

Hepatitis C AccuVert™ Seroconversion Panel PHV919 (0610-0217)

A SERACARE PANEL PRODUCT

INTENDED USE

The Hepatitis C (HCV) AccuVert™ Seroconversion Panel (PHV919) is intended for use by diagnostic manufacturers, researchers, and clinical laboratories to develop, evaluate, or troubleshoot HCV test methods. Characterized samples and comprehensive data are provided for comparative analysis. For research use only. Not for use in diagnostic procedures.

PRODUCT DESCRIPTION

This product is a 7-member seroconversion panel. Panel members represent serial bleeds from a single individual during the development of a HCV infection and subsequent response. No preservatives were added.

Cat. No. 0610-0217 1 vial per member
7 members, 1.0 mL per vial

STORAGE

Panel members should be stored at -70°C or colder. SeraCare Life Sciences recommends that the panel members be divided into smaller aliquots to avoid multiple freeze-thaw cycles, if appropriate. If turbidity or particulate matter is observed, the samples should be centrifuged in accordance with each test kit manufacturer's instructions for sample preparation.

INTERPRETATION OF RESULTS

The Data Sheet for HCV AccuVert™ Seroconversion Panel (PHV919) lists results for panel members generated using commercially-available screening, monitoring, and confirmatory test methods. Tests were performed at SeraCare or at recognized reference laboratories (RL) by

individuals who routinely use these procedures. Information regarding specific test methods is available on the Data Sheet. Data Sheets are updated when new data are available.

LIMITATIONS

The HCV AccuVert™ Seroconversion Panel (PHV919) 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.

PRECAUTIONS

Follow Universal Precautions.¹ The units that make up this panel were tested and found negative for anti-HIV-1/2 and HBsAg. This does not ensure the absence of these or other human pathogens.

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.

REFERENCES

1. Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings

For assistance, contact SeraCare Technical Support at 508.244.6400.

The PI and Data Sheet for this panel in PDF form can be found at www.seracare.com

A printed copy of the Data Sheet may be requested by email at info@seracare.com, or by phone at 508.244.6400

ASK ABOUT RELATED SERACARE PRODUCTS

- ACCURUN® Quality Controls
- AccuType™ Viral Isolates
- SeraCon™ and Basematrix Processed Plasma

SeraCare Life Sciences
Hepatitis C Seroconversion Panel PHV919 (0610-0217)
HCV Genotype 1a
Data Sheet

-----U.S. Licensed HCV EIA test methods-----

-----U.S. Licensed HCV RNA test methods-----

Member <u>I.D. #</u>	Bleed <u>Dates</u>	Days Since <u>1st Bleed</u>	U.S. Licensed HCV EIA test methods				U.S. Licensed HCV RNA test methods			
			Abbott HCV 2.0 EIA s/co <u>SeraCare</u>	Abbott AxSYM HCV s/co <u>SeraCare</u>	Abbott Architect HCV s/co <u>RL53</u>	Ortho HCV 3.0 s/co <u>SeraCare</u>	Roche COBAS Amplicor HCV Monitor V 1.5 IU/ml <u>SeraCare</u>	Abbott <i>m2000</i> TM RT-HCV IU/ml <u>RL39</u>	Siemens Versant [®] HCV RNA bDNA 3.0 IU/ML <u>RL40</u>	Gen-Probe PROCLEIX [®] HIV-1/HCV s/co <u>RL52</u>
PHV919-01	31 DEC 99	0	0.2	0.6	0.8	0.8	BLD	BLD	BLD	0.1
PHV919-02	07 JAN 00	7	0.2	0.6	0.8	0.6	BLD	BLD	BLD	0.2
PHV919-03	12 JAN 00	12	0.2	0.6	0.7	0.7	BLD	BLD	BLD	0.2
PHV919-04	25 JAN 00	25	0.2	0.7	0.9	0.8	3 x 10 ⁴	5 x 10 ⁴	2 x 10 ⁴	21.6
PHV919-05	28 JAN 00	28	0.7	4.7	6.9	>4.9	5 x 10 ³	1 x 10 ⁴	4 x 10 ³	22.3
PHV919-06	01 FEB 00	32	1.3	53.2	13.1	>4.9	1 x 10 ⁴	3 x 10 ⁴	1 x 10 ⁴	22.0
PHV919-07	04 FEB 00	35	1.4	62.5	13.7	>4.9	2 x 10 ⁴	4 x 10 ⁴	2 x 10 ⁴	21.6
Run Date:			7-Oct-09	7-Oct-09	23-Nov-09	8-Oct-09	12-Oct-09	23-Nov-09	18-Nov-09	18-Nov-09/04-Dec-09
Kit Lot #:			76953M100	75230M200	75807HN00	TXE519	M03568	278142	C038	413561
Exp. Date:			12-Jan-10	16-Dec-09	4-Jun-10	20-Apr-10	31-Mar-10	31-Mar-10	20-May-10	15-Aug-10
Product #:			4A14	5C36	01L79	930740	87101	08L50-60	02553870	301026-Procleix TM

BIOHAZARD CAUTION: Potentially infectious materials. Follow Universal Precautions. Panel members were tested and some were found positive by a test for anti-HCV.

