

HIV Seroconversion Panel PRB961

BBI Diagnostics
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INTENDED USE

The HIV Seroconversion Panel PRB961 is a group of serial bleeds from an individual plasma donor during seroconversion. This Panel is intended for use by diagnostics manufacturers and clinical laboratorians to evaluate their HIV test systems using well-characterized specimens, and to provide comprehensive data for comparative analysis. For Research Use Only. Not for use in diagnostic procedures.

PRODUCT DESCRIPTION

PRB961 consists of a set of 9 undiluted plasma samples from a single plasma donor collected during a period of HIV seroconversion. All units were maintained in a frozen state, except for the interval of dispensing into vials. No preservatives were added.

REAGENTS

Cat No. PRB961-1.0 1 vial per member
 9 members, 1.0 ml per vial

PRECAUTIONS

These materials have not been treated and should be considered biohazardous. Follow Universal Precautions. Panel members were tested and some were found positive by tests for HIV markers including HIV-1 RNA, HIV-1 antigen and anti-HIV.

The units that make up this panel were tested and found negative for anti-HCV, HBsAg, HBV DNA, and HCV RNA. 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 -65°C to -80°C to preserve HIV-1 RNA. HIV antibody and antigen will be preserved at -10°C or colder. BBI Diagnostics 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 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 Diagnostics and at internationally recognized referee laboratories (RL) by laboratorians who routinely use these test procedures. All EIA results are expressed as signal to cutoff ratios (s/co). Ratios >1.0 are considered reactive. 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. BBI Diagnostics does not claim that others can duplicate these results exactly.

For assistance, contact BBI Diagnostics Technical Support



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BBI Diagnostics
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HIV Seroconversion Panel (PRB961)
Data Sheet

-----U.S. Tests-----												
Member I.D. #	Bleed Dates	Days Since 1st Bleed	Roche		Coulter	Perkin Elmer	Zeptometrix	Abbott	Orasure	Maxim**		
			Ultra Sensitive HIV-1 RNA copies/ml	Standard HIV-1 RNA copies/ml	ELISA HIV-1 Ag s/co	ELISA HIV-1 Ag s/co	ELISA HIV-1 Ag s/co	EIA HIV-1/2 s/co	Rapid HIV-1 Result	Western Blot HIV-1 Band Pattern Result		
PRB961-01	8-Oct-97	0	<50	NT	0.3	0.1	0.0	0.1	NEG	f24	IND	
PRB961-02	13-Oct-97	5	<50	NT	0.3	0.2	0.0	0.1	NEG	f24	IND	
PRB961-03	15-Oct-97	7	<50	NT	0.3	0.3	0.0	0.1	NEG	f24	IND	
PRB961-04	20-Oct-97	12	<50	NT	0.3	0.2	0.0	0.1	NEG	f24	IND	
PRB961-05	22-Oct-97	14	<50	NT	0.3	0.2	0.2	0.1	NEG	f24, f160	IND	
PRB961-06	27-Oct-97	19	<50	NT	0.4	0.2	0.1	0.1	NEG	f24	IND	
PRB961-07	29-Oct-97	21	4.8 x 10 ²	NT	0.5	0.2	0.2	0.1	NEG	f24	IND	
PRB961-08	4-Nov-97	27	NT	1.5 x 10 ⁵	11.4	9.5	5.6	0.1	NEG	f24	IND	
PRB961-09	6-Nov-97	29	NT	2.0 x 10 ⁵	28.4	27.4	17.0	0.2	NEG	f24	IND	
Test Site:			BBI	BBI	BBI	BBI	BBI	BBI	BBI	BBI	BBI	
Run Date:			23-Apr-07	20-Apr-07	1-Feb-07	24-May-07	2-Apr-07	18-May-07	18-May-07	28-Jun-07	28-Jun-07	
Kit Lot #:			H14002	H04637	2066F514	394387	303199	50178M200	6601644	C7242-076	C7242-076	
Exp. Date:			Feb-08	Aug-07	18-Apr-07	16-Nov-07	18-Jan-08	10-Jul-07	30-Sep-07	30-Aug-07	30-Aug-07	
Product #:			21118560018	21118560018	626391	NEK 050A	801111	3A77	6341	98002	98002	

