

OVERVIEW

This Data Sheet contains test results specific for HCV Seroconversion Panel PHV922, genotype 3a.

Panel Members are undiluted aliquots from plasma units collected from a 22-year old male in the U.S. Midwest in 2008. No preservatives were added.

CAUTION: Potentially infectious materials. Follow Universal Precautions. Some panel members were found positive for anti-HCV; all were found negative for HBsAg and anti-HIV.

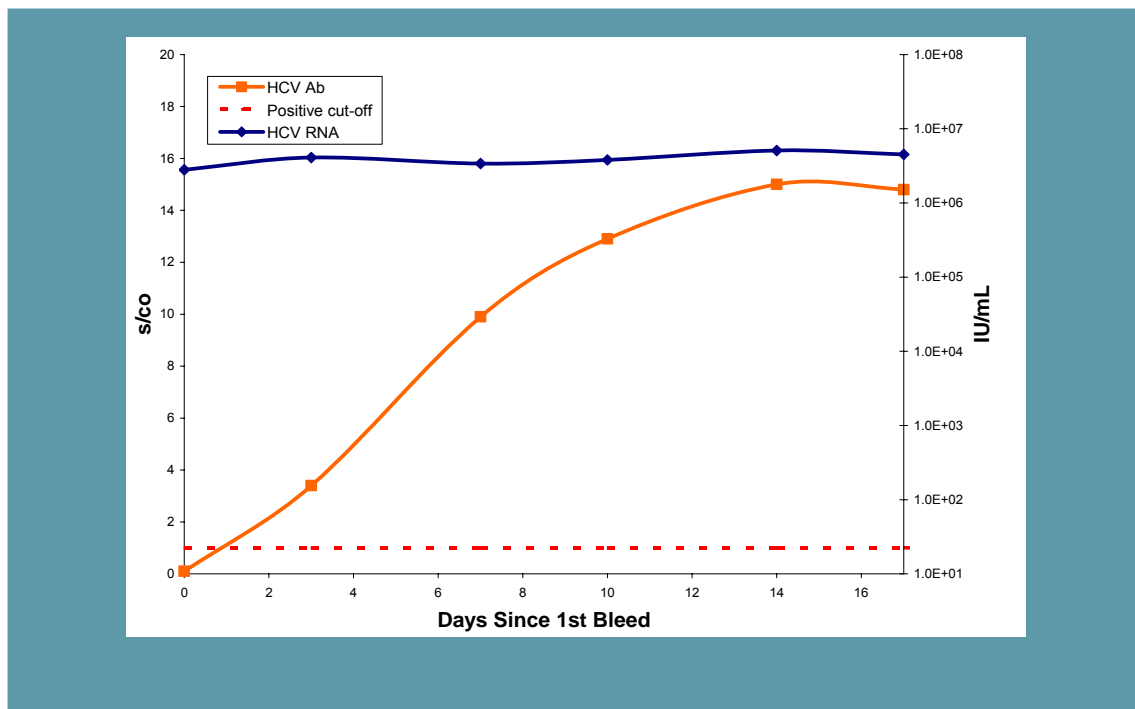
For Research Use Only.

Not for use in diagnostic procedures.

Data are offered for informational purposes only. SeraCare Life Sciences does not claim these results can be duplicated exactly.

For assistance, contact SeraCare Technical Support at 508.244.6400

EVOLUTION OF HCV MARKERS IN EARLY INFECTION



A printed Package Insert (PI) and Data Sheet may be requested by email to info@seracare.com, or by phone to 508.244.6400

This graph demonstrates the evolution of early HCV infection, illustrated with test results over time for different analytes or analyte combinations.

DATA SHEET

PHV922

HCV RNA (numeric results are expressed in IU/mL)

Panel Member	Bleed Date	Days Since 1 st Bleed	Abbott m2000	GenProbe Procleix Ultrio	Roche CAP/CTM v1.0	Siemens Versant bDNA
PHV922-01	22-Oct-08	0	6.2 x 10 ⁶	Pos	1.6 x 10 ⁷	2.8 x 10 ⁶
PHV922-02	25-Oct-08	3	9.2 x 10 ⁶	Pos	1.9 x 10 ⁷	4.1 x 10 ⁶
PHV922-03	29-Oct-08	7	6.2 x 10 ⁶	Pos	1.6 x 10 ⁷	3.4 x 10 ⁶
PHV922-04	01-Nov-08	10	6.3 x 10 ⁶	Pos	1.7 x 10 ⁷	3.8 x 10 ⁶
PHV922-05	05-Nov-08	14	9.0 x 10 ⁶	Pos	2.6 x 10 ⁷	5.1 x 10 ⁶
PHV922-06	08-Nov-08	17	6.9 x 10 ⁶	Pos	1.9 x 10 ⁷	4.5 x 10 ⁶
Test Date			19-Jul-10	22-Jul-10	20-Aug-10	16-Jul-10
Test Site			RL	RL	SC	RL
Kit Part Code			6L18	567514	03568555 190	Box-1: 02553870 Box-2: 02554338
Kit Lot No.			422834	03D0911463	N03786	C039
Kit Exp Date			31-Dec-10	15-Jun-11	30-Nov-11	23-Sep-10

