

AccuVert™ HIV-1 Seroconversion Panel

PRB974 (0600-0258) / Batch #10283366

OVERVIEW

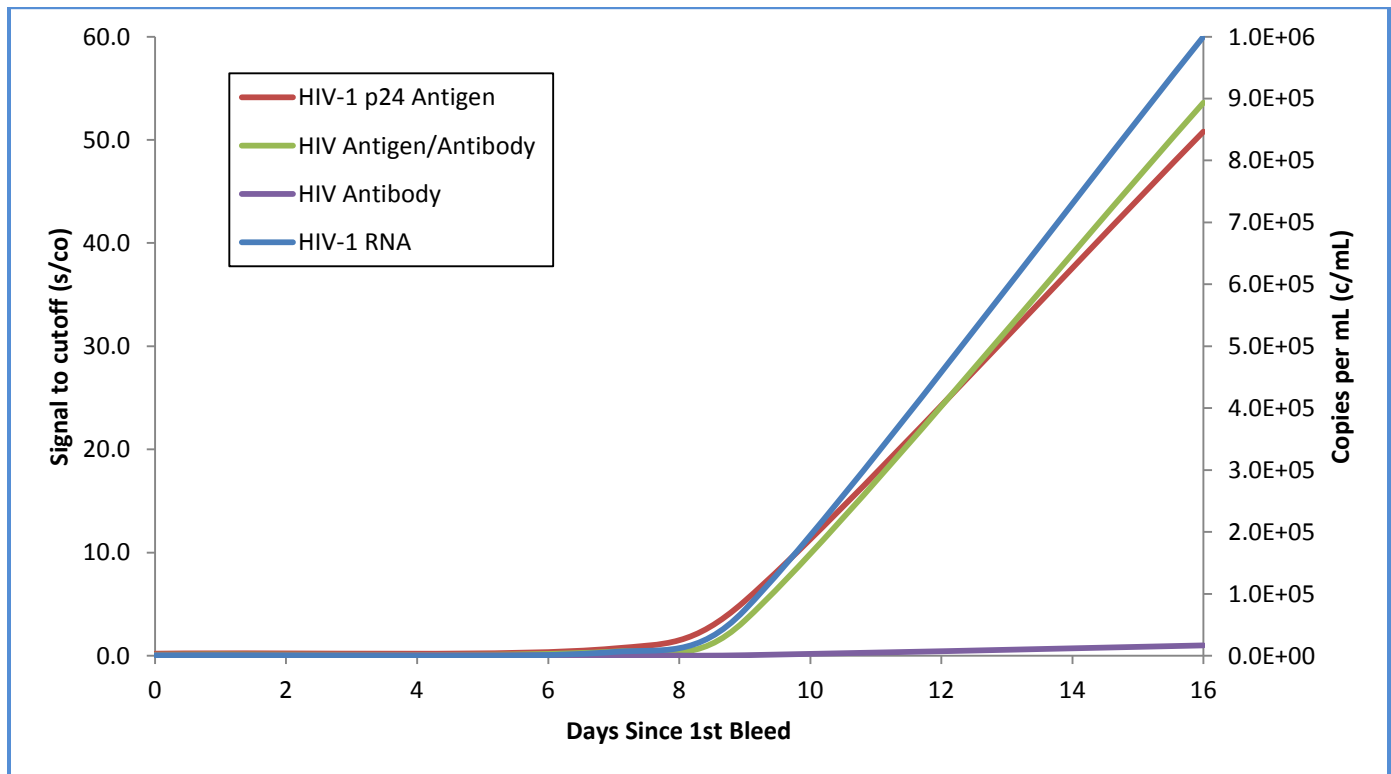
AccuVert™ HIV-1 Seroconversion Panel PRB974 (0600-0258) / Batch #10283366 is a 4-member panel collected of undiluted, naturally occurring plasma samples (1 vial per member, 1.2mL). Panel members represent serial bleeds collected from a single individual over 16 days in 2000 during the development of an HIV infection and subsequent response.

