

AccuVert[™] HCV Seroconversion Panel 0610-0293 / Batch #10687292

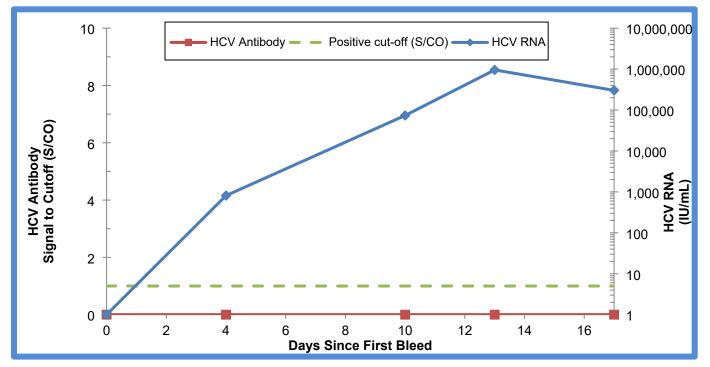
OVERVIEW

AccuVert[™] HCV Seroconversion Panel 0610-0293 / Batch #10687292 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 the course of 17 days in 2006 from a 49-year old female with HCV 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 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.



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 1 st Bleed
01	BM206284	BD102731	13-Jun-2006	0
02	BM206285	BD102731	17-Jun-2006	4
03	BM206286	BD102731	23-Jun-2006	10
04	BM206287	BD102731	26-Jun-2006	13
05	BM206288	BD102731	30-Jun-2006	17

HCV RNA¹

	Roche cobas®	Abbott
	6800/8800	Alinity m
	HCV RNA	HCV RNA
Panel Member	(IU/mL)	(IU/mL)
01	TND	TND
02	8.13 x 10 ²	1.12 x 10 ³
03	7.38 x 10 ⁴	7.10 x 10 ⁴
04	9.56 x 10⁵	1.22 x 10 ⁶
05	3.03 x 10⁵	2.20 x 10⁵
Test Date	09-Dec-2023	07-Dec-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; Not Available



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Anti-HCV¹

	Abbott ARCHITECT Anti-HCV	Roche cobas [®] Elecsys Anti-HCV II	Abbott Alinity s Anti-HCV (S/CO)	
Panel Member	(S/CO)	(COI)		
01	0.09	0.04	0.03	
02	0.07	0.04	0.03	
03	0.06	0.05	0.03	
04	0.07	0.04	0.03	
05	0.07	0.04	0.03	
Test Date	05-Dec-2023	08-Jan-2024	05-Dec-2023	
Test Site	LGC	RL	RL	
Kit Part Code	1L79	NA	NA	
Kit Lot No.	56375BE00	NA	53019BE00	
Kit Exp. Date	28-Jul-2024	NA	16-May-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

Panel Member	INNOGENETICS [®] INNO-LIA™ HCV Score Band Results						
	01	NEG	-	-	-	-	-
02	NEG	-	-	-	-	-	-
03	NEG	-	-	-	-	-	-
04	NEG	-	-	-	-	-	-
05	NEG	-	-	-	-	-	-
Test Date	18-Dec-2023						
Test Site	RL						
Kit Part Code	NA						
Kit Lot No.	411025						
Kit Exp. Date	30-Jun-2024						

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

RL = Reference Lab; NA = Not Available

NEG = Negative

The package insert for this panel can be found at <u>www.seracare.com</u>.

A printed copy of the package insert or data sheet may be requested by email at <u>CDx-Info@LGCGroup.com</u> or by phone at 508.244.6400.