

AccuVert™ HCV Seroconversion Panel

0610-0217 / Batch #10653166

OVERVIEW

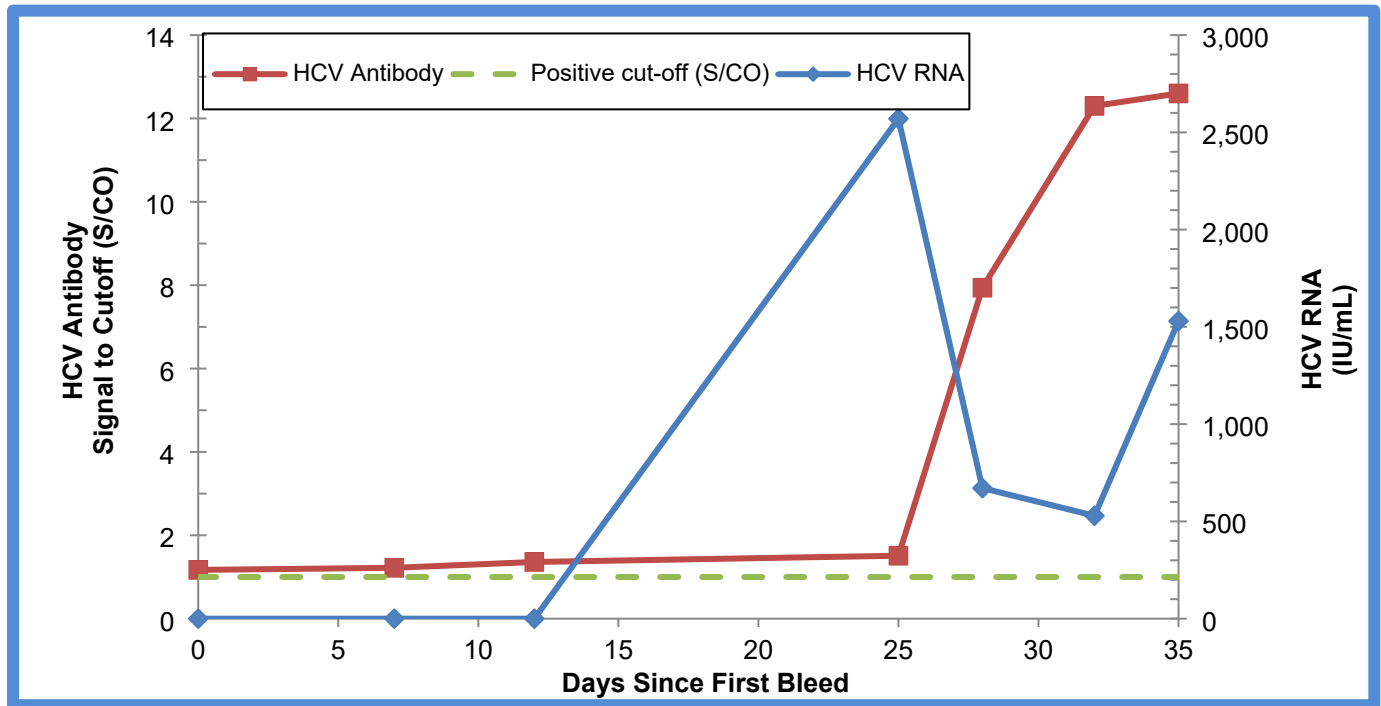
AccuVert™ HCV Seroconversion Panel 0610-0217 / Batch #10653166 is a 7-member validation panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.0 mL per vial). Panel members represent serial bleeds collected over the course of 35 days during the development of an HCV infection and subsequent response. 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 RNA.

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.

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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 #	Bleed Date	Days Since 1 st Bleed
01	9106278	31-Dec-1999	0
02	9106279	07-Jan-2000	7
03	9106280	12-Jan-2000	12
04	9106281	25-Jan-2000	25
05	9106282	28-Jan-2000	28
06	9106283	01-Feb-2000	32
07	9106284	04-Feb-2000	35

HCV RNA and Anti-HCV

Panel Member	Roche COBAS® Ampliprep/COBAS® Taqman® HCV Test, v2.0	Abbott ARCHITECT Anti-HCV	Abbott Alinity s Anti-HCV
	(IU/mL) ¹	(S/CO) ¹	(S/CO) ¹
01	TND	1.17	0.55
02	TND	1.22	0.51
03	TND	1.36	0.60
04	2.57 x 10³	1.51	0.58
05	6.71 x 10²	7.94	5.43
06	5.29 x 10²	12.30	9.32
07	1.53 x 10³	12.60	9.16
Test Date	15-Feb-2023	03-Feb-2023	02-Feb-2023
Test Site	RL	SC	RL
Kit Part Code	NA	1L79	NA
Kit Lot No.	J12718	43025BE00	43219BE00
Kit Exp. Date	31-Jul-2023	28-Jun-2023	06-Aug-2023

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

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Anti-HCV

Panel Member	Roche cobas® Elecsys Anti-HCV II (COI) ¹	Siemens ADVIA Centaur® aHCV (IgG) (Index) ¹	ORTHO HCV Version 3.0 ELISA (S/CO) ¹
01	59.24	1.31	1.12
02	62.09	1.26	0.96, 1.04*
03	64.86	1.43	1.13
04	65.45	1.47	1.09
05	115.60	>11.00	6.03
06	38.81	>11.00	>6.48
07	22.52	>11.00	>6.48
Test Date	03-Feb-2023	07-Feb-2023	03-Feb-2023
Test Site	RL	RL	SC
Kit Part Code	NA	NA	6195566
Kit Lot No.	652924	13881437	SXE022
Kit Exp. Date	30-Jun-2023	19-Jul-2023	28-Apr-2023

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

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

*Interpretation variability; individual replicates reported.

HCV Confirmatory Assay**INNOGENETICS® INNO-LIA™ HCV Score¹****Band Results**

Panel Member	HCV Antibody Interpretation	C1	C2	E2	NS3	NS4	NS5
01	NEG	-	-	-	-	-	-
02	NEG	-	-	-	-	-	-
03	NEG	-	-	-	-	-	-
04	IND	2+	-	-	-	-	-
05	POS	2+	2+	-	2+	-	-
06	POS	3+	2+	-	3+	-	-
07	POS	3+	2+	-	4+	+/-	-
Test Date	20-Feb-2023						
Test Site	RL						
Kit Part Code	NA						
Kit Lot No.	410396						
Kit Exp. Date	31-Dec-2023						

¹Results are reported as singlicate testing; positive/reactive results are noted in bold red.

RL = Reference Lab; NA = Not Available

NEG = Negative; POS = Positive; 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.