For research use only. Not for use in diagnostic procedures. Data are offered for informational purposes. SeraCare Life Sciences does not claim that others can duplicate these results exactly. Antibody test results were generated using assays commercially available in the U.S., performed at SeraCare Life Sciences (formerly Boston Biomedica Inc. - BBI) and at internationally recognized reference laboratories (RL). EIA results are means of duplicates expressed as specimen absorbance to cutoff ratios (s/co). Ratios ≥1.0 are considered reactive. Confirmatory tests are interpreted according to the manufacturer's instructions. The genotype 1a was determined by using the Inno-LiPA HCV II assay, (K-1045).

Specimens are undiluted aliquots from plasma units collected from a single donor. No preservatives were added.

POS = Positive, NEG = Negative, BLD = Below Limit of Detection

SeraCare Life Sciences
Hepatitis C Seroconversion Panel PHV919 (0610-0217)
HCV Genotype 1a
Data Sheet

Member <u>I.D. #</u>	Bleed <u>Dates</u>	Days Since <u>1st Bleed</u>	U.S. FDA-Licensed Anti-HCV EIA Tests		----- CONFIRMATORY TEST -----						HCV RNA
			Abbott 2.0 <u>BBI</u> <u>s/co</u>	Ortho 3.0 <u>BBI</u> <u>s/co</u>	Ortho RIBA 3.0 BBI						Roche COBAS Amplicor PCR <u>BBI</u> <u>IU/ml</u>
					<u>c100(p)</u> <u>(NS4)</u>	<u>c33c</u> <u>(NS3)</u>	<u>c22(p)</u> <u>(CORE)</u>	<u>NS5</u> <u>(NS5)</u>	<u>SOD</u>	<u>Result</u>	
PHV919-01	31 DEC 99	0	0.1	0.1	-	-	-	-	-	NEG	BLD
PHV919-02	07 JAN 00	7	0.2	0.1	-	-	-	-	-	NEG	BLD
PHV919-03	12 JAN 00	12	0.1	0.1	-	-	-	-	-	NEG	BLD
PHV919-04	25 JAN 00	25	0.2	0.1	-	-	-	-	-	NEG	2 X 10 ⁵
PHV919-05	28 JAN 00	28	1.3	0.8	-	1+	1+	-	-	POS	2 X 10 ⁴
PHV919-06	01 FEB 00	32	2.4	>4.8	-	4+	3+	-	-	POS	1 X 10 ⁵
PHV919-07	04 FEB 00	35	2.6	>4.8	-	4+	3+	-	-	POS	1 X 10 ⁵
Run Date:			17 Aug 00	20 Jun 00					12-Jun-00		24 Aug 00
Kit Lot #:			65153M201	TXE290-05					QA1158		B01592
Exp. Date:			06 Mar 01	01 Jul 00					12 Dec 00		30 Nov 00
Product #:			4A14	930740					930600		83782

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HCV Genotype 1a
Data Sheet

-----INTERNATIONAL Anti-HCV EIA Tests-----								
Member I.D. #	Bleed Dates	Days Since 1st Bleed	Abbott	Abbott	Abbott	Abbott	Diag. Past.	Ortho Enhanced
			AxSYM 3.0	IMx 3.0	PRISM HCV	HCV EIA 3.0	Monolisa PLUS	SAVe BBI
			RL23	RL23	RL23	BBI	RL23	s/co
			s/co	s/co	s/co	s/co	s/co	
PHV919-01	31 DEC 99	0	0.9	0.4	0.5	0.1	0.1	0.1
PHV919-02	07 JAN 00	7	1.3	0.5	0.6	0.1	0.2	0.1
PHV919-03	12 JAN 00	12	0.9	0.4	0.5	0.1	0.1	0.1
PHV919-04	25 JAN 00	25	1.3	0.5	0.6	0.1	0.2	0.1
PHV919-05	28 JAN 00	28	9.1	4.1	3.5	0.3	0.8	1.3
PHV919-06	01 FEB 00	32	71.8	29.4	6.7	5.1	2.0	>4.8
PHV919-07	04 FEB 00	35	77.2	31.6	6.3	4.6	2.0	>4.8
Run Date:			01 Sep 00	11 Sep 00	13 Sep 00	07 Jun 00	28 Aug 00	05 Jun 00
Kit Lot #:			67337LU02	65249LU00	64151HP00	58372HP00	OH515Q	GECV868
Exp. Date:			21 Mar 01	18 Dec 00	01 Mar 01	04 Aug 00	15 Jun 01	30 Sep 00
Product #:			3B44	5C71	6A52-48	7A16-23	72317	940994