

OVERVIEW

PRB976 is a four member HIV Seroconversion Panel collected from a single donor over a 9 day period in 1999, prior to antibody seroconversion. Member 2 is a potentially challenging sample for HIV antigen and Ag/Ab tests, and the panel clearly demonstrates improvement in sensitivity with the introduction of the '4th generation' HIV Ag/Ab tests.

Panel Members are undiluted aliquots from plasma units. No preservatives were added.

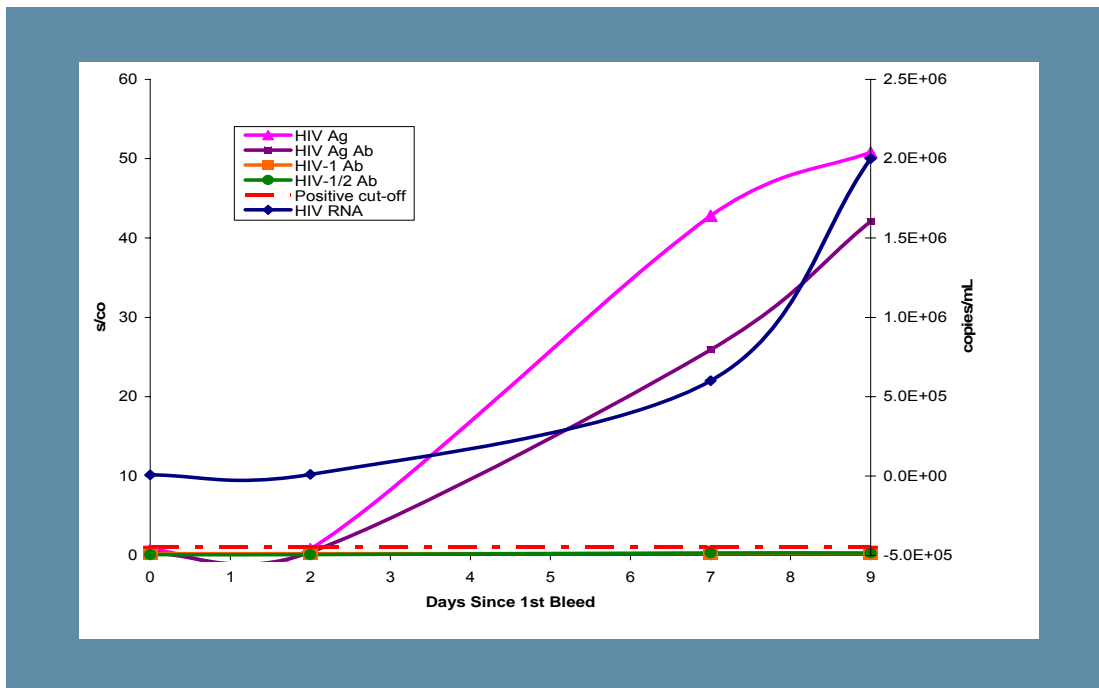
CAUTION: Potentially infectious materials. Follow Universal Precautions. Panel members were found positive for markers of HIV infection; all were found negative for HBsAg and anti-HCV.

For Research Use Only. Not for use in diagnostic procedures.

Data are provided for informational purposes. SeraCare does not claim that others can duplicate test results exactly.

For assistance, contact SeraCare Technical Support at 508.244.6400.

EVOLUTION OF HIV MARKERS IN EARLY INFECTION



This graph demonstrates the evolution of early HIV infection, illustrated with test results over time for different analytes or analyte combinations.

DATA SHEET

HIV RNA (copies/mL)

Panel Member	Bleed Date	Days Since 1 st Bleed	Fiebig Stage ¹	Abbott RealTime HIV-1 RNA <i>m2000</i>	Roche COBAS [®] AmpliPrep COBAS [®] TaqMan [®] HIV-1 Test v 2.0	Siemens Versant [®] HIV-1 RNA 3.0 Assay (bDNA)
PRB976-01	04-Nov-99	0	I	7.4 x 10 ³	1.6 x 10 ⁴	3.9 x 10 ³
PRB976-02	06-Nov-99	2	I	1.2 x 10 ⁴	3.0 x 10 ⁴	7.4 x 10 ³
PRB976-03	11-Nov-99	7	II	6.1 x 10 ⁵	6.5 x 10 ⁵	2.5 x 10 ⁵
PRB976-04	13-Nov-99	9	II	1.5 x 10 ⁶	2.3 x 10 ⁶	>5.0 x 10 ⁵
Test Date				3-Feb-12	24-Jan-12	1-Feb-12
Test Site				RL	SC	RL
Kit Part Code				6L18	05212308190	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 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 Antigen

