## DATA SHEET

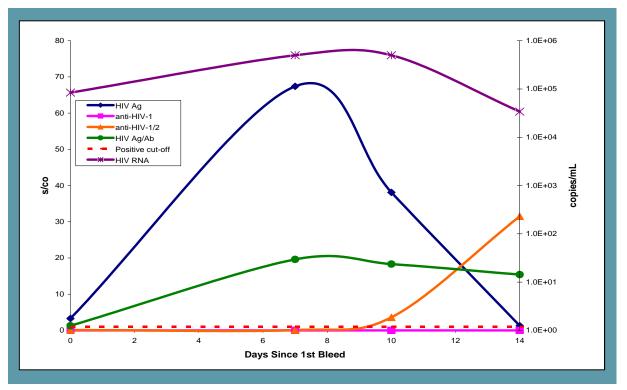
#### OVERVIEW

HIV-1 AccuVert<sup>™</sup> Seroconversion Panel PRB970 is a 4 member, 1.0 mL per vial panel of undiluted, naturally-occurring plasma samples. Panel members represent serial bleeds collected from a single individual over the course of 14 days during the development of HIV infection and subsequent response.

Test results from commercially available HIV assays are included for characterization of the panel members. This panel of human plasma samples is positive for HIV-1 RNA and p24 antigen and demonstrates a change in expression from negative to positive for HIV antibody during the development and progression of HIV infection.

For Research Use Only. Not for use in diagnostic procedures. Data are provided for informational purposes. SeraCare Life Sciences does not claim that others can duplicate test results exactly.

CAUTION: Potentially infectious materials. Follow Universal Precautions. Some panel members were found positive for anti-HIV-1. All panel members were found negative for HBsAg and anti-HCV.



### Expression of HIV-1 Markers During Progression of Infection

This graph demonstrates the development and progression of HIV infection in a single individual utilizing test results for various HIV analytes and analyte combinations. Lines connecting data points are not indicative of marker reactivity between bleed dates.



# HIV-1 AccuVert<sup>™</sup> Seroconversion Panel PRB970 (0600-0252)

## DATA SHEET

# HIV RNA (copies/mL)

Panel Member	Bleed Date	Days Since 1 <sup>st</sup> Bleed	Fiebig Stage <sup>1</sup>	Abbott HIV RNA m2000	Roche HIV RNA CAP/CTM v1.0	Siemens HIV RNA bDNA
PRB970-01	03-Jun-08	0	П	<b>2.0 x 10<sup>5</sup></b>	1.1 x 10 <sup>5</sup>	8.4 x 10 <sup>4</sup>
PRB970-02	10-Jun-08	7	II	>1.0 x 10 <sup>8</sup>	>1.0 x 10 <sup>7</sup>	>5.0 x 10⁵
PRB970-03	13-Jun-08	10	111	3.5 x 10 <sup>6</sup>	<b>2.1 x 10<sup>6</sup></b>	>5.0 x 10 <sup>5</sup>
PRB970-04	17-Jun-08	14	IV	6.6 x 10 <sup>4</sup>	6.4 x 10 <sup>4</sup>	<b>3.4 x 10</b> <sup>4</sup>
Test Date				13-May-10	19-May-10	18-Jun-10
Test Site				RL	SC	RL
Kit Part Code				6L18	03542998 190	127418 A&B
Kit Lot No.				422866	M15645	D079
Kit Exp Date				5-May-11	31-Jan-11	28-Sep-10

<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.

RL = Reference Lab; SC = SeraCare

## **HIV Antigen**

Panel Member	Bleed Date	Days Since 1 <sup>st</sup> Bleed	Perkin Elmer HIVAg p24 (s/co) <sup>1</sup>	Zeptometrix HIVAg p24 (s/co) <sup>1</sup>	bioMerieux HIVAg VIDAS p24 (pg/mL) <sup>2</sup>
PRB970-01	03-Jun-08	0	1.6	3.3	13.0
PRB970-02	10-Jun-08	7	172.2	67.4	>400.0
PRB970-03	13-Jun-08	10	27.8	38.1	299.6
PRB970-04	17-Jun-08	14	1.4	1.3	9.3
Test Date			07-Apr-14	25-May-10	30-Jun-10
Test Site			SC	SC	RL
Kit Part Code			NEK050A	801111	30 117
Kit Lot No.			990-13514	306346	838404801
Kit Exp Date			01-Oct-14	12-Mar-11	17-Oct-10

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

RL = Reference Lab; SC = SeraCare



# HIV-1 AccuVert<sup>™</sup> Seroconversion Panel PRB970 (0600-0252)

# 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 AxSYM Combo	Abbott HIV Ag/Ab PRISM Combo	Abbott HIV Ag/Ab ARCHITECT Combo	Bio-Rad Genscreen Ultra HIV Ag/Ab Combo	Murex HIV Ag/Ab Combo
PRB970-01	03-Jun-08	0	1.1	1.6	2.1	1.7	1.3
PRB970-02	10-Jun-08	7	73.0	193.4	565.9	>11.0	19.6
PRB970-03	13-Jun-08	10	20.2	39.7	45.2	>11.0	18.3
PRB970-04	17-Jun-08	14	10.1	4.1	21.6	>11.0	15.4
Test Date			27-May-10	12-Jul-10	09-May-14	29-Jun-10	22-Jun-10
Test Site			RL	RL	SC	SC	RL
Kit Part Code			268320	7G46-48	2P36	72386	7G79-02
Kit Lot No.			87248LF00	89287HN00	37206L100	0A1050	L397910
Kit Exp Date			02-Sep-10	07-Dec-10	16-Nov-14	30-May-11	31-Dec-10

