

**OVERVIEW**

PRB973 is a four member HIV Seroconversion Panel collected from a single donor over a period of 11 days in 2000. Member 3 is a low titer HIV antigen sample, challenging for antigen and Ag/Ab tests, and Member 4 is a challenging sample for antibody assays.

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

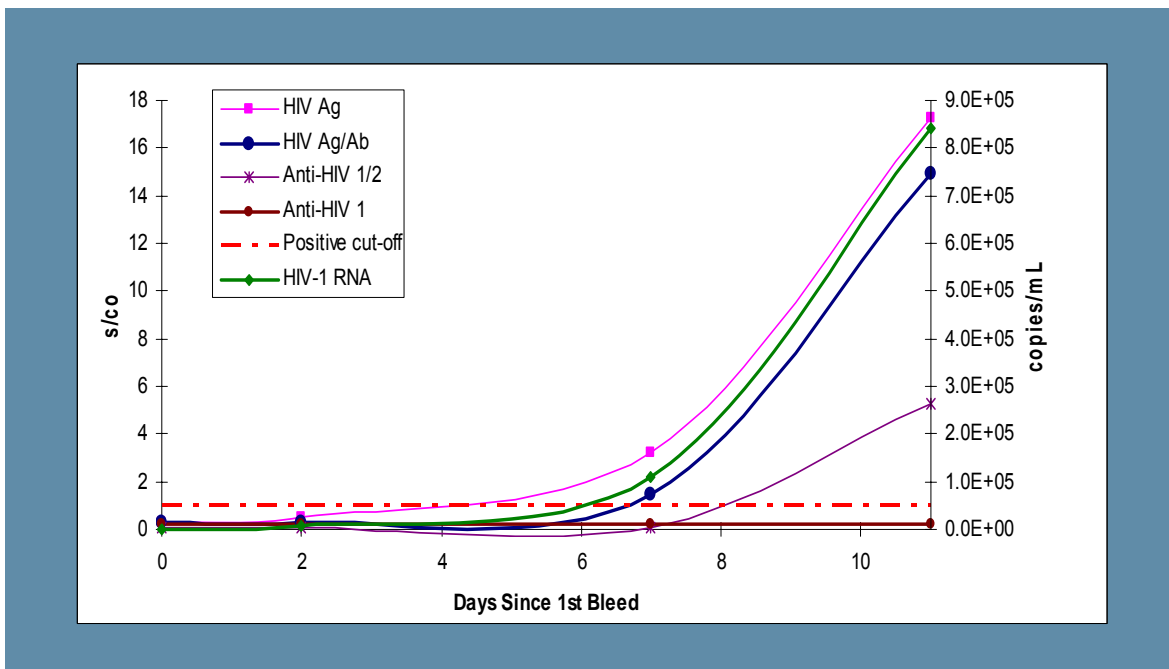
CAUTION: Potentially infectious materials. Follow Universal Precautions. Panel members were found positive for markers of HIV infection; all were found negative for HBsAg and anti-HCV.

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

Data are offered for informational purposes only. SeraCare Life Sciences does not claim these results can be duplicated 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 HIV RealTime HIV-1 RNA <i>m2000</i>	Roche COBAS <sup>®</sup> Ampliprep COBAS <sup>®</sup> TaqMan <sup>®</sup> HIV-1 Test v2.0	Siemens Versant <sup>®</sup> HIV-1 RNA 3.0 Assay (bDNA)
PRB973-01	6-Jun-00	0	I	8.1 x 10 <sup>2</sup>	2.7 x 10 <sup>3</sup>	6.8 x 10 <sup>2</sup>
PRB973-02	8-Jun-00	2	I	6.4 x 10 <sup>3</sup>	2.8 x 10 <sup>4</sup>	7.1 x 10 <sup>3</sup>
PRB973-03	13-Jun-00	7	II	1.1 x 10 <sup>5</sup>	2.2 x 10 <sup>5</sup>	9.1 x 10 <sup>4</sup>
PRB973-04	17-Jun-00	11	III/IV	8.4 x 10 <sup>5</sup>	2.2 x 10 <sup>6</sup>	>5.0 x 10 <sup>5</sup>
Test Date				1-Feb-12	31-Jan-12	2-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

