HIV-1 INCIDENCE/PREVALENCE PERFORMANCE PANEL PRB601

BBI Diagnostics
A Boston Biomedica Company
TEL: (508) 580-1900
US Toll Free: (800) 676-1881
FAX: (508) 580-2202

INTENDED USE

The HIV-1 Incidence/Prevalence Performance Panel PRB601, is a panel of naturally occurring plasma specimens. This Panel is intended for use by diagnostic manufacturers and clinical laboratorians to evaluate assays that determine incidence (new infections) vs. prevalence (long-standing infections) using well-characterized specimens, and to provide comprehensive data for comparative analysis. For Research Use Only. Not for use in diagnostic procedures.

PRODUCT DESCRIPTION

PRB601 consists of a set of 15 aliquots of plasma from different donors: seven members are characterized as incident and eight as prevalent, based on consensus results from nine tests using five different methods. Specimens are undiluted aliquots from plasma units collected from HIV positive deferred plasma donors in the United States whose dates of infection and seroconversion are unknown. Units were aseptically filtered and no preservative was added.

REAGENTS

Cat. No. PRB601-1.0	1 vial per member 15 members, 1.0 ml per vial

PRECAUTIONS

These materials have not been inactivated and should be considered biohazardous. Use the Centers for Disease Control and Prevention (CDC) recommended universal precautions for handling this product.[1] Panel members were tested and all were found positive by tests for anti-HIV 1.

The units that make up this panel were tested for HBsAg and HCV. All panel members were found to be non-reactive for HBsAg. One HCV reactive member is indicated on the data sheet.

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 –20°C or colder. BBI recommends that the panel members be divided into smaller aliquots 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 (page1) provides the results of assays for HIV-1 antigen, HIV RNA and HIV antibody generated using commercially available screening and confirmatory tests. Pages 2 and 3 provide results from incidence/prevalence tests. Testing was performed at BBI and at internationally recognized non-commercial referee laboratories (RL) by laboratorians who routinely use these test procedures

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.

REFERENCES

1. CDC recommendations for prevention of HIV transmission in health care settings. MMWR 36 (sup.2) 1997.

For assistance, contact BBI Technical Support

BBI Diagnostics
A Boston Biomedica Company

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

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Boston Biomedica, Inc.
HIV-1 INCIDENCE/PREVALENCE PERFORMANCE PANEL (PRB601)
DATA SHEET

HIV DIAGNOSTIC TESTS

	US FDA Licensed HIV Tests				
	results expressed as s/co				
Member I.D.#	Abbott HIV 1/2 BBI	Bio-Rad HIV 1/2 BBI	Coulter HIV Ag BBI	Calypte Anti-HIV-1 Western blot BBI	Roche HIV-1 RNA c/ml BBI
PRB601-01	18.5	>9.9	0.2	18,24,31,41,51,55,65,120,160	3×10^4
PRB601-02	17.4	>9.9	0.2	18,24,31,41,51,55,65,120,160	4×10^3
PRB601-03	17.4	>9.9	0.2	18,24,31,41,51,55,65,120,160	<400
PRB601-04	17.4	>9.9	0.2	18,24,31,41,51,55,65,120,160	4×10^3
PRB601-05	15.8	>9.9	1.8	18,24,31,41,51,55,65,120,160	4×10^5
PRB601-06	17.4	>9.9	0.2	18,24,31,41,51,55,65,120,160	2×10^4
PRB601-07	18.5	>9.9	1.1	18,24,31,41,51,55,65,120,160	2×10^5
PRB601-08	17.4	>9.9	0.2	18,24,31,41,51,55,65,120,160	1×10^5
PRB601-09	17.4	>9.9	0.2	18,24,31,41,51,55,65,120,160	1×10^4
PRB601-10	17.4	>9.9	0.7	18,24,31,41,51,55,65,120,160	4×10^4
PRB601-11	18.5	>9.9	0.2	18,24,31,41,51,65,120,160	5×10^3
PRB601-12	17.4	>9.9	0.2	18,24,31,41,51,55,65,120,160	2×10^3
PRB601-13	17.4	>9.9	0.2	18,24,31,41,51,55,65,120,160	3×10^3
PRB601-14	17.4	>9.9	1.3	18,24,31,41,51,55,65,120,160	3×10^5
PRB601-15	17.4	>9.9	0.2	18,24,31,41,51,55,65,120,160	4×10^4
Run Date:	6-Mar-04	4-Mar-04	12-Mar-04	18-Mar-04	
Kit Lot#:	10905M100	318WBB-05	2063K194	A4316-394	
Exp.Date:	15-Apr-04	13-Aug-04	16-Jun-04	11-Nov-04	
Product #:	3A77-28	32588	6604535	98002	

