

AccuVert™ HCV Seroconversion Panel

PHV926 (0610-0225) / Batch #10311477

OVERVIEW

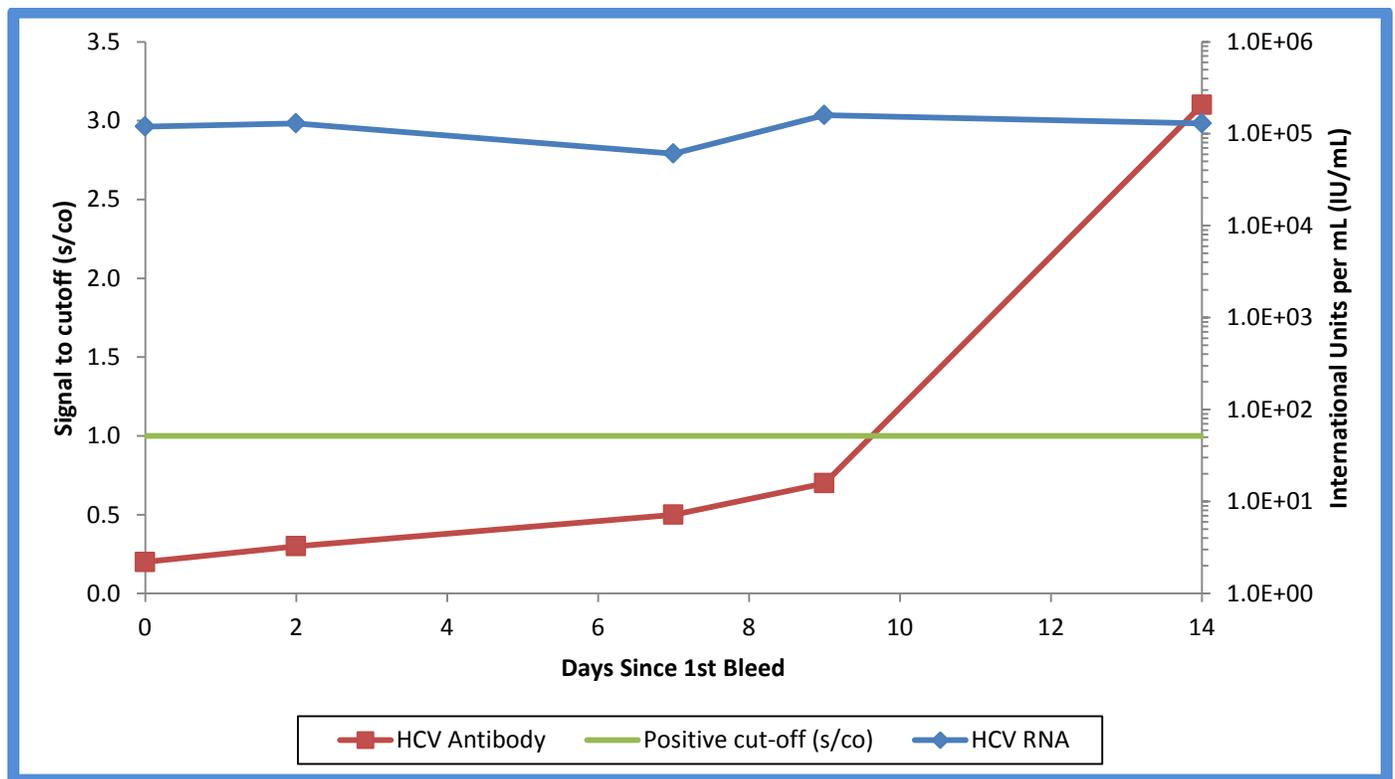
AccuVert™ HCV Seroconversion Panel PHV926 (0610-0225) / Batch #10311477 is a 5-member validation panel of naturally occurring plasma samples (1 vial per member, 1.2 mL per vial). Panel Members are undiluted aliquots from plasma units collected over 14 days from a 37-year old male with HCV genotype 3a in the United States in 2009. Test results from commercially available HCV RNA, antibody, genotype and antibody confirmatory assays are included. 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.

Evolution of HCV Markers in Early Infection



This graph demonstrates the evolution of early HCV infection, illustrated with Siemens ADVIA Centaur HCV Antibody and Abbott m2000 HCV RNA test results over time.