<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. RL = Reference Lab; SC = SeraCare

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

Panel Member	Bleed Date	Days Since 1 <sup>st</sup> Bleed	Avioq HIV-1 Microelisa System	Genetic Systems HIV-1 rLAV	Abbott HIV-1/HIV-2 rDNA	Bio-Rad HIV-1/HIV- 2 Plus O Gen Sys
PRB970-01	03-Jun-08	0	0.4	0.1	0.2	0.1
PRB970-02	10-Jun-08	7	0.2	0.1	0.3	0.1
PRB970-03	13-Jun-08	10	0.2	0.1	4.1	2.7
PRB970-04	17-Jun-08	14	1.4	2.5	9.9	>11.1
Test Date			14-Jun-10	11-May-10; 25-May-10	22-Jun-10	15-Jul-10
Test Site			SC	SC	SC	SC
Kit Part Code			100384	32511	3A77-68	32588
Kit Lot No.			J0904	197DAA-05	83470M500	042EBB-05
Kit Exp Date			12-Jan-11	01-Jun-10	22-Aug-10	14-Oct-10

<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. SC = SeraCare

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



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# DATA SHEET

Panel Member	Bleed Date	Days Since 1 <sup>st</sup> Bleed	Ortho HIV-1/HIV-2 Vitros Eci	Siemens HIV1/O/2 Enhanced Advia Centaur
PRB970-01	03-Jun-08	0	0.1	0.0
PRB970-02	10-Jun-08	7	0.1	0.0
PRB970-03	13-Jun-08	10	3.6	1.8
PRB970-04	17-Jun-08	14	31.5	41.1
Test Date			08-Jul-10	22-Jun-10
Test Site			RL	RL
Kit Part Code			6801861	01463908
Kit Lot No.			0330	53445061
Kit Exp Date			25-Jan-11	19-Sep-10

<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.

RL = Reference Lab

## **Anti-HIV Confirmatory and Rapid Tests**

Panel Member	Bleed Date	Days Since 1 <sup>st</sup> Bleed	Calypte/MAXIM Western Blot Band Pattern	Calypte/MAXIM Western Blot Result	Innogenetics INNO-LIA HIV I/II Band Pattern	Innogenetics INNO-LIA HIV I/II Result
PRB970-01	03-Jun-08	0	No Bands	NEG	No Bands	NEG
PRB970-02	10-Jun-08	7	No Bands	NEG	No Bands	NEG
PRB970-03	13-Jun-08	10	No Bands	NEG	No Bands	NEG
PRB970-04	17-Jun-08	14	24	IND	24, 41	POS
Test Date			7-Jun-10	7-Jun-10	30-Jun-10	30-Jun-10
Test Site			SC	SC	RL	RL
Kit Part Code			98002	98002	80540	80540
Kit Lot No.			A1034-083	A1034-083	202524	202524
Kit Exp Date			03-Feb-11	03-Feb-11	01-Jan-11	01-Jan-11

RL = Reference Lab; SC = SeraCare

NEG = Negative; POS = Positive; IND = Indeterminate



### DATA SHEET

# HIV-1 AccuVert™ Seroconversion Panel PRB970 (0600-0252)

### **Anti-HIV Confirmatory and Rapid Tests**

Panel Member	Bleed Date	Days Since 1 <sup>st</sup> Bleed	Inverness Determine HIV-1/2 Ag/Ab Combo HIV Ag	Inverness Determine HIV-1/2 Ag/Ab Combo HIV-1/2
PRB970-01	03-Jun-08	0	NEG	NEG
PRB970-02	10-Jun-08	7	POS	NEG
PRB970-03	13-Jun-08	10	POS	NEG
PRB970-04	17-Jun-08	14	NEG	POS
Test Date			25-Jun-10	25-Jun-10
Test Site			SC	SC
Kit Part Code			7D26-46	7D26-46
Kit Lot No.			100203	100203
Kit Exp Date			04-Dec-10	04-Dec-10
SC = SeraCare				

SC = SeraCare

NEG = Negative; POS = Positive

The Package Insert for this panel in PDF form can be found at <u>www.seracare.com</u>

A printed copy of the Package Insert or Data Sheet may be requested by email at <u>info@seracare.com</u>, or by phone at 508.244.6400

#### ASK ABOUT RELATED SERACARE PRODUCTS

- AccuVert<sup>TM</sup> Seroconversion Panels
- ACCURUN<sup>®</sup> independent quality controls
- SeraCon<sup>™</sup> and Basematrix Processed Plasma



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