CAUTION: Panel members were tested and were found positive by tests for HIV. Panel member 8 was found reactive for HCV.

For research use only. Not for use in diagnostic procedures. Data are offered for informational purposes. BBI does not claim that others can duplicate these tests results exactly. Testing was performed at BBI or at internationally recognized referee laboratories (RL) by individuals who routinely use these procedures. EIA results are expressed as specimen absorbance to cutoff ratios (s/co). Ratios $\geq$1.0 are considered reactive. Specimens are undiluted aliquots from plasma units collected from 1996 through 1998.

HIV INCIDENCE TESTS

		----------LESS SENSITIVE (LS)----------				----------AVIDITY INDEX (AI)------		----------OTHER APPROACHES----		
	Mfg.:	Abbott	BioMerieux	BioMerieux	BioMerieux	Bio-Rad	BioMerieux		In-House	
	Method:	3A11	Vironostika	Vironostika	Vironostika+O	Genetic Systems	Vironostika	HIV RI	BED CEIA	NRL
	Units:	SOD	SOD	SOD	SOD	%	%	Mean OD	Mean OD-n	µg/ml
Member		HIV-1	HIV-1	HIV-1/2	HIV-1/2	rLAV	HIV-1/2	HIV 1	HIV 1	HIV-1
I.D.#	CONSENSUS	RL11	RL7	RL36	RL 20	RL7	RL20	RL38	RL20	RL36
PRB601-01	I	0.156	0.180	0.166	0.365	24	12	0.220	0.364	24
PRB601-02	I	0.051	0.100	0.093	0.195	12	18	0.160	0.132	36
PRB601-03	P	1.204	2.240	1.616	2.710	89	80	0.680	1.091	0
PRB601-04	P	1.163	1.910	2.148	4.459	94	80	0.970	1.412	0
PRB601-05	I	-0.060	0.010	0.028	0.187	10	8	0.160	0.332	67
PRB601-06	P	1.314	1.840	1.436	1.882	77	45	0.870	1.171	13
PRB601-07	I	0.209	0.220	0.186	0.294	30	20	0.260	0.239	28
PRB601-08	P	5.649	17.630	5.893	8.120	97	87	0.990	2.994	0
PRB601-09	I	0.349	0.340	0.261	0.526	46	18	0.340	0.436	35
PRB601-10	P	3.172	7.110	4.881	8.653	98	93	0.990	3.078	2
PRB601-11	P	2.376	4.790	2.793	5.015	86	77	0.900	1.213	11
PRB601-12	I	0.200	0.090	0.166	0.523	36	27	0.280	0.345	41
PRB601-13	P	5.100	11.080	5.512	6.785	98	90	0.990	3.034	0
PRB601-14	I	0.153	0.010	0.079	0.206	25	10	0.200	0.743	32
PRB601-15	P	1.021	1.920	1.566	2.544	92	72	0.940	1.683	0
CUTOFF		0.75	1.00	1.00	1.00	55	30	0.500	1.00	20

