

**OVERVIEW**

PRB975 is a five member HIV Seroconversion Panel collected from a single donor over a 14 day period in 2002, prior to antibody seroconversion. PRB975-03 is a challenging sample for HIV RNA assays, and the panel clearly demonstrates improvement in sensitivity with the introduction of the '4<sup>th</sup> generation' HIV Ag/Ab tests.

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

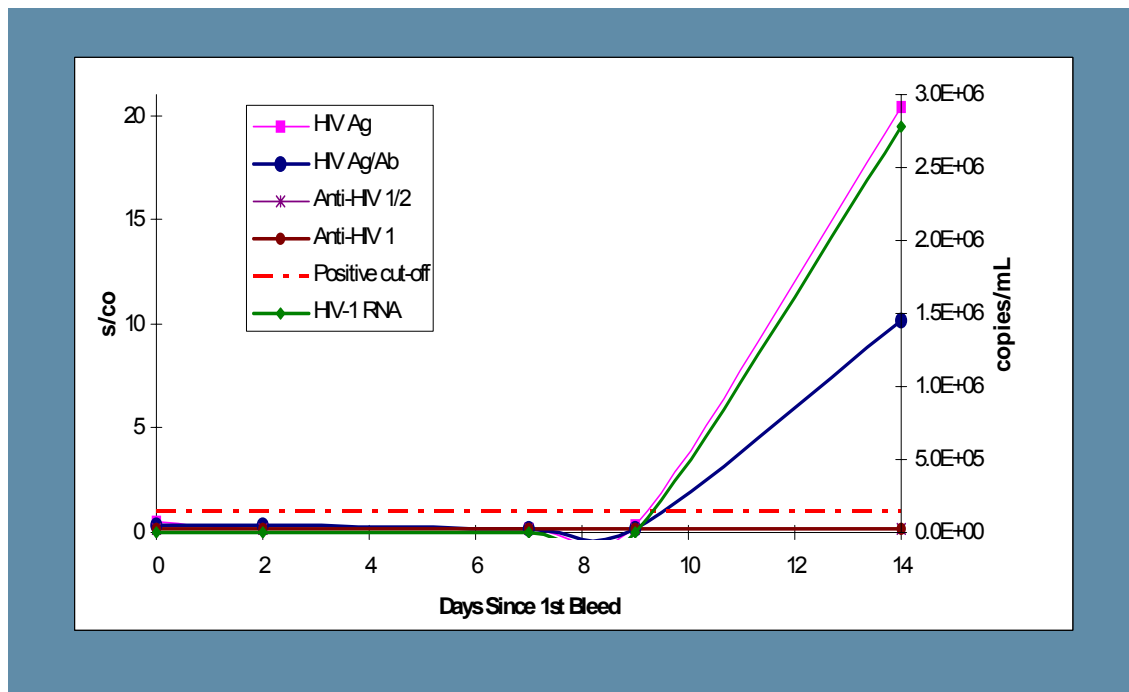
CAUTION: Potentially infectious materials. Follow Universal Precautions. Some panel members were found positive for markers of HIV infection; all were found negative for HBsAg and anti-HCV.

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 <sup>st</sup> Bleed	Fiebig Stage <sup>1</sup>	Abbott RealTime HIV-1 RNA <i>m2000</i>	Roche COBAS <sup>®</sup> AmpliPrep COBAS <sup>®</sup> TaqMan <sup>®</sup> HIV-1 Test v 2.0	Siemens Versant <sup>®</sup> HIV-1 RNA 3.0 Assay (bDNA)
PRB975-01	14-May-02	0	NA	BLD	BLD	BLD
PRB975-02	16-May-02	2	NA	BLD	BLD	BLD
PRB975-03	21-May-02	7	I	5.7 x 10 <sup>1</sup>	2.2 x 10 <sup>2</sup>	BLD
PRB975-04	23-May-02	9	I	7.8 x 10 <sup>2</sup>	3.4 x 10 <sup>3</sup>	7.2 x 10 <sup>2</sup>
PRB975-05	28-May-02	14	II	8.1 x 10 <sup>5</sup>	2.8 x 10 <sup>6</sup>	4.4 x 10 <sup>5</sup>
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

