

HIV Seroconversion Panel AV

PRB946

INTENDED USE

The HIV Seroconversion Panel PRB946 is a group of serial bleeds from an individual plasma donor during seroconversion for HIV-1 antibody, p24 antigen, and HIV-1 RNA. This Panel is intended for use by manufacturers and other laboratories to evaluate their anti-HIV, HIV antigen and HIV-1 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

PRB946 consists of a set of 4 undiluted plasma samples 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. Units were processed by filtration. No preservatives were added.

REAGENTS

Cat No. PRB946-00-1.0 1 vial per member,
4 members, 1.0 ml per vial

INTERPRETATION OF RESULTS

The attached data sheet lists results for panel members generated using commercially available screening and confirmatory tests. Additionally, the results of internationally approved screening tests are provided. The testing was performed at BBI, which is now a part of SeraCare Life Sciences and at internationally recognized reference laboratories (RL) by individuals who routinely use these test procedures. All EIA results are means of duplicates, expressed as signal to cutoff ratios (s/co). Ratios ≥ 1.0 are considered reactive. Samples were tested in singlicate using HIV-1 RNA tests. HIV-1 RNA is expressed as copies/ml.

PRECAUTIONS

BIOHAZARD CAUTION: Potentially infectious materials. Use the Centers for Disease Control (CDC) recommended universal precautions for handling this product¹. These materials have not been treated and should be considered biohazardous. Panel members were tested and some were found positive by tests for anti-HIV, HIV antigen and HIV-1 RNA.

The units that make up this panel were tested and found negative for anti-HCV and HBsAg. This does not ensure the absence of these or other human pathogens.

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 at -10°C or colder. SeraCare Life Sciences recommends that the panel members be divided into smaller aliquots if necessary to avoid repeated 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.

LIMITATIONS

PRB946 is offered for research use only. Not for use in diagnostic procedures. The data are provided for informational purposes only. SeraCare Life Sciences does not claim that others can duplicate these results exactly.

REFERENCES

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

For assistance, contact SeraCare Life Sciences Technical Support

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

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SeraCare Life Sciences
HIV-1 Seroconversion Panel AV
PRB946
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
PRB946-01	17 DEC 96	0	0.2	0.0	0.5	0.2	0.3
PRB946-02	21 DEC 96	4	0.2	0.0	0.5	0.2	0.3
PRB946-03	24 DEC 96	7	0.2	0.1	0.4	0.2	0.3
PRB946-04	28 DEC 96	11	0.2	0.1	0.5	0.2	0.3
	Run Date:		02 MAY 97	01 MAY 97	05 MAY 97	03 MAY 97	06 MAY 97
	Kit Lot #:		26903M101	26746M201	341NX1-05	073PR1-05	160056
	Exp. Date:		14 MAY 97	29 JUL 97	17 JUL 97	16 JAN 98	10 APR 98
	Product #:		3A11	3A77	0218-02	0230	59605

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

Member I.D. #	Abbott	Coulter	Dupont	Innogenetics	Org. Tek.	Perkin Elmer	Roche PCR	Chiron bDNA	
	BBI s/co	BBI s/co	BBI s/co	RL29 s/co	BBI s/co	SCLS s/co	HIV RNA BBI copies/ml	HIV RNA BBI copies/ml	
PRB946-01	0.4	0.1	0.2	0.4	0.2	0.1	BLD	BLD	
PRB946-02	0.5	0.8	0.4	1.2	0.3	0.4	3 x 10 ⁴	1 x 10 ⁴	
PRB946-03	4.0	23.1	7.9	>35.7	5.4	15.3	7 x 10 ⁵	6 x 10 ⁵	
PRB946-04	14.7	>41.7	>28.0	>35.7	15.4	44.9	>8 x 10 ⁵	>8 x 10 ⁵	
	Run Date:	06 MAY 97	07 MAY 97	10 MAY 97	29 MAY 97	06 MAY 97	22 MAY 08	27 MAR 97	09 MAY 97
	Kit Lot #:	25780M201	2067A594	189228	61125635	D02400D	465436	88167	MMA279
	Exp. Date:	15 MAY 97	12 SEP 97	24 JUN 97	30 NOV 97	21 JAN 98	14 FEB 09	30 SEP 97	05 JUN 97
	Product #:	2A81	933180	NEK-060	K1048	59464	NEK 050A	83088	6002-027

*An additional specimen from the same donor was collected on April 4, 1997 (day 108) 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.

