

OVERVIEW

HIV-1 Seroconversion Panel PRB974 is a four-member panel collected from a single individual over 16 days in 2000. Panel members are undiluted, unpreserved aliquots from plasma units. PRB974-02 is a moderate positive HIV RNA sample, challenging for HIV antigen assays, PRB974-03 is detected at very low signal to cutoff by all HIV Ag/Ab methods tested, and PRB974-04 is a very challenging sample for anti-HIV assays.

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.

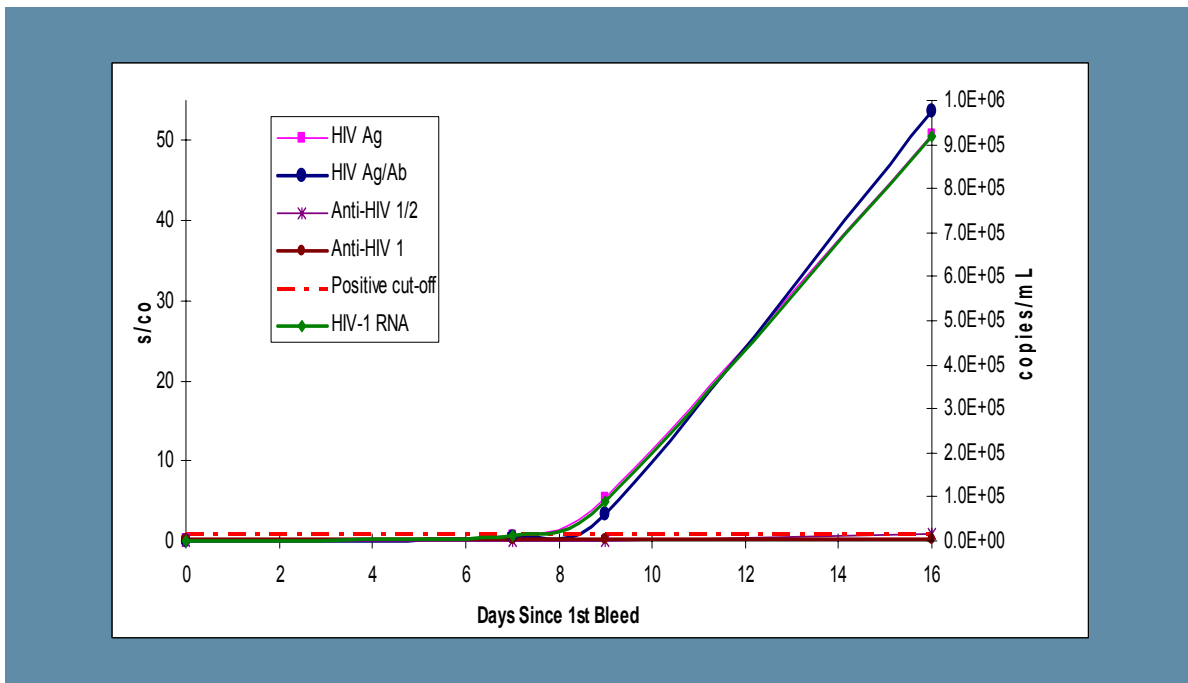
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EVOLUTION OF HIV MARKERS IN EARLY INFECTION



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 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)
PRB974-01	14-Jun-00	0	NA	BLD	BLD	BLD
PRB974-02	21-Jun-00	7	I	6.1 x 10 ³	1.1 x 10 ⁴	3.8 x 10 ³
PRB974-03	23-Jun-00	9	II	7.4 x 10 ⁴	9.1 x 10 ⁴	4.7 x 10 ⁴
PRB974-04	30-Jun-00	16	II/III	1.0 x 10 ⁶	9.2 x 10 ⁵	>5.0 x 10 ⁵
Test Date				01-Feb-12	31-Jan-12	02-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

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	bioMérieux VIDAS p24 II (pg/mL) ¹	Perkin Elmer Alliance HIV-1 p24 Ag ELISA (s/co) ²
PRB974-01	14-Jun-00	0	<3.0	0.2
PRB974-02	21-Jun-00	7	<3.0	0.7
PRB974-03	23-Jun-00	9	22.5	5.3
PRB974-04	30-Jun-00	16	347.2	50.8
Test Date			12-Mar-12	01-Feb-12
Test Site			RL	SC
Kit Part Code			30117	NEK050A
Kit Lot No.			120507-0	990-11521
Kit Exp. Date			17-Jul-12	01-Oct-12
Kit Regulatory Status			CE	RUO

¹ Quantitative HIV Antigen results are the means of duplicates expressed as pg/mL. Ratios ≥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 = 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 1 st 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
PRB974-01	14-Jun-00	0	0.1	0.5	0.1	0.3
PRB974-02	21-Jun-00	7	0.4	0.6	0.3	0.4
PRB974-03	23-Jun-00	9	3.4	2.3	3.3	1.4
PRB974-04	30-Jun-00	16	53.6	19.8	34.5	8.8
Test Date			30-Jan-12	06-Feb-12	06-Feb-12	16-Mar-12
Test Site			RL	RL	RL	SC
Kit Part Code			2P36	2G83-20	7G46-48	72386
Kit Lot No.			08414LI00	11457LF00	12321LI00	1C1067
Kit Exp. Date			30-Apr-12	16-May12	17-Nov-12	30-Aug-12
Kit Regulatory Status			CE	CE	CE	CE

HIV Antigen/Antibody (s/co)¹

Panel Member	Bleed Date	Days Since 1 st 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
PRB974-01	14-Jun-00	0	0.2	0.3	NEG	NEG
PRB974-02	21-Jun-00	7	0.5	0.4	NEG	NEG
PRB974-03	23-Jun-00	9	3.5	1.7	NEG	NEG
PRB974-04	30-Jun-00	16	11.8	16.9	POS	NEG
Test Date			15-Mar-12	31-Jan-12	05-Mar-12	
Test Site			SC	RL	SC	
Kit Part Code			26217	7G79-11	7D26-46	
Kit Lot No.			315FJJ-02	D078310	110524ALCE & 111228ALCE	
Kit Exp. Date			27-Sep-12	31-Dec-12	25-Mar-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 red.

POS = positive; NEG = negative; BLD = below the limit of detection; IND = indeterminate; NA = not available, NT = not tested
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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	Siemens HIV1/O/2 Enhanced ADVIA Centaur
PRB974-01	14-Jun-00	0	0.2	0.1	<0.05
PRB974-02	21-Jun-00	7	0.2	0.1	<0.05
PRB974-03	23-Jun-00	9	0.2	0.1	<0.05
PRB974-04	30-Jun-00	16	0.2	0.2	1.0
Test Date			01-Feb-12	31-Jan-12	01-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
PRB974-01	14-Jun-00	0	No bands	NEG	No bands	NEG
PRB974-02	21-Jun-00	7	No bands	NEG	No bands	NEG
PRB974-03	23-Jun-00	9	No bands	NEG	No bands	NEG
PRB974-04	30-Jun-00	16	No bands	NEG	No bands	NEG
Test Date				09-Feb-12		06-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 st Bleed	Innogenetics INNO-LIA HIV I/II Band Pattern	Innogenetics INNO-LIA HIV I/II Result
PRB974-01	14-Jun-00	0	No Bands	NEG
PRB974-02	21-Jun-00	7	No Bands	NEG
PRB974-03	23-Jun-00	9	No Bands	NEG
PRB974-04	30-Jun-00	16	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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RUO = research use only

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