

14459-01

December 2024

AccuVert[™] HCV Seroconversion Panel 0610-0225 / Batch #10724087

OVERVIEW

AccuVert[™] HCV Seroconversion Panel 0610-0225 / Batch #10724087 is a 5-member validation 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 Genotype 3a in the United States in 2009. No preservatives were added.

Test results from commercially-available HCV assays are included for characterization of the panel members. 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; all were found negative for anti-HIV-1/2 and HBsAg. This does not ensure the absence of these or other human pathogens.

40 10,000 35 30 1.000 **HCV** Antibody Signal to Cutoff (s/co) 25 Positive cut-off (S/CO) **HCV RNA** 100 20 15 10 10 5 0 2 3 7 4 5 6 8 9 10 11 12 13 14 **Days Since First Bleed**

AccuVert™ HCV Seroconversion Panel

This graph demonstrates the evolution of early HCV infection amongst panel members from the Roche cobas® 6800/8800 HCV Test (HCV RNA) and the Abbott Alinity's Anti-HCV (HCV Antibody) test methods.

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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 RNA¹

	Roche cobas [®]	Abbott		
	6800/8800	Alinity m		
	HCV RNA	HCV RNA		
Panel Member	(IU/mL)	(IU/mL)		
01	4.54 x 10 ³	6.78 x 10 ³		
02	3.19 x 10 ³	4.82 x 10 ³		
03	2.16 x 10 ³	2.31 x 10 ³		
04	3.13 x 10 ³	4.50 x 10 ³		
05	7.58 x 10 ³	8.70 x 10 ³		
Test Date	05-Nov-2024	06-Nov-2024		
Test Site	RL	RL		
Kit Part Code	NA	NA		
Kit Lot No.	NA	400201		
Kit Exp. Date	NA	11-Dec-2025		

¹Results are reported as the mean result of duplicate testing; positive/reactive results are noted in bold red. RL = Reference Lab; Not Available

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Anti-HCV1

	Abbott Alinity s Anti-HCV	Roche cobas [®] Elecsys Anti-HCV II	Siemens ADVIA Centaur® HCV (IgG)	Ortho® HCV Version 3.0 ELISA	
Panel Member	(S/CO)	(COI)	(Index Value)	(S/CO)	
01	1.62	5.72	0.45	0.03	
02 2.56		7.77	0.53	0.04	
03	5.84	31.10	0.73	0.06	
04	10.14	66.90	0.94*	0.12	
05 32.42		300.00	3.26	1.16	
Test Date	05-Nov-2024	15-Nov-2024	07-Nov-2024	04-Nov-2024	
Test Site	Test Site RL		RL	LGC	
Kit Part Code NA		NA	NA	6195566	
Kit Lot No. 62454BE00		NA	86234473	SXE058	
Kit Exp. Date	28-Apr-2025	NA	07-May-2025	03-May-2025	

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

HCV Confirmatory Assay¹

Panel Member	INNOGENETICS [®] INNO-LIA™ HCV Score							
	Band Results							
	HCV Antibody Interpretation	C1	C2	E2	NS3	NS4	NS5	
01	NEG	-	-	-	-	-	-	
02	NEG	-	-	-	-	-	-	
03	NEG	-	-	-	-	-	-	
04	NEG	-	-	-	-	-	-	
05	IND	-	-	-	1+	-	-	
Test Date	19-Nov-2024							
Test Site	RL							
Kit Part Code	NA							
Kit Lot No.	290596							
Kit Exp. Date	30-Jun-2025							

¹Results are reported as singlicate testing. RL = Reference Lab; NA = Not Available NEG = Negative; IND = Indeterminate

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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

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