

# Anti-HIV-1 Low Titer Performance Panel Modified PRB109(M) (0800-0301)

## A SERACARE PANEL PRODUCT

### INTENDED USE

The Anti-HIV-1 Low Titer Performance Panel Modified PRB109(M) is intended for use by diagnostic manufacturers, researchers, and clinical laboratories to develop, evaluate, or troubleshoot HIV test methods. Characterized samples and comprehensive data are provided for comparative analysis. For research use only. Not for use in diagnostic procedures.

### PRODUCT DESCRIPTION

This product is a modified 16-member panel originating from Anti-HIV-1 Low Titer Performance Panel PRB109-1.0. Panel members 5, 6, 9, and 18 from the original 20-member panel are no longer available. Panel members are undiluted, naturally occurring plasma samples collected from blood donors in the United States. Samples were selected to provide anti-HIV-1 reactivity near the sensitivity limits of anti-HIV screening test methods. Criteria for inclusion in this panel included on-scale sample signal to cut-off ratio (s/co) for at least one FDA-licensed anti-HIV screening test, and one of the following: a minimally positive, indeterminate, or negative Western Blot, and detectable HIV-1 RNA. One sample is included as a non-reactive sample and is negative by all methods tested. No preservatives were added.

Cat. No. 0800-0301      1 vial per member  
   16 members, 1.0 mL per vial

### STORAGE

Panel members should be stored at -20°C or colder. SeraCare Life Sciences recommends that the panel members be divided into smaller aliquots to avoid multiple freeze-thaw cycles, if appropriate. If turbidity or particulate matter is observed, the samples should be centrifuged in accordance with each test kit manufacturer's instructions for sample preparation.

The Data Sheet for this panel in PDF form can be found at [www.seracare.com](http://www.seracare.com)

A printed copy of the Data Sheet may be requested by email at [info@seracare.com](mailto:info@seracare.com), or by phone at 508.244.6400

### INTERPRETATION OF RESULTS

The Data Sheet for the Anti-HIV-1 Low Titer Performance Panel Modified is available at [www.seracare.com](http://www.seracare.com). The Data Sheet lists results for panel members generated using commercially-available screening, monitoring, and confirmatory test methods. Tests were performed at SeraCare or at recognized reference laboratories (RL) by individuals who routinely use these procedures. Information regarding specific test methods is available on the Data Sheet. Data Sheets are updated when new data are available.

### LIMITATIONS

The Anti-HIV-1 Low Titer Performance Panel Modified is offered for research use only, not for use in diagnostic procedures. Data are provided for informational purposes. SeraCare Life Sciences does not claim that others can duplicate test results exactly.

### PRECAUTIONS

Follow Universal Precautions.<sup>1</sup> The units that make up this panel were tested and found negative for HBsAg and anti-HCV. This does not ensure the absence of these or other human pathogens. Most panel members were found positive by tests for anti-HIV-1.

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.

### REFERENCES

1. Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings

**For assistance, contact SeraCare Technical Support at 508.244.6400.**

### ASK ABOUT RELATED SERACARE PRODUCTS

- ACCURUN<sup>®</sup> Quality Controls
- AccuType<sup>™</sup> Viral Isolates
- SeraCon<sup>™</sup> and Basematrix Processed Plasma



**SeraCare Life Sciences**  
**Anti-HIV-1 Low Titer AccuSet™ Performance Panel Modified**  
**PRB109(M) (0800-0301)**  
**Data Sheet**