DESCRIPTION OF METHODS

Less Sensitive (LS) tests involve "detuning" a commercially available HIV method to make it less sensitive by diluting samples, so that samples from early infection (positive on an unmodified test) will be below a specified cutoff, while samples from a long-standing infection will be above the cutoff. Results are expressed as Standard Optical Density (SOD) using a calibrator to normalize results. [1,2]

Avidity Index (AI) tests exploit the lower avidity of early vs."mature" antibodies for the target HIV protein antigens. In AI methods, the sample is split, one aliquot is treated with a chaotropic agent in buffer and the other with buffer alone. Both aliquots are tested using a commercially available anti-HIV test method, and results are expressed as a percent of treated to untreated sample. In early infection samples, antibody-antigen complexes are disrupted by the chaotroic agent. [3,4]

HIV RI (recent infection) is an EIA that detects antibody responses to HIV epitopes empirically found to be expressed in early infection more intensely than in long-standing infection. In the HIV RI method, results are expressed as mean OD and compared to a calibrator. [5]

BED-CEIA is an IgG-capture EIA in which increased amounts of gp41-IDR specific antibodies are detected by BED-biotin peptide. Results are normalized using a calibrator OD and expressed as OD-n.[6]

NRL HIV-1 is an assay that identifies individuals infected with HIV-1 within 120+/-16 days by detecting a specific antigen-antibody interaction that is transient in recent infection. Results are quantified using a standard curve, and values above 20 ug/ml are considered indicative of early infection. To identify HIV-1 infected individuals prior to day 30, this assay must be performed in parallel with a p24 antigen assay. [7]

HIV INCIDENCE TESTS

	----------LESS SENSITIVE (LS)----------				--------AVIDITY INDEX (AI)--------		--------OTHER APPROACHES----		
Mfg.:	Abbott	BioMerieux	BioMerieux	BioMerieux	Bio-Rad	BioMerieux		In-House	
Method:	3A11	Vironostika	Vironostika	Vironostika+O	Genetic Systems	Vironostika	HIV RI	BED CEIA	NRL
Units:	SOD	SOD	SOD	SOD	%	%	Mean OD	Mean OD-n	µg/ml
Member	HIV-1	HIV-1	HIV-1/2	HIV-1/2	rLAV	HIV-1/2	HIV 1	HIV 1	HIV-1
I.D.#	RL11	RL7	RL36	RL 20	RL7	RL20	RL38	RL20	RL36
INCIDENT									
PRB601-01	0.156	0.180	0.166	0.365	24	12	0.220	0.364	24
PRB601-02	0.051	0.100	0.093	0.195	12	18	0.160	0.132	36
PRB601-05	-0.060	0.010	0.028	0.187	10	8	0.160	0.332	67
PRB601-07	0.209	0.220	0.186	0.294	30	20	0.260	0.239	28
PRB601-09	0.349	0.340	0.261	0.526	46	18	0.340	0.436	35
PRB601-12	0.200	0.090	0.166	0.523	36	27	0.280	0.345	41
PRB601-14	0.153	0.010	0.079	0.206	25	10	0.200	0.743	32
PREVALENT									
PRB601-03	1.204	2.240	1.616	2.710	89	80	0.680	1.091	0
PRB601-04	1.163	1.910	2.148	4.459	94	80	0.970	1.412	0
PRB601-06	1.314	1.840	1.436	1.882	77	45	0.870	1.171	13
PRB601-08	5.649	17.630	5.893	8.120	97	87	0.990	2.994	0
PRB601-10	3.172	7.110	4.881	8.653	98	93	0.990	3.078	2
PRB601-11	2.376	4.790	2.793	5.015	86	77	0.900	1.213	11
PRB601-13	5.100	11.080	5.512	6.785	98	90	0.990	3.034	0
PRB601-15	1.021	1.920	1.566	2.544	92	72	0.940	1.683	0
CUTOFF	0.75	1.00	1.00	1.00	55	30	0.500	1.00	20

References:

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