Panel Member	Bleed Date	Days Since 1 st Bleed	bioMerieux VIDAS HIV p24 II pg/mL	Perkin Elmer Alliance HIV-1 p24 Ag ELISA s/co ²
PRB976-01	04-Nov-99	0	<3.0	0.7
PRB976-02	06-Nov-99	2	<3.0	0.8
PRB976-03	11-Nov-99	7	227.9	42.8
PRB976-04	13-Nov-99	9	>400	>50.8
Test Date			12-Mar-12	1-Feb-12
Test Site			RL	SC
Kit Part Code			30117	NEK050A
Kit Lot No.			120507-0	990-11521
Kit Exp. Date			17-Jul-12	1-Oct-12
Kit Regulatory Status			CE	RUO

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

POS = positive; NEG = negative; BLD = below the limit of detection; IND = indeterminate; NA = not available, NT = not tested
MFG = Manufacturer; RL = Reference Lab; SC = SeraCare

ASR = analyte specific reagent; CE = Conformité Européenne or CE Marking; IVD = for in vitro diagnostic use; LDT = laboratory developed test; RUO = research use only

DATA SHEET

HIV Antigen/Antibody (s/co)¹

Panel Member	Bleed Date	Days Since ^{1st} Bleed	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
PRB976-01	04-Nov-99	0	0.4	0.6	0.3	0.4
PRB976-02	06-Nov-99	2	0.6	0.7	0.4	0.5
PRB976-03	11-Nov-99	7	40.7	15.4	25.9	10.3
PRB976-04	13-Nov-99	9	72.6	26.4	42.1	>11.9
Test Date			6-Feb-12	8-Feb-12	16-Feb-12	16-Mar-12
Test Site			RL	RL	RL	SC
Kit Part Code			4J27	2G83	7G46-48	72386
Kit Lot No.			08413L100	11457LF00	12312L100	1C1067
Kit Exp. Date			30-Apr-12	16-May-12	17-Nov-12	30-Aug-12
Kit Regulatory Status			CE	CE	CE	CE

HIV Antigen/Antibody

Panel Member	Bleed Date	Days Since ^{1st} Bleed	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
PRB976-01	04-Nov-99	0	0.1	0.6	NEG	NEG
PRB976-02	06-Nov-99	2	0.7	0.6	NEG	NEG
PRB976-03	11-Nov-99	7	>11.7	17.0	POS	NEG
PRB976-04	13-Nov-99	9	>11.7	18.9	POS	NEG
Test Date			15-Feb-12	16-Feb-12	5-Mar-12	
Test Site			SC	RL	SC	
Kit Part Code			26217	GE41/42	7D26-46	
Kit Lot No.			315FJJ-02	D078110	111228ALCE	
Kit Exp. Date			27-Sep-12	31-Jan-13	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 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.

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DATA SHEET

HIV Antibody (s/co)¹

Panel Member	Bleed Date	Days Since 1 st Bleed	Avioq HIV-1 Microelisa System	Bio-Rad GS HIV-1/HIV-2 Plus O EIA	Siemens HIV 1/O/2 Enhanced ADVIA Centaur
PRB976-01	04-Nov-99	0	0.2	0.1	<0.05
PRB976-02	06-Nov-99	2	0.2	0.1	<0.05
PRB976-03	11-Nov-99	7	0.2	0.3	<0.05
PRB976-04	13-Nov-99	9	0.2	0.3	<0.05
Test Date			1-Feb-12	31-Jan-12	7-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 red.

HIV Confirmatory

Panel Member	Bleed Date	Days Since 1 st Bleed	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
PRB976-01	04-Nov-99	0	No Bands	Neg	No Bands	Neg
PRB976-02	06-Nov-99	2	No Bands	Neg	No Bands	Neg
PRB976-03	11-Nov-99	7	No Bands	Neg	No Bands	Neg
PRB976-04	13-Nov-99	9	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

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DATA SHEET

HIV Confirmatory

Panel Member	Bleed Date	Days Since 1 st Bleed	Innogenetics INNO-LIA™ HIV I/II Band Pattern	Innogenetics INNO-LIA™ HIV I/II Result
PRB976-01	04-Nov-99	0	No Bands	NEG
PRB976-02	06-Nov-99	2	No Bands	NEG
PRB976-03	11-Nov-99	7	No Bands	NEG
PRB976-04	13-Nov-99	9	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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ASR = analyte specific reagent; CE = Conformité Européenne or CE Marking; IVD = in vitro diagnostic use; LTD = laboratory developed test; RUO = research use only

The Product Insert for this panel in PDF form can be found at www.seracarecatalog.com
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