

DATA SHEET

OVERVIEW

PRB978 is a seven member HIV-1 Seroconversion panel collected from a single individual over 33 days in 2010.

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

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

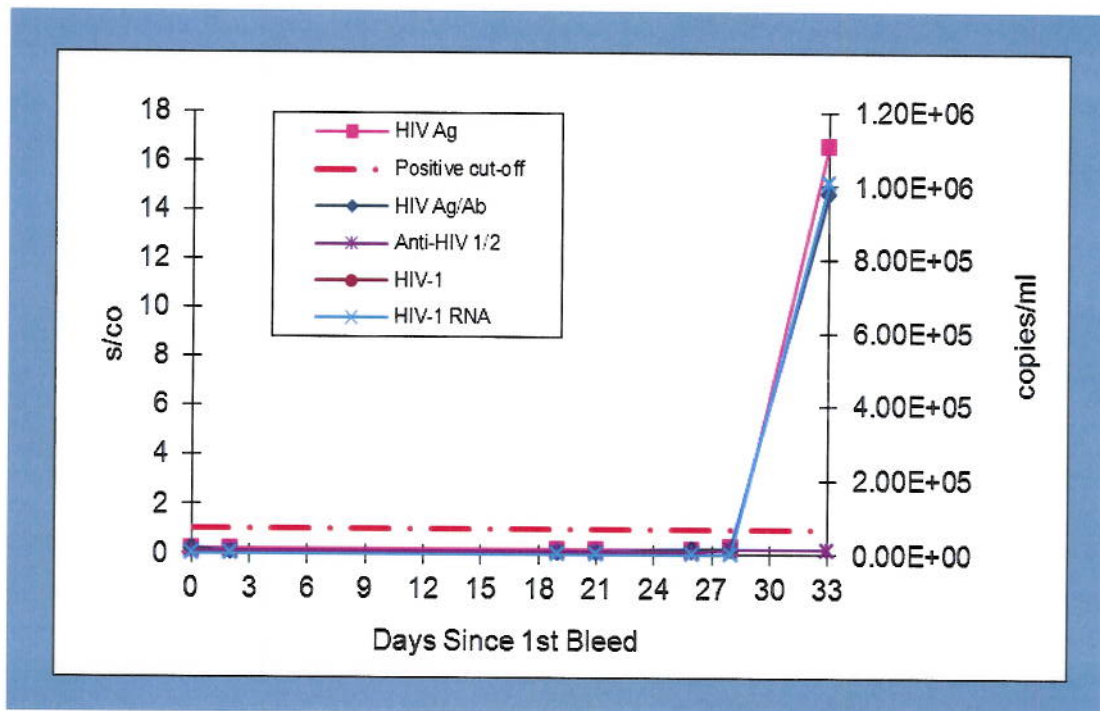
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Not for use in diagnostic procedures.

Data are offered for informational purposes only. SeraCare Life Sciences does not claim these results can be duplicated exactly.

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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*

# HIV-1 Seroconversion Panel PRB978

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### 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>m</i> 2000	Roche COBAS® AmpliPrep COBAS® TaqMan® HIV-1 Test v2.0	Siemens Versant® HIV-1 RNA 3.0 Assay (bDNA)
PRB978-01	26-Jun-10	0	Eclipse	BLD	BLD	BLD
PRB978-02	28-Jun-10	2	Eclipse	BLD	BLD	BLD
PRB978-03	15-Jul-10	19	Eclipse	BLD	BLD	BLD
PRB978-04	17-Jul-10	21	Eclipse	BLD	BLD	BLD
PRB978-05	22-Jul-10	26	I	1.0 x 10 <sup>2</sup>	2.1 x 10 <sup>2</sup>	BLD
PRB978-06	24-Jul-10	28	I	3.7 x 10 <sup>3</sup>	1.1 x 10 <sup>4</sup>	2.0 x 10 <sup>3</sup>
PRB978-07	29-Jul-10	33	II	1.0 x 10 <sup>6</sup>	1.6 x 10 <sup>6</sup>	4.5 x 10 <sup>5</sup>
Test Date				23-Nov-12	27-Nov-12	26-Nov-12
Test Site				RL	RL	RL
Kit Part Code				6L18-90	R00290	127418A/127418B
Kit Lot No.				439355	N/A	D094
Kit Exp. Date				14-Sep-13	01-Apr-13	06-Apr-13
Kit Regulatory Status				CE, IVD	CE, IVD, FDA	CE, IVD, FDA

<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) <sup>1</sup>	Perkin Elmer Alliance HIV-1 p24 Ag ELISA (s/co) <sup>2</sup>
PRB978-01	26-Jun-10	0	<3.0	0.2
PRB978-02	28-Jun-10	2	<3.0	0.2
PRB978-03	15-Jul-10	19	<3.0	0.2
PRB978-04	17-Jul-10	21	<3.0	0.2
PRB978-05	22-Jul-10	26	<3.0	0.2
PRB978-06	24-Jul-10	28	<3.0	0.3
PRB978-07	29-Jul-10	33	65.9	16.6
Test Date			27-Nov-12	28-Nov-12
Test Site			RL	SC
Kit Part Code			30117	NEK 050A/B
Kit Lot No.			121205	990-12371
Kit Exp. Date			05-Dec-12	01-May-13
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.

