HCV Seroconversion Panel Genotype 2b
PHV917(M)

INTENDED USE
HCV Seroconversion Panel PHV917(M) 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 diagnostic manufacturers and clinical laboratories to evaluate HCV assays with well-characterized specimens and comprehensive data, and by researchers to study early HCV infection.

PRODUCT DESCRIPTION
PHV917(M) is a set of 9 undiluted plasma samples from a single plasma donor collected during HCV seroconversion. All units were maintained frozen, except for the interval of dispensing into vials. No preservatives were added.

REAGENTS
Cat No. PHV917(M)-1.0 1 vial per member
9 members, 1.0 mL per vial

INTERPRETATION OF RESULTS
The attached data sheet lists results generated using commercially available screening and confirmatory tests. Tests were performed at SeraCare, at the manufacturer (MFG), and at internationally recognized referee laboratories (RL) by individuals who routinely use these test procedures. EIA results are means of duplicates expressed as signal to cutoff ratios (s/co); a ratio of ≥1.0 is considered reactive. Confirmatory results are interpreted as indicated by the manufacturer's package insert. The HCV structural and nonstructural proteins are indicated by both their generic name and the manufacturer's designation. The genotype 2b was determined by using the line probe assay, INNO-LIPA HCV II. The INNO-LIPA II uses the reverse hybridization principle to distinguish the 6 major types of HCV and their subtypes.

PRECAUTIONS
These materials have not been treated and should be considered biohazardous. Follow universal precautions.[1] Panel members were tested and some were found positive by tests HCV.

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

Never 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. SeraCare recommends dividing the samples into smaller aliquots if appropriate to avoid multiple freeze-thaw cycles. If turbidity or particulate matter is observed, the samples should be centrifuged in accordance with each test kit manufacturer's instructions for sample preparation.

LIMITATIONS
PHV917(M) 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 these test results exactly.

REFERENCES
1. CDC recommendations for prevention of HIV transmission in health care settings. MMWR 36 (suppl. 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

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SeraCare Life Sciences
Hepatitis C Seroconversion Panel PHV917(M)
HCV Genotype 2b
Data Sheet

			--------U.S. Licensed HCV EIA Tests Methods-------			--U.S. Licensed HCV RNA Test Methods--	
Member I.D. #	**Bleed Dates**	**Days Since 1st Bleed**	**Abbott AxSYM HCV s/co SeraCare**	**Abbott PRISM HCV s/co RL54**	**Ortho HCV 3.0 s/co SeraCare**	**Roche COBAS Amplicor HCV Monitor Test IU/ml SeraCare**	**Roche CAP/CTM HCV Test IU/ml SeraCare**
PHV917-01	29 MAY 96	0	0.2	0.1	0.0	BLD	BLD
PHV917-02	11 JUN 96	13	NA	NA	NA	NA	NA
PHV917-03	18 JUN 96	20	0.1	0.1	0.0	2×10^5	1×10^5
PHV917-04	20 JUN 96	22	0.2	0.2	0.0	6×10^3	5×10^3
PHV917-05	22 AUG 96	85	18.3	6.1	>5.0	BLD	BLD
PHV917-06	7 OCT 96	131	10.1	5.7	>5.0	BLD	BLD
PHV917-07	11 OCT 96	135	11.6	6.0	>5.0	BLD	BLD
PHV917-08	14 OCT 96	138	12.5	5.9	>5.0	BLD	BLD
PHV917-09	22 OCT 96	146	34.8	6.8	>5.0	BLD	BLD
PHV917-10	28 OCT 96	152	27.7	7.0	>5.0	BLD	BLD
Run Date:			02 DEC 09	16 DEC 09	04 DEC 09	16 DEC 09	22 DEC 09
Kit Lot #:			75230M200	70550M100	TXE522	M08199	M02993
Exp. Date:			16 DEC 09	15 FEB 10	22 JUN 10	30 JUN 10	31 MAY 10
Product #:			5C36	34-4547/R2	930740	87101	03568555 190

Panel Member 2 is no longer available. Data are provided for informational purposes.

