

HIV p24 Antigen Mixed Titer AccuSet™ Performance Panel Modified PRA204(M) (0800-0300)

DATA SHEET

OVERVIEW

HIV p24 Antigen Mixed Titer AccuSet™ Performance Panel Modified is an 18 member, 1.5 mL per vial panel of undiluted, naturally-occurring plasma samples. No preservatives were added. This modified panel originates from HIV p24 Mixed Titer Performance Panel PRA204-1.5. Panel members 1, 4, 7, 13, 16, 18 and 24 from the original 25-member panel are no longer available.

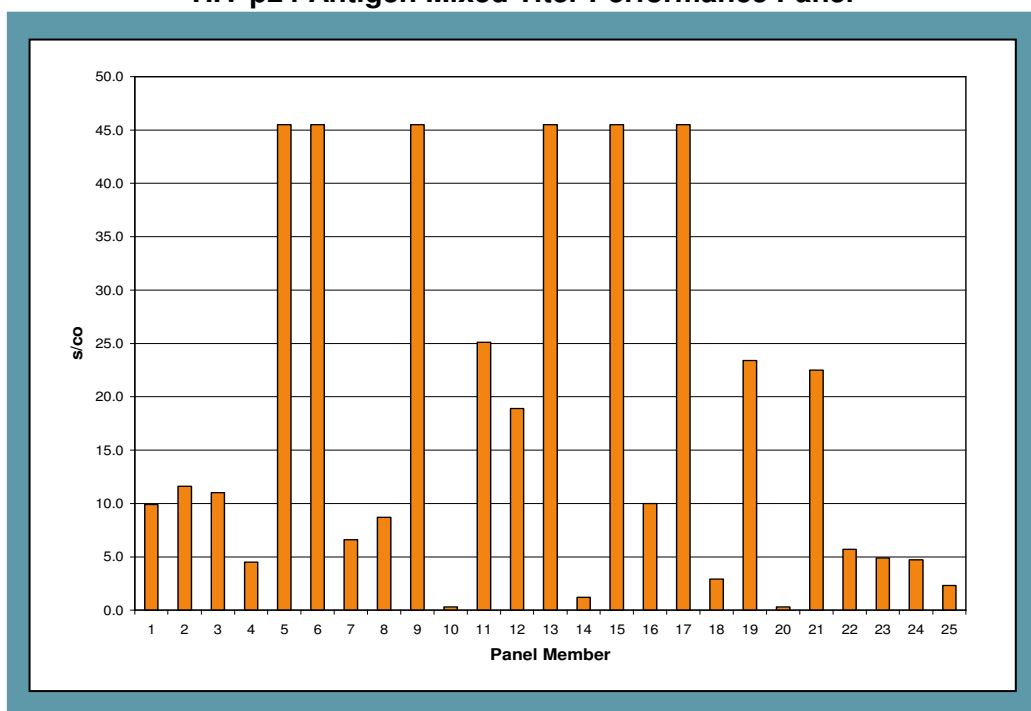
HIV p24 Antigen Mixed Titer AccuSet™ Performance Panel Modified is designed for use by manufacturers and laboratories to evaluate the sensitivity and specificity of HIV antigen and HIV antigen/antibody combination assays using well-characterized specimens. This data sheet includes Fiebig stage and test results for thirteen commercially available assays for HIV p24 antigen, HIV antigen/antibody, anti-HIV, and HIV RNA. HIV p24 antigen concentration ranges from <3 to >400 pg/mL, in these samples, and Fiebig stages II through VI are represented.

CAUTION: Potentially infectious materials. Follow Universal Precautions. Some panel members were found positive for HIV Ag and/or anti-HIV-1; all were found negative for HBsAg and anti-HCV.

For Research Use Only. Not for use in diagnostic procedures. Data are provided for informational purposes only. SeraCare Life Sciences does not claim these results can be duplicated exactly.

For assistance, contact SeraCare Technical Support at 508.244.6400

HIV p24 Antigen Mixed Titer Performance Panel



This graph demonstrates the breadth of HIV antigen levels among panel members with the Perkin Elmer HIV p24 Antigen test. Panel members 1, 4, 7, 13, 16, 18, and 24 are no longer available. Data are provided for informational purposes only.

