2+	-	-	-	IND	2.0	1.7	1
PHV915-04	14	0.6	2.8	-	3+	-	-	-	IND	4.7	5.5	3.2
<b>Run Date:</b>		2-Sep-97	18-Oct-97					10-Sep-97		10-Feb-10	10-Feb-10	9-Feb-10
<b>Kit Lot #:</b>		30384M100	TXE236-5					MMB252		78603HM00	81305M100	TXE527
<b>Exp. Date:</b>		19 Mar 98	8-Feb-98					8-Mar-98		6-Mar-10	7-Jun-10	28-Sep-10
<b>Product #:</b>		4A14	930740					930780		01L79	5C36	10 Apr 48

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BLD = Below the limit of Detection; NA = Not available; POS = Positive; NEG = Negative; IND = Indeterminate