Member I.D. #	Bleed Dates	Fiebig Stage*	-----US FDA licensed anti-HIV EIA Tests-----			-----HIV p24 Antigen Tests-----		-----HIV-1 RNA Test-----
			Results expressed as s/co-----			-----Results expressed as s/co-----		Results expressed as c/mL
			Abbott HIV 1/2 SeraCare <sup>2</sup>	Bio-Rad HIV 1/2 Plus O SeraCare <sup>2</sup>	Genetic Systems HIV 1 rLAV SeraCare <sup>2</sup>	Perkin Elmer HIVAg SeraCare	Zeptometrix HIVAg SeraCare	Roche Amplicor Monitor HIV-1 RNA SeraCare
PRB109-01	13-Oct-01	IV	4.1	>10.9	0.2	33.2	6.2	5.5 x 10 <sup>5</sup>
PRB109-02	18-Jan-02	II / III	0.7	>10.9	0.1	>46.0	24.2	4.8 x 10 <sup>6</sup>
PRB109-03†	18-Feb-02	IV	0.6	8.5	0.1	5.3	1.5	2.3 x 10 <sup>5</sup>
PRB109-04†	20-Feb-02	IV	2.1	>10.9	0.2	10.5	2.5	2.7 x 10 <sup>5</sup>
PRB109-05 <sup>1</sup>	02-May-02	IV	18.4	>10.9	1.7	1.4	1.0	3.2 x 10 <sup>4</sup>
PRB109-06 <sup>1</sup>	06-Jun-02	IV	3.6	4.1	1.2	12.6	3.6	2.3 x 10 <sup>5</sup>
PRB109-07	31-May-02	III	0.7	1.3	0.2	3.6	1.3	6.2 x 10 <sup>4</sup>
PRB109-08	31-Jul-03	NA	0.1	0.1	0.1	0.3	0.7	BLD
PRB109-09 <sup>1</sup>	22-Oct-02	IV	2.5	>10.9	0.6	5.3	2.4	2.1 x 10 <sup>5</sup>
PRB109-10‡	22-May-06	IV	10.3	>10.9	1.0	3.5	1.3	1.2 x 10 <sup>5</sup>
PRB109-11‡	24-May-06	IV	7.4	>10.9	2.1	10.6	2.4	5.7 x 10 <sup>5</sup>
PRB109-12	21-Oct-04	V	11.8	>10.9	2.1	8.7	2.4	4.1 x 10 <sup>5</sup>
PRB109-13††	14-Sep-07	IV	0.5	0.3	0.2	19.7	4.2	5.0 x 10 <sup>5</sup>
PRB109-14††	19-Sep-07	IV	10.1	>10.9	3.1	>46.0	11.8	2.4 x 10 <sup>6</sup>
PRB109-15††	21-Sep-07	V	7.2	>10.9	3.9	>46.0	8.4	7.0 x 10 <sup>5</sup>
PRB109-16	20-Dec-07	IV	6.1	>10.9	0.3	>46.0	16.5	5.7 x 10 <sup>6</sup>
PRB109-17‡‡	12-Oct-02	IV	2.2	>10.9	0.4	28.0	6.8	1.7 x 10 <sup>5</sup>
PRB109-18‡‡ <sup>1</sup>	14-Oct-02	V	7.7	>10.9	1.5	3.7	1.3	7.8 x 10 <sup>4</sup>
PRB109-19	29-Apr-08	V	16.3	>10.9	3.3	0.4	0.7	2.1 x 10 <sup>4</sup>
PRB109-20	13-Jun-02	V	1.5	>10.9	2.2	1.1	0.9	6.9 x 10 <sup>3</sup>
<b>Run Date:</b>			15 Jun 09	15 Jun 09	15 Jun 09	18 Jun 09	16 Jun 09	18 Jun 09, 29 Jun 09
<b>Kit Lot #:</b>			76625M100	324CBB	221CAA	990-090302	304824	K10107
<b>Exp. Date:</b>			02 Aug 09	13 Aug 09	01 Jul 09	01 Jan 10	15 Dec 09	31 Oct 09
<b>Product #:</b>			3A77	32588	32511	NEK 050B	0801111	83377

<sup>1</sup>Panel members 5, 6, 9, and 18 are no longer available. Data are provided for informational purposes only.

<sup>2</sup>EIA results are means of duplicates expressed as specimen signal to cutoff ratios (s/co). Ratios ≥1.0 are considered reactive.

†PRB109-04 is a bleed from the same donor as PRB109-03, collected 2 days later.

††PRB109-13, 14, 15 are same donor bleeds collected 5 days and 2 days apart, respectively.

‡PRB109-11 is a bleed from the same donor as PRB109-10, collected 2 days later.

‡‡ PRB109-18 is a bleed from the same donor as PRB109-17, collected 2 days later.

NA = Not Applicable; BLD = Below the Limit of Detection

\*Fiebig stage is assigned according to EW Fiebig et al, Dynamics of HIV viremia and antibody seroconversion in plasma donors: implications for diagnosis and staging of primary HIV infection. AIDS 2003, 17:1871-1879.

