

AccuVert™ HCV Seroconversion Panel

0610-0224 / Batch #10643205

OVERVIEW

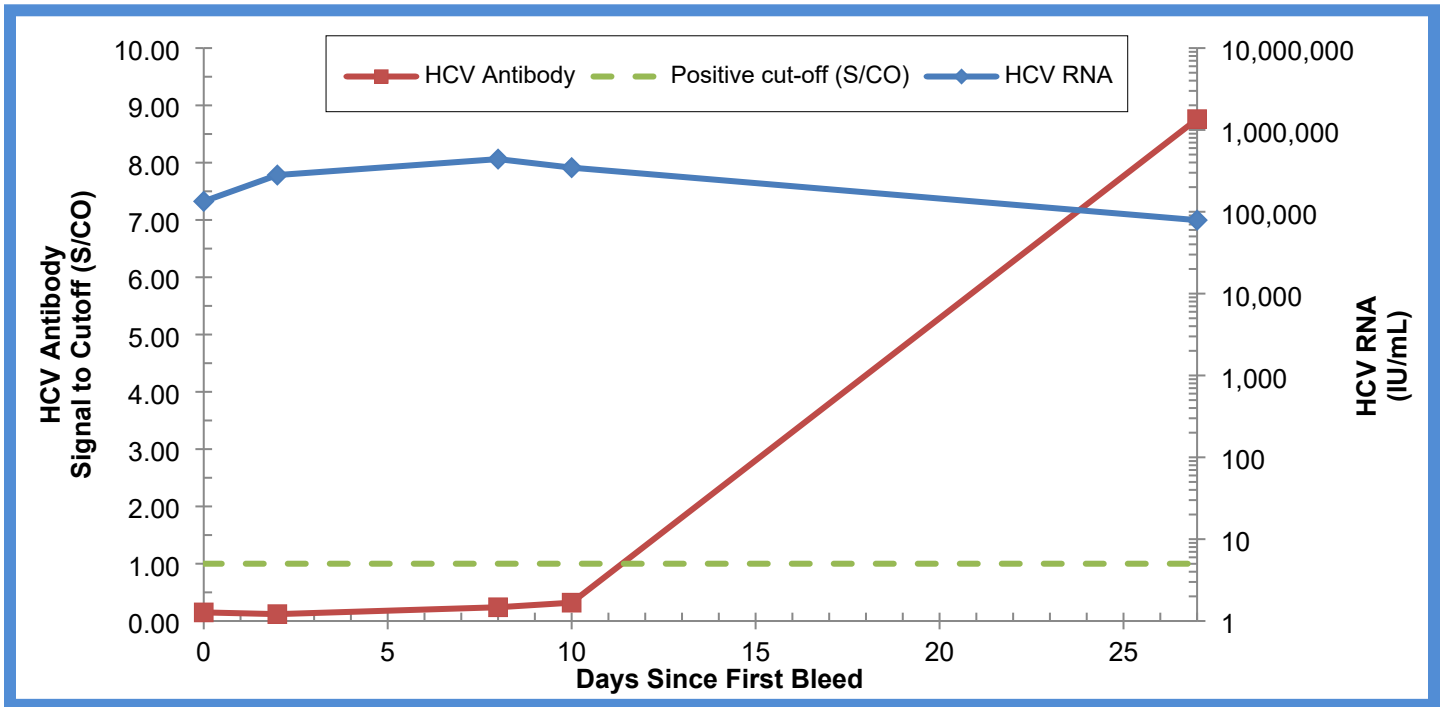
AccuVert™ HCV Seroconversion Panel 0610-0224 / Batch #10643205 is a 5-member validation panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.2 mL per vial). Panel members represent serial bleeds collected from a 24-year-old donor over the course of 27 days in 2008 during the development of an HCV infection and subsequent response. This donor has been characterized as genotype 1a. 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 anti-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.

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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 #	SeraCare Donor ID #	Bleed Date	Days Since 1 st Bleed
01	9239419	BD107566	03-Dec-2008	0
02	9239420	BD107566	05-Dec-2008	2
03	9239421	BD107566	11-Dec-2008	8
04	9239422	BD107566	13-Dec-2008	10
05	9239423	BD107566	30-Dec-2008	27

HCV RNA and Anti-HCV

Panel Member	Roche COBAS® Ampliprep/COBAS® Taqman® HCV Test, v2.0 (IU/mL) ¹	Abbott ARCHITECT Anti-HCV (S/CO) ¹	Abbott Alinity s Anti-HCV (S/CO) ¹
	01	1.34 x 10⁵	0.15
02	2.81 x 10⁵	0.12	0.04
03	4.40 x 10⁵	0.24	0.11
04	3.46 x 10⁵	0.32	0.19
05	7.90 x 10⁴	8.76	6.74
Test Date	28-Nov-2022	15-Nov-2022	16-Nov-2022
Test Site	RL	SC	RL
Kit Part Code	NA	1L79	NA
Kit Lot No.	J12718	41461BE00	41457BE00
Kit Exp. Date	31-Jul-2023	18-Apr-2023	12-May-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

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	0.04	0.05
02	0.05	0.05	0.02
03	3.60	0.12	0.05
04	13.10	0.26	0.08
05	66.65	>11.00	>6.58
Test Date	01-Dec-2022	21-Nov-2022	21-Nov-2022
Test Site	RL	RL	SC
Kit Part Code	NA	NA	6195566
Kit Lot No.	NA	13879437	SXE022
Kit Exp. Date	NA	19-Jul-2023	28-Apr-2023

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

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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	NEG	-	-	-	-	-	-
05	POS	4+	2+	-	3+	1+	2+
Test Date	29-Nov-2022						
Test Site	RL						
Kit Part Code	NA						
Kit Lot No.	410202						
Kit Exp. Date	31-Aug-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

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.