

SeraCare Life Sciences
HIV-1 Seroconversion Panel BC
(PRB953)

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 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.

PRODUCT DESCRIPTION

SeraCare Life Sciences 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.

INTERPRETATION OF RESULTS

The attached data sheet lists EIA 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. EIA and confirmatory tests were performed in the laboratories of SeraCare Life Sciences and at internationally recognized referee laboratories (RL as indicated) by individuals who routinely use these test procedures. All EIA results are means of duplicates, except where noted as single observation, expressed as specimen absorbance to cutoff ratios (s/co). Ratios ≥ 1.0 are considered reactive. Viral RNA was detected using the Chiron Quantiplex® HIV RNA 2.0 Assay (bDNA), the Organon Teknika NucliSens™ HIV-1 QT (NASBA) Assay and the Roche Amplicor™ HIV-1 Monitor™ Test (PCR). For NucliSens™ 0.2 ml of plasma was tested per sample. Samples were tested once with NucliSens™ and Amplicor™ and in duplicate with Quantiplex®. Results are expressed as RNA copies/ml.

PRECAUTIONS

BIOHAZARD CAUTION: Potentially infectious materials. Follow Universal Precautions. Panel members were tested and some were found positive by tests for anti-HIV, HIVAg and HIV 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 frozen. Avoid repeated freeze-thaw cycles.

LIMITATIONS

This Panel is provided 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 these results exactly.

For assistance, contact SeraCare Technical Support (800) 676-1881



375 West Street, West Bridgewater, MA 02379 USA
e-mail: info@seracare.com website: www.seracare.com

SeraCare Life Sciences
HIV-1 Seroconversion Panel BC (PRB953)
Data Sheet

----- 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
PRB953-01	25 JUN 97	0	0.1	0.2	0.2	0.2	0.4
PRB953-02	28 JUN 97	3	0.1	0.1	0.1	0.2	0.3
PRB953-03	02 JUL 97	7	0.1	1.1	0.2	0.1	0.5
PRB953-04	05 JUL 97	10	0.5	>16.5	0.2	1.3	0.5
Run Date:			23 APR 98	08 MAY 98	04 MAY 98	24 APR 98	27 APR 98
Kit Lot #:			37041M401	38238M301	328PX1-5	296PP1-5	160076
Exp. Date:			12 MAY 98	29 JUN 98	24 AUG 98	25 JUL 98	14 JAN 99
Product #:			3A11	3A77	0218-05	32551	59605

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

Member I.D. #	Abbott	Coulter	Innogenetics	Org. Tek.	
	BBI s/co	BBI s/co	Innotest s/co	BBI s/co	
PRB953-01	0.3	0.1	0.3	0.2	
PRB953-02	0.5	0.6	1.2	0.4	
PRB953-03	2.2	8.8	12.4	1.6	
PRB953-04	4.8	19.3	24.1	2.2	
Run Date:		23 APR 98	07 MAY 98	23 APR 98	05 MAY 98
Kit Lot #:		37581M201	2067J045	70930877	150360
Exp. Date:		21 MAY 98	21 AUG 98	30 SEP 98	30 OCT 98
Product #:		2A81	933084	K-1048	59464

----- HIV-1 RNA -----

Chiron bDNA	Org. Tek. NASBA	Roche PCR		
copies/ml BBI	copies/ml BBI	copies/ml BBI		
1 x 10 ³	2 x 10 ³	4 x 10 ³		
2 x 10 ⁴	3 x 10 ⁴	8 x 10 ⁴		
1 x 10 ³	3 x 10 ³	7 x 10 ³		
3 x 10 ³	6 x 10 ³	1 x 10 ³		
Run Date:		16 APR 98	09 APR 98	10 APR 98
Kit Lot #:		MNA777	9705150	00058
Exp. Date:		03 AUG 98	30 APR 00	30 JUL 98
Product #:		6002-027	84046	83088

SeraCare Life Sciences
HIV-1 Seroconversion Panel BC (PRB953)
Data Sheet

Member I.D. #	Days Since 1st Bleed	---- U.S. FDA-Licensed Anti-HIV 1 Confirmatory Tests ----		Waldheim
		Ortho/Cambridge Western Blot¹ BBI	Result	IFA RL1 Result
PRB953-01	0	No Bands	Neg	Neg
PRB953-02	3	No Bands	Neg	Neg
PRB953-03	7	No Bands	Neg	Neg
PRB953-04	10	No Bands	Neg	Neg
Run Date:		28 APR 98		12 MAY 98
Kit Lot #:		A8294-185		71200K50
Exp. Date:		21 OCT 98		30 SEP 98
Product #:		98002		

CAUTION: These materials have not been inactivated and should be handled as potentially biohazardous. Follow good laboratory safety practices. Panel members were tested and some were found positive by tests for HIV. Panel members were tested and found negative for HBsAg and anti-HCV. The potential for transmission of infectious disease is present.

