OVERVIEW

HCV Seroconversion Panel PHV929 (genotype 1a) is a 6-member panel of undiluted, naturally-occurring plasma samples, collected in the United States over 22 days in 2007 from a 27-year old female. No preservatives were added.

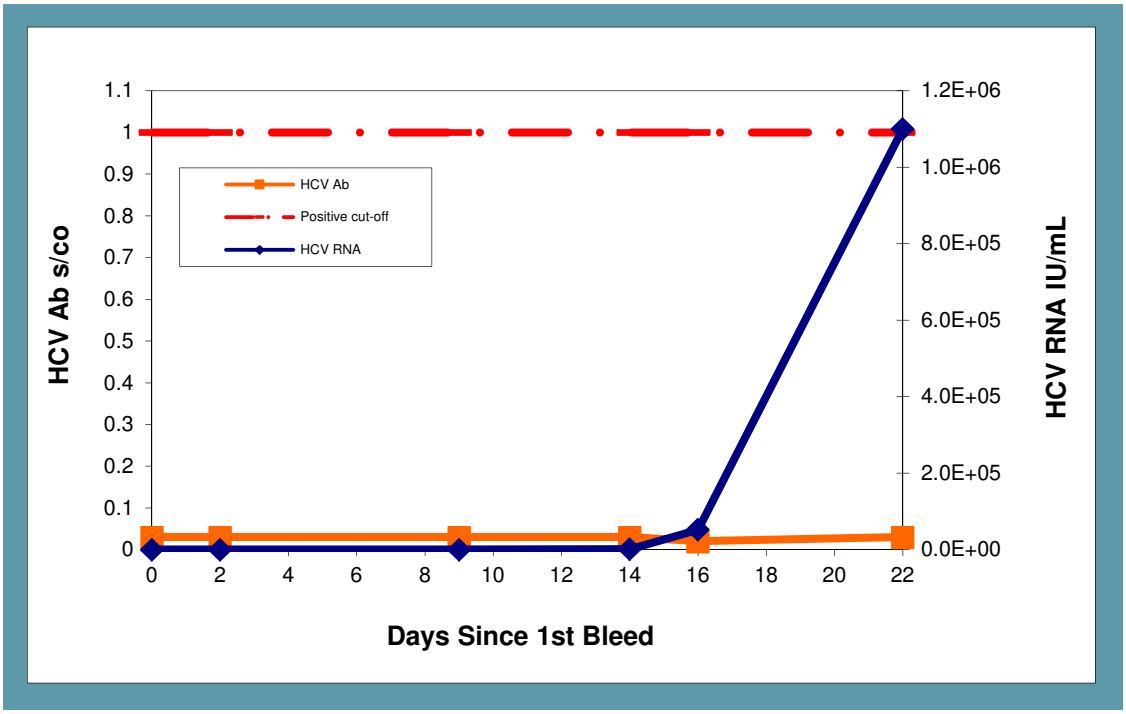
Test results from commercially-available HCV RNA, antibody, genotype, and antibody confirmatory assays are included. The Innogenetics INNO-LIA HCV Score antibody confirmatory assay is included to replace the discontinued Chiron RIBA 3.0 HCV antibody confirmatory test, providing users with the opportunity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

For Research Use Only. Not for use in diagnostic procedures. Data are provided for informational purposes. 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.

For assistance, contact SeraCare Technical Support at 508.244.6400.

EVOLUTION OF HCV MARKERS IN EARLY INFECTION



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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DATA SHEET

HCV RNA

Panel Member	Bleed Date	Days Since 1st Bleed	Abbott *m*2000 HCV RNA[1]	Gen-Probe Procleix® Ultrio® HCV RNA[2]	Roche COBAS® AmpliPrep/TaqMan® HCV RNA[1]	Siemens Versant® bDNA 3.0 HCV RNA[1]
PHV929-01	20 Aug 07	0	BLD	NEG	BLD	BLD
PHV929-02	22 Aug 07	2	BLD	NEG	BLD	BLD
PHV929-03	29 Aug 07	9	BLD	NEG	BLD	BLD
PHV929-04	03 Sep 07	14	1.0×10^3	24.8	2.6×10^3	1.5×10^3
PHV929-05	05 Sep 07	16	5.2×10^4	24.5	1.5×10^5	7.8×10^4
PHV929-06	11 Sep 07	22	1.1×10^6	25.3	3.1×10^6	9.7×10^5
Test Date			09 May 13	16 May 13	06 May 13	08 May 13
Test Site			RL	RL	SC	RL
Kit Part Code			04J70-24	302577	03568555190	02553870/02554338
Kit Lot No.			10283431	1761520015	R00325	CO46
Kit Expiration Date			28 Feb 14	15 Aug 14	31 Jul 14	17 Jul 13
Kit Regulatory Status			IVD/CE	IVD/CE	IVD	IVD/CE

