AccuVert™ HCV Seroconversion Panel

PHV925 (0610-0224) / Batch #10375695

OVERVIEW

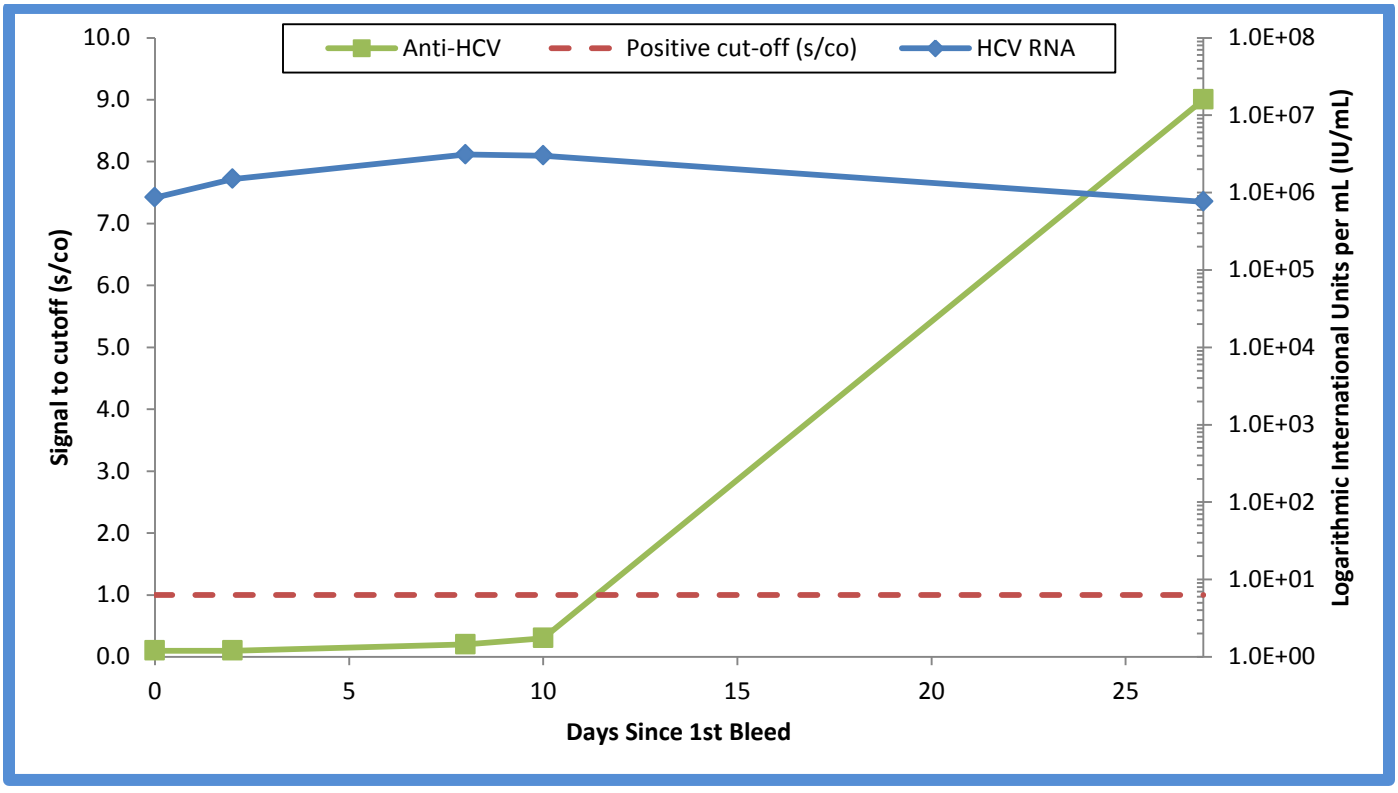
AccuVert™ HCV Seroconversion Panel PHV925 (0610-0224) / Batch #10375695 is a 5-member panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.2 mL) collected over 27 days from a 24-year old in 2008 during a period of HCV seroconversion. This donor has been characterized as genotype 1a.

Test results from commercially-available HCV RNA, antibody and confirmatory assays are included for reference. This panel converts from negative to positive for anti-HCV.

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

CAUTION: Potentially infectious materials. Follow Universal Precautions. The units that make up this panel were tested and found negative for Anti-HIV-1/2 and HBsAg. 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 (Anti-HCV) and Abbott m2000 (HCV RNA) test methods.

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Panel Member Information

Panel Member	SeraCare Batch #	SeraCare Donor ID #	Bleed Date	Days Since 1st Bleed
01	9239419	BD107566	03-Dec-2008	0
02	9239420	BD107566	05-Dec-2008	2
03	9239421	BD107566	11-Dec-2008	8
04	9239423	BD107566	13-Dec-2008	10
05	9239424	BD107566	30-Dec-2008	27

HCV RNA and HCV Confirmatory

Panel Member	Abbott m2000 Realtime HCV (IU/mL)[1,2]	Roche COBAS® AmpliPrep/COBAS® TaqMan® HCV Quantitative Test, v2.0 (IU/mL)[1,2]	Fujirebio INNO-LIA® HCV Score Band Pattern	Fujirebio INNO-LIA® HCV Score Interpretation
01	**8.6E+05**	**1.0E+06**	No Bands	NEG
02	**1.5E+06**	**3.4E+06**	No Bands	NEG
03	**3.1E+06**	**3.7E+06**	No Bands	NEG
04	**3.0E+06**	**3.8E+06**	No Bands	NEG
05	**7.6E+05**	**8.6E+05**	**C1, C2, NS3, NS4, NS5**	**POS**
Test Date	01-Nov-2018	01-Nov-2018	15-Nov-2018	
Test Site	RL	RL	RL	
Kit Part Code	NA	NA	NA	
Kit Lot No.	NA	NA	404975	
Kit Exp. Date	NA	NA	28-Feb-2019	
Kit Regulatory Status	IVD	IVD/CE	IVD/CE	

[1]Results are reported as international units per mL (IU/mL); positive/reactive results are noted in bold red.
[2]Results are reported as the mean result of duplicate testing.
NA = Not Available
RL = Reference Lab
IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking

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Anti-HCV

Panel Member	Abbott ARCHITECT Anti-HCV (s/co)[1,3]	Ortho® HCV Version 3.0 ELISA Test System (s/co)[1,3]	Roche Elecsys® Anti-HCV (s/co)[1,3]	Siemens ADVIA Centaur® Anti-HCV (INDEX)[2,3]
01	0.1	0.0	0.1	0.1
02	0.1	0.0	0.1	0.1
03	0.2	0.0	**2.3**	0.1
04	0.3	0.0	**9.4**	0.3
05	**9.0**	**>6.5**[4]	**56.8**	**>11.0**[4]
Test Date	29-Oct-2018	26-Oct-2018	08-Nov-2018	31-Oct-2018
Test Site	SC	SC	RL	RL
Kit Part Code	1L79	930740	NA	NA
Kit Lot No.	83370LI00	TXE670	NA	NA
Kit Exp. Date	15-Nov-2018	10-May-2019	NA	NA
Kit Regulatory Status	IVD/CE	IVD	IVD	IVD/CE

[1]Results are reported as a signal to cutoff ratio (s/co); positive/reactive results are noted in bold red.
[2]Results are reported as an Index value (INDEX); positive/reactive results are noted in bold red.
[3]Results are reported as the mean result of duplicate testing.
[4]Off-scale
NA = Not Available
SC = SeraCare; RL = Reference Lab
IVD = In Vitro Diagnostic; 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.