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HIV Antigen and RNA

Panel Member	Fiebig Stage ¹	bioMerieux HIVAg VIDAS p24 (pg/mL) ²	Perkin Elmer HIVAg p24 (s/co) ³	Zeptometrix HIVAg p24 (s/co) ³	Roche HIV RNA CAP/CTM v 1.0 (copies/mL)
PRA204-01 ⁴	VI	33.9	9.9	0.8	1.5 x 10 ⁶
PRA204-02	VI	45.3	11.6	3.3	5.1 x 10 ⁴
PRR204-03	VI	66.0	11.0	1.4	5.5 x 10 ⁵
PRA204-04 ⁴	V	15.9	4.5	1.0	6.1 x 10 ⁴
PRA204-05	IV	96.9	23.4	15.0	6.7 x 10 ⁴
PRA204-06	III	>400.0	>45.5	49.9	2.5 x 10 ⁶
PRA204-07 ⁴	V	27.2	6.6	4.5	4.1 x 10 ⁵
PRA204-08	V	25.7	8.7	2.2	4.7 x 10 ⁵
PRA204-09	II	>400.0	>45.5	75.1	4.1 x 10 ⁶ *
PRA204-10	NA	<3.0	0.3	0.1	BLD
PRA204-11	II	84.6	25.1	15.9	2.9 x 10 ⁵
PRA204-12	II	60.1	18.9	13.5	1.1 x 10 ⁵
PRA204-13 ⁴	II	169.5	>45.5	40.5	4.9 x 10 ⁵
PRA204-14	VI	<3.0	1.2	0.0	3.0 x 10 ⁴
PRA204-15	II	192.4	>45.5	35.6	6.0 x 10 ⁵
PRA204-16 ⁴	V	39.3	10.0	5.6	9.2 x 10 ⁴
PRA204-17	II	>400.0	>45.5	61.2	3.5 x 10 ⁶
PRA204-18 ⁴	II	12.4	2.9	0.2	1.0 x 10 ⁴
PRA204-19	III	318.0	32.4	40.3	5.7 x 10 ⁵
PRA204-20	NA	<3.0	0.3	0.2	BLD
PRA204-21	II	68.4	22.5	17.5	4.8 x 10 ⁵
PRA204-22	II/III	17.2	5.7	0.8	7.6 x 10 ⁴
PRA204-23	II	13.6	4.9	2.4	3.2 x 10 ⁴
PRA204-24 ⁴	II	14.7	4.7	2.7	7.7 x 10 ⁴
PRA204-25	I/II	6.2	2.3	0.4	1.6 x 10 ⁴
Test Date		5-Jul-10	13-Apr-10	13-Apr-10	20-Apr-10, 10-May-10
Test Site		RL	SC	SC	SC
Kit Part Code		30117	NEK050B	801111	03542998 190
Kit Lot No.		838404801	990-100306	305803	M11331, M15645
Kit Exp Date		17-Oct-10	01-Nov-10	25-Sep-10	30-Nov-10, 31-Jan-11

¹Fiebig stages are categories that define phases of early HIV infection. See Fiebig EW, et al. Dynamics of HIV viremia and antibody seroconversion in plasma donors: implications for diagnosis and staging of primary HIV infection. AIDS 2003, 17:1871-9, and Lee HY, et al. Modeling sequence evolution in acute HIV-1 infection. JTB 2009, 261:341-360. ²Quantitative HIV antigen results are means of duplicates expressed in pg/mL. Results ≥3.0 are considered positive and noted in red. ³Immunoassay results are means of duplicates expressed as signal to cutoff ratios (s/co). Ratios ≥1.0 are considered reactive and noted in red. ⁴Panel members 1, 4, 7, 13, 16, 18, and 24 are no longer available. Data are provided for informational purposes only. *Sample was diluted 1:10 and back calculated.
BLD = Below the limit of detection; NA = Not applicable; RL = Reference Lab; SC = SeraCare

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DATA SHEET

HIV Antigen/Antibody (s/co)¹

Panel Member	Abbott HIV Ag/Ab Combo ARCHITECT	Abbott HIV Ag/Ab Combo AxSYM	Abbott HIV Ag/Ab Combo PRISM	Bio-Rad Genscreen Ultra HIV Ag/Ab Combo	Murex HIV Ag/Ab Combo
PRA204-01 ²	28.3	11.3	12.1	10.7	16.6
PRA204-02	476.5	42.9	54.8	11.0	18.1
PRR204-03	574.2	55.5	44.0	11.6	17.5
PRA204-04 ²	40.7	8.4	7.8	10.7	12.5
PRA204-05	28.3	20.7	22.5	10.6	16.6
PRA204-06	95.2	37.7	68.0	10.6	18.7
PRA204-07 ²	33.1	24.1	17.9	10.6	17.2
PRA204-08	34.1	18.3	12.8	11.3	16.9
PRA204-09	350.2	68.2	139.4	11.4	18.4
PRA204-10	0.1	0.3	0.1	0.5	0.3
PRA204-11	18.6	9.4	12.7	7.0	9.4
PRA204-12	15.0	7.7	9.5	4.4	7.8
PRA204-13 ²	53.2	17.2	27.2	10.4	16.8
PRA204-14	549.1	58.4	37.9	11.7	17.6
PRA204-15	40.0	19.6	34.3	9.1	16.2
PRA204-16 ²	18.4	11.7	16.1	10.5	16.2
PRA204-17	139.3	42.4	77.9	10.7	ALR
PRA204-18 ²	2.2	1.4	4.2	1.4	1.0
PRA204-19	64.2	28.4	65.2	10.7	18.5
PRA204-20	0.1	0.4	0.1	0.5	0.6
PRA204-21	23.1	8.6	10.6	7.2	10.8
PRA204-22	5.2	3.0	4.0	2.8	2.7
PRA204-23	3.3	1.2	2.8	1.8	1.9
PRA204-24 ²	3.0	2.2	2.8	2.4	2.1
PRA204-25	1.2	1.1	1.1	1.1	1.2
Test Date	26-Apr-10	06-May-10	12-Jul-10	16-Jul-10	22-Jun-10
Test Site	RL	RL	RL	RL	RL
Kit Part Code	4J27-30	2G8320	7G46-48	72386	7G79-02
Kit Lot No.	81321HN00	86267LF01	89287HN00	OD1053	L397910
Kit Exp Date	06-Aug-10	08-Aug-10	07-Dec-10	31-Dec-11	31-Dec-10