[1]Results are reported as the mean result of duplicate testing expressed as International Units per mL (IU/mL).
[2]Results are reported as the mean result of duplicate testing expressed as a sample to cut-off value (S/CO).

HCV Antibody

Panel Member	Bleed Date	Days Since 1st Bleed	Abbott ARCHITECT® HCV Ab[1]	Abbott PRISM® HCV Ab[1]	Ortho Ver. 3.0 ELISA HCV Ab[1]	Ortho Enhanced SAVe HCV Ab[1]
PHV929-01	20 Aug 07	0	0.03	0.05	0.01	0.00
PHV929-02	22 Aug 07	2	0.03	0.05	0.01	0.01
PHV929-03	29 Aug 07	9	0.03	0.04	0.01	0.01
PHV929-04	03 Sep 07	14	0.03	0.05	0.01	0.01
PHV929-05	05 Sep 07	16	0.02	0.05	0.00	0.01
PHV929-06	11 Sep 07	22	0.03	0.05	0.01	0.01
Test Date			13 May 13	18 May 13	06 May 13	06 May 13
Test Site			RL	RL	SC	SC
Kit Part Code			6C37-25	6A5248	930740	930800
Kit Lot No.			22432LI00	23266LI00	TXE590	EXE219
Kit Expiration Date			25 Jul 13	05 Aug 13	07 Feb 14	31 May 13
Kit Regulatory Status			IVD/CE	IVD/CE	IVD/CE	CE

[1]Results are reported as the mean result of duplicate testing expressed as a sample to cut-off value (S/CO). Results in red are considered positive/reactive.

BLD = Below Limit of Detection; NEG = Negative
RL = Reference Lab; SC = SeraCare
IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking

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DATA SHEET

HCV Antibody

Panel Member	Bleed Date	Days Since 1st Bleed	Ortho Vitros® ECi HCV Ab[1]	Siemens ADVIA Centaur® HCV Ab[1]
PHV929-01	20 Aug 07	0	0.01	0.07
PHV929-02	22 Aug 07	2	0.01	0.08
PHV929-03	29 Aug 07	9	0.01	0.07
PHV929-04	03 Sep 07	14	0.01	0.07
PHV929-05	05 Sep 07	16	0.01	0.07
PHV929-06	11 Sep 07	22	0.01	0.07
Test Date			08 May 13	29 May 13
Test Site			RL	RL
Kit Part Code			SP6801325	3438099
Kit Lot No.			8770	236
Kit Expiration Date			31 Jan 13	25 Sep 13
Kit Regulatory Status			IVD/CE	IVD/CE

[1]Results are reported as the mean result of duplicate testing expressed as a sample to cut-off value (S/CO). Results in red are considered positive/reactive.

HCV Genotype/HCV Antibody Confirmatory

Panel Member	Bleed Date	Days Since 1st Bleed	Siemens TRUGENE® HCV Genotype	Innogenetics INNO-LIA™ HCV Score C1	C2	E2	NS3	NS4	NS5	Result
PHV929-01	20 Aug 07	0	NA[1]	-	-	-	-	-	-	NEG
PHV929-02	22 Aug 07	2	NA[1]	-	-	-	-	-	-	NEG
PHV929-03	29 Aug 07	9	NA[1]	-	-	-	-	-	-	NEG
PHV929-04	03 Sep 07	14	1a	-	-	-	-	-	-	NEG
PHV929-05	05 Sep 07	16	1a	-	-	-	-	-	-	NEG
PHV929-06	11 Sep 07	22	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			
Kit Regulatory Status			RUO				IVD/HC/CE			

[1]Unable to genotype.
NA = Not Available; NEG = Negative; RL = Reference Lab; SC = SeraCare; IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking
HC = Health Canada; RUO = Research Use Only

The Package Insert for this panel in PDF form 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

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