

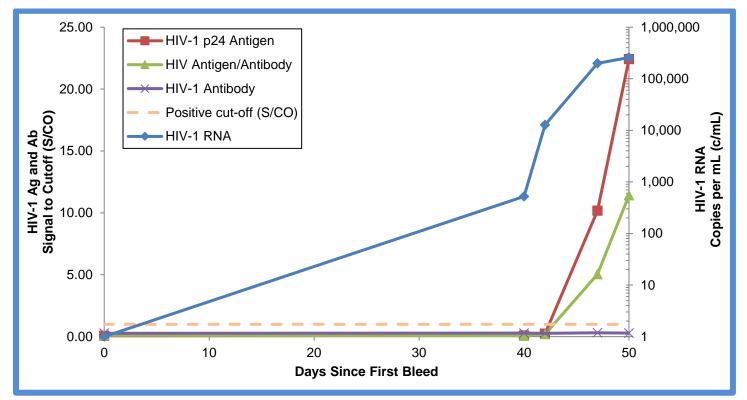
OVERVIEW

AccuVert[™] HIV-1 Seroconversion Panel 0600-0240 / Batch #10602404 is a 5-member panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.0 mL per vial) collected from an HIV-1 donor. Panel members represent serial bleeds collected from a single donor over 50 days in 1997 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 of expression from negative to positive for HIV-1 antigen and antibodies 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 markers of HIV infection; all were found negative for HBsAg and anti-HCV. This does not ensure the absence of these or other human pathogens.



AccuVert[™] HIV-1 Seroconversion Panel

This graph demonstrates the evolution of early HIV infection amongst panel members from the Perkin Elmer (HIV-1 p24 Antigen), Abbott ARCHITECT (HIV-1 Antigen/Antibody), Aviog HIV-1 microelisa (HIV-1 Antibody) and Roche COBAS (HIV-1 RNA) test methods.

www.seracare.com



Panel Member Information

Panel Member	SeraCare Batch #	Bleed Date	Days Since 1 st Bleed	Fiebig Stage ¹
01	10000689	03-Jul-1997	0	NA
02	10000690	12-Aug-1997	40	I
03	10000691	14-Aug-1997	42	I
04	10000692	19-Aug-1997	47	II
05	10000693	22-Aug-1997	50	III

¹ Fiebig stages are categories that define phases of early HIV infection. See Fiebig EW, et al. Dynamics of HIV viremia and antibody seroconversion in plasma donors: implications for diagnosis and staging of primary HIV infection. AIDS 2003, 17:1871-9, and Lee HY, et al. Modeling sequence evolution in acute HIV-1 infection. JTB 2009, 261:341-360.

HIV RNA and HIV Antigen Assays

Panel Member	Roche COBAS [®] AmpliPrep/COBAS [®] TaqMan HIV-1 Test v2.0 (copies/mL) ¹	PerkinElmer HIV-1 p24 ELISA (S/CO) ¹
01	TND	0.07
02	5.22 X 10 ²	0.10
03	1.27 X 10 ⁴	0.24
04	1.99 X 10⁵	10.18
05	2.58 X 10⁵	22.42
Test Date	23-Feb-2022	4-Feb-2022
Test Site	RL	SC
Kit Part Code	NA	NEK050B
Kit Lot No.	G33450	990-21091
Kit Exp. Date	31-Aug-2022	1-Mar-2022

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

TND=Target Not Detected



HIV Antigen/Antibody Assays

Panel Member	Abbott ARCHITECT HIV Ag/Ab Combo (S/CO) ¹	Abbott Alinity i HIV Ag/Ab Combo (S/CO) ¹	Roche cobas [®] Elecsys HIV combi PT (COI) ¹	Ortho VITROS HIV combo (S/CO) ¹
01	0.11	0.05	0.18	0.09
02	0.07	0.06	0.19	0.11
03	0.20	0.12	0.36	0.17
04	5.05	4.49	8.93	12.75
05	11.42	10.21	23.80	33.85
Test Date	2-Feb-2022	2-Feb-2022	14-Feb-2022	2-Feb-2022
Test Site	SC	RL	RL	RL
Kit Part Code	2P36	NA	NA	NA
Kit Lot No.	33399BE00	29335BE00	NA	0320
Kit Exp. Date	28-May-2022	1-Mar-2022	NA	4-Aug-2022

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

HIV Antigen/Antibody, HIV Antibody, and HIV Rapid Assays

Panel Member	Bio-Rad GS	Avioq	Alere Determine™ HIV-1/2 Ag/Ab Combo²		
	HIV-1/HIV-2 PLUS O EIA (S/CO) ¹	HIV-1 Microelisa System (S/CO) ¹	HIV Ag	HIV Ab	
01	0.07	0.27	NEG NE		
02	0.07	0.29	NEG NE		
03	0.06	0.27	NEG	NEG	
04	0.07	0.31	POS	NEG	
05	0.35	0.29	POS	NEG	
Test Date	3-Feb-2022	3-Feb-2022	1-Feb-2022		
Test Site	SC	SC	SC		
Kit Part Code	32588	100384	7D2648		
Kit Lot No.	156RBB-05	21103H	161165		
Kit Exp. Date	30-Apr-2022	2-Mar-2022	28-Sep-2022		

¹Results are reported as the mean result of duplicate testing.

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

SC = SeraCare

POS = Positive; NEG = Negative



HIV Confirmatory Assay

	Bio-Rad Genetic Systems™ HIV-1 Western Blot¹				
Panel Member	Band Pattern	Interpretation			
01	No Bands	NEG			
02	No Bands	NEG			
03	No Bands	NEG			
04	No Bands	NEG			
05	No Bands	NEG			
Test Date	28-1	Feb-2022			
Test Site		SC			
Kit Part Code	:	32508			
Kit Lot No.	64456713				
Kit Exp. Date	1-Sep-2022				

¹Results are reported as singlicate testing. SC = SeraCare NEG = Negative

HIV Confirmatory Assay (continued)

Panel Member	INNOGENETICS [®] INNO-LIA™ HIV I/II Score¹ Band Results							
								HIV-1/2 Antibody Interpretation
	01	NEG	-	-	-	-	-	-
02	NEG	-	-	-	-	-	-	-
03	NEG	-	-	-	-	-	-	-
04	NEG	-	-	-	-	-	-	-
05	NEG	-	-	-	-	-	-	-
Test Date	10-Feb-2022							
Test Site	RL							
Kit Part Code	NA							
Kit Lot No.	409067							
Kit Exp. Date	31-Aug-2022							
				-				

_ @

¹Results are reported as singlicate testing.

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.