

# HIV-1 Seroconversion Panel AU

## PRB945

### INTENDED USE

This HIV-1 Seroconversion Panel is a group of serial bleeds from an individual plasma donor during seroconversion for HIV-1 antibody, p24 antigen, and/or HIV RNA. This Panel is intended for use by manufacturers and other laboratories in evaluating their anti-HIV, HIV antigen and HIV RNA assays with well-characterized specimens, and to provide comprehensive data for comparative analysis. For Research Use Only. Not for use in diagnostic procedures.

### PRODUCT DESCRIPTION

SeraCare has assembled this set of undiluted plasma samples from serial bleeds from a single plasma donor collected during a period of HIV-1 seroconversion. All units were maintained in a frozen state, except for the interval of dispensing into vials. No preservatives were added. This panel is provided as 1.0 ml volume per vial.

### REAGENTS

Cat No. PRB945-00-1.0 1 vial per member  
6 members, 1.0 mL per vial

### PRECAUTIONS

**BIOHAZARD CAUTION:** Potentially infectious materials. Use the Centers for Disease Control (CDC) recommended universal precautions for handling this product.<sup>1</sup> These materials have not been treated and should be considered biohazardous. Panel members were tested and were found positive by tests for anti-HIV 1/2, HIV Ag and HIV-1 RNA. Panel members were tested and found negative for HBsAg and anti-HCV.

Never pipette by mouth. Do not smoke, eat or drink in areas where specimens are handled.

These materials should be disposed of in a manner that will inactivate pathogenic agents.

### STORAGE

Panel members should be stored at -70°C or colder to preserve HIV-1 RNA, or -10°C or colder to preserve antibody and antigen. SeraCare recommends that the panel members be divided into smaller aliquots, as appropriate, for ease in repeated testing and to avoid multiple freeze-thaw cycles. If turbidity or particulate matter is observed, the samples should be centrifuged in accordance with each test kit manufacturer's instructions for sample preparation.

### INTERPRETATION OF RESULTS

The attached data sheet lists immunoassay results for Panel members generated using commercially available anti-HIV-1, anti-HIV-1/2 and HIV-1 antigen screening tests and results of related confirmatory methods. Immunoassay and confirmatory tests were performed in the laboratories of SeraCare and at internationally recognized reference laboratories (RL) by individuals who routinely use these test procedures. All immunoassay results are means of duplicates, expressed as specimen absorbance to cutoff ratios (s/co). Ratios  $\geq 1.0$  are considered reactive. Viral RNA results are expressed as RNA copies/mL.

### LIMITATIONS

PRB945 is offered 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.

### REFERENCES

1. CDC recommendations for prevention of HIV transmission in health care settings. MMWR 36 (suppl. 2) 1987.

**For assistance, contact SeraCare Life Sciences Technical Support**

Phone (508) 244-6400 or US Toll Free (800) 676-1881

Visit our website at [www.seracare.com](http://www.seracare.com)



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**SeraCare Life Sciences**  
**HIV-1 Seroconversion Panel AU PRB945**  
**Data Sheet**

Member I.D. #	Bleed Dates	Days Since 1st Bleed	Perkin Elmer HIV-1 p24 Ag s/co <u>SeraCare</u>	Abbott ARCHITECT HIV Ag/Ab s/co <u>RL53</u>	Abbott HIV 1/2 s/co <u>SeraCare</u>	Abbott PRISM® HIV O Plus s/co <u>RL54</u>	Ortho VITROS® Anti HIV 1+2 s/co <u>RL48</u>	Siemens ADVIA Centaur® HIVC s/co <u>RL46</u>
PRB945-01	06 NOV 96	0	0.3	0.1	0.2	0.4	0.1	< 0.1
PRB945-02	09 NOV 96	3	0.3	0.2	0.2	0.6	0.1	< 0.1
PRB945-03	13 NOV 96	7	1.0	0.7	0.2	0.4	0.1	< 0.1
PRB945-04	19 NOV 96	13	11.8	11.7	2.0	3.3	7.9	9.6
PRB945-05	21 NOV 96	15	21.5	34.0	>19.0	76.1	36.9	>50.0
PRB945-06	26 NOV 96	20	13.3	54.8	>19.0	153.6	71.8	>50.0
<b>Run Date:</b>			16-MAR-10	18-MAR-10	16-MAR-10	18-MAR-10	17-MAR-10	18-MAR-10
<b>Kit Lot #:</b>			990-100103	81321HN00	84792M500	82663M100	0310	50053060
<b>Exp. Date:</b>			1-OCT-10	6-AUG-10	5-MAY-10	20-JUL-10	28-JUL-10	6-AUG-10
<b>Product #:</b>			NEK050A	4J27-30	3A77-68	3L68-68	6801861	01622429

