

OVERVIEW

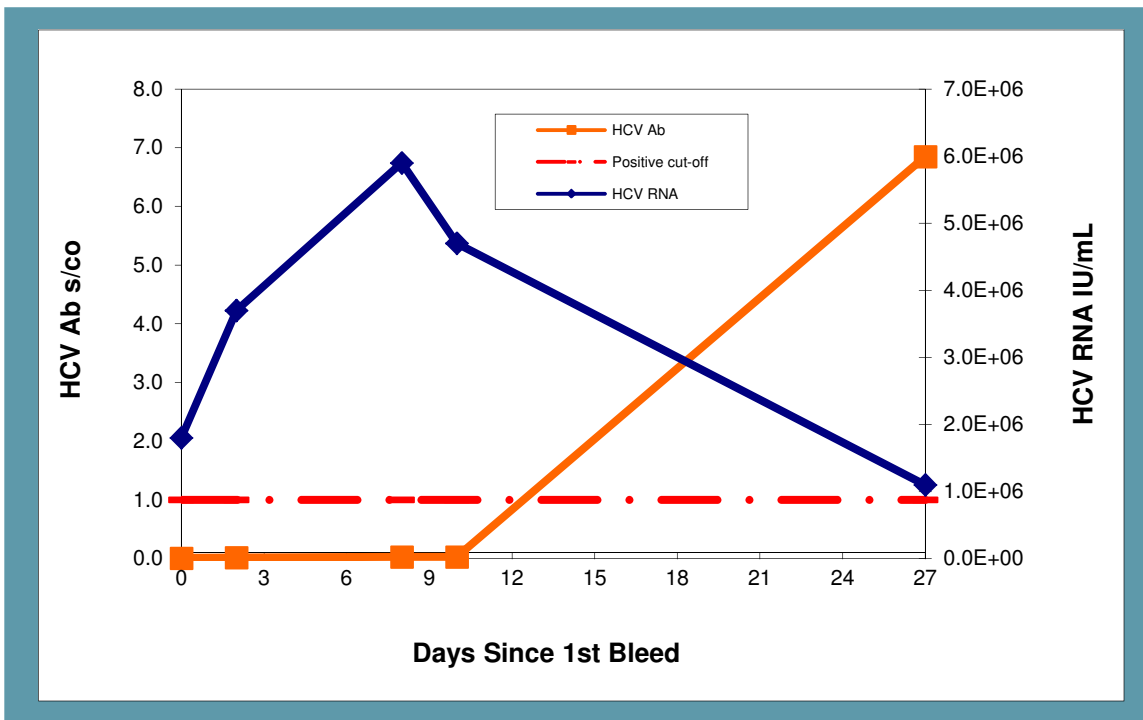
This Data Sheet contains test results specific for HCV Seroconversion Panel PHV925, genotype 1a. Panel Members are undiluted aliquots from plasma units collected over 27 days from a 24-year old in the United States in 2008. INNOGENETICS INNO-LIA HCV Score antibody confirmatory assay is used to replace the discontinued Chiron RIBA 3.0 HCV antibody confirmatory test, giving users the opportunity to see performance of another commercially available kit. 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 Abbott ARCHITECT HCV Antibody and Abbott m2000 HCV RNA test results over time for different analytes or analyte combinations.

HCV Seroconversion Panel PHV925

DATA SHEET

HCV RNA (IU/mL)

Panel Member	Bleed Date	Days Since 1st Bleed	Abbott m2000 HCV RNA	Gen-Probe Procleix [®] Ultrio HCV RNA	Roche COBAS [®] AmpliPrep/TaqMan [®] HCV RNA	Siemens Versant [®] bDNA 3.0 HCV RNA
PHV925-01	03 Dec 08	0	1.8 x 10 ⁶	21.9	2.8 x 10 ⁶	1.2 x 10 ⁶
PHV925-02	05 Dec 08	2	3.7 x 10 ⁶	21.3	9.8 x 10 ⁶	2.8 x 10 ⁶
PHV925-03	11 Dec 08	8	5.9 x 10 ⁶	21.9	1.8 x 10 ⁷	4.9 x 10 ⁶
PHV925-04	13 Dec 08	10	4.7 x 10 ⁶	22.3	1.6 x 10 ⁷	3.8 x 10 ⁶
PHV925-05	30 Dec 08	27	1.1 x 10 ⁶	21.4	3.6 x 10 ⁶	6.6 x 10 ⁵
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 Expiration Date			30 Oct 13	15 Oct 13	13 Sep 13	17 Jul 13
Kit Regulatory Status			IVD/CE	IVD/CE	IVD	IVD/CE

