DATA SHEET

OVERVIEW

PRB947 is a 4-member HIV Seroconversion Panel collected from a single donor during seroconversion for HIV-1 p24 antigen and anti-HIV.

Panel members are undiluted aliquots from plasma units. All members were processed by filtration through 0.8µm filters. No preservatives were added.

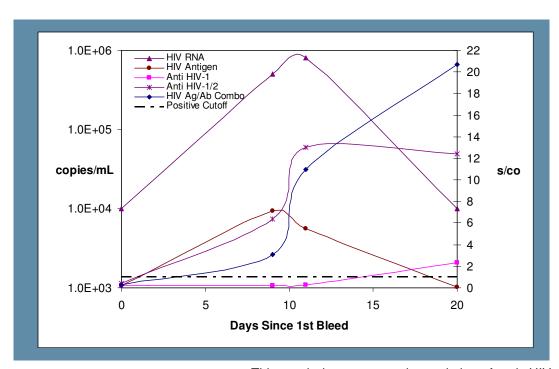
CAUTION: Potentially infectious materials. Follow Universal Precautions. Panel members were found positive for markers of HIV. All members were found negative for HBsAg and anti-HCV.

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.

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



Page 1 of 5 August 2012 12555-01

PRB947 DATA SHEET

Nucleic Acid Tests

Panel Member:	Bleed Dates ²	Days Since 1st Bleed	Fiebig Stage ¹	Chiron bDNA HIV RNA (copies/ml)	Roche PCR HIV RNA (copies/ml)
PRB947-01	17-Dec-96	0	l	4 x 10 ³	1 x 10 ⁴
PRB947-02	26-Dec-96	9	III / IV	4 x 10 ⁵	5 x 10 ⁵
PRB947-03	28-Dec-96	11	IV	3 x 10 ⁵	>8 x 10 ⁵
PRB947-04	06-Jan-97	20	IV / V	2 x 10 ³	1 x 10 ⁴
Test Date				09-May-97	27-Mar-97
Test Site				SC	SC
Kit Part Code				6002-027	83088
Kit Lot No.				MMA279	88167
Kit Exp. Date				05-Jun-97	30-Sep-97

¹Fiebig 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

An additional specimen from the same donor was collected April 3, 1997 (day 107) and found to be strongly reactive on Abbott HIV 1/2 and Genetic

HIV Antigen Tests¹

THE FRIENDS					
Panel Member	Abbott HIVAG-1 Monoclonal	Coulter HIV-1 p24 Antigen Kit	Du Pont HIV p24 Core Profile Kit	Innogenetics Innotest HIV Antigen mAb	Organon Teknika
PRB947-01	0.4	0.3	0.2	0.7	0.3
PRB947-02	2.8	7.6	7.1	15.4	1.6
PRB947-03	3.0	6.6	5.5	13.6	1.7
PRB947-04	0.4	0.1	0.1	0.6	0.2
Test Date	20-Mar-97	16-Apr-97	17-Apr-97	29-May-97	18-Apr-97
Test Site	SC	SC	SC	RL	SC
Kit Part Code	2A81	PN6604535	NEK-060	K1048	59464
Kit Lot No.	25006M401	2067A594	189228	61125635	D02400D
Kit Exp. Date	30-Jun-97	12-Sep-97	24-Jun-97	30-Nov-97	21-Jan-98

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 Life Sciences



Systems HIV 1/2 EIA assays with the following bands on Ortho/Cambridge HIV 1 Western Blot: 18,24,31,41,51,55,65,120,160.

DATA SHEET PRB947

International HIV	Antigen / A	Antibody Test	Kits, results	expressed as	s/co1
-------------------	-------------	---------------	---------------	--------------	-------

Panel Member	Bleed Dates ²	Days Since 1st Bleed	bioMerieux VIDAS DUO	Roche Enzymun-Test Combi	
PRB947-01	17-Dec-96	0	0.4	0.3	
PRB947-02	26-Dec-96	9	2.6	3.1	
PRB947-03	28-Dec-96	11	2.5	11.0	
PRB947-04	06-Jan-97	20	26.7	20.7	
Test Date			17-Mar-99	13-Nov-97	
Test Site			RL	RL	
Kit Part Code			NA	NA	
Kit Lot No.			723488201	19438201	
Kit Exp. Date			03-Sep-99	30-Nov-98	

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.

US FDA-Licensed Anti-HIV EIA tests, Results expressed as s/co¹

			-			Genetic	
Panel	Bleed Dates ²	Days Since	Abbott	Abbott HIV-	Genetic	Systems	Organon
Member:		1st Bleed	HIV	1/2	Systems HIV	HIV-1/2	Teknika HIV
PRB947-01	17-Dec-96	0	0.2	0.0	0.3	0.2	0.3
PRB947-02	26-Dec-96	9	0.3	11.4	0.2	0.2	0.3
PRB947-03	28-Dec-96	11	0.4	>18.9	0.4	0.3	0.5
PRB947-04	06-Jan-97	20	1.4	>18.9	2.2	2.3	1.2
Test Date			16-Apr-97	19-Mar-97	7-May-97	18-Apr-97	23-Apr-97
Test Site			SC	SC	SC	SC	SC
Kit Part Code			3A11	3A77	0218-02	0230	59605
Kit Lot No.			26903M101	24325M301	341NX1-05	073PR1-05	160056

18-May-97

17-Jul-97

14-May-97

RL = Reference Lab; SC = SeraCare Life Sciences

Kit Exp. Date



16-Jan-98

RL = Reference Lab; SC = SeraCare Life Sciences; NA = Information not available

Immunoassay results are means of duplicates expressed as signal to cutoff ratios (s/co). Ratios ≥1.0 are considered reactive and noted in red.