Panel Member #02 is a moderately positive HIV RNA sample, challenging for HIV antigen assays. Member #3 is detected at very low signal to cutoff by all HIV Ag/Ab methods tested, and Member #4 is a very challenging sample for anti-HIV assays.

For Research Use Only. Not for use in diagnostic procedures. Data are offered for informational purposes only. SeraCare Life Sciences does not claim these results can be duplicated 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.

Evolution of HIV Markers in Early Infection



This graph demonstrates the evolution of early HIV infection amongst panel members from the Abbott m2000, Perkin Elmer, Abbott ARCHITECT and Siemens Centaur test methods. Note: Members 01, 02 and 03 on the Siemens Centaur HIV-1 Antibody test were plotted at 0.05 s/co.

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Panel Member Information

Panel Member	SeraCare Batch #	Bleed Date	Days Since 1 st Bleed	¹ Fiebig Stage
01	9251239	14-Jun-00	0	NA
02	9251240	21-Jun-00	7	I
03	9251241	23-Jun-00	9	II
04	9251242	30-Jun-00	16	II/III

¹Fiebig 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 (copies/mL)¹

Panel Member	Abbott HIV RealTime HIV-1 RNA m2000	Roche COBAS® AmpliPrep COBAS® TaqMan HIV-1 Test v2.0	Siemens Versant HIV-1 RNA 3.0 Assay (bDNA)
01	BLD	BLD	BLD
02	6.1 x 10³	1.1 x 10⁴	3.8 x 10³
03	7.4 x 10⁴	9.1 x 10⁴	4.7 x 10⁴
04	1.0 x 10⁶	9.2 x 10⁵	>5.0 x 10⁵
Test Date	01-Feb-12	31-Jan-12	02-Feb-12
Test Site	RL	SC	RL
Kit Part Code	6L18	05212308 190	127418 A & B
Kit Lot No.	10055501	P07463	D088
Kit Exp. Date	31-Dec-12	31-Aug-12	06-Jun-12
Kit Regulatory Status	IVD	IVD	IVD

¹ Quantitative HIV RNA results are expressed as copies/mL. Members considered reactive are noted in bold red.

BLD = Below the Limit of Detection

RL = Reference Lab; SC = SeraCare

IVD = In vitro diagnostic use

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HIV Antigen

Panel Member	bioMérieux VIDAS p24 II (pg/mL) ¹	Perkin Elmer Alliance HIV-1 p24 Ag ELISA (s/co) ²
01	<3.0	0.2
02	<3.0	0.7
03	22.5	5.3
04	347.2	50.8
Test Date	12-Mar-12	01-Feb-12
Test Site	RL	SC
Kit Part Code	30117	NEK050A
Kit Lot No.	120507-0	990-11521
Kit Exp. Date	17-Jul-12	01-Oct-12
Kit Regulatory Status	CE	RUO

¹ Quantitative HIV Antigen results are the means of duplicates expressed as pg/mL. Ratios ≥3.0 are considered reactive and noted in bold red.

² Immunoassay results are means of duplicates expressed as signal to cutoff ratios (s/co). Ratios ≥1.0 are considered reactive and noted in bold red.

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CE = Conformité Européenne or CE Marking; RUO = Research Use Only

HIV Antigen/Antibody (s/co)¹

Panel Member	Abbott HIV Ag/Ab ARCHITECT Combo	Abbott HIV Ag/Ab AxSYM Combo	Abbott HIV Ag/Ab PRISM Combo	Bio-Rad Genscreen Ultra HIV Ag/Ab Combo
01	0.1	0.5	0.1	0.3
02	0.4	0.6	0.3	0.4
03	3.4	2.3	3.3	1.4
04	53.6	19.8	34.5	8.8
Test Date	30-Jan-12	06-Feb-12	06-Feb-12	16-Mar-12
Test Site	RL	RL	RL	SC
Kit Part Code	2P36	2G83-20	7G46-48	72386
Kit Lot No.	08414LI00	11457LF00	12321LI00	1C1067
Kit Exp. Date	30-Apr-12	16-May-12	17-Nov-12	30-Aug-12
Kit Regulatory Status	CE	CE	CE	CE

Immunoassay results are means of duplicates expressed as signal to cutoff ratios (s/co). Ratios ≥1.0 are considered reactive and noted in bold red.