HCV Antibody (s/co)¹

Panel Member	Bleed Date	Days Since 1st Bleed	Abbott ARCHITECT HCV Ab	Abbott PRISM HCV Ab	Ortho Ver. 3.0 ELISA HCV Ab	Ortho Enhanced SAVE HCV Ab
PHV925-01	03 Dec 08	0	0.02	0.08	0.01	0.02
PHV925-02	05 Dec 08	2	0.02	0.08	0.01	0.02
PHV925-03	11 Dec 08	8	0.03	0.14	0.02	0.03
PHV925-04	13 Dec 08	10	0.03	0.23	0.05	0.08
PHV925-05	30 Dec 08	27	6.85	5.79 ²	4.98	4.95
Test Date			28 Dec 12	08 Jan 13	19 Dec 12	19 Dec 12
Test Site			RL	RL	SC	SC
Kit Part Code			6C37-25	6A52-48	930740	930800
Kit Lot No.			19514LI00	18924LI00	TXE576	EXE213
Kit Expiration Date			06 May 13	30 Mar 13	26 Apr 13	11 Apr 13
Kit Regulatory Status			IVD/CE	IVD/CE	IVD/CE	CE

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

²Result is a mean of four replicates.

RL = Reference Lab; SC = SeraCare

CE = Conformité Européenne or CE Marking; IVD = in vitro diagnostic use

HCV Seroconversion Panel PHV925

DATA SHEET

HCV Antibody (s/co)¹

Panel Member	Bleed Date	Days Since 1 st Bleed	Ortho Vitros [®] ECi HCV Ab	Siemens ADVIA Centaur HCV Ab
PHV925-01	03 Dec 08	0	0.01	0.05
PHV925-02	05 Dec 08	2	0.01	0.03
PHV925-03	11 Dec 08	8	0.02	0.08
PHV925-04	13 Dec 08	10	0.09	0.26
PHV925-05	30 Dec 08	27	24.1	>11.0
Test Date			19 Dec 12	24 Jan 13
Test Site			RL	RL
Kit Part Code			SP6801325	C6235
Kit Lot No.			8770	235.0
Kit Expiration Date			31 Jan 13	25 Sep 13
Kit Regulatory Status			IVD/CE	IVD/CE

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

HCV Genotype/HCV Antibody Confirmatory

Panel Member	Bleed Date	Days Since 1 st Bleed	Siemens TRUGENE [®] HCV Genotype	Innogenetics INNO-LIA [™] HCV Score						Result
				C1	C2	E2	NS3	NS4	NS5	
PHV925-01	03 Dec 08	0	1a	-	-	-	-	-	-	Neg
PHV925-02	05 Dec 08	2	1a	-	-	-	-	-	-	Neg
PHV925-03	11 Dec 08	8	1a	-	-	-	-	-	-	Neg
PHV925-04	13 Dec 08	10	NA ²	-	-	-	+/-	-	-	IND
PHV925-05	30 Dec 08	27	1a	4+	4+	-	4+	2+	2+	Pos
Test Date			28 Dec 12				09 Jan 13			
Test Site			RL				RL			
Kit Part Code			NA				80538			
Kit Lot No.			NA				228056			
Kit Expiration Date			NA				30 Sep 13			
Kit Regulatory Status			RUO				IVD/HC/CE			

²Not applicable, unable to genotype.

NEG = negative; POS = positive; IND = Indeterminate
RL = Reference Lab

CE = Conformité Européenne or CE Marking; IVD = in vitro diagnostic use; RUO = Research Use Only; HC = Health Canada

The Product Insert for this panel in PDF form can be found at www.seracare.com

The printed 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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