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**Data Sheet**

Member	-----HIV-1 Western Blot-----		-----European HIV Ag/Ab Tests-----			
	Calypte Western Blot SeraCare		Abbott ARCHITECT Combo RL23	Abbott PRISM Combo RL23	Murex Combination EIA RL23	Roche Elecsys Combi RL23
	<u>I.D. #</u>	<u>Band Pattern</u>	<u>s/co</u>	<u>s/co</u>	<u>s/co</u>	<u>s/co</u>
PRB109-01	24	IND	40.9	16.6	17.8	8.2
PRB109-02	No Bands	NEG	281.3	121.7	18.9	36.7
PRB109-03†	f24	IND	3.5	2.3	2.8	5.7
PRB109-04†	f24	IND	10.7	4.8	6.4	2.0
PRB109-05 <sup>2</sup>	f24, 160	IND	10.2	4.9	17.5	37.5
PRB109-06 <sup>2</sup>	f160	IND	4.1	4.1	3.8	0.9
PRB109-07	No Bands	NEG	3.9	2.7	3.4	1.1
PRB109-08	No Bands	NEG	0.3	0.2	0.4	0.3
PRB109-09 <sup>2</sup>	f24, f160	IND	10.6	4.6	8.0	4.1
PRB109-10‡	160	IND	20.5	8.4	12.3	9.5
PRB109-11‡	f24, f120, 160	IND	36.5	15.5	14.3	50.1
PRB109-12	24, f120, 160	POS	34.1	7.6	17.5	193.0
PRB109-13††	18	IND	23.6	12.6	9.6	1.8
PRB109-14††	18, f24, 160	IND	127.5	50.3	18.8	41.9
PRB109-15††	18, 24, 160	POS	127.9	41.9	17.8	108.0
PRB109-16	f160	IND	116.7	55.1	17.9	24.0
PRB109-17‡‡	f24, 160	IND	41.6	16.9	15.6	5.6
PRB109-18‡‡ <sup>2</sup>	24, f41, f51, f120, 160	POS	58.6	6.7	14.3	13.2
PRB109-19	24, f41, f51, 55, 66, f120, 160	POS	23.5	6.0	17.9	291.3
PRB109-20	24, f55, 160	POS	13.7	3.4	7.9	39.9
<b>Run Date:</b>	29 May 09		29 Jul 09	05 Aug 09	03 Aug 09, 07 Aug 09	13 Aug 09
<b>Kit Lot #:</b>	B9295-053		72331HN00	79496HN00	L283810	153019-01
<b>Exp. Date:</b>	22 Oct 09		14 Sep 09	28 Sep 09	31 Mar 10	31 Oct 09
<b>Product #:</b>	98002		4J27-20	7G46-48	GE42 (7G79-02)	4860446

<sup>1</sup>Western Blots were interpreted using ASTPHLD/CDC criteria (MMWR, vol. 38, S-7, 1989).

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‡PRB109-11 is a bleed from the same donor as PRB109-10, collected 2 days later.

‡‡ PRB109-18 is a bleed from the same donor as PRB109-17, collected 2 days later.

f = Faint; POS = Positive; IND= Indeterminate; NEG = Negative

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Member I.D. #	-----HIV Rapid Tests-----				
	Bio-Rad Multispot HIV-1/HIV-2 SeraCare		OraSure OraQuick ADVANCE® SeraCare	Inverness Determine® HIV-1/2 Ag/Ab Combo SeraCare	
	<u>HIV-1 Result</u>	<u>HIV-2 Result</u>	<u>HIV-1/2 Result</u>	<u>HIV Ag Result</u>	<u>HIV-1/2 Ab Result</u>
PRB109-01	NEG	NEG	NEG	POS	NEG
PRB109-02	NEG	NEG	NEG	POS	POS
PRB109-03†	NEG	NEG	NEG	NEG	NEG
PRB109-04†	NEG	NEG	NEG	NEG	POS
PRB109-05 <sup>1</sup>	NEG	NEG	NEG	NEG	POS
PRB109-06 <sup>1</sup>	NEG	NEG	NEG	POS	NEG
PRB109-07	NEG	NEG	NEG	NEG	NEG
PRB109-08	NEG	NEG	NEG	NEG	NEG
PRB109-09 <sup>1</sup>	NEG	NEG	NEG	NEG	POS
PRB109-10‡	NEG	NEG	NEG	NEG	POS
PRB109-11‡	NEG	NEG	POS	NEG	POS
PRB109-12	POS	NEG	POS	NEG	POS
PRB109-13††	NEG	NEG	NEG	NEG	NEG
PRB109-14††	POS	NEG	NEG	POS	POS
PRB109-15††	POS	NEG	POS	NEG	POS
PRB109-16	NEG	NEG	NEG	POS	POS
PRB109-17‡‡	NEG	NEG	NEG	POS	POS
PRB109-18‡‡ <sup>1</sup>	POS	NEG	POS	NEG	POS
PRB109-19	POS	NEG	POS	NEG	POS
PRB109-20	NEG	NEG	NEG	NEG	POS

  

<b>Run Date:</b>	15 Dec 08, 12 Jun 09	15 Dec 08, 10 Feb 09	13 Aug 09, 24 Aug 09
<b>Kit Lot #:</b>	956768, 960383	6611458, 6612575	090216
<b>Exp. Date:</b>	21 Jul 09, 20 Feb 10	31 Mar 09, 30 Jun 09	22 Nov 09
<b>Product #:</b>	25228	39-6341	2647

<sup>1</sup>Panel members 5, 6, 9, and 18 are no longer available. Data are provided for informational purposes only.

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‡PRB109-11 is a bleed from the same donor as PRB109-10, collected 2 days later.

††PRB109-13, 14, 15 are same donor bleeds collected 5 days and 2 days apart, respectively.

‡‡ PRB109-18 is a bleed from the same donor as PRB109-17, collected 2 days later.

POS = Positive; NEG = Negative