<sup>1</sup> 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 <sup>st</sup> Bleed	bioMerieux VIDAS HIV p24 II pg/mL	Perkin Elmer Alliance HIV-1 p24 Ag ELISA s/co <sup>2</sup>
PRB975-01	14-May-02	0	<3.0	0.5
PRB975-02	16-May-02	2	<3.0	0.2
PRB975-03	21-May-02	7	<3.0	0.2
PRB975-04	23-May-02	9	<3.0	0.3
PRB975-05	28-May-02	14	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

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

<sup>2</sup> 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 = in vitro diagnostic use; LDT = laboratory developed test;  
RUO = research use only

HIV Antigen/Antibody (s/co)<sup>1</sup>

Panel Member	Bleed Date	Days Since <sup>1st</sup> 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
PRB975-01	14-May-02	0	0.1	0.5	0.1	0.4
PRB975-02	16-May-02	2	0.1	0.4	0.4	0.4
PRB975-03	21-May-02	7	0.1	0.5	0.4	0.4
PRB975-04	23-May-02	9	0.1	0.5	0.1	0.4
PRB975-05	28-May-02	14	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

HIV Antigen/Antibody

Panel Member	Bleed Date	Days Since <sup>1st</sup> Bleed	Bio-Rad GS HIV Combo Ag/Ab EIA s/co <sup>1</sup>	Murex HIV Ag/Ab Combination s/co <sup>2</sup>	Alere Determine™ HIV-1/2 Ag/Ab Combo HIV Ag	Alere Determine™ HIV-1/2 Ag/Ab Combo HIV Ab
PRB975-01	14-May-02	0	0.3	0.3	NEG	NEG
PRB975-02	16-May-02	2	0.2	0.3	NEG	NEG
PRB975-03	21-May-02	7	0.3	0.2	NEG	NEG
PRB975-04	23-May-02	9	0.3	0.2	NEG	NEG
PRB975-05	28-May-02	14	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	

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

<sup>2</sup> 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)<sup>1</sup>

Panel Member	Bleed Date	Days Since 1 <sup>st</sup> Bleed	Avioq HIV-1 Microelisa System	Bio-Rad GS HIV-1/HIV-2 Plus O EIA	Siemens HIV 1/O/2 Enhanced ADVIA Centaur
PRB975-01	14-May-02	0	0.2	0.2	<0.05
PRB975-02	16-May-02	2	0.2	0.2	<0.05
PRB975-03	21-May-02	7	0.2	0.2	<0.05
PRB975-04	23-May-02	9	0.2	0.2	<0.05
PRB975-05	28-May-02	14	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

<sup>1</sup> Immunoassay results are means of duplicates expressed as signal to cutoff ratios (s/co). Ratios  $\geq 1.0$  are considered reactive and noted in red.

HIV Confirmatory

Panel Member	Bleed Date	Days Since 1 <sup>st</sup> 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
PRB975-01	14-May-02	0	No Bands	Neg	No Bands	Neg
PRB975-02	16-May-02	2	No Bands	Neg	No Bands	Neg
PRB975-03	21-May-02	7	No Bands	Neg	No Bands	Neg
PRB975-04	23-May-02	9	No Bands	Neg	No Bands	Neg
PRB975-05	28-May-02	14	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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**HIV Confirmatory**

Panel Member	Bleed Date	Days Since 1 <sup>st</sup> Bleed	Innogenetics INNO-LIA™ HIV I/II Band Pattern	Innogenetics INNO-LIA™ HIV I/II Result
PRB975-01	14-May-02	0	No Bands	NEG
PRB975-02	16-May-02	2	No Bands	NEG
PRB975-03	21-May-02	7	No Bands	NEG
PRB975-04	23-May-02	9	No Bands	NEG
PRB975-05	28-May-02	14	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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