

AccuVert™ HCV Seroconversion Panel

0610-0293 (PHV927) / Batch #124537

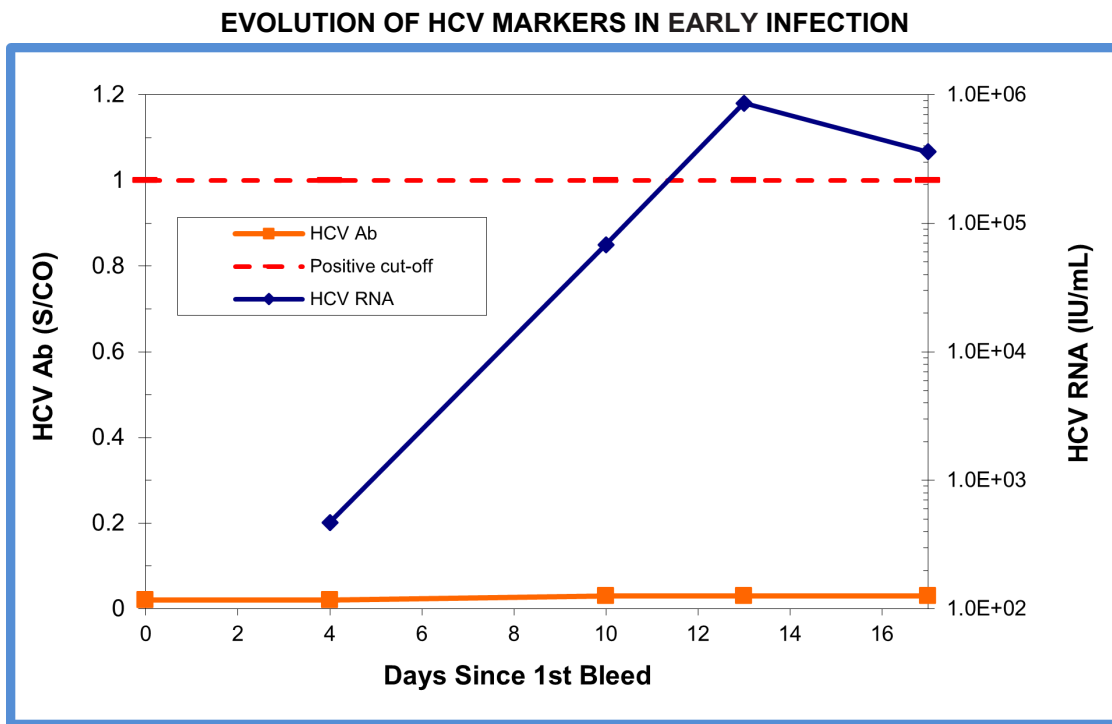
OVERVIEW

HCV Seroconversion Panel 0610-0293 (PHV927) Batch #124537 (genotype 1a) is a 5-member panel of undiluted, naturally-occurring plasma samples, collected in the United States over 17 days in 2006 from a 49-year old female. No preservatives were added.

Test results from commercially-available HCV RNA, antibody, genotype, and antibody confirmatory assays are included. The Innogenetics INNO-LIA HCV Score antibody confirmatory assay is included to replace the discontinued Chiron RIBA 3.0 HCV antibody confirmatory test, providing users with the opportunity to view performance from another commercially available kit.

For Research Use Only. Not for use in diagnostic procedures. Data are provided 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 graph demonstrates the evolution of early HCV infection, illustrated with Abbott ARCHITECT HCV Antibody and Abbott m2000 HCV RNA test results over time for different analytes or analyte combinations.