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POS = Positive; IND = Indeterminate; NEG = Negative; f = faint band.; BLD= Below Limit of Detection.

\*Western Blots are interpreted using ASTPHLD/CDC criteria (MMWR, vol. 38, S-7, 1989). Faintly staining bands are recorded, but interpreted as indeterminate according to specific manufacturer's instructions.

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----- U.S. FDA-Licensed Anti-HIV EIA Tests, results expressed as s/co -----

Member I.D. #	Bleed Dates	Days Since 1st Bleed	Abbott	Abbott	Gen. Sys.	Gen. Sys.	Org. Tek.
			HIV BBI	HIV-1/2 BBI	HIV BBI	HIV-1/2 BBI	HIV BBI
PRB945-01	06 NOV 96	0	0.2	0.1	0.1	0.1	0.3
PRB945-02	09 NOV 96	3	0.2	0.1	0.1	0.1	0.2
PRB945-03	13 NOV 96	7	0.2	0.1	0.1	0.1	0.3
PRB945-04	19 NOV 96	13	0.2	2.9	0.1	0.1	0.3
PRB945-05	21 NOV 96	15	0.5	>17.9	0.1	0.1	0.3
PRB945-06	26 NOV 96	20	5.8	>17.9	0.5	0.8	1.1
<b>Run Date:</b>			20 FEB 97	20 FEB 97	01 MAR 97	07 MAR 97	07 MAR 97
<b>Kit Lot #:</b>			25799M201	22703M401	341NX1-05	270NR1	160052
<b>Exp. Date:</b>			17 MAR 97	21 APR 97	17 JUL 97	01 AUG 97	04 FEB 98
<b>Product #:</b>			3A11	3A77	0218-02	0230	59605

----- HIV Antigen Tests -----

Member I.D. #	Abbott	Coulter	Dupont	Innogenetics	Org. Tek.	Roche PCR HIV RNA	Chiron bDNA HIV RNA	
	BBI s/co	BBI s/co	BBI s/co	RL29 s/co	BBI s/co	BBI copies/mL	BBI copies/mL	
PRB945-01	0.4	0.1	0.1	0.4	0.2	3 x 10 <sup>2</sup>	BLD	
PRB945-02	0.4	0.2	0.2	0.5	0.2	7 x 10 <sup>2</sup>	BLD	
PRB945-03	0.7	0.4	0.8	1.4	0.5	9 x 10 <sup>4</sup>	2 x 10 <sup>4</sup>	
PRB945-04	4.0	4.7	9.8	19.6	5.7	>8 x 10 <sup>5</sup>	2 x 10 <sup>5</sup>	
PRB945-05	7.1	11.6	17.5	31.3	8.0	>8 x 10 <sup>5</sup>	6 x 10 <sup>5</sup>	
PRB945-06	6.0	7.7	13.4	24.8	5.4	>8 x 10 <sup>5</sup>	7 x 10 <sup>5</sup>	
<b>Run Date:</b>		21 FEB 97	24 FEB 97	27 FEB 97	29 MAY 97	28 FEB 97	04 MAR 97	09 MAY 97
<b>Kit Lot #:</b>		23705M201	2066J304	189227	61125635	D02400D	98126	MMA279
<b>Exp. Date:</b>		09 JUL 97	27 MAR 97	21 MAR 97	30 NOV 97	21 JAN 98	30 JUL 97	05 JUN 97
<b>Product #:</b>		2A81	PN6604535	NEK-060B	K1048	59464	83088	6002-027

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----- Anti-HIV-1 Confirmatory Tests -----

