

AccuVert™ HCV Seroconversion Panel

PHV929 (0610-0295) / Batch #124539

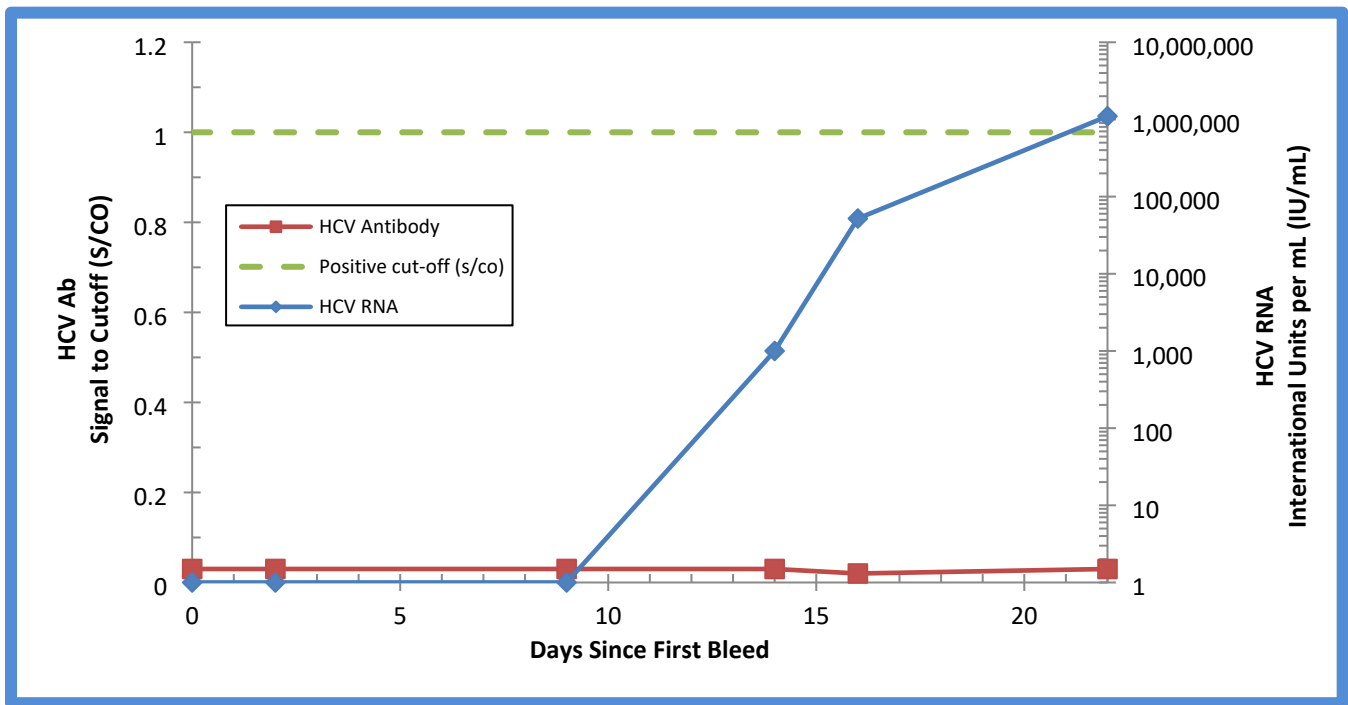
OVERVIEW

AccuVert™ HCV Seroconversion Panel PHV929 (0610-0295) / Batch #124539 is a 6-member seroconversion panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.2 mL per vial). Panel members represent bleeds collected in the United States over 22 days in 2007 from a 27 year old female with HCV genotype 1a. Test results from commercially available HCV RNA, antibody, genotype, and antibody confirmatory assays are included for characterization of the panel members. Each sample represents a single collection event. No preservatives were added.

For Research Use Only. Not for use in diagnostic procedures. Data are offered for informational purposes. LGC/SeraCare Life Sciences does not claim that others can duplicate test results exactly.

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. This does not ensure the absence of these or other human pathogens.

Evolution of HCV Markers in Early Infection



This graph demonstrates the evolution of early HCV infection amongst panel members from the Abbott ARCHITECT HCV Antibody and Abbott m2000 HCV RNA test methods.

