

AccuVert[™] HIV-1 Seroconversion Panel 0600-0271 / Batch #10691939

OVERVIEW

AccuVert[™] HIV-1 Seroconversion Panel 0600-0271 / Batch #10691939 is an 8-member panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.0 mL per vial). Panel members represent serial bleeds collected from a single individual over 25 days in 2015 during the development of an HIV infection and subsequent response. Each sample represents a single collection event. No preservatives were added.

Test results from commercially-available HIV 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 HIV antigen/antibody during the development and progression of an HIV 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. Some panel members were found positive for HIV-1; all were found negative for anti-HCV and HBsAg. This does not ensure the absence of these or other human pathogens.

HIV-1 Antibody HIV Antigen/Antibody Positive cut-off (S/CO) HIV-1 RNA 70 10,000,000 60 1,000,000 Signal to Cutoff (S/CO) 50 100,000 Copies per mL (c/mL HIV Ag and Ab 40 10,000 30 1,000 20 100 10 10 0 2 4 6 10 12 14 16 18 20 22 24 0 8 **Days Since First Bleed**

AccuVert™ HIV-1 Seroconversion Panel

This graph demonstrates the evolution of early HIV infection amongst panel members from the Avioq Microelisa (HIV-1 Antibody), Abbott Alinity s (HIV Antigen/Antibody), and Roche cobas® (HIV-1 RNA) test methods. Please note that member 5 (14 days since first bleed) is off-scale for Roche cobas®.

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Panel Member Information

Panel Member	SeraCare Batch #	SeraCare Donor ID #	Bleed Date	Days Since 1st Bleed
01	10266915	BD328463	28-Aug-2015	0
02	10266916	BD328463	31-Aug-2015	3
03	10266917	BD328463	04-Sep-2015	7
04	10266918	BD328463	07-Sep-2015	10
05	10266919	BD328463	11-Sep-2015	14
06	10266920	BD328463	15-Sep-2015	18
07	10266921	BD328463	18-Sep-2015	21
08	10266922	BD328463	22-Sep-2015	25

HIV RNA and HIV Antigen Assays¹

	Roche cobas® 6800/8800	Perkin Elmer
	HIV-1 RNA	HIV-1 p24 ELISA
Panel Member	(copies/mL)	(S/CO)
01	9.06 x 10 ²	0.15
02	1.42 x 10⁵	1.38
03	9.54 x 10 ⁶	62.27, >66.67*
04	4.21 x 10 ⁶	47.72
05	>1.00 x 10 ⁷	>66.67
06	1.48 x 10 ⁶	12.83
07	2.59 x 10 ⁵	2.63
08	1.24 x 10 ⁵	0.93
Test Date	06-Mar-2024	06-Mar-2024
Test Site	RL	LGC
Kit Part Code	NA	NEK050A
Kit Lot No.	NA	990-23527
Kit Exp. Date	NA	01-Oct-2024

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

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^{*}Individual replicates reported, mean could not be determined.

RL = Reference Lab; LGC = LGC Clinical Diagnostics; NA = Not Available



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HIV Antigen/Antibody Assays¹

Panel Member	Abbott ARCHITECT HIV Ag/Ab Combo (S/CO)	Abbott Alinity s HIV Ag/Ab Combo (S/CO)	Roche cobas [®] Elecsys HIV combi PT (COI)	Siemens ADVIA Centaur [®] HIV Ag/Ab Combo (Index)
01	0.16	0.07	0.24	< 0.05
02	0.68	0.57	0.61	0.51
03	46.23	42.56	36.42	>12.00
04	28.26	25.58	19.15	>12.00
05	76.00	66.81	58.66	>12.00
06	16.80	14.06	17.44	5.57
07	15.38	12.56	17.56	2.25
08	24.60	19.45	21.82	1.53
Test Date	06-Mar-2024	06-Mar-2024	02-Apr-2024	07-Mar-2024
Test Site	LGC	RL	RL	RL
Kit Part Code	2P36	NA	NA	NA
Kit Lot No.	59215BE00	56547BE00	NA	23635352
Kit Exp. Date	13-Aug-2024	13-Sep-2024	NA	31-Aug-2024

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HV-1 Antibody & HIV Rapid Assays

		Alere Determine™		
	Avioq HIV-1 Microelisa	піч-п/2 Аул	AD COMBO	
Panel Member	(S/CO) ¹	HIV Ag	HIV Ab NEG NEG NEG POS NEG POS POS POS POS D24, 15-Mar-2024 LGC 7D2648	
01	0.25	NEG	NEG	
02	0.22	NEG	NEG	
03	0.23	POS	NEG	
04	0.67	POS	POS	
05	0.23	POS	NEG	
06	1.82	NEG	POS	
07	3.64	NEG	POS	
08	4.04	NEG	POS	
Test Date	07-Mar-2024	14-Mar-2024	15-Mar-2024	
Test Site	LGC			
Kit Part Code	100384	7D2648		
Kit Lot No.	23106H	845391		
Kit Exp. Date	02-Dec-2024	28-Ju	l-2025	

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

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²Results are reported as singlicate testing; positive/reactive results are noted in bold red.

LGC = LGC Clinical Diagnostics; POS = Positive; NEG = Negative



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HIV Confirmatory Assay¹

Panel Member	INNOGENETICS® INNO-LIA™ HIV I/II Score Band Results							
	01	IND	1+	-	-	-	-	-
02	NEG	+/-	-	-	-	-	-	-
03	NEG	+/-	-	-	-	-	-	-
04	IND	+/-	2+	-	-	-	-	-
05	NEG	-	-	-	-	-	-	-
06	POS	-	2+	-	1+	-	-	-
07	POS	-	2+	_	2+	1+	-	-
08	POS	+/-	2+	-	2+	1+	-	-
Test Date	15-Mar-2024							
Test Site	RL							
Kit Part Code	NA							
Kit Lot No.	411205							
Kit Exp. Date	31-Oct-2024							

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

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