An additional specimen from the same donor was collected April 3, 1997 (day 107) and found to be strongly reactive on Abbott HIV 1/2 and Genetic Systems HIV 1/2 EIA assays with the following bands on Ortho/Cambridge HIV 1 Western Blot: 18,24,31,41,51,55,65,120,160.

DATA SHEET PRB947

International Anti-HIV 1/2 Test Kits¹

							Dade	
Panel	Days	Abbott	Abbott	Abbott	Biotest	Boehringer	Behring	Diagnostics
Member	Since	3rd	3rd	AxSYM	HIV 1/2	Mannheim	Enzygnost	Pasteur
	1st Bleed	Generation	Generation			Enzymun	Anti-HIV1/2	Genscreen
			PLUS			Gen. 3	Plus	
PRB947-01	0	0.1	0.4	0.4	0.2	0.2	0.1	0.3
PRB947-02	9	12.5	6.4	5.2	1.5	9.3	3.0	>15.5
PRB947-03	11	>18.2	>13.0	14.3	4.4	25.1	>6.8	>15.5
PRB947-04	20	>18.2	12.4	12.9	>7.6	25.3	>6.8	>15.5
Test Date		13-May-97	12-May-97	26-May-97	23-May-97	07-May-97	21-May-97	22-May-97
Test Site		RL	RL	RL	RL	SC	RL	RL
Kit Part Code		3A10	7A84	9A44	807004	1557319	QQFK	72276
Kit Lot No.		26758M201	27448 HP 00	28382 LU 04	101106	190583-01	29085	7A109U
Kit Exp. Date		17-Aug-97	11-Sep-97	14-Oct-97	07-Jun-97	30-Sep-97	05-Feb-98	15-Dec-97

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.

International HIV Antibody Tests

Panel	Innogenetics	Murex/Wellcome	Murex	Organon Teknika	In House	In House
Member	Innotest	HIV 1/2	ICE HIV 1.O.2	Uni-form II PLUS	lgΑ	lgM
PRB947-01	0.0	0.3	0.3	0.4	0.3	0.5
PRB947-02	0.0	2.9	3.0	2.3	2.0	3.9
PRB947-03	0.0	6.4	6.3	3.4	2.8	9.6
PRB947-04	0.5	8.9	>10.7	5.6	3.0	10.0
Test Date	07-May-97	08-May-97	06-May-97	22-May-97	12-May-97	12-May-97
Test Site	RL	RL	RL	RL	RL	RL
Kit Part Code	M421	VK55	00A1/A2/A3	80495	In House	In House
Kit Lot No.	61220885	K181510	BP F046210	96091805	NA	NA
Kit Exp. Date	30-Mar-98	28-Jun-97	28-Sep-97	28-Aug-97	19-Aug-97	19-Aug-97

 $Immuno assay \ results \ are \ means \ of \ duplicates \ expressed \ as \ signal \ to \ cutoff \ ratios \ (s/co). \ Ratios \ \ge 1.0 \ are \ considered \ reactive \ and \ noted \ in \ red.$

RL = Reference Lab; SC = SeraCare Life Sciences, Inc.; NA = Information not available



Page 4 of 5 August 2012 12555-01

28-Jul-97

DATA SHEET PRB947

U.S. FDA-Licensed Anti-HIV-1 Confirmatory Tests

		BioRad		Epito		Ortho/Cambridge		
		Western Blot ¹		Westerr	Western Blot ¹		Blot ¹	
Panel	Days Since	Band		Band				
Member	First Bleed	Pattern	Result	Pattern	Result	Band Pattern	Result	
PRB947-01	0	No Bands	NEG	No Bands	NEG	No Bands	NEG	
PRB947-02	9	No Bands	NEG	No Bands	NEG	24	IND	
PRB947-03	11	24	IND	24	IND	24	IND	
PRB947-04	20	24,25	IND	24	IND	24,55,65,160	POS	
Test Date		02-May-97		06-Ma	y-97	18-Apr-97		
Test Site		SC		SC		SC		
Kit Part Code		1971	101	728	72827		98002	
Kit Lot No.		9711	013	M1111	M1111601		C7209-056	

31-Oct-97

13-Jul-97

POS = positive; NEG = negative; IND = indeterminate

RL = Reference Lab; SC = SeraCare Life Sciences

Kit Exp. Date

The Product Insert for this panel in PDF form can be found at www.seracarecatalog.com

A printed copy of the Package Insert or Data Sheet may be requested by email at 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



Page 5 of 5 August 2012 12555-01

Western Blots are interpreted using ASTPHLD/CDC criteria (MMWR, vol. 38, S-7, 1989)