For research use only. Not for use in diagnostic procedures. Data are offered for informational purposes. SeraCare Life Sciences does not claim that others can duplicate these test results exactly. EIA and confirmatory results were generated using commercially available tests, performed at SeraCare and at internationally recognized referee laboratories (RL) by individuals who routinely use these procedures. All HIV antigen and antibody numeric results are means of duplicates, except where noted as single observation, expressed as specimen absorbance to cutoff ratios (s/co). Ratios ≥ 1.0 are considered reactive. HIV RNA results are expressed as RNA copies/ml. Specimens are undiluted aliquots of plasma collected from a single donor in 1997.

BLD= Below Limits of Detection; NEG = Negative.

¹Western Blots are interpreted using ASTPHLD/CDC criteria (MMWR, vol. 38, S-7, 1989).

SeraCare LifeSciences
HIV-1 Seroconversion Panel BC (PRB953)
Data Sheet

-----INTERNATIONAL Anti-HIV 1/2 Test Kits-----

Member <u>I.D. #</u>	Days Since <u>1st Bleed</u>	Abbott	Abbott	Abbott	Behring	BioChem	Biotest	Boeh. Mann.	Diag. Past.
		3rd Gen. PLUS	AxSYM	PRISM	Enzygnost	Detect HIV	HIV 1/2	Enzymun Gen. 3	Access
		RL23	RL23	RL33	RL23	BBI	RL29	RL23	RL33
		<u>s/co</u>	<u>s/co</u>	<u>s/co</u>	<u>s/co</u>	<u>s/co</u>	<u>s/co</u>	<u>s/co</u>	<u>s/co</u>
PRB953-01	0	0.2	0.3	0.4	0.1	0.1	0.4	0.3	0.5
PRB953-02	3	0.2	0.4	0.5	0.1	0.1	0.4	0.3	0.5
PRB953-03	7	0.6	0.5	0.7	0.3	0.0	0.5	0.3	0.6
PRB953-04	10	>17.3	8.7	32.4	>6.3	0.5	2.2	1.4	2.3
Run Date:		13 MAY 98	12 MAY 98	20 MAY 98	14 MAY 98	26 MAR 98	19 MAY 98	15 MAY 98	23 MAY 98
Kit Lot #:		40059HP00	40777LU00	309061HP00	29804	98-1101-2	1181097	194539-01	894642
Exp. Date:		19 OCT 98	25 SEP 98	29 AUG 98	28 JAN 99	31 JAN 99	31 JUL 98	28 FEB 99	02 JAN 99
Product #:		7A8424	9A44	4A27	OQFK12/13	RHD-902W	807004	1557319	34000

Member <u>I.D. #</u>	Diag. Past.	Murex	Org. Tek.	Ortho	Roche	Fujirebio	In House	In House
	Genscreen	HIV 1.2.O	Uni-form II PLUS	Capture	DAGS	Serodia	IgA	IgM
	RL29	BBI	RL29	RL29	RL23	RL23	RL12	RL12
	<u>s/co</u>	<u>s/co</u>	<u>s/co</u>	<u>s/co</u>	<u>s/co</u>	<u>Result</u> ²	<u>s/co</u>	<u>s/co</u>
PRB953-01	0.7	0.3	0.4	0.0	0.1	-/-	0.4	0.4
PRB953-02	0.7	0.3	0.4	0.0	0.1	-/-	0.3	0.4
PRB953-03	1.0	0.7	0.5	1.2	0.1	-/-	0.5	0.5
PRB953-04	>16.5	>11.2	4.6	>11.5	1.9	+/-	6.7	5.7
Run Date:	13 MAY 98	26 MAR 98	15 MAY 98	15 MAY 98	13 MAY 98	14 MAY 98	11 MAY 98	11 MAY 98
Kit Lot #:	8C119R	F439510	97100502	HVK112-2	P0342	TP80304	NA	NA
Exp. Date:	30 MAR 99	28 SEP 98	30 SEP 98	31 MAY 98	30 APR 99	31 MAR 99	NA	NA
Product #:	72276	GE94	84017	932360	756059	FJ4557	In House	In House

²Results for this particle agglutination assay are expressed for HIV-1/HIV-2 respectively.