HIV Seroconversion Panel PRB949(M)

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INTENDED USE

The HIV Seroconversion Panel PRB949(M) is a group of serial bleeds from an individual plasma donor during seroconversion for HIV-1 antibody, HIV-1 antigen, and HIV-1 RNA. This Panel is intended for use by manufacturers and other laboratories to evaluate their anti-HIV, HIV-1 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

PRB949(M) 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. PRB949(M)-1.0 1 vial per member,
4 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[1]. 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-1 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.

Do not 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 recommends that the panel members be divided into smaller aliquots if 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 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 singlet with the Roche Amplicor™ HIV-1 Monitor ™ test (PCR). HIV-1 RNA is expressed as copies/ml.

LIMITATIONS

This Panel is offered for research use only. Not for use in diagnostic procedures. The data are provided for informational purposes only. SeraCare 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

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SeraCare Life Sciences
HIV-1 Seroconversion Panel AY PRB949(M)
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 HIV BBI**	**Abbott HIV-1/2 BBI**	**Gen. Sys. HIV BBI**	**Gen. Sys. HIV-1/2 BBI**	**Org. Tek. HIV BBI**
PRB949-01	17 APR 97	0	0.2	0.2	0.1	0.1	0.3
PRB949-02	23 APR 97	6	0.2	0.2	0.1	0.1	0.3
PRB949-03	26 APR 97	9	0.2	0.2	0.1	0.1	0.3
PRB949-04	05 MAY 97	18	0.2	0.8	0.1	0.1	0.3
PRB949-05	07 MAY 97	20	0.3	10.9	0.1	0.1	0.4
	Run Date:		08 OCT 97	01 AUG 97	14 OCT 97	14 OCT 97	18 OCT 97
	Kit Lot #:		31505M101	30216M201	101PX1-05	202PP1-10	138081
	Exp. Date:		30 OCT 97	19 OCT 97	18 DEC 97	09 JUN 98	10 SEP 98
	Product #:		3A11	3A77	0218-02	32542	59605

	---------- HIV-1 Antigen Tests, results expressed as s/co ----------					---------- HIV-1 RNA ----------		
Member I.D. #	**Abbott BBI**	**Coulter BBI**	**Dupont BBI**	**Innogenetics BBI**	**Org. Tek. BBI**	**Chiron bDNA BBI copies/ml**	**Org. Tek. NASBA BBI copies/ml**	**Roche PCR BBI copies/ml**
PRB949-01	0.4	0.5	0.1	0.3	0.3	BLD	BLD	BLD
PRB949-02	0.5	0.0	0.1	0.3	0.3	BLD	BLD	5×10^2
PRB949-03	0.4	0.1	0.4	0.8	0.3	6×10^3	9×10^3	1×10^4
PRB949-04	3.7	21.8	25.1	26.9	1.4	6×10^5	4×10^5	6×10^5
PRB949-05	7.1	42.2	47.9	>30.6	3.7	$>8 \times 10^5$	5×10^5	$>8 \times 10^5$
Run Date:	08 OCT 97	10 OCT 97	14 OCT 97	07 NOV 97	09 OCT 97	10 OCT 97	13 OCT 97	09 OCT 97
Kit Lot #:	31556M101	2067D725	201465	70329734	D02521D	MME430	97051603	88257
Exp. Date:	27 DEC 97	04 DEC 97	16 JAN 98	MAR 98	12 MAY 98	30 OCT 97	MAY 98	01 NOV 97
Product #:	2A81	PN6604535	NEK-050B	K1048	59464	6002-027	80434	83088

Panel member 05 is no longer available. Data are provided for informational purposes.

BIOHAZARD CAUTION: Potentially infectious materials. Follow Universal Precautions. 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.