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Panel Member Information

Panel Member	Bleed Date	Days Since 1 st Bleed
PHV927-01	13-Jun-2006	0
PHV927-02	17-Jun-2006	4
PHV927-03	23-Jun-2006	10
PHV927-04	26-Jun-2006	13
PHV927-05	30-Jun-2006	17

HCV RNA¹

Panel Member	Abbott m2000 HCV RNA (IU/mL)	Gen-Probe Procleix® Ultrio® HCV RNA (S/CO)	Roche COBAS® AmpliPrep/TaqMan® HCV Test, v2.0 (IU/mL)	Siemens Versant® bDNA 3.0 HCV RNA (IU/mL)
PHV927-01	BLD	NEG	TND	BLD
PHV927-02	4.7 x 10²	25.9	8.15 X 10²	BLD
PHV927-03	6.8 x 10⁴	25.6	6.25 X 10⁴	4.8 x 10⁴
PHV927-04	8.6 x 10⁵	23.9	4.15 X 10⁵	5.3 x 10⁵
PHV927-05	3.6 x 10⁵	25.4	2.17 X 10⁵	1.8 x 10⁵
Test Date	09-May-13	16-May-13	23-Oct-23	08-May-13
Test Site	RL	RL	RL	RL
Kit Part Code	04J70-24	302577	NA	02553870/02554338
Kit Lot No.	10283431	1761520015	K04281	CO46
Kit Expiration Date	28-Feb-14	15-Aug-14	30-Apr-24	17-Jul-13

¹Results are reported as the mean result of duplicate testing. Positive/reactive results are noted in bold red.
BLD = Below Limit of Detection; NEG = Negative; TND = Target Not Detected; RL = Reference Lab

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HCV Antibody¹

Panel Member	Abbott ARCHITECT® HCV Ab (S/CO)	Abbott PRISM® HCV Ab (S/CO)	Ortho Ver. 3.0 ELISA HCV Ab (S/CO)
PHV927-01	0.02	0.07	0.00
PHV927-02	0.02	0.05	0.01
PHV927-03	0.03	0.06	0.01
PHV927-04	0.03	0.06	0.01
PHV927-05	0.03	0.06	0.01
Test Date	13-May-13	18-May-13	06-May-13
Test Site	RL	RL	SC
Kit Part Code	6C37-25	6A5248	930740
Kit Lot No.	22432LI00	23266LI00	TXE590
Kit Expiration Date	25-Jul-13	05-Aug-13	07-Feb-14

¹Results are reported as the mean result of duplicate testing. Positive/reactive results are noted in bold red.
RL = Reference Lab; SC = SeraCare

HCV Antibody¹

Panel Member	Ortho Enhanced SAve HCV Ab (S/CO)	Ortho Vitros® ECi HCV Ab (S/CO)	Siemens ADVIA Centaur® HCV Ab (S/CO)
PHV927-01	0.01	0.01	0.07
PHV927-02	0.01	0.01	0.06
PHV927-03	0.00	0.01	0.07
PHV927-04	0.01	0.01	0.07
PHV927-05	0.01	0.01	0.07
Test Date	06-May-13	08-May-13	29-May-13
Test Site	SC	RL	RL
Kit Part Code	930800	SP6801325	3438099
Kit Lot No.	EXE219	8770	236
Kit Expiration Date	31-May-13	31-Jan-13	25-Sep-13

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HCV Genotype/HCV Antibody Confirmatory

Panel Member	Siemens	C1	C2	E2	Innogenetics			Result
	TRUGENE® HCV Genotype				NS3	NS4	NS5	
PHV927-01	NA ¹	-	-	-	-	-	-	NEG
PHV927-02	1a	-	-	-	-	-	-	NEG
PHV927-03	1a	-	-	-	-	-	-	NEG
PHV927-04	1a	-	-	-	-	-	-	NEG
PHV927-05	1a	-	-	-	-	-	-	NEG
Test Date	08-May-13						10-Jun-13	
Test Site	RL						RL	
Kit Part Code	NA						80538	
Kit Lot No.	NA						234013	
Kit Expiration Date	NA						01-Jan-14	

¹Unable to genotype.

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

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.