

## OVERVIEW

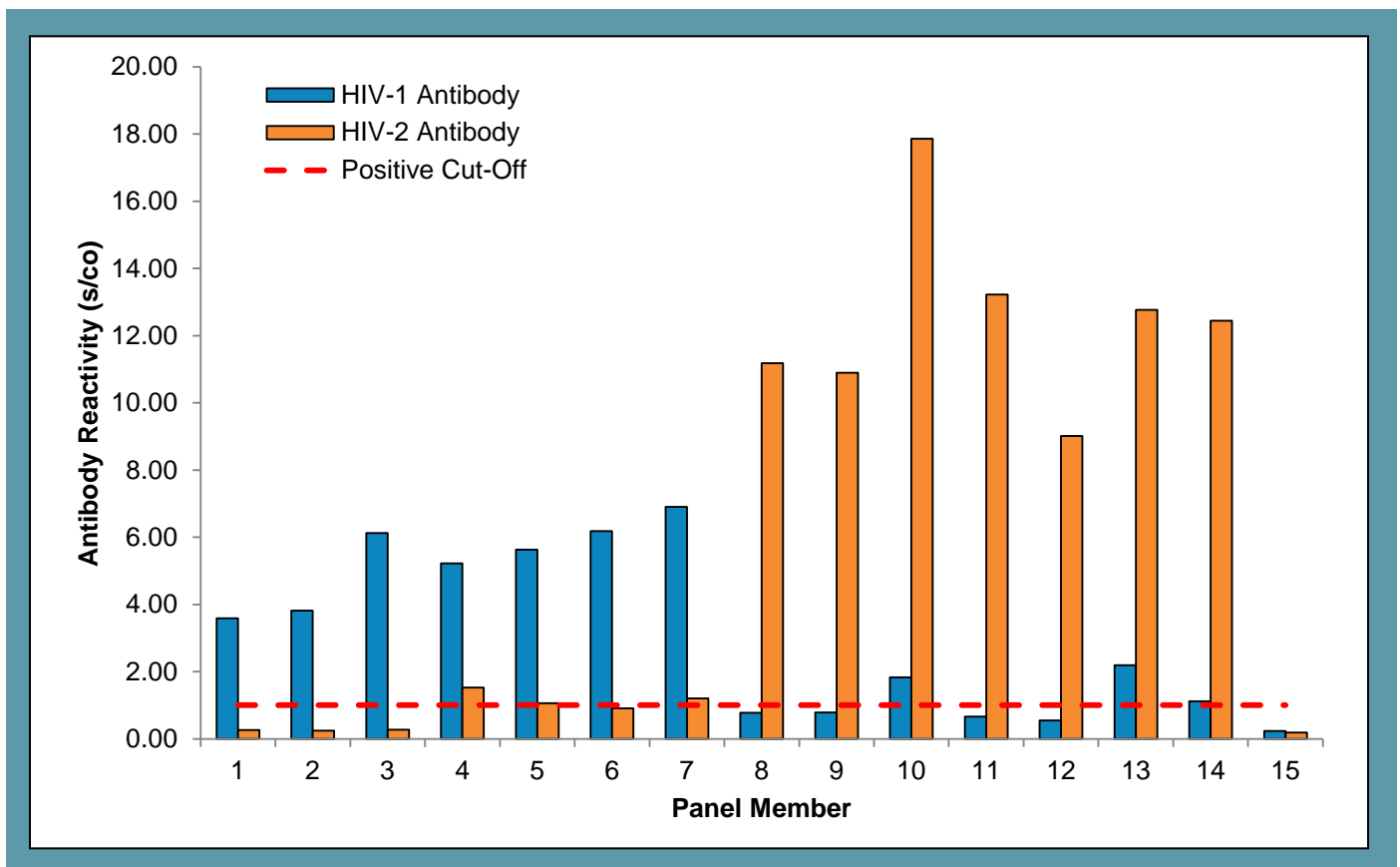
HIV-1/2 Mixed Titer AccuSet™ Performance Panel (0800-0331) is a 15-member validation panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.2 mL per vial). Panel members represent bleeds from multiple individuals (unique donors) positive for antibodies to HIV-1 and/or HIV-2. Each sample represents a single collection event. No preservatives were added.

Test results from commercially-available HIV assays are included for characterization of the panel members. This panel of human plasma samples demonstrates a range of antibody reactivity for anti-HIV-1 and anti-HIV-2. One sample is included as a non-reactive sample and is negative for all HIV test methods performed.

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.