For research use only. Not for use in diagnostic procedures. Data are offered for informational purposes. SeraCare does not claim that others can duplicate these test results exactly. EIA and confirmatory results were generated using commercially available tests, performed at BBI and at internationally recognized referee laboratories (RL) by individuals who routinely use these procedures. All HIV-1 antigen and antibody numeric results are means of duplicates, expressed as specimen absorbance to cutoff ratios (s/co). Ratios ≥ 1.0 are considered reactive. HIV-1 RNA results are expressed as copies/ml. Specimens are undiluted aliquots of plasma collected from a single donor in 1997.
BLD = Below limit of detection

		U.S. FDA-Licensed Anti-HIV-1 Confirmatory Tests						
		BioRad Western Blot[1] BBI		Epitope Western Blot[1] BBI		Ortho/Cambridge Western Blot[1] BBI		Waldheim IFA RL1
Member I.D. #	Days Since 1st Bleed	Band Pattern	Result	Band Pattern	Result	Band Pattern	Result	Result
PRB949-01	0	No Bands	NEG	No Bands	NEG	No Bands	NEG	NEG
PRB949-02	6	No Bands	NEG	No Bands	NEG	No Bands	NEG	NEG
PRB949-03	9	No Bands	NEG	No Bands	NEG	No Bands	NEG	NEG
PRB949-04	18	No Bands	NEG	No Bands	NEG	No Bands	NEG	NEG
PRB949-05	20	24	IND	No Bands	NEG	f51,f65	IND	NEG
Run Date:		23 OCT 97		23 OCT 97		11 OCT 97		20 NOV 97
Kit Lot #:		97110351		M051270		B8098-404		70400K50
Exp. Date:		08 JAN 98		MAR 98		08 APR 98		FEB 98
Product #:		1971101		72827		98002		32501

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POS = Positive; IND = Indeterminate; NEG = Negative; f = faint; BLD = Below limit of detection

[1]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.

		EUROPEAN Anti-HIV-1/2 Test Kits				
Member I.D. #	Days Since 1st Bleed	Abbott PLUS 3rd Gen RL19 s/co	Abbott AxSYM RL23 s/co	Behring Enzygnost RL23 s/co	Biotest HIV-1/2 RL29 s/co	Boeh. Mann. Enzymun Gen 3 RL23 s/co
PRB949-01	0	0.4	0.4	0.1	0.4	0.3
PRB949-02	6	0.4	0.4	0.1	0.4	0.3
PRB949-03	9	0.4	0.4	0.1	0.4	0.3
PRB949-04	18	0.9	0.4	0.3	0.9	0.6
PRB949-05	20	6.0	2.6	4.5	3.2	3.3
Run Date:		08 DEC 97	04 DEC 97	08 DEC 97	27 NOV 97	09 DEC 97
Kit Lot #:		31225HP00	35784LU00	29405	1270397	190678-01
Exp. Date:		30 DEC 97	03 JUN 98	16 JUL 98	10 DEC 97	31 DEC 97
Product #:		7A8424	9A44	OQFK12/13	807004	1557319

Member I.D. #	Diag. Past. Genscreen RL29 s/co	Murex ICE HIV 1.O.2 RL19 s/co	Org. Tek. Uni-form II PLUS RL29 s/co	Ortho Capture BBI s/co	Fujirebio Serodia HIV-1/2[2] RL23 Result
PRB949-01	0.3	0.3	0.4	0.0	-/-
PRB949-02	0.4	0.3	0.4	0.0	-/-
PRB949-03	0.4	0.3	0.5	0.0	-/-
PRB949-04	3.4	0.4	1.0	0.6	±/-
PRB949-05	20.0	1.4	2.4	3.2	±/-
Run Date:	25 NOV 97	25 NOV 97	25 NOV 97	04 NOV 97	01 DEC 97
Kit Lot #:	7F112R	F219220B	97070402	HVK108-5	TP70805
Exp. Date:	15 MAR 98	28 MAR 98	28 JUN 98	27 NOV 97	31 AUG 98
Product #:	72276	00A1/A2/A3	84017	932360	576063

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

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