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Panel Member Information

Panel Member	SeraCare Batch #	SeraCare Donor ID #	Bleed Date	Days Since 1 st Bleed
01	9242336	BD110059	05-May-09	0
02	9242337	BD110059	07-May-09	2
03	9242338	BD110059	12-May-09	7
04	9242339	BD110059	14-May-09	9
05	9242340	BD110059	19-May-09	14

HCV RNA (IU/mL)¹

Panel Member	Abbott m2000 HCV RNA	Gen-Probe Procleix® Ultrio HCV RNA	Roche COBAS® AmpliPrep/TaqMan® HCV RNA	Siemens Versant® bDNA 3.0 HCV RNA
01	1.2 x 10⁵	20.8	1.8 x 10⁵	6.1 x 10⁴
02	1.3 x 10⁵	22.1	1.8 x 10⁵	5.2 x 10⁴
03	6.1 x 10⁴	22.0	3.4 x 10⁵	3.2 x 10⁴
04	1.6 x 10⁵	21.2	3.0 x 10⁵	8.5 x 10⁴
05	1.3 x 10⁵	20.7	1.6 x 10⁵	7.4 x 10⁴
Test Date	21-Dec-12	02-Jan-13	22-Dec-12	28-Dec-12
Test Site	RL	RL	RL	RL
Kit Part Code	1N30-90	302577	03568555 190	02553870/02554338
Kit Lot No.	10216701	0359993715	R00323	CO46
Kit Exp. Date	30-Oct-13	15-Oct-13	13-Sep-13	17-Jul-13
Kit Regulatory Status	IVD/CE	IVD/CE	IVD	IVD/CE

¹Positive/reactive results are noted in bold red.

RL = Reference Lab

IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking

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HCV Antibody (s/co)^{1,2}

Panel Member	Abbott ARCHITECT HCV Ab	Abbott PRISM HCV Ab	Ortho Ver. 3.0 ELISA HCV Ab	Ortho Vitros® ECi HCV Ab	Siemens ADVIA Centaur HCV Ab	Ortho Enhanced SAVE HCV Ab
01	0.0	0.2	0.1	0.1	0.2	0.0
02	0.0	0.2	0.0	0.1	0.3	0.1
03	0.0	0.2	0.0	0.1	0.5	0.1
04	0.1	0.3	0.1	0.2	0.7	0.1
05	0.2	1.3	0.9	1.4	3.1	1.0
Test Date	28-Dec-12	26-Dec-12	19-Dec-17	19-Dec-12	24-Jan-13	19-Dec-12
Test Site	RL	RL	SC	RL	RL	SC
Kit Part Code	6C37-25	3223	930740	SP6801325	C6235	930800
Kit Lot No.	19514LI00	18640M500	TXE660	8770	235.0	EXE213
Kit Exp. Date	06-May-13	06-Jan-13	26-May-18	31-Jan-13	25-Sep-13	11-Apr-13
Kit Regulatory Status	IVD/CE	IVD/CE	IVD/CE	IVD/CE	IVD/CE	CE

¹Results are reported as a signal to cutoff ratio (s/co); positive/reactive results are noted in bold red.

²Results are reported as the mean result of duplicate testing.

SC = SeraCare; RL = Reference Lab

IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking

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HCV Genotype / HCV Antibody Confirmatory

Panel Member	Siemens TRUGENE® HCV Genotype	Innogenetics INNO-LIA™ HCV Score						Result
		C1	C2	E2	NS3	NS4	NS5	
01	3a	-	-	-	-	-	-	Neg
02	3a	-	-	-	-	-	-	Neg
03	3a	-	-	-	-	-	-	Neg
04	3a	-	-	-	-	-	-	Neg
05	3a	-	-	-	2+	-	-	IND
Test Date	07-Jan-13	09-Jan-13						
Test Site	RL	RL						
Kit Part Code	NA	80538						
Kit Lot No.	NA	228056						
Kit Exp. Date	NA	30-Sep-13						
Kit Regulatory Status	RUO	IVD/HC/CE						

Neg = Negative; IND = Indeterminate

RL = Reference Lab

NA = Not Available

RUO = Research Use Only; IVD = In Vitro Diagnostic; HC = Health Canada; CE = Conformité Européenne or CE Marking

The package insert for this panel can be found at www.seracare.com.

A printed copy of the package insert or data sheet may be requested by email at info@seracare.com, or by phone at 508.244.6400.