

www.seracare.com

November 2023

14285-01

AccuVert[™] HCV Seroconversion Panel 0610-0223 / Batch #10683758

OVERVIEW

AccuVert[™] HCV Seroconversion Panel 0610-0223 / Batch #10683758 is a 6-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 the course of 88 days in 2008 from a 46-year old male with HCV genotype 2b. Each sample represents a single collection event. 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 converts from negative to positive for HCV Antibody.

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

10.000.000 14 HCV Antibody — Positive cut-off (S/CO) — HCV RNA 1,000,000 12 10 100.000 HCV Antibody Signal to Cutoff (S/CO) 8 10.000 1,000 🛣 6 100 4 2 10 40 10 20 30 50 60 70 80 **Days Since First Bleed**

AccuVert™ HCV Seroconversion Panel

This graph demonstrates the evolution of early HCV infection amongst panel members from the Abbott ARCHITECT (Anti-HCV) and the Roche COBAS (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	9235383	BD107287	22-Sep-2008	0	
02	9235384	BD107287	25-Sep-2008	3	
03	9235385	BD107287	29-Sep-2008	7	
04	9235300	BD107287	20-Nov-2008	59	
05	9235519	BD107287	25-Nov-2008	64	
06	9237286	BD107287	19-Dec-2008	88	

HCV RNA1

	Roche cobas®	Abbott
	6800/8800	Alinity m
	HCV RNA	HCV RNA
Panel Member	(IU/mL)	(IU/mL)
01	1.21 x 10 ⁶	9.80 x 10⁵
02	4.74 x 10 ⁵	3.79 x 10⁵
03	4.10 x 10⁵	2.98 x 10 ⁵
04	3.23 x 10 ³	2.84 x 10 ³
05	1.26 x 10 ³	1.20 x 10 ³
06	6.30 x 10 ²	4.16 x 10 ²
Test Date	12-Oct-2023	12-Oct-2023
Test Site	RL	RL
Kit Part Code	NA	NA
Kit Lot No.	NA	385356
Kit Exp. Date	NA	10-Feb-2025

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

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Anti-HCV1

	Abbott ARCHITECT Anti-HCV	Roche cobas [®] Elecsys Anti-HCV II	Abbott Alinity s Anti-HCV	ORTHO HCV Version 3.0 ELISA
Panel Member	(S/CO)	(COI)	(S/CO)	(S/CO)
01	0.40	0.08	0.20	0.05
02	0.35	0.08	0.18	0.04
03	0.27	0.09	0.14	0.03
04	9.24	176.50	5.31	4.71
05	10.89	182.35	5.92	>6.56
06	13.37	87.54	10.18	>6.56
Test Date	10-Oct-2023	08-Nov-2023	10-Oct-2023	10-Oct-2023
Test Site	LGC	RL	RL	LGC
Kit Part Code	1L79	NA	NA	6195566
Kit Lot No.	52011BE00	NA	51608BE00	SXE037
Kit Exp. Date	05-Mar-2024	NA	04-Apr-2024	20-Jan-2024

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

HCV Confirmatory Assay¹

INNOGENETICS®	DINNO-LIA™	HCV Scor	e
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30-Jun-2024

	Band Results						
Panel Member	HCV Antibody Interpretation	C1	C2	E2	NS3	NS4	NS5
01	NEG	-	-	-	-	-	-
02	NEG	-	-	-	-	-	-
03	NEG	-	-	-	-	-	-
04	POS	1+	-	-	2+	-	+/-
05	POS	2+	-	-	2+	-	+/-
06	POS	2+	-	-	3+	-	-
Test Date		20-Oct-2023					
Test Site	RL						
Kit Part Code	NA						
Kit Lot No.	411025						

¹Results are reported as singlicate testing; positive/reactive results are noted in bold red. RL = Reference Lab; NA = Not Available

NEG = Negative; POS = Positive

Kit Exp. Date

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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