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

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

POS = positive; NEG = negative; IND = indeterminate; BLD = below the limit of detection; BQR = below quantitative range; NA = not available

Member I.D. #	Bleed Dates	Days Since 1st Bleed	U.S. FDA-Licensed Anti-HCV EIA Tests Abbott 2.0 SeraCare s/co	Ortho 3.0 SeraCare s/co	HCV RNA Roche Amplicor PCR SeraCare copies/ml	CONFIRMATORY TESTS FOR RESEARCH USE ONLY Abbott Anti-HCV Matrix MFG NS4(e)	NS4(y)	NS3	CORE	Result	INTERNATIONAL Ortho RIBA 3.0[1] MFG c100(p) (NS4)	c33c (NS3)	c22(p) (CORE)	NS5 (NS5)	SOD	Result
PHV917-01	29 MAY 96	0	0.2	0.0	BLD	0.1	0.1	0.0	0.1	NEG	-	-	-	-	-	NEG
PHV917-02	11 JUN 96	13	0.2	0.0	>5 x 10^5	0.1	0.0	0.0	0.0	NEG	-	-	-	-	-	NEG
PHV917-03	18 JUN 96	20	0.2	0.0	>5 x 10^5	0.1	0.0	0.1	0.0	NEG	-	-	-	-	-	NEG
PHV917-04	20 JUN 96	22	0.1	0.0	>5 x 10^5	0.1	0.0	0.1	0.0	NEG	-	-	-	-	-	NEG
PHV917-05	22 AUG 96	85	0.8	>4.7	BQR	0.1	0.0	0.1	0.8	NEG	-	4+	2+	-	-	POS
PHV917-06	7 OCT 96	131	0.8	>4.7	BQR	0.1	0.0	1.9	0.3	IND	-	4+	2+	-	-	POS
PHV917-07	11 OCT 96	135	1.0	>4.7	3 x 10^3	0.1	0.0	4.0	0.4	IND	-	4+	2+	-	-	POS
PHV917-08	14 OCT 96	138	1.2	>4.7	BLD	0.1	0.0	7.3	0.3	IND	-	4+	2+	-	-	POS
PHV917-09	22 OCT 96	146	3.6	>4.7	BLD	0.1	0.0	14.6	0.3	IND	+/-	4+	2+	-	-	POS
PHV917-10	28 OCT 96	152	3.9	>4.7	BQR	0.2	0.0	15.4	0.2	IND	1+	4+	2+	-	-	POS
Run Date:			27 JAN 98	01 MAY 98	10 APR 98			08 MAY 98					11 JUN 98			
Kit Lot #:			35497M300	TXE244-5	82438			NA					MMH101			
Exp. Date:			15 MAR 98	12 JUN 98	30 SEP 98			NA					03 AUG 98			
Product #:			4A14	930740	87382			NA					930780			

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[1]Band intensities scored by use of the Chiron automated RIBA processor.

		INTERNATIONAL Anti-HCV EIA Tests								
Member I.D. #	Days Since 1st Bleed	Abbott AxSYM 3.0 RL 19 s/co	Abbott IMx 3.0 RL23 s/co	Abbott PRISM HCV RL23 s/co	Abbott HCV EIA 3.0 RL19 s/co	Diag. Past. Monolisa PLUS RL23 s/co	Ortho Enhanced SAVe RL23 s/co	Roche Cobas Core RL23 s/co	BioRad Access HCV Ab Plus RL45 s/co	Ortho Vitros ECI HCV RL45 s/co
PHV917-01	0	0.1	0.2	0.1	0.1	0.1	0.0	0.2	0.0	0.1
PHV917-02	13	0.1	0.2	0.1	0.2	0.1	0.0	0.2	0.0	0.1
PHV917-03	20	0.1	0.2	0.1	0.2	0.1	0.0	0.2	0.0	0.1
PHV917-04	22	0.1	0.2	0.1	0.2	0.1	0.0	0.2	0.0	0.1
PHV917-05	85	30.4	16.9	5.4	3.3	5.8	3.9	1.0	5.9	11.3
PHV917-06	131	19.8	11.3	4.3	2.4	5.5	3.7	1.8	5.3	10.9
PHV917-07	135	20.3	12.5	4.6	2.5	5.9	3.9	2.7	5.7	11.9
PHV917-08	138	25.1	14.3	5.5	3.1	6.4	4.5	3.1	6.7	12.0
PHV917-09	146	44.3	23.9	5.9	>5.4	7.2	4.8	7.7	8.4	15.8
PHV917-10	152	45.1	24.7	5.2	>5.4	6.9	4.9	9.3	8.4	15.9
Run Date:		18 MAY 98	09 JUN 98	14 MAY 98	18 MAY 98	14 MAY 98	13 MAY 98	14 MAY 98	NA	NA
Kit Lot #:		40264HP00	40136HP00	40082HP00	37100HP00	7M520Q	GECV256	P 1137	194822.0	100
Exp. Date:		14 DEC 98	21 NOV 98	08 DEC 98	15 SEP 98	01 OCT 98	19 MAR 99	30 NOV 98	NA	NA
Product #:		3B44	5C71	6A52	7A16	72312	940994	751898	34330	1318450

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