HCV Antibody (s/co) ¹

Panel Member	Bleed Date	Days Since 1 st Bleed	Abbott ARCHITECT	Abbott AxSYM US	Abbott AxSYM EU	Abbott PRISM
PHV922-01	22-Oct-08	0	0.1	0.2	0.3	0.2
PHV922-02	25-Oct-08	3	1.9	1.0	0.8	0.6
PHV922-03	29-Oct-08	7	4.7	3.3	2.6	1.3
PHV922-04	01-Nov-08	10	5.3	3.2	2.6	1.5
PHV922-05	05-Nov-08	14	5.4	2.9	2.3	1.4
PHV922-06	08-Nov-08	17	5.7	3.1	2.4	1.6
Test Date			15-Jul-10	26-Jul-10	19-Jul-10	13-Sep-10
Test Site			RL	SC	RL	RL
Kit Part Code			6C37	5C36	2G8320	6A52-48
Kit Lot No.			87708HN00	84536M500	87096LF02	90550HN00
Kit Exp Date			25-Dec-10	04-Oct-10	05-Oct-10	02-Apr-11

¹ Immunoassay results are means of duplicates expressed as signal to cutoff ratios (s/co). Ratios ≥1.0 are considered reactive and noted in red

POS=positive; NEG=negative; BLD=below the limit of detection; NA=not available; f=faint; IND=Indeterminate
MFG = Manufacturer; RL = Reference Lab; SC = SeraCare

DATA SHEET

PHV922

HCV Antibody (s/co) ¹

Panel Member	Bleed Date	Days Since 1 st Bleed	Ortho Ver. 3.0 ELISA	Ortho Enhanced SAVE	Ortho Vitros ECi	Siemens ADVIA Centaur
PHV922-01	22-Oct-08	0	0.0	0.0	0.1	0.0
PHV922-02	25-Oct-08	3	0.9	1.9	3.4	0.1
PHV922-03	29-Oct-08	7	4.5	>5.0	9.9	0.9
PHV922-04	01-Nov-08	10	>5.0	>5.0	12.9	1.7
PHV922-05	05-Nov-08	14	>5.0	>5.0	15.0	3.7
PHV922-06	08-Nov-08	17	>5.0	>5.0	14.8	4.6
Test Date			24-Aug-10	30-Aug-10	19-Jul-10	19-Jul-10
Test Site			SC	SC	RL	RL
Kit Part Code			930740	930800	SP6801325	3438099
Kit Lot No.			TXE541	EXE183	8160	C6217
Kit Exp Date			05-Feb-11	20-Nov-10	12-Oct-10	07-Jan-11

¹ Immunoassay results are means of duplicates expressed as signal to cutoff ratios (s/co). Ratios ≥1.0 are considered reactive and noted in red

HCV Antibody Confirmatory
CHIRON RIBA HCV 3.0 SIA

Panel Member	Bleed Date	Days Since 1 st Bleed	c100(p) (NS4)	c33c (NS3)	c22(p) (CORE)	NS5	SOD	Results
PHV922-01	22-Oct-08	0	-	-	-	+/-	-	NEG
PHV922-02	25-Oct-08	3	-	-	+/-	+/-	-	NEG
PHV922-03	29-Oct-08	7	-	+/-	3+	+/-	-	IND
PHV922-04	01-Nov-08	10	-	-	3+	+/-	-	IND
PHV922-05	05-Nov-08	14	+/-	+/-	3+	+/-	+/-	IND
PHV922-06	08-Nov-08	17	-	+/-	3+	+/-	-	IND
Test Date								30-Aug-10
Test Site								RL
Kit Part Code								930600
Kit Lot No.								110221
Kit Exp Date								26-Mar-11

POS=positive; NEG=negative; BLD=below the limit of detection; NA=not available; f=faint; IND=Indeterminate
MFG = Manufacturer; RL = Reference Lab; SC = SeraCare