

# AccuSet™ HIV-1 p24 Antigen Mixed Titer Performance Panel

0800-0420 / Batch 10440678

## OVERVIEW

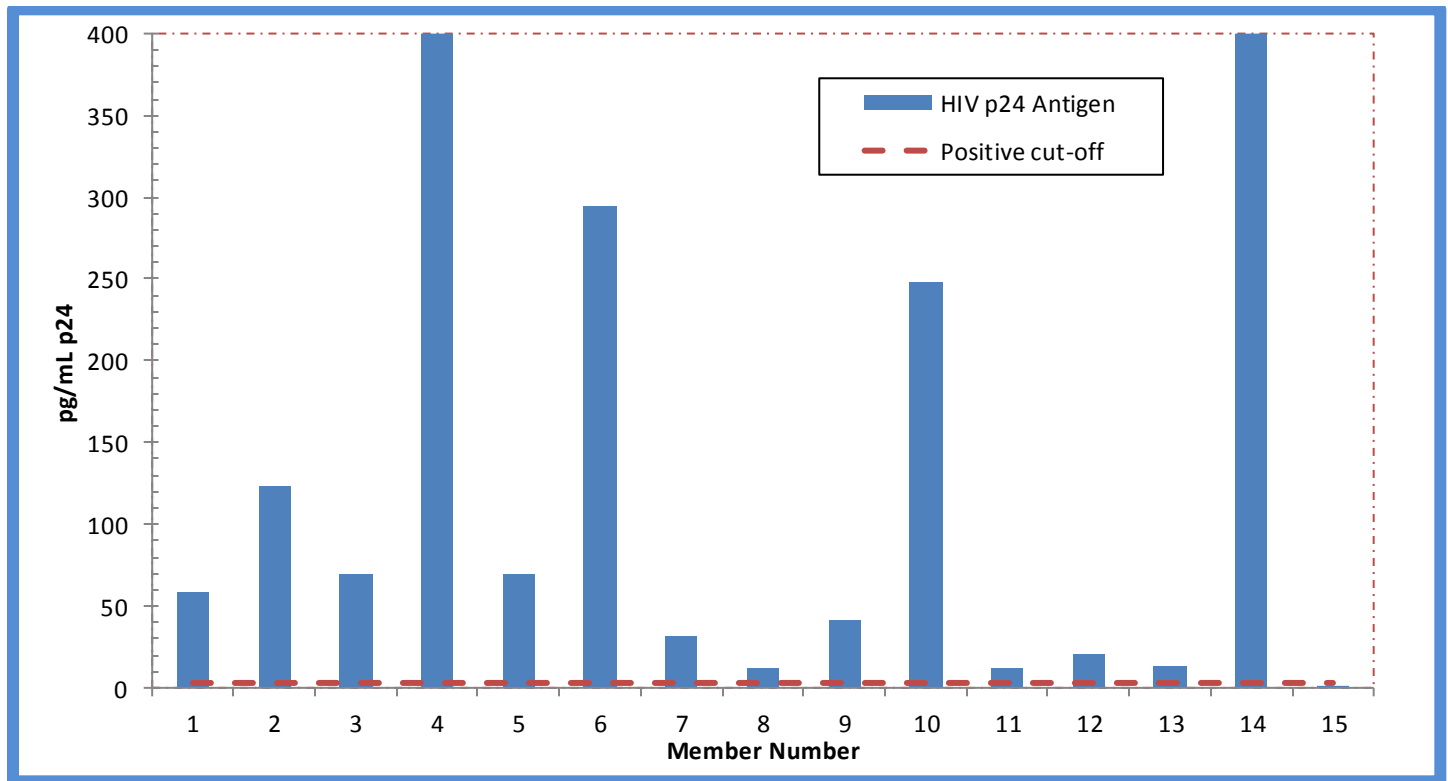
AccuSet™ HIV-1 p24 Antigen Mixed Titer Performance Panel 0800-0420 / Batch 10440678 is a 15-member panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.0 mL per vial). Panel members represent bleeds from multiple individuals positive for antibodies to HIV. Each sample represents 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 which approach the sensitivity limits for several anti-HIV test methods. 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 offered for informational purposes. SeraCare Life Sciences does not claim that others can duplicate test results exactly.

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

AccuSet™ HIV-1 p24 Antigen Mixed Titer Performance Panel



This graph demonstrates HIV-1 Ag reactivity amongst panel members utilizing test results from the BioMerieux VIDAS® HIV P24 II assay. Data are provided for informational purposes only.

