

## OVERVIEW

PRD201 is a 9 member, 1.2 mL per vial panel of cultured virus samples from multiple HIV-1 genotypes. This panel is intended for use by diagnostics manufacturers, clinical laboratories and researchers to develop, evaluate or troubleshoot HIV RNA, HIV Ag, and HIV Ag/Ab test methods.

The positive panel members represent HIV genotypes AG, B, C, D, AE, F, G, and H. Each virus culture was quantified by electron microscopy and assigned a genotype by sequencing. The cultures were diluted to approximately 50,000 virus particles per mL in defibrinated human plasma negative for HIV-1 RNA. The negative member was prepared from diluent tested and found negative for HIV-1 RNA, HBsAg and antibodies to HIV 1/2 and HCV. Sodium azide (0.09%) was added to all members as a preservative.

**CAUTION:** Potentially infectious materials. Follow Universal Precautions. These materials have not been inactivated and should be considered biohazardous.

For Research Use Only.

Not for use in diagnostic procedures.

Data are offered for informational purposes only. SeraCare Life Sciences does not claim test results can be duplicated exactly.

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

### Worldwide Prevalence of HIV-1 Genotypes



DATA SHEET

HIV Genotype<sup>1</sup>

Panel Member	Genotype	Country of Origin	VQA ID
PRD201-01	AG	Djibouti	DJ258
PRD201-02	B	Thailand	BK132
PRD201-03	C	Ethiopia	ETH2220
PRD201-04	D	Senegal	SE365
PRD201-05	AE	Thailand	POC30506
PRD201-06	F	Brazil	BZ162
PRD201-07	G	Zaire	BCF-DIOUM
PRD201-08	H	Zaire	BCF-KITA
PRD201-09	Panel diluent	----	----

<sup>1</sup> HIV Genotypes were assigned by sequence analysis of the virus cultures used to manufacture each positive panel member. The HIV-1 pol and env regions were amplified by RT-PCR. Following gel electrophoresis, PCR products were purified and sequenced. Each virus culture was identified as to genotype by the BLAST and HIV-1 GENTYPING program operated by the National Center for Biotechnology Information (<http://www.ncbi.nlm.nih.gov/retroviruses/subtype/subpreHIV1.html>).

HIV RNA

Panel Member	Abbott m2000 copies/mL	GenProbe Procleix Ultrio	Roche Ampliprep/TaqMan HIV RNA v2.0 copies/mL	Siemens HIV RNA bDNA copies/mL
PRD201-01	2 x 10 <sup>5</sup>	POS	9 x 10 <sup>4</sup>	5 x 10 <sup>4</sup>
PRD201-02	8 x 10 <sup>4</sup>	POS	1 x 10 <sup>5</sup>	7 x 10 <sup>4</sup>
PRD201-03	1 x 10 <sup>5</sup>	POS	1 x 10 <sup>5</sup>	3 x 10 <sup>4</sup>
PRD201-04	1 x 10 <sup>5</sup>	POS	1 x 10 <sup>5</sup>	5 x 10 <sup>4</sup>
PRD201-05	2 x 10 <sup>5</sup>	POS	1 x 10 <sup>5</sup>	5 x 10 <sup>4</sup>
PRD201-06	2 x 10 <sup>5</sup>	POS	1 x 10 <sup>5</sup>	5 x 10 <sup>4</sup>
PRD201-07	4 x 10 <sup>5</sup>	POS	3 x 10 <sup>5</sup>	1 x 10 <sup>5</sup>
PRD201-08	2 x 10 <sup>5</sup>	POS	1 x 10 <sup>5</sup>	3 x 10 <sup>4</sup>
PRD201-09	BLD	NEG	BLD	BLD
Test Date	14-Oct-11	13-Oct-11	11-Oct-11	13-Oct-11
Test Site	RL	RL	SC	RL
Kit Part Code	6L18	NA	05212308 190	127418A/B
Kit Lot Number	327300	587793	P03169	D085
Kit Expiration Date	31-Aug-12	15-Feb-13	30-Apr-12	30-Oct-11

POS = positive; NEG = negative; BLD = below the limit of detection; NA = not available  
RL = Reference Lab; SC = SeraCare

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

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

DATA SHEET

HIV Antigen<sup>1</sup>

Panel Member	DSI DS-EIA-HIV-AG-screen s/co	Perkin Elmer HIV Ag p24 s/co	Perkin Elmer HIV Ag p24 pg/mL	Zeptomatrix HIV Ag p24 s/co
PRD201-01	8.9	3.4	7.1	1.3
PRD201-02	32.9	3.9	8.6	1.7
PRD201-03	8.0	1.8	4.1	0.7
PRD201-04	28.2	4.0	8.9	1.6
PRD201-05	31.5	3.4	9.1	1.8
PRD201-06	21.3	3.2	7.0	1.4
PRD201-07	34.1	5.5	13.8	2.5
PRD201-08	44.6	3.0	7.3	1.7
PRD201-09	0.2	0.0	0.0	0.6

  

Test Date	13-Oct-11	10-Oct-11	18-Nov-11	7-Oct-11
Test Site	SC	SC	SC	SC
Kit Part Code	I-1452	NEK050A	NEK050A	801111
Kit Lot Number	20	990-11312	990-11391	307427
Kit Expiration Date	4-Mar-12	1-Jun-12	1-Jun-12	7-Jan-12

<sup>1</sup> Immunoassay results are means of duplicates. For those expressed as signal to cutoff ratios (s/co) and pg/ml, ratios ≥1.0 are considered reactive and noted in red.

HIVAg/Ab and HIV Ag/Ab Discriminatory Rapid<sup>1</sup>

Panel Member	Abbott HIV Ag/Ab Combo ARCHITECT s/co	Bio-Rad Genscreen Ultra HIV Ag/Ab Combo s/co	Siemens Enzygnost HIV Integral II s/co	Alere Determine HIV Ag Result	Alere Determine HIV Ab Result
PRD201-01	2.7	2.0	2.4	NEG	NEG
PRD201-02	2.2	2.1	2.8	NEG	NEG
PRD201-03	2.0	2.1	0.4	NEG	NEG
PRD201-04	3.2	2.4	2.9	NEG	NEG
PRD201-05	4.0	2.2	3.2	NEG	NEG
PRD201-06	2.4	2.3	2.5	NEG	NEG
PRD201-07	5.1	2.6	4.7	NEG	NEG
PRD201-08	3.4	2.0	2.5	NEG	NEG
PRD201-09	0.1	0.3	0.1	NEG	NEG

  

Test Date	17-Oct-11	11-Nov-11	4-Nov-11	11-Oct-11
Test Site	SC	SC	SC	SC
Kit Part Code	2P36	72386	OPAA09	7D2646
Kit Lot Number	06074L100	1F1068	40554	110524ALCE
Kit Expiration Date	9-Feb-12	15-Nov-12	19-Jul-12	25-Mar-12

<sup>1</sup> Immunoassay results are means of duplicates. For those expressed as signal to cutoff ratios (s/co), ratios ≥1.0 are considered reactive and noted in red.

POS = positive; NEG = negative; BLD = below the limit of detection; NA = not available  
RL = Reference Lab; SC = SeraCare