CAUTION: Potentially infectious materials. Follow Universal Precautions. Panel members were tested and most were found positive by tests for HIV-1. All panel members were tested and found negative for anti-HCV, HBsAg, HBV DNA and HCV RNA. 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. BBI Diagnostics does not claim that others can duplicate these results exactly. Results were generated using commercially available tests, performed at BBI Diagnostics or at internationally recognized reference laboratories (RL), by individuals who routinely use these methods. All EIA results are expressed as signal to cutoff ratios (s/co). Ratios ≥ 1.0 are considered reactive. Nucleic acid testing was performed by BBI Diagnostics or at recognized reference laboratories (RL) by individuals who routinely use these procedures. Results are reported as instructed in the test kit package insert. All results are from undiluted aliquots from plasma units, except where noted.

Additional data may be available. Please contact BBI Diagnostics Technical Support for current information. Telephone: (508) 580-1900 or US Toll Free: (800) 676-1881, or visit us on the Web at www.seracare.com.

**Formerly Calypte - Cambridge Biotech Western Blot

NT = not tested, NEG = negative, IND = indeterminate, POS = positive, f = faint

-----International Tests-----

Member I.D. #	Days Since 1st Bleed	Abbott	Abbott	Abbott	Dade Behring	Roche	Abbott	Roche	Abbott	Abbott	Siemens	Abbott
		ARCHITECT Combo	AxSYM Combo	PRISM Combo	Enzygnost Integral II	Elecsys Combi	Murex Combination	Elecsys	PRISM HIV O plus	AxSYM	Advia Centaur enhanced	Murex HIV 1.2.O
		HIV Ag/Ab s/co	HIV Ag/Ab s/co	HIV Ag/Ab s/co	HIV Ag/Ab s/co	HIV Ag/Ab s/co	HIV Ag/Ab s/co	HIV-1 Ag s/co	HIV 1/2 gO s/co	HIV 1/2 gO s/co	HIV 1/2 gO s/co	HIV 1/2 gO s/co
PRB961-01	0	0.1	0.5	0.1	0.1	0.3	0.3	0.2	0.3	0.5	0.1	0.2
PRB961-02	5	0.1	0.5	0.1	0.1	0.2	0.3	0.2	0.1	0.5	0.1	0.2
PRB961-03	7	0.1	0.5	0.1	0.1	0.3	0.3	0.2	0.3	0.5	0.1	0.3
PRB961-04	12	0.1	0.5	0.1	0.1	0.2	0.4	0.2	0.3	0.5	0.1	0.3
PRB961-05	14	0.1	0.6	0.1	0.1	0.2	0.3	0.3	0.4	0.5	0.1	0.2
PRB961-06	19	0.1	0.5	0.1	0.1	0.2	0.3	0.2	0.3	0.5	<0.05	0.2
PRB961-07	21	0.1	0.6	0.1	0.1	0.2	0.3	0.3	0.4	0.5	0.1	0.2
PRB961-08	27	8.8	4.7	5.2	5.6	1.6	3.7	9.6	0.4	0.5	0.1	0.3
PRB961-09	29	28.7	12.1	15.8	11.6	4.7	9.8	31.4	0.3	0.5	0.4	0.3
Test Site:		RL23	RL23	RL23	RL23	RL23	RL23	RL23	RL23	RL23	RL23	RL23
Run Date:		10-May-07	14-May-07	16-May-07	23-May-07	23-May-07	23-May-07	23-May-07	24-May-07	23-May-07	25-May-07	24-May-07
Kit Lot #:		52051HN00	52433LU00	52387HN00	36815	178860-01	L000010	176936-01	52543HN00	49034LU00	96445025	L000710
Exp. Date:		2-Jan-08	12-Oct-07	23-Oct-07	6-Jun-08	Nov-07	30-Nov-07	Aug-07	8-Jan-08	14-Aug-07	19-Mar-08	28-Feb-08

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