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## Panel Member Information

Panel Member	SeraCare Batch #	SeraCare Donor ID #	Bleed Date
01	9223268	BD106008	23-Nov-2007
02	10000750	NA	NA
03	10000774	BD201417	30-Jan-1996
04	10266891	BD328452	14-May-2016
05	10266905	BD328458	29-Apr-2016
06	10418760	BD406213	27-Dec-2018
07	10418764	BD406215	18-Jan-2019
08	10430738	BD407037	06-May-2019
09	10430739	BD407037	01-May-2019
10	BM202306	NA	12-Nov-2002
11	BM216456	BD102986	12-Jun-2006
12	BM217817	BD105711	03-Oct-2007
13	9241479	BD110026	03-Jul-2009
14	10418762	BD406214	03-Dec-2018
15	9191377	BD111239	15-Nov-2004

NA = Not Available

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## HIV RNA and Antigen

Panel Member	Roche cobas® 6800HIV-1 (c/mL) <sup>1,4</sup>	Perkin ElmerHIV-1 p24 Ag(s/co) <sup>2,4</sup>	BioMerieux VIDAS® HIV P24 II (pg/mL) <sup>3,4</sup>
01	<b>147,500</b>	<b>7.0</b>	<b>58.3</b>
02	<b>55,950</b>	<b>33.5</b>	<b>123.1</b>
03	<b>563,000</b>	<b>14.2</b>	<b>69.5</b>
04	<b>10,000,000<sup>5</sup></b>	<b>72.7<sup>5</sup></b>	<b>400.0<sup>5</sup></b>
05	<b>981,000</b>	<b>13.3</b>	<b>69.3</b>
06	<b>4,410,000</b>	<b>54.3</b>	<b>295.0</b>
07	<b>1,555,000</b>	<b>6.7</b>	<b>31.8</b>
08	<b>273,000</b>	<b>2.8</b>	<b>11.9</b>
09	<b>823,000</b>	<b>10.7</b>	<b>42.0</b>
10	<b>72,800</b>	<b>44.5</b>	<b>248.7</b>
11	<b>204,500</b>	<b>6.1</b>	<b>12.1</b>
12	<b>165,000</b>	<b>6.6</b>	<b>21.1</b>
13	<b>243,000</b>	<b>6.0</b>	<b>13.0</b>
14	<b>10,000,000<sup>5</sup></b>	<b>70.8, 72.7<sup>6</sup></b>	<b>400.0<sup>5</sup></b>
15	TND	0.1	<3.0
Test Date	30-Sep-19	01-Oct-19	29-Oct-19
Test Site	RL	SC	RL
Kit Part Code	NA	NEK050A	NA
Kit Lot No.	NA	990-19352	1007479400
Kit Exp. Date	NA	01-Aug-20	04-May-20

<sup>1</sup>Results are reported as copies per milliliter (c/mL); positive/reactive results are noted in bold red.

<sup>2</sup>Results are reported as signal to cutoff (s/co); positive/reactive results are noted in bold red.

<sup>3</sup>Results are reported as picograms per milliliter; positive/reactive results are noted in bold red.

<sup>4</sup>Results are reported as the mean result of duplicate testing.

<sup>5</sup>Results for both replicates were off-scale.

<sup>6</sup>Result is off-scale.

SC = SeraCare; RL = Reference Lab; NA = Not Available; TND = Target Not Detected

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## HIV Antigen/Antibody

Panel Member	Abbott ARCHITECT HIV Ag/Ab Combo (s/co) <sup>1,2</sup>	Ortho VITROS® HIV Combo (s/co) <sup>1,2</sup>	Siemens ADVIA Centaur® HIV Ag/Ab Combo (Index) <sup>2,3</sup>	Roche Elecsys HIV combi PT (s/co) <sup>1,2</sup>	DiaSorin Liaison XL Murex HIV Ab/Ag (s/co) <sup>1,2</sup>
01	<b>1021.6</b>	<b>170.5</b>	<b>12.0<sup>4</sup></b>	<b>1802.0</b>	<b>7.9</b>
02	<b>51.5</b>	<b>92.2</b>	<b>12.0<sup>4</sup></b>	<b>69.5</b>	<b>11.5</b>
03	<b>50.3</b>	<b>33.4</b>	<b>12.0<sup>4</sup></b>	<b>150.6</b>	<b>5.5</b>
04	<b>310.3</b>	<b>325.5</b>	<b>12.0<sup>4</sup></b>	<b>254.8</b>	<b>146.0</b>
05	<b>23.6</b>	<b>22.4</b>	<b>12.0<sup>4</sup></b>	<b>57.6</b>	<b>7.1</b>
06	<b>55.5</b>	<b>46.5</b>	<b>12.0<sup>4</sup></b>	<b>114.3</b>	<b>31.4</b>
07	<b>35.7</b>	<b>30.8</b>	<b>12.0<sup>4</sup></b>	<b>143.2</b>	<b>3.6</b>
08	<b>20.4</b>	<b>14.8</b>	<b>6.7</b>	<b>119.8</b>	<b>0.9</b>
09	<b>27.1</b>	<b>15.2</b>	<b>12.0<sup>4</sup></b>	<b>48.0</b>	<b>2.0</b>
10	<b>44.6</b>	<b>76.0</b>	<b>12.0<sup>4</sup></b>	<b>16.3</b>	<b>18.9</b>
11	<b>32.8</b>	<b>23.1</b>	<b>12.0<sup>4</sup></b>	<b>13.3</b>	<b>2.7</b>
12	<b>6.8</b>	<b>9.1</b>	<b>3.8</b>	<b>2.9</b>	<b>2.4</b>
13	<b>6.0</b>	<b>8.1</b>	<b>3.9</b>	<b>3.0</b>	<b>2.7</b>
14	<b>156.4</b>	<b>139.5</b>	<b>12.0<sup>4</sup></b>	<b>257.6</b>	<b>91.2</b>
15	0.1	0.1	0.1	0.3	0.3
Test Date	01-Oct-19	01-Oct-19	01-Oct-19	14-Oct-19	11-Oct-19
Test Site	SC	RL	RL	RL	RL
Kit Part Code	2P36	NA	NA	NA	310260
Kit Lot No.	05207BE00	0090	210	NA	139040B
Kit Exp. Date	14-Mar-20	07-Apr-20	22-Feb-20	NA	08-Jul-20

