AccuVert™ HIV-1 Seroconversion Panel

PRB978 (0600-0263) / Batch #10375852

OVERVIEW

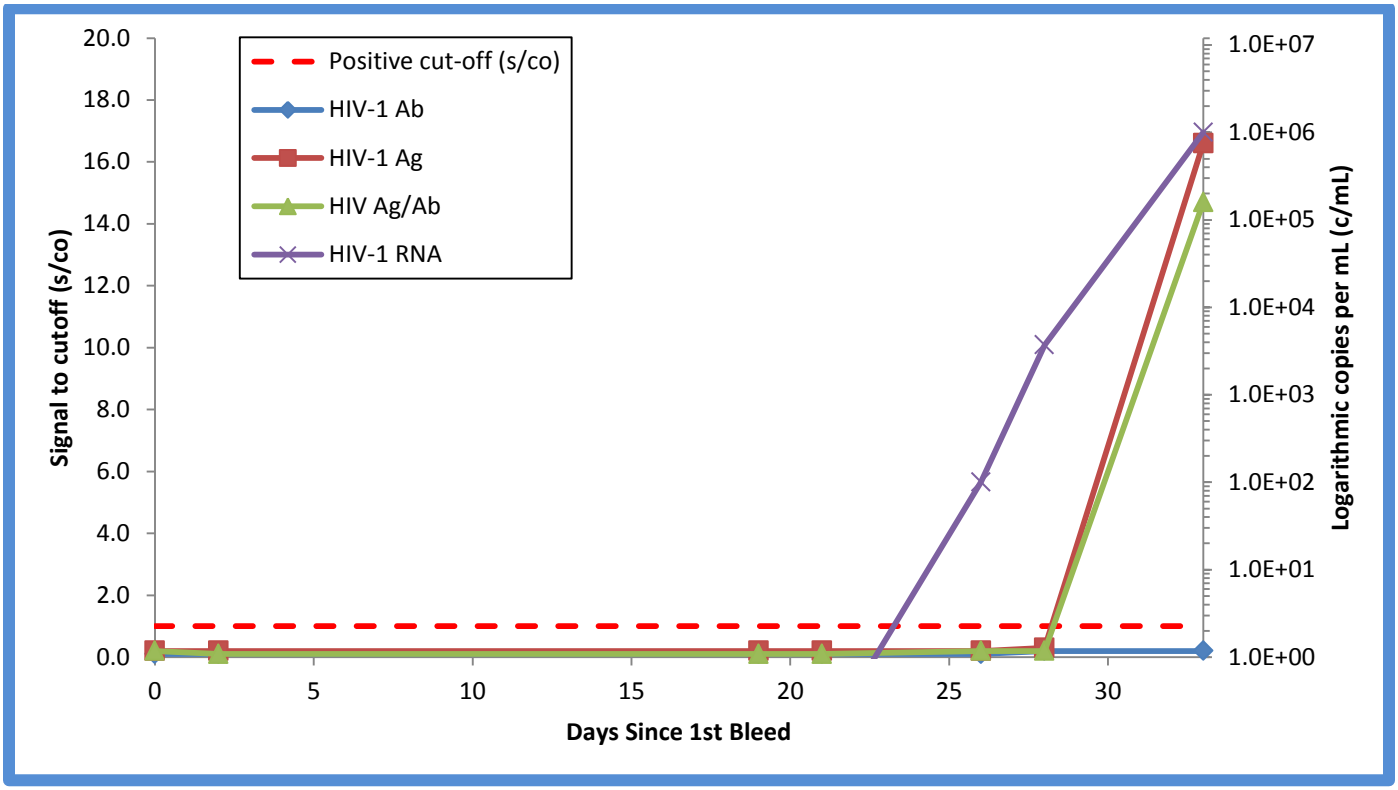
AccuVert™ HIV-1 Seroconversion Panel PRB978 (0600-0263) / Batch #10375852 is a 7-member panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.2 mL) collected over 33 days in 2010.

Test results from commercially-available HIV RNA, antigen, antibody, and confirmatory assays are included for reference. This panel converts from negative to positive for HIV-1 RNA and HIV antigen.

For Research Use Only. Not for use in diagnostic procedures. Data are offered for informational purposes. SeraCare Life Sciences does not claim that others can duplicate test results exactly.

CAUTION: Potentially infectious materials. Follow Universal Precautions. The units that make up this panel were tested and 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 RealTime HIV-1 RNA m2000 (HIV-1 RNA), Perkin Elmer Alliance HIV-1 p24 Ag ELISA (HIV-1 Ag), Abbott HIV Ag/Ab ARCHITECT Combo (HIV Ag/Ab), and Avioq HIV-1 Microelisa System (HIV-1 Ab) test methods.

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Panel Member Information

Panel Member	SeraCare Batch #	SeraCare Donor ID #	Bleed Date	Fiebig Stage[1]	Days Since 1st Bleed
01	9254196	BD110974	26-Jun-2010	Eclipse	0
02	9254197	BD110974	28-Jun-2010	Eclipse	2
03	9254200	BD110974	15-Jul-2010	Eclipse	19
04	9254201	BD110974	17-Jul-2010	Eclipse	21
05	9254198	BD110974	22-Jul-2010	I	26
06	9254199	BD110974	24-Jul-2010	I	28
07	9254202	BD110974	29-Jul-2010	II	33

[1] Fiebig stages are categories that define phases of early HIV infection. See Fiebig E.W., 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 H.Y., et al. Modeling sequence evolution in acute HIV-1 infection. JTB 2009, 261:341-360.

