

AccuVert™ HIV-1 Seroconversion Panel

PRB975 (0600-0260) / Batch #10285688

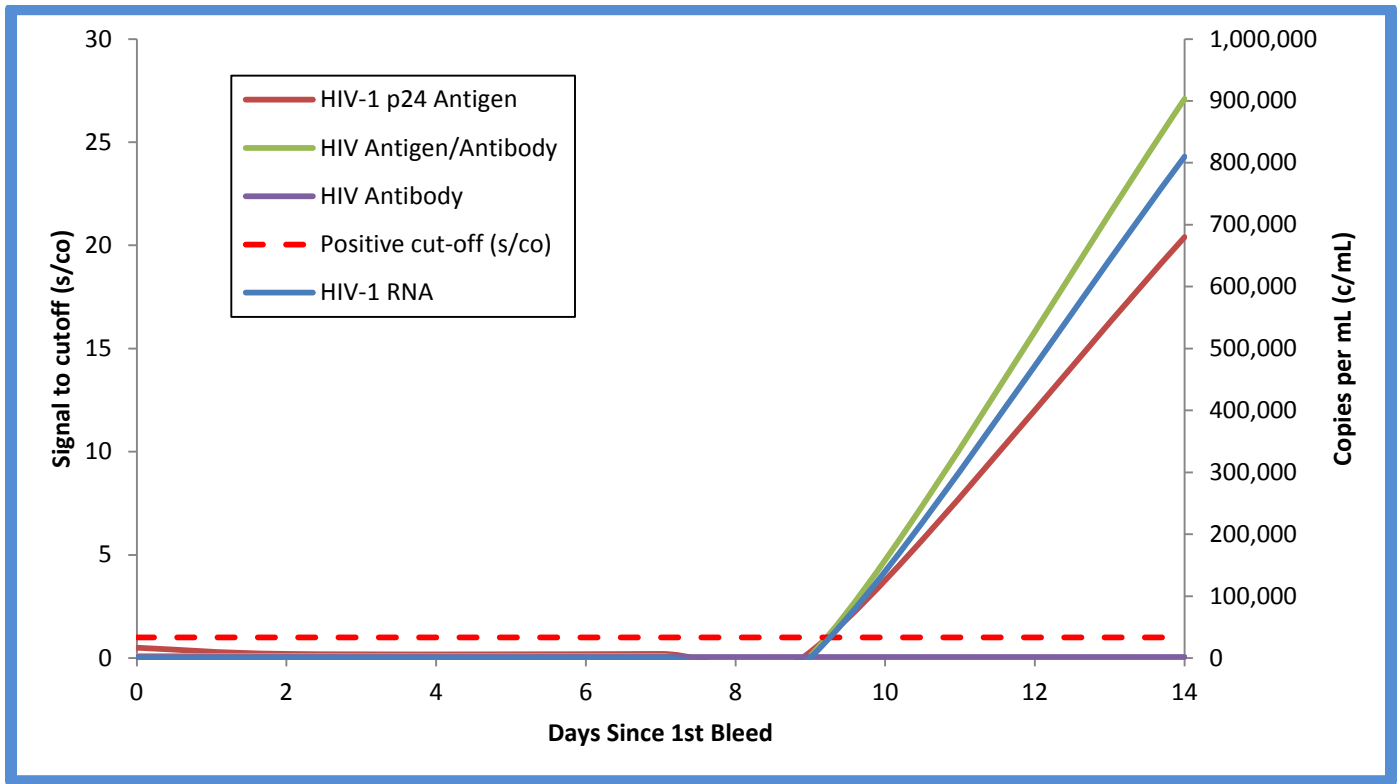
OVERVIEW

AccuVert™ HIV-1 Seroconversion Panel PRB975 (0600-0260) / Batch #10285688 is a 5-member panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.2mL). Panel members represent serial bleeds collected from a single individual over 14 days in 2002 during the development of an HIV infection and subsequent response.

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 Perkin Elmer (HIV-1 p24 Antigen), Abbott ARCHITECT (HIV-1 Antigen/Antibody), Siemens Centaur (HIV-1 Antibody) and Abbott m2000 (HIV-1 RNA) test methods. Note: Members 01 to 05 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	Fiebig Stage ¹
01	9251690	14-May-02	0	NA
02	9252330	16-May-02	2	NA
03	9251691	21-May-02	7	I
04	9252331	23-May-02	9	I
05	9251692	28-May-02	14	II

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, 26:341-360.

NA = Not Available

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	BLD	BLD	BLD
03	5.7 x 10¹	2.2 x 10²	BLD
04	7.8 x 10²	3.4 x 10³	7.2 x 10²
05	8.1 x 10⁵	2.8 x 10⁶	4.4 x 10⁵
Test Date	25-Jan-12	30-Jan-12	26-Jan-12
Test Site	RL	SC	RL
Kit Part Code	6L18	05212308 190	127418A/B
Kit Lot No.	10055501	P07463	D088
Kit Exp. Date	31-Dec-12	31-Aug-12	6-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	0.5
02	<3.0	0.2
03	<3.0	0.2
04	<3.0	0.3
05	126.6	20.4
Test Date	12-Mar-12	9-Feb-12
Test Site	RL	SC
Kit Part Code	30117	NEK050A
Kit Lot No.	120507-0	990-11481
Kit Exp. Date	17-Jul-12	1-Oct-12
Kit Regulatory Status	CE	RUO

¹ Quantitative HIV Antigen results are the means of duplicates expressed as pg/mL. Results ≥ 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.

RL = Reference Lab; SC = SeraCare

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	0.4
02	0.1	0.4	0.4	0.4
03	0.1	0.5	0.4	0.4
04	0.1	0.5	0.1	0.4
05	27.1	8.7	26.0	8.8
Test Date	30-Jan-12	6-Feb-12	6-Feb-12	6-Feb-12
Test Site	RL	RL	RL	SC
Kit Part Code	2P36	2G83-20	7G46-48	72386
Kit Lot No.	08413LI00	11457LF00	123212L100	1F1068
Kit Exp. Date	30-Apr-12	16-May-12	17-Nov-12	15-Nov-12
Kit Regulatory Status	CE	CE	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.

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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) ²	Alere Determine™ HIV-1/2 Ag/Ab Combo HIV Ag	Alere Determine™ HIV-1/2 Ag/Ab Combo HIV Ab
01	0.3	0.3	NEG	NEG
02	0.2	0.3	NEG	NEG
03	0.3	0.2	NEG	NEG
04	0.3	0.2	NEG	NEG
05	10.4	10.2	POS	NEG
Test Date	15-Mar-12	31-Jan-12		5-Mar-2012
Test Site	SC	RL		SC
Kit Part Code	26217	7G79-11		7D26-46
Kit Lot No.	315FJJ-02	D078310		111228ALCE
Kit Exp. Date	27-Sep-12	31-Dec-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.

² Immunoassay results are a single result expressed as signal to cutoff ratios (s/co). Ratios ≥1.0 are considered reactive and noted in red.

POS = Positive; NEG = Negative

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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 EIA	Siemens HIV1/O/2 Enhanced ADVIA Centaur
01	0.2	0.2	<0.05
02	0.2	0.2	<0.05
03	0.2	0.2	<0.05
04	0.2	0.2	<0.05
05	0.2	0.2	<0.05
Test Date	27-Jan-12	25-Jan-12	1-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
05	No Bands	Neg	No Bands	Neg
Test Date	9-Feb-12		6-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
05	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	

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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