CAUTION: Potentially infectious materials. Follow Universal Precautions. The units that make up this panel were tested for HBsAg and anti-HCV and found to be negative. This does not ensure the absence of these or other human pathogens.

HIV-1/2 Mixed Titer AccuSet™ Performance Panel



This graph demonstrates HIV-1 and HIV-2 antibody reactivity amongst panel members utilizing test results from the Bio-Rad Genetic Systems HIV-2 EIA and Avioq HIV-1 Microelisa System test methods.

## Panel Member Information

Panel Member	SeraCare Donor ID	SeraCare Batch #
01	BD110060	9118517
02	BD102726	BM206262
03	BD104207	BM217425
04	BD111025	9253923
05	BD111093	9251696
06	BD111021	9253083
07	BD111084	9251518
08	BD110644*	9250494
09	BD200286*	10001736
10	BD110613*	10043358
11	BD211282*	10058290
12	BD211298*	10058301
13	BD110417*	10083419
14	BD225451*	10083433
15	BD217201*	10035035

\*Donors were utilized in SeraCare HIV-2 Mixed Titer AccuSet™ Performance Panel (0800-0343).

# HIV-1/2 Mixed Titer AccuSet™ Performance Panel

0800-0331

DATA SHEET

## HIV-1 and HIV-2 Antibody

Panel Member	Avioq HIV-1 Microelisa System (s/co) <sup>1,2</sup>	Bio-Rad Genetic Systems HIV-2 EIA (s/co) <sup>1,2</sup>	Bio-Rad Genetic Systems™ HIV-1/HIV-2 Plus O EIA (s/co) <sup>1,2</sup>	Siemens ADVIA Centaur HIV-1/O/2 Enhanced (EHIV) (Index) <sup>3</sup>
01	<b>3.59</b>	0.26	<b>&gt;11.49*</b>	<b>22.40</b>
02	<b>3.82</b>	0.24	<b>&gt;11.49*</b>	<b>7.54</b>
03	<b>6.13</b>	0.27	<b>&gt;11.49*</b>	<b>&gt;50.00*</b>
04	<b>5.22</b>	<b>1.53</b>	<b>&gt;11.49*</b>	<b>&gt;50.00*</b>
05	<b>5.63</b>	1.06**	<b>&gt;11.49*</b>	<b>47.21</b>
06	<b>6.18</b>	0.91**	<b>&gt;11.49*</b>	<b>&gt;50.00*</b>
07	<b>6.90</b>	<b>1.20</b>	<b>&gt;11.49*</b>	<b>&gt;50.00*</b>
08	0.78	<b>11.18</b>	<b>&gt;11.49*</b>	<b>&gt;50.00*</b>
09	0.79	<b>10.90</b>	<b>&gt;11.49*</b>	<b>&gt;50.00*</b>
10	<b>1.83</b>	<b>17.86</b>	<b>&gt;11.49*</b>	<b>&gt;50.00*</b>
11	0.66	<b>13.22</b>	<b>&gt;11.49*</b>	<b>&gt;50.00*</b>
12	0.55	<b>9.01</b>	<b>&gt;11.49*</b>	<b>&gt;50.00*</b>
13	<b>2.19</b>	<b>12.77</b>	<b>&gt;11.49*</b>	<b>&gt;50.00*</b>
14	<b>1.12</b>	<b>12.44</b>	<b>&gt;11.49*</b>	<b>&gt;50.00*</b>
15	0.23	0.19	0.07	<0.05
Test Date	16-Jan-15	12-Jan-15	15-Jan-15	21-Jan-15
Test Site	SC	SC	SC	SC
Kit Part Code	100384	32536	32588	C343L/H A
Kit Lot No.	J4895	066JY1-05	283JBB-05	47542143
Kit Exp. Date	06-Aug-15	13-Jan-15	30-Jun-15	30-Mar-15
Kit Regulatory Status	IVD	IVD	IVD/CE	IVD

<sup>1</sup>Results are reported as a signal to cut-off value (s/co); positive/reactive results are noted in bold red.

<sup>2</sup>Results are reported as the mean result of duplicate testing.

<sup>3</sup>Results are reported as an index value.

\*Result is above the limit of reactivity (ALR).

\*\*Result is equivocal/grey.