<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	bioMérieux VIDAS p24 II (pg/mL) <sup>1</sup>	Perkin Elmer Alliance HIV-1 p24 ELISA (s/co) <sup>2</sup>
PRB973-01	6-Jun-00	0	<3.0	0.3
PRB973-02	8-Jun-00	2	<3.0	0.5
PRB973-03	13-Jun-00	7	15.9	3.2
PRB973-04	17-Jun-00	11	90.1	17.3
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

<sup>1</sup> Quantitative HIV Antigen results are means of duplicates expressed as pg/mL. Ratios ≥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

DATA SHEET

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

Panel Member	Bleed Date	Days Since 1 <sup>st</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
PRB973-01	6-Jun-00	0	0.1	0.5	0.1	0.3
PRB973-02	8-Jun-00	2	0.3	0.5	0.3	0.4
PRB973-03	13-Jun-00	7	1.8	1.4	3.8	1.4
PRB973-04	17-Jun-00	11	21.2	8.7	17.0	8.8
Test Date			30-Jan-12	6-Feb-12	6-Feb-12	16-Mar-12
Test Site			RL	RL	RL	SC
Kit Part Code			2P36	2G83-20	12321LI00	72386
Kit Lot No.			08413LI00	11457LF00	7G46-48	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 (s/co)<sup>1</sup>

Panel Member	Bleed Date	Days Since 1 <sup>st</sup> Bleed	Bio-Rad GS HIV Combo Ag/Ab EIA	Murex HIV Ag/Ab Combination	Alere Determine™ HIV -1/2 Ag/Ab Combo HIV Ag	Alere Determine™ HIV-1/2 Ag/Ab Combo HIV-Ab
PRB973-01	6-Jun-00	0	0.2	0.3	NEG	NEG
PRB973-02	8-Jun-00	2	0.4	0.3	NEG	NEG
PRB973-03	13-Jun-00	7	2.3	1.5	NEG	NEG
PRB973-04	17-Jun-00	11	11.3	14.9	NEG	NEG
Test Date			15-Mar-12	31-Jan-12		05-Mar-12
Test Site			SC	RL		SC
Kit Part Code			26217	D078310		7D26-46
Kit Lot No.			315FJJ-02	7G79-11		110524ALCE
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.

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

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
PRB973-01	6-Jun-00	0	0.2	0.1	<0.05
PRB973-02	8-Jun-00	2	0.2	0.1	<0.05
PRB973-03	13-Jun-00	7	0.2	0.1	<0.05
PRB973-04	17-Jun-00	11	0.2	5.3	17.5
Test Date			1-Feb-12	31-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 ≥1.0 are considered reactive and noted in red.

Anti-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
PRB973-01	6-Jun-00	0	No bands	NEG	No bands	NEG
PRB973-02	8-Jun-00	2	No bands	NEG	No bands	NEG
PRB973-03	13-Jun-00	7	No bands	NEG	No bands	NEG
PRB973-04	17-Jun-00	11	f24	IND	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	

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

**Anti-HIV Confirmatory and Rapid Tests**

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
PRB973-01	6-Jun-00	0	No bands	NEG
PRB973-02	8-Jun-00	2	No bands	NEG
PRB973-03	13-Jun-00	7	No bands	NEG
PRB973-04	17-Jun-00	11	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

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

The Product Insert for this panel in PDF form can be found at [www.seracarecatalog.com](http://www.seracarecatalog.com)

The printed Package Insert or Data Sheet may be requested by email at [info@seracare.com](mailto:info@seracare.com), or by phone at 508.244.6400

*ASK ABOUT RELATED SERACARE PRODUCTS*

- ACCURUN® independent quality controls
- SeraCon™ and other processed plasma products
- Global Patient Sample (GPS) Program – access to a vast and evolving inventory of single test patient samples

