# **HIV Seroconversion Panel PRB960**

# **BBI Diagnostics**

A SeraCare Company

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#### **INTENDED USE**

The HIV Seroconversion Panel PRB960 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

PRB960 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. PRB960-1.0 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. Panel members were tested and some were found positive for HCV RNA.

The units that make up this panel were tested and found negative for anti-HCV, HBsAg, and HBV DNA. 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. 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 A SeraCare Company HIV Seroconversion Panel (PRB960) Data Sheet

			U.S. Tests									
			Roche		Coulter	Perkin Elmer Zeptometrix		Abbott	Orasure	Maxim**		
			Ultra Sensitive	Standard	ELISA	ELISA	ELISA	EIA	Rapid	Western Blot HIV-1		
Member	Bleed	Days Since	HIV-1 RNA	HIV-1 RNA	HIV-1 Ag	HIV-1 Ag	HIV-1 Ag	HIV-1/2	HIV-1			
<u>I.D. #</u>	<u>Dates</u>	1st Bleed	copies/ml	copies/ml	s/co	s/co	s/co	s/co	Result	<b>Band Pattern</b>	Result	
PRB960-01	9-Oct-97	0	<50	NT	0.2	0.2	0.2	0.2	NEG	f24	IND	
PRB960-02	13-Oct-97	4	<50	NT	0.2	0.1	0.1	0.1	NEG	f24	IND	
PRB960-03	16-Oct-97	7	<50	NT	0.2	0.2	0.2	0.1	NEG	f24	IND	
PRB960-04	20-Oct-97	11	<50	NT	0.2	0.1	0.2	0.1	NEG	f24	IND	
PRB960-05	23-Oct-97	14	<50	NT	0.2	0.1	0.1	0.1	NEG	NO BANDS	NEG	
PRB960-06	27-Oct-97	18	<50	NT	0.3	0.2	0.1	0.1	NEG	f24	IND	
PRB960-07	30-Oct-97	21	$2.9 \times 10^{2}$	NT	0.2	0.2	0.2	0.1	NEG	NO BANDS	NEG	
PRB960-08	6-Nov-97	28	NT	2.8 x 10 <sup>7</sup> *	>40.0	>49.2	70.8	0.1	NEG	NO BANDS	NEG	
PRB960-09	8-Nov-97	30	NT	1.1 x 10 <sup>7</sup> *	>40.0	>49.2	75.3	0.1	NEG	NO BANDS	NEG	
	Test Site:		BBI	BBI	BBI	BBI	BBI	BBI	BBI	BBI		
	Run Date:		24-Apr-07	23-Apr-07	4-Apr-07	24-May-07	18-Jan-07	18-May-07	18-May-07	28-Jun-	07	
Kit Lot #: Exp. Date:			H04637	H04637	2066F514	394387	302999	50178M200	6601644	C7242-072		
			Aug-07	Aug-07	18-Apr-07	16-Nov-07	22-Aug-07	10-Jul-07	30-Sep-07	30-Aug-		
	Product #:		21118560018	21118560018	626391	NEK 050A	801111	3A77	6341	98002	<u> </u>	

**CAUTION:** Potentially infectious materials. Follow Universal Precautions. Panel members were tested and most were found positive by tests for HIV-1. Panel members were tested and found negative for anti-HCV, HBsAg, and HBV DNA. Panel members tested positive for 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 referee 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.

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

<sup>\*</sup>Result was calculated from a 1:100 dilution value.

<sup>\*\*</sup>Formerly Calypte - Cambridge Biotech Western Blot

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

		Abbott ARCHITECT Combo	Abbott AxSYM Combo	Abbott PRISM Combo	Dade Behring Enzygnost Integral II	Roche Elecsys Combi	Abbott Murex Combination	Roche Elecsys	Abbott PRISM HIV O plus	Abbott AxSYM	Siemens Advia Centaur enhanced	Abbott Murex HIV 1.2.0
Member	Days Since	HIV Ag/Ab	HIV Ag/Ab	. •	. •	HIV Ag/Ab	_	HIV-1 Ag	HIV 1/2 gO		HIV 1/2 gO	HIV 1/2 gO
<u>I.D. #</u>	1st Bleed	<u>s/co</u>	<u>s/co</u>	s/co	<u>s/co</u>	s/co	<u>s/co</u>	<u>s/co</u>	<u>s/co</u>	s/co	<u>s/co</u>	s/co
PRB960-01	0	0.1	0.5	0.1	0.0	0.3	0.3	0.4	0.3	0.5	0.1	0.3
PRB960-02	4	0.1	0.5	0.1	0.1	0.2	0.2	0.3	0.3	0.4	0.1	0.2
PRB960-03	7	0.1	0.5	0.1	0.1	0.2	0.3	0.4	0.4	0.5	0.1	0.2
PRB960-04	11	0.1	0.5	0.1	0.1	0.2	0.3	0.3	0.3	0.4	0.1	0.2
PRB960-05	14	0.1	0.7	0.1	0.0	0.2	0.3	0.3	0.3	0.7	0.1	0.2
PRB960-06	18	0.1	0.5	0.1	0.1	0.3	0.3	0.3	0.4	0.5	< 0,05	0.2
PRB960-07	21	0.2	0.5	0.1	0.1	0.2	0.3	0.3	0.4	0.4	0.1	0.3
PRB960-08	28	461.7	40.2	131.8	0.3	69.5	>max	512.3	0.3	0.4	0.1	0.3
PRB960-09	30	556.7	43.5	159.6	0.3	90.5	17.9	604.0	0.4	0.5	0.1	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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