Member I.D. #	Days Since 1st Bleed	BioRad Western Blot*		Epitope Western Blot*		Ortho/Cambridge Western Blot*	
		Band Pattern BBI	Result	Band Pattern BBI	Result	Band Pattern BBI	Result
PRB945-01	0	No Bands	NEG	No Bands	NEG	No Bands	NEG
PRB945-02	3	No Bands	NEG	No Bands	NEG	No Bands	NEG
PRB945-03	7	No Bands	NEG	No Bands	NEG	No Bands	NEG
PRB945-04	13	No Bands	NEG	No Bands	NEG	No Bands	NEG
PRB945-05	15	No Bands	NEG	No Bands	NEG	No Bands	NEG
PRB945-06	20	24, f160	IND	160	IND	24,160	POS

Run Date:	05 MAR 97	25 FEB 97	11 MAR 97
Kit Lot #:	9711005	M019601	C7209-035
Exp. Date:	09 JUN 97	31 AUG 97	28 JUL 97
Product #:	197-1101	72827	98002

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Member I.D. #	Days Since 1st Bleed	----- International Anti-HIV 1/2 Test Kits -----								
		Abbott 3rd Gen. RL23 s/co	Abbott 3rd Gen. PLUS RL19 s/co	Abbott AxSYM RL19 s/co	Behring ENZ PLUS RL23 s/co	BioChem Detect HIV BBI s/co	Biotest HIV 1/2 RL29 s/co	Roche Enzymun Combi RL12 s/co	Diag. Past. Genscreen RL29 s/co	
PRB945-01	0	0.1	0.4	0.5	0.1	0.1	0.1	0.3	0.3	
PRB945-02	3	0.1	0.4	0.5	0.1	0.1	0.1	0.3	0.3	
PRB945-03	7	0.1	0.4	0.4	0.2	0.0	0.1	0.3	0.3	
PRB945-04	13	2.9	1.5	0.9	0.7	0.0	0.2	2.9	6.2	
PRB945-05	15	>18.2	>12.9	14.9	>6.8	0.1	1.1	6.8	>15.5	
PRB945-06	20	>18.2	>13.0	34.5	>6.8	0.9	7.4	>43.9	>15.5	
<b>Run Date:</b>		13 MAY 97	12 MAY 97	26 MAY 97	21 MAY 97	03 MAR 97	23 MAY 97	13 NOV 97	22 MAY 97	
<b>Kit Lot #:</b>		26758M201	27448 HP 00	28382 LU 04	29085	11168-2	101106	19438201	7A109U	
<b>Exp. Date:</b>		17 AUG 97	11 SEP 97	14 OCT 97	05 FEB 98	30 JUN 97	07 JUN 97	30 NOV 98	15 DEC 97	
<b>Product #:</b>		3A10	7A84	9A44	OQFK	RHD-902W	807004	1557319	72276	

Member I.D. #	bioMerieux VIDAS DUO RL 12 s/co	Innogenetics Innotest RL12 s/co	Murex/Well. HIV 1/2 RL12 s/co	Murex ICE HIV 1.O.2 RL19 s/co	Org. Tek. Uni-form II PLUS RL23 s/co	In House IgA RL12 s/co	In House IgM RL12 s/co
	PRB945-01	0.2	0.0	0.3	0.3	0.5	0.2
PRB945-02	0.2	0.0	0.3	0.2	0.5	0.2	0.3
PRB945-03	0.3	0.0	0.3	0.3	0.5	0.2	0.3
PRB945-04	2.0	0.0	0.9	0.4	0.5	0.4	2.1
PRB945-05	2.8	0.0	>11.9	2.4	1.5	1.8	11.4
PRB945-06	26.6	0.6	>11.9	>10.7	3.5	17.2	0.3
<b>Run Date:</b>	12 MAR 99	12 MAY 97	08 MAY 97	06 MAY 97	22 MAY 97	12 MAY 97	12 MAY 97
<b>Kit Lot #:</b>	725688601	61220665	K181510	BP F046210	97042301	NA	NA
<b>Exp. Date:</b>	19 JUL 99	30 MAR 98	28 JUN 97	28 SEP 97	28 MAR 98	19 AUG 97	19 AUG 97
<b>Product #:</b>	30114	M4421	VK55	00A1/A2/A3	80495	In House	In House

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