BLD = below the limit of detection

RL = Reference Lab; SC = SeraCare

CE = Conformité Européenne or CE Marking; IVD = in vitro diagnostic use; RUO = research use only

# HIV-1 Seroconversion Panel PRB978

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### 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 PRISM Combo	Bio-Rad Genscreen Ultra HIV Ag/Ab Combo
PRB978-01	26-Jun-10	0	0.2	0.1	0.1
PRB978-02	28-Jun-10	2	0.1	0.1	0.1
PRB978-03	15-Jul-10	19	0.1	0.1	0.1
PRB978-04	17-Jul-10	21	0.1	0.1	0.1
PRB978-05	22-Jul-10	26	0.2	0.1	0.1
PRB978-06	24-Jul-10	28	0.2	0.1	0.5
PRB978-07	29-Jul-10	33	14.7	6.1	1.7
Test Date			09-Jan-13	03-Dec-12	19-Feb-13
Test Site			RL	RL	RL
Kit Part Code			4J27	7G46-48	72388
Kit Lot No.			19116LI00	23322LI000	121071
Kit Exp. Date			05-Oct-13	18-Sep-13	15-Apr-13
Kit Regulatory Status			CE, IVD	CE, IVD	CE, IVD

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

Panel Member	Bleed Date	Days Since 1 <sup>st</sup> Bleed	Murex HIV Ag/Ab Combination	Alere Determine™ HIV-1/2 Ag/Ab Combo HIV Ag
PRB978-01	26-Jun-10	0	0.3	Neg
PRB978-02	28-Jun-10	2	0.2	Neg
PRB978-03	15-Jul-10	19	0.2	Neg
PRB978-04	17-Jul-10	21	0.4	Neg
PRB978-05	22-Jul-10	26	0.3	Neg
PRB978-06	24-Jul-10	28	0.4	Neg
PRB978-07	29-Jul-10	33	4.1	Neg
Test Date			03-Dec-12	03-Dec-12
Test Site			RL	SC
Kit Part Code			7G79-09	7D2646
Kit Lot No.			D078410	44238K101
Kit Exp. Date			31-Jan-13	24-May-13
Kit Regulatory Status			CE, IVD	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.

NEG = negative  
 RL = Reference Lab; SC = SeraCare  
 CE = Conformité Européenne or CE Marking

# HIV-1 Seroconversion Panel PRB978

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### 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
PRB978-01	26-Jun-10	0	0.2	0.1	Neg
PRB978-02	28-Jun-10	2	0.2	0.1	Neg
PRB978-03	15-Jul-10	19	0.2	0.1	Neg
PRB978-04	17-Jul-10	21	0.2	0.1	Neg
PRB978-05	22-Jul-10	26	0.2	0.1	Neg
PRB978-06	24-Jul-10	28	0.2	0.2	Neg
PRB978-07	29-Jul-10	33	0.2	0.2	Neg

Test Date			
Test Site	27-Nov-12	20-Nov-12	29-Nov-12
Kit Part Code	SC	SC	RL
Kit Lot No.	100384	32588	01622429
Kit Exp. Date	J3728	208GBB-05	97771130
Kit Regulatory Status	18-Oct-13	29-Mar-13	14-Aug-13
	IVD	CE, IVD	CE, IVD

### HIV Confirmatory (s/co)<sup>1</sup>

Panel Member	Bleed Date	Days Since 1 <sup>st</sup> Bleed	Bio-Rad GS HIV-1 Western Blot Result	Innogenetics INNO-LIA™ HIV I/II Result	Calypte/MAXIM HIV-1 Western Blot Result
PRB978-01	26-Jun-10	0	Neg	Neg	Neg
PRB978-02	28-Jun-10	2	Neg	Neg	Neg
PRB978-03	15-Jul-10	19	Neg	Neg	Neg
PRB978-04	17-Jul-10	21	Neg	Neg	Neg
PRB978-05	22-Jul-10	26	Neg	Neg	Neg
PRB978-06	24-Jul-10	28	Neg	Neg	Neg
PRB978-07	29-Jul-10	33	Neg	Neg	Neg

Test Date			
Test Site	06-Dec-12	27-Nov-12	19-Nov-12
Kit Part Code	SC	RL	SC
Kit Lot No.	32508	80540	A3143-067
Kit Exp. Date	111042	L227698	98002
Kit Regulatory Status	08-Dec-12	01-Jun-13	23-May-13
	IVD	CE	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.

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CE = Conformité Européenne or CE Marking; IVD = in vitro diagnostic use

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

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