AccuVert™ HCV Seroconversion Panel

PHV929 (0610-0295) / Batch #124539

Panel Member Information

Panel Member	SeraCare Batch #	SeraCare Donor ID #	Bleed Date	Days Since 1 st Bleed
01	124539	NA	20-Aug-2007	0
02	124539	NA	22-Aug-2007	2
03	124539	NA	29-Aug-2007	9
04	124539	NA	03-Sep-2007	14
05	124539	NA	05-Sep-2007	16
06	124539	NA	11-Sep-2007	22

NA = Not Available

HCV RNA

Panel Member	Abbott m2000 HCV RNA ^{1,3}	Gen-Probe Procleix® Ultrio® HCV RNA ^{2,3}	Roche COBAS® AmpliPrep / COBAS® TaqMan® HCV RNA ^{1,3}	Siemens Versant® bDNA 3.0 HCV RNA ^{1,3}
01	BLD	NEG	TND	BLD
02	BLD	NEG	TND	BLD
03	BLD	NEG	TND	BLD
04	1.0 x 10³	24.8	2.3 x 10³	1.5 x 10³
05	5.2 x 10⁴	24.5	8.4 x 10⁴	7.8 x 10⁴
06	1.1 x 10⁶	25.3	1.4 x 10⁶	9.7 x 10⁵
Test Date	09-May-2013	16-May-2013	25-Jul-2023	08-May-2013
Test Site	RL	RL	RL	RL
Kit Part Code	04J70-24	302577	NA	02553870/02554338
Kit Lot No.	10283431	1761520015	J18949	CO46
Kit Exp. Date	28-Feb-2014	15-Aug-2014	31-Oct-2023	17-Jul-2013

¹Results are reported as the mean result of duplicate testing expressed as International Units per mL (IU/mL).

²Results are reported as the mean result of duplicate testing expressed as a signal to cut-off value (S/CO).

³Positive/reactive results are noted in bold red.

RL = Reference Lab; NA = Not Available; BLD = Below Limit of Detection; NEG = Negative

TND = Target Not Detected

AccuVert™ HCV Seroconversion Panel

PHV929 (0610-0295) / Batch #124539

HCV Antibody

Panel Member	Abbott ARCHITECT® HCV Ab ^{1,2}	Abbott PRISM® HCV Ab ^{1,2}	Ortho Version 3.0 ELISA HCV Ab ^{1,2}	Ortho HCV Enhanced SAVE HCV Ab ^{1,2}	Ortho Vitros® Eci HCV Ab ^{1,2}	Siemens ADVIA Centaur® HCV Ab ^{1,2}
01	0.03	0.05	0.01	0.00	0.01	0.07
02	0.03	0.05	0.01	0.01	0.01	0.08
03	0.03	0.04	0.01	0.01	0.01	0.07
04	0.03	0.05	0.01	0.01	0.01	0.07
05	0.02	0.05	0.00	0.01	0.01	0.07
06	0.03	0.05	0.01	0.01	0.01	0.07
Test Date	13-May-2013	18-May-2013	06-May-2013	06-May-2013	08-May-2013	29-May-2013
Test Site	RL	RL	LGC	LGC	RL	RL
Kit Part Code	6C37-25	6A5248	930740	930800	SP6801325	3438099
Kit Lot No.	22432LI00	23266LI00	TXE590	EXE219	8770	236
Kit Exp. Date	25-Jul-2013	05-Aug-2013	07-Feb-2014	31-May-2013	31-Jan-2013	25-Sep-2013

¹Results are reported as a signal to cut-off value (S/CO); positive/reactive results are noted in bold red.

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

LGC = LGC Clinical Diagnostics; RL = Reference Lab

HCV Genotype / HCV Antibody Confirmatory

Panel Member	Siemens TRUGENE® HCV Genotype	Innogenetics INNO-LIA™ HCV Score					Result
		C1	C2	E2	NS3	NS4	
01	NA ¹	-	-	-	-	-	NEG
02	NA ¹	-	-	-	-	-	NEG
03	NA ¹	-	-	-	-	-	NEG
04	1a	-	-	-	-	-	NEG
05	1a	-	-	-	-	-	NEG
06	1a	-	-	-	-	-	NEG
Test Date	08-May-2013			10-Jun-2013			
Test Site	RL			RL			
Kit Part Code	NA			80538			
Kit Lot No.	NA			234013			
Kit Exp. Date	NA			01-Jan-2014			

¹Unable to genotype.

RL = Reference Lab; NA = Not Available; NEG = Negative

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 CDx-Info@LGCGroup.com or
by phone at 508.244.6400.