¹Immunoassay results are means of duplicates expressed as signal to cutoff ratios (s/co). Ratios ≥1.0 are considered reactive and noted in red.

²Panel members 1, 4, 7, 13, 16, 18, and 24 are no longer available. Data are provided for informational purposes only.

RL = Reference Lab

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DATA SHEET

HIV Antibody (s/co) ¹

Panel Member	Abbott HIV-1/HIV-2 rDNA	Bio-Rad HIV-1/HIV-2 Plus O Gen Sys	Ortho HIV-1/HIV-2 Vitros Eci
PRA204-01 ²	14.7	>10.1	28.2
PRA204-02	>18.6	>10.1	63.6
PRR204-03	>18.6	>10.1	75.9
PRA204-04 ²	7.9	>10.1	48.5
PRA204-05	>18.6	>10.1	61.2
PRA204-06	3.4	5.9	11.1
PRA204-07 ²	>18.6	>10.1	87.1
PRA204-08	>18.6	>10.1	66.1
PRA204-09	0.2	0.1	0.1
PRA204-10	0.2	0.1	0.1
PRA204-11	0.2	0.1	0.2
PRA204-12	0.3	0.1	0.1
PRA204-13 ²	0.5	0.3	0.2
PRA204-14	>18.6	>10.1	86.7
PRA204-15	0.4	0.2	0.6
PRA204-16 ²	13.3	>10.1	29.0
PRA204-17	0.1	0.1	0.1
PRA204-18 ²	0.5	0.2	0.3
PRA204-19	>18.6	>10.1	22.2
PRA204-20	0.1	0.2	0.1
PRA204-21	0.2	0.2	0.1
PRA204-22	0.4	0.2	1.8
PRA204-23	0.2	0.1	0.1
PRA204-24 ²	0.0	0.2	0.1
PRA204-25	0.3	0.2	0.1
Test Date	14-Jun-10	20-Jul-10	20-Apr-10
Test Site	SC	SC	RL
Kit Part Code	3A77-68	32588	6801861
Kit Lot No.	83470M500	104EBB-05	0320
Kit Exp Date	22-Aug-10	08-Dec-10	06-Jan-11

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Bio-Rad HIV Western Blot

Panel Member	Band Pattern	Result
PRA204-01	24,31,f41,160	POS
PRA204-02	f24,31,41,51,65,120,160	POS
PRR204-03	f24,31,41,51,55,65,120,160	POS
PRA204-04	24,160	POS
PRA204-05	f18,24,f31,f55,f160	IND
PRA204-06	NO BANDS	NEG
PRA204-07	24,55,160	POS
PRA204-08	24,55,160	POS
PRA204-09	NO BANDS	NEG
PRA204-10	NO BANDS	NEG
PRA204-11	NO BANDS	NEG
PRA204-12	NO BANDS	NEG
PRA204-13	f18	IND
PRA204-14	18,24,31,41,f51,55,65,120,160	POS
PRA204-15	NO BANDS	NEG
PRA204-16	f18,24,160	POS
PRA204-17	NO BANDS	NEG
PRA204-18	NO BANDS	NEG
PRA204-19	NO BANDS	NEG
PRA204-20	NO BANDS	NEG
PRA204-21	NO BANDS	NEG
PRA204-22	NO BANDS	NEG
PRA204-23	NO BANDS	NEG
PRA204-24	NO BANDS	NEG
PRA204-25	NO BANDS	NEG

Test Date 27-Jul-10, 16-Aug-10

Test Site SC

Kit Part Code 32508

Kit Lot No. 966550, 1000348

Kit Exp Date 03-Dec-10, 22-Feb-11

*Panel members 1, 4, 7, 13, 16, 18, and 24 are no longer available. Data are provided for informational purposes only.
POS = Positive; NEG = Negative; IND = Indeterminate; SC = SeraCare

The Package Insert for this panel in PDF form can be found at www.seracare.com

A printed copy of the Package Insert or Data Sheet may be requested by email at info@seracare.com, or by phone at 508.244.6400