<sup>1</sup>Results are reported as a signal to cutoff ratio (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; positive/reactive results are noted in bold red.

<sup>4</sup>Results for both replicates were off-scale.

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## HIV Antibody and Rapid Test

Panel Member	Bio-Rad GS HIV-1/HIV-2 Plus O (s/co) <sup>1,2</sup>	Avioq HIV-1 Microelisa (s/co) <sup>1,2</sup>	OraSure OraQuick® ADVANCE HIV- 1/2 Rapid Test
01	<b>13.7<sup>3</sup></b>	<b>9.3</b>	<b>POS</b>
02	<b>13.7<sup>3</sup></b>	<b>2.6</b>	<b>POS</b>
03	<b>13.7<sup>3</sup></b>	<b>4.7</b>	<b>POS</b>
04	<b>13.7<sup>3</sup></b>	<b>3.4</b>	<b>POS</b>
05	<b>13.7<sup>3</sup></b>	<b>6.4</b>	<b>POS</b>
06	<b>13.7<sup>3</sup></b>	<b>4.5</b>	<b>POS</b>
07	<b>13.7<sup>3</sup></b>	<b>7.9</b>	<b>POS</b>
08	<b>13.7<sup>3</sup></b>	<b>6.2</b>	<b>POS</b>
09	<b>13.7<sup>3</sup></b>	<b>3.7</b>	<b>POS</b>
10	0.2	0.2	NEG
11	<b>13.7<sup>3</sup></b>	<b>1.9</b>	NEG
12	0.2	0.2	NEG
13	0.2	0.2	NEG
14	<b>13.7<sup>3</sup></b>	<b>4.5</b>	<b>POS</b>
15	0.1	0.3	NEG
Test Date	01-Oct-19	01-Oct-19, 02-Oct-19	30-Sep19
Test Site	SC	SC	SC
Kit Part Code	32588	100384	1001.0079
Kit Lot No.	123PBB-05	18105H	0006672842
Kit Exp. Date	31-Jan-20	11-Jun-20	30-Nov-21

<sup>1</sup>Results are reported as a signal to cutoff ratio (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 for both replicates were off-scale.

POS = Positive; NEG = Negative; SC = SeraCare

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## Anti-HIV Confirmatory

### BIO-RAD GS HIV-1 Western Blot

Panel Member	Band Pattern	Result <sup>1</sup>
01	f24, 31, 41, 55, 65, 120, 160	<b>POS</b>
02	24, f55, 160	<b>POS</b>
03	18, 24, 160	<b>POS</b>
04	f24, 160	IND
05	24, f55, f65, 160	<b>POS</b>
06	24, f55, 160	<b>POS</b>
07	18, 24, 55, f65, 120, 160	<b>POS</b>
08	24, f55, 160	<b>POS</b>
09	24, f55, 160	<b>POS</b>
10	No Bands	NEG
11	f160	IND
12	No Bands	NEG
13	No Bands	NEG
14	18, 24, f55, 160	<b>POS</b>
15	No Bands	NEG
Test Date	02-Oct-2019	
Test Site	SC	
Kit Part Code	32508	
Kit Lot No.	64203868	
Kit Exp. Date	2-Nov-2019	

<sup>1</sup>Positive/reactive results are noted in bold red.  
f = faint, POS = Positive; IND = Indeterminate; NEG = Negative  
SC = SeraCare; NA = Not Available

The package insert for this panel 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.