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BLD = Below Limit of Detection

----- U.S. FDA-Licensed 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
PRB946-01	0	No Bands	NEG	No Bands	NEG	No Bands	NEG
PRB946-02	4	No Bands	NEG	No Bands	NEG	No Bands	NEG
PRB946-03	7	No Bands	NEG	No Bands	NEG	No Bands	NEG
PRB946-04	11	No Bands	NEG	No Bands	NEG	No Bands	NEG
Run Date:			2 MAY 97		06 MAY 97		08 MAY 97
Kit Lot #:			9711013		M1111601		C7209-05
Exp. Date:			13 JUL 97		31 OCT 97		28 JUL 97
Product #:			1971101		72827		PN98002

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NEG = Negative

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

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

Member I.D. #	Days Since 1st Bleed	Abbott	Abbott	Abbott	Behring	BioChem	Biotest	Boeh. Mann.	Diag. Past.
		3rd Gen. RL23 <u>s/co</u>	3rd Gen. PLUS RL19 <u>s/co</u>	AxSYM RL19 <u>s/co</u>	ENZ PLUS RL23 <u>s/co</u>	Detect HIV BBI <u>s/co</u>	HIV 1/2 RL12 <u>s/co</u>	Enzymun Gen. 3 BBI <u>s/co</u>	Genscreen RL29 <u>s/co</u>
PRB946-01	0	0.1	0.4	0.4	0.1	0.1	0.1	0.2	0.3
PRB946-02	4	0.1	0.4	0.4	0.1	0.1	0.1	0.3	0.3
PRB946-03	7	0.1	0.4	0.5	0.1	0.1	0.0	0.2	0.4
PRB946-04	11	0.3	0.5	0.5	0.2	0.0	0.1	0.2	0.7
Run Date:		13 MAY 97	12 MAY 97	26 MAY 97	21 MAY 97	03 MAY 97	08 MAY 97	07 MAY 97	22 MAY 97
Kit Lot #:		26758M201	27448 HP 00	28382 LU 04	29085	11159-2	123116	190583-01	7A109U
Exp. Date:		17 AUG 97	11 SEP 97	14 OCT 97	05 FEB 98	30 JUN 97	19 JUL 97	30 SEP 97	15 DEC 97
Product #:		3A10	7A84	9A44	OQFK	RHD-902B	807005	1557319	72276

Member I.D. #	Innogenetics	Murex/Well.	Murex	Org. Tek.	Ortho	In House	In House
	Innotest RL12 <u>s/co</u>	HIV 1/2 RL12 <u>s/co</u>	ICE HIV 1.O.2 RL19 <u>s/co</u>	Uni-form II PLUS RL29 <u>s/co</u>	Capture RL29 <u>s/co</u>	IgA RL12 <u>s/co</u>	IgM RL12 <u>s/co</u>
PRB946-01	0.0	0.3	0.3	0.4	0.0	0.2	0.2
PRB946-02	0.0	0.3	0.3	0.4	0.0	0.3	0.2
PRB946-03	0.0	0.5	0.3	0.5	0.0	0.3	0.2
PRB946-04	0.0	0.4	0.3	0.5	0.1	0.3	0.3
Run Date:	07 MAY 97	08 MAY 97	06 MAY 97	05 MAY 97	28 MAY 97	12 MAY 97	12 MAY 97
Kit Lot #:	6122065	K181510	BP F046210	96091805	HVK 103-2	NA	NA
Exp. Date:	30 MAR 98	28 JUN 97	28 SEP 97	28 AUG 97	16 JUN 97	19 AUG 97	19 AUG 97
Product #:	M421	VK55	00A1/A2/A3	80495	932360	In House	In House

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