

AccuVert[™] HCV Seroconversion Panel PHV926 (0610-0225) / Batch 10571151

OVERVIEW

AccuVert[™] HCV Seroconversion Panel PHV926 (0610-0225) Batch 10571151 is a 5-member panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.2 mL per vial). Panel members represent serial bleeds collected over 14 days from a 37-year old male with HCV Genotype¹ 3a in the United States in 2009. No preservatives were added.

Test results from commercially-available HCV assays are included for characterization of each panel member. This panel of human plasma samples demonstrates a change in expression from negative to positive for antibodies to HCV during the development and progression of an HCV infection.

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. All panel members were found positive for HCV and negative for anti-HIV-1/2 and HBsAg. This does not ensure the absence of these or other human pathogens.

160 100,000 140 10,000 120 Cutoff Index (COI) **HCV** Antibody 100 1,000 **HCV RNA** Positive cut-off (COI) 80 **HCV RNA** 100 60 40 10 20 0 1 2 8 4 6 10 12 14 **Days Since First Bleed**

AccuVert™ HCV Seroconversion Panel PHV926 (0610-0225)

This graph demonstrates the evolution of early HCV infection amongst panel members from the Roche COBAS® AmpliPrep / COBAS® TaqMan® HCV Test, v2.0 (HCV RNA) and the Roche cobas® Elecsys Anti-HCV II (HCV antibody) test methods.

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¹ Individual member units tested at a reference lab 07-Jan-2013 using Siemens TRUGENE assay and identified as HCV Genotype 3a.



AccuVert™ HCV Seroconversion Panel

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Panel Member Information

Panel Member	SeraCare Batch#	SeraCare Donor ID #	Bleed Date	Days Since 1st Bleed
01	9242336	BD110059	05-May-2009	0
02	9242337	BD110059	07-May-2009	2
03	9242338	BD110059	12-May-2009	7
04	9242339	BD110059	14-May-2009	9
05	9242340	BD110059	19-May-2009	14

HCV RNA

Panel Member	Abbott RealTime HCV m2000 RT-PCR (IU/mL) ^{1,2}	Roche COBAS [®] AmpliPrep / COBAS [®] TaqMan [®] HCV Test, v2.0 (IU/mL) ^{1,2}		
01	1.2 x 10 ⁴	2.6 x 10 ⁴		
02	8.1 x 10 ³	1.8 x 10 ⁴		
03	6.5 x 10 ³	1.4 x 10 ⁴		
04	8.9 x 10 ³	1.8 x 10 ⁴		
05	2.2 x 10 ⁴	4.4 x 10 ⁴		
Test Date	15-Sep-2021	16-Sep-2021		
Test Site	RL	RL		
Kit Part Code	NA	NA		
Kit Lot No.	10002586	H07572		
Kit Exp. Date	31-Jul-2022	31-Dec-2021		

¹Results are reported as International Units per mL (IU/mL); positive/reactive results are noted in bold red.

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

RL = Reference Lab; NA = Not Available



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HCV Antibody

Panel Member	Abbott ARCHITECT Anti-HCV (S/CO) ¹	ORTHO® HCV Version 3.0 ELISA (S/CO)¹	Siemens ADVIA Centaur [®] HCV (aHCV) (Index) ¹	Roche cobas® Elecsys Anti-HCV II (COI)¹	
01	0.1	0.1	0.3	8.7	
02	0.1	0.1	0.3	9.9	
03	0.2	0.1	0.7	38.9	
04	0.3	0.2	0.8*	63.8	
05	2.1	1.6	3.2	145.5	
Test Date	23-Sep-2021	13-Sep-2021	14-Sep-2021	13-Oct-2021	
Test Site	SC	SC	RL	RL	
Kit Part Code	1L79	930740	NA	NA	
Kit Lot No.	22295BE00	TXE708	413	NA	
Kit Exp. Date	11-Oct-2021	27-May-2022	14-Jun-2022	NA	

 $^{^{1}}$ Results are reported as the mean result of duplicate testing; positive/reactive results are noted in bold red.

HCV Antibody (Supplemental)

Panel Member	Fujirebio INNO-LIA™ HCV Score¹						
	C 1	C2	E2	NS3	NS4	NS5	Result
01	-	-	-	-	-	-	Neg
02	-	-	-	-	-	-	Neg
03	-	-	-	-	-	-	Neg
04	-	-	-	-	-	-	Neg
05	-	-	-	1+	-	-	IND
Test Date	22-Sep-2021						
Test Site	RL						
Kit Part Code	NA						
Kit Lot No.	408103						
Kit Exp. Date	31-Jan-2022						

¹Results are reported based on singlicate testing.

RL = Reference Lab; NA = Not Available

NEG = Negative; IND = Indeterminate

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.

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^{*}Result is considered equivocal.

SC = SeraCare; RL = Reference Lab; NA = Not Available