SC = SeraCare; IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking

# HIV-1/2 Mixed Titer AccuSet™ Performance Panel

0800-0331

DATA SHEET

## HIV Confirmatory and Rapid Antibody

Panel Member	Bio-Rad Genetic Systems™ HIV-1	Fujirebio Innogenetics INNO-LIA® HIV I/II	OraSure OraQuick® ADVANCE Rapid HIV-1/2 Antibody Test	Bio-Rad Multispot HIV-1/HIV-2 Rapid Test	
	Western Blot	Score		HIV-1	HIV-2
01	Indeterminate	HIV-1	Positive	Positive	Negative
02	Positive	HIV-1	Positive	Positive	Negative
03	Positive	HIV-1	Positive	Positive	Negative
04	Positive	HIV-1	Positive	Positive	Negative
05	Positive	HIV-1	Positive	Positive	Negative
06	Positive	HIV-1	Positive	Positive	Negative
07	Positive	HIV-1	Positive	Positive	Negative
08	Indeterminate	HIV-2	Positive	Negative	Positive
09	Indeterminate	HIV-2	Positive	Negative	Positive
10	Indeterminate	HIV-2	Positive	Negative	Positive
11	Indeterminate	HIV-2	Positive	Negative	Positive
12	Indeterminate	HIV-2	Positive	Negative	Positive
13	Indeterminate	HIV-2	Positive	Negative	Positive
14	Indeterminate	HIV-2	Positive	Negative	Positive
15	Negative	Negative	Negative	Negative	Negative
Test Date	16-Jan-15; 03-Feb-15	28-Jan-15	21-Jan-15	14-Jan-15	
Test Site	SC	RL	SC	SC	
Kit Part Code	32508	NA	1001-0079	25228	
Kit Lot No.	64008601	400453	0006643812	11132404	
Kit Exp. Date	02-Oct-15	31-Aug-15	30-Apr-17	30-Sep-15	
Kit Regulatory Status	IVD	CE	IVD	IVD	

SC = SeraCare; RL = Reference Lab; IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking

# HIV-1/2 Mixed Titer AccuSet™ Performance Panel

0800-0331

## DATA SHEET

### HIV-1 p24 Antigen and HIV Antigen/Antibody

Panel Member	bioMerieux VIDAS® p24 II (s/co) <sup>1,2</sup>	Perkin Elmer p24 HIV Antigen ELISA (s/co) <sup>1,2</sup>	Abbott ARCHITECT HIV Ag/Ab Combo (s/co) <sup>1,2</sup>	Alere Determine HIV-1/2 Ag/Ab Combo <sup>2</sup>	
				HIV-1/2 Ab	HIV-1 p24
01	<3.00	0.62	<b>22.00</b>	<b>Positive</b>	Negative
02	4.40*	<b>1.20</b>	<b>63.89</b>	<b>Positive</b>	Negative
03	<3.00	0.29	<b>122.60</b>	<b>Positive</b>	Negative
04	<3.00	0.34	<b>14.20</b>	<b>Positive</b>	Negative
05	<3.00	0.55	<b>60.65</b>	<b>Positive</b>	Negative
06	<3.00	0.20	<b>68.04</b>	<b>Positive</b>	Negative
07	<3.00	0.24	<b>314.38</b>	<b>Positive</b>	Negative
08	<3.00	0.25	<b>77.12</b>	<b>Positive</b>	Negative
09	<3.00	0.24	<b>194.43</b>	<b>Positive</b>	Negative
10	<3.00	0.26	<b>250.12</b>	<b>Positive</b>	Negative
11	<3.00	0.27	<b>250.81</b>	<b>Positive</b>	Negative
12	<3.00	0.31	<b>179.95</b>	<b>Positive</b>	Negative
13	<3.00	0.28	<b>155.84</b>	<b>Positive</b>	Negative
14	<3.00	0.30	<b>178.25</b>	<b>Positive</b>	Negative
15	<3.00	0.38	0.14	Negative	Negative
Test Date	28-Jan-15	19-Jan-15	09-Jan-15	03-Feb-15	
Test Site	RL	SC	SC	SC	
Kit Part Code	NA	NEK 050A	2P36	7D2648	
Kit Lot No.	1003315900	990-14361	44744LI00	150107	
Kit Exp. Date	24-Apr-15	01-May-15	26-Jul-15	16-Mar-16	
Kit Regulatory Status	CE	RUO	IVD	IVD	

<sup>1</sup>Results are reported as a signal to cut-off value (s/co); positive/reactive results are noted in bold red.

<sup>2</sup>Results are reported as the mean result of duplicate testing.

\*Result is equivocal/grey.

SC = SeraCare; RL = Reference Lab; NA = Not Available; IVD = In Vitro Diagnostic; RUO = Research Use Only

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

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

#### ASK ABOUT RELATED SERACARE PRODUCTS

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