HIV RNA and Antigen

Panel Member	Abbott RealTime HIV-1 RNA *m*2000 (c/mL)[1]	Roche COBAS® AmpliPrep COBAS® TaqMan® HIV-1 Test v2.0 (c/mL)[1]	Siemens Versant® HIV-1 RNA 3.0 Assay bDNA (c/mL)[1]	bioMerieux VIDAS HIV p24 II (pg/mL)[2,4]	Perkin Elmer Alliance HIV-1 p24 Ag ELISA (s/co)[3,4]
01	BLD	BLD	BLD	<3.0	0.2
02	BLD	BLD	BLD	<3.0	0.2
03	BLD	BLD	BLD	<3.0	0.2
04	BLD	BLD	BLD	<3.0	0.2
05	**1.0×10^2**	**2.1×10^2**	BLD	<3.0	0.2
06	**3.7×10^3**	**1.1×10^4**	**2.0×10^3**	<3.0	0.3
07	**1.0×10^6**	**1.6×10^6**	**4.5×10^5**	**65.9**	**16.6**
Test Date	23-Nov-2012	27-Nov-2012	26-Nov-2012	27-Nov-2012	28-Nov-2012
Test Site	RL	RL	RL	RL	SC
Kit Part Code	6L18-90	R00290	127418A/127418B	30117	NEK 050A/B
Kit Lot No.	439355	N/A	D094	121205	990-12371
Kit Exp. Date	14-Sep-2013	01-Apr-2013	06-Apr-2013	05-Dec-2012	01-May-2013
Kit Regulatory Status	IVD/CE	IVD/CE	IVD/CE	CE	RUO

[1]Results are reported as copies per mL (c/mL); positive/reactive results are noted in bold red.
[2]Results are reported as a picogram per milliliter (pg/mL); positive/reactive results are noted in bold red.
[3]Results are reported as a signal to cutoff ratio (s/co); positive/reactive results are noted in bold red.
[4]Results are reported as the mean result of duplicate testing.
BLD = Below limit of detection
SC = SeraCare; RL = Reference Lab
IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking; RUO = Research Use Only

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HIV Antigen/Antibody

Panel Member	Abbott HIV Ag/Ab ARCHITECT Combo[1,2]	Abbott HIV Ag/Ab PRISM Combo[1,2]	Bio-Rad Genscreen Ultra HIV Ag/Ab Combo[1,2]	Murex HIV Ag/Ab Combination[1,2]	Alere Determine™ HIV-1/2 Ag/Ab Combo HIV Ag
01	0.2	0.1	0.1	0.3	Neg
02	0.1	0.1	0.1	0.2	Neg
03	0.1	0.1	0.1	0.2	Neg
04	0.1	0.1	0.1	0.4	Neg
05	0.2	0.1	0.1	0.3	Neg
06	0.2	0.1	0.5	0.4	Neg
07	**14.7**	**6.1**	**1.7**	**4.1**	Neg
Test Date	09-Jan-2013	03-Dec-2012	19-Feb-2013	03-Dec-2012	03-Dec-2012
Test Site	RL	RL	RL	RL	SC
Kit Part Code	4J27	7G46-48	72388	7G79-09	7D2646
Kit Lot No.	19116LI00	23322LI000	121071	D078410	44238K101
Kit Exp. Date	05-Oct-2013	18-Sep-2013	15-Apr-2013	31-Jan-2013	24-May-2013
Kit Regulatory Status	IVD/CE	IVD/CE	IVD/CE	IVD/CE	CE

[1]Results are reported as a signal to cutoff ratio (s/co); positive/reactive results are noted in bold red.
[2]Results are reported as the mean result of duplicate testing.
Neg = Negative
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HIV Antibody

Panel Member	Avioq HIV-1 Microelisa System[1,2]	Bio-Rad GS HIV-1/HIV-2 *Plus* O EIA[1,2]	Siemens HIV 1/O/2 Enhanced ADVIA Centaur[2]
01	0.2	0.1	Neg
02	0.2	0.1	Neg
03	0.2	0.1	Neg
04	0.2	0.1	Neg
05	0.2	0.1	Neg
06	0.2	0.2	Neg
07	0.2	0.2	Neg
Test Date	27-Nov-2012	20-Nov-2012	29-Nov-2012
Test Site	SC	SC	RL
Kit Part Code	100384	32588	01622429
Kit Lot No.	J3728	208GBB-05	97771130
Kit Exp. Date	18-Oct-2013	29-Mar-2013	14-Aug-2013
Kit Regulatory Status	IVD	IVD/CE	IVD/CE

[1]Results are reported as a signal to cutoff ratio (s/co); positive/reactive results are noted in bold red.
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HIV Confirmatory

Panel Member	Bio-Rad GS HIV-1 Western Blot Result	Innogenetics INNO-LIA™ HIV I/II Result	Calypte/MAXIM HIV-1 Western Blot Result
01	Neg	Neg	Neg
02	Neg	Neg	Neg
03	Neg	Neg	Neg
04	Neg	Neg	Neg
05	Neg	Neg	Neg
06	Neg	Neg	Neg
07	Neg	Neg	Neg
Test Date	06-Dec-2012	27-Nov-2012	19-Nov-2012
Test Site	SC	RL	SC
Kit Part Code	32508	80540	A3143-067
Kit Lot No.	111042	L227698	98002
Kit Exp. Date	08-Dec-2012	01-Jun-2013	23-May-2013
Kit Regulatory Status	IVD	CE	IVD

Neg = Negative
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IVD = In Vitro Diagnostic; 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.