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HIV Antigen/Antibody

Panel Member	Bio-Rad GS HIV Combo Ag/Ab EIA (s/co) ¹	Murex HIV Ag/Ab Combination (s/co) ¹	Alere Determine™ HIV-1/2 Ag/Ab Combo HIV Ag	Alere Determine™ HIV-1/2 Ag/Ab Combo HIV Ab
01	0.2	0.3	NEG	NEG
02	0.5	0.4	NEG	NEG
03	3.5	1.7	NEG	NEG
04	11.8	16.9	POS	NEG
Test Date	15-Mar-12	31-Jan-12	05-Mar-12	
Test Site	SC	RL	SC	
Kit Part Code	26217	7G79-11	7D26-46	
Kit Lot No.	315FJJ-02	D078310	110524ALCE & 111228ALCE	
Kit Exp. Date	27-Sep-12	31-Dec-12	25-Mar-12 & 11-Nov-12	
Kit Regulatory Status	IVD	CE	CE	

¹ Immunoassay results are means of duplicates expressed as signal to cutoff ratios (s/co). Ratios ≥ 1.0 are considered reactive and noted in bold red.

POS = Positive; NEG = Negative

RL = Reference Lab; SC = SeraCare

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HIV Antibody (s/co)¹

Panel Member	Avioq HIV-1 Microelisa System	Bio-Rad GS HIV- 1/HIV-2 Plus O	Siemens HIV1/O/2 Enhanced ADVIA Centaur
01	0.2	0.1	<0.05
02	0.2	0.1	<0.05
03	0.2	0.1	<0.05
04	0.2	0.2	1.0
Test Date	01-Feb-12	31-Jan-12	01-Feb-12
Test Site	SC	SC	RL
Kit Part Code	100384	32588	01622429
Kit Lot No.	J2299	279FBB-05	82415114
Kit Exp. Date	12-Oct-12	15-May-12	20-Apr-12
Kit Regulatory Status	IVD	IVD	IVD

¹ Immunoassay results are means of duplicates expressed as signal to cutoff ratios (s/co). Ratios ≥ 1.0 are considered reactive and noted in bold red.

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HIV Confirmatory

Panel Member	Bio-Rad GS HIV-1 Western Blot Band Pattern	Bio-Rad GS HIV-1 Western Blot Result	Calypte/MAXIM HIV-1 Western Blot Band Pattern	Calypte/MAXIM HIV-1 Western Blot Result
01	No bands	NEG	No bands	NEG
02	No bands	NEG	No bands	NEG
03	No bands	NEG	No bands	NEG
04	No bands	NEG	No bands	NEG
Test Date	09-Feb-12		06-Feb-12	
Test Site	SC		SC	
Kit Part Code	1971101		98002	
Kit Lot No.	109338		A2322-227	
Kit Exp. Date	24-Jun-12		17-Nov-12	
Kit Regulatory Status	IVD		IVD	

NEG = Negative

SC = SeraCare

IVD = In vitro diagnostic use

HIV Confirmatory

Panel Member	Innogenetics INNO-LIA HIV I/II Band Pattern	Innogenetics INNO-LIA HIV I/II Result
01	No Bands	NEG
02	No Bands	NEG
03	No Bands	NEG
04	No Bands	NEG
Test Date	12-Mar-12	
Test Site	RL	
Kit Part Code	INX22206	
Kit Lot No.	220376	
Kit Exp. Date	31-Jan-13	
Kit Regulatory Status	CE	

NEG = Negative

RL = Reference Lab

CE = Conformité Européenne or CE Marking;

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 info@seracare.com, or by phone at 508.244.6400