

# AccuSet™ HIV-1 Mixed Titer Performance Panel

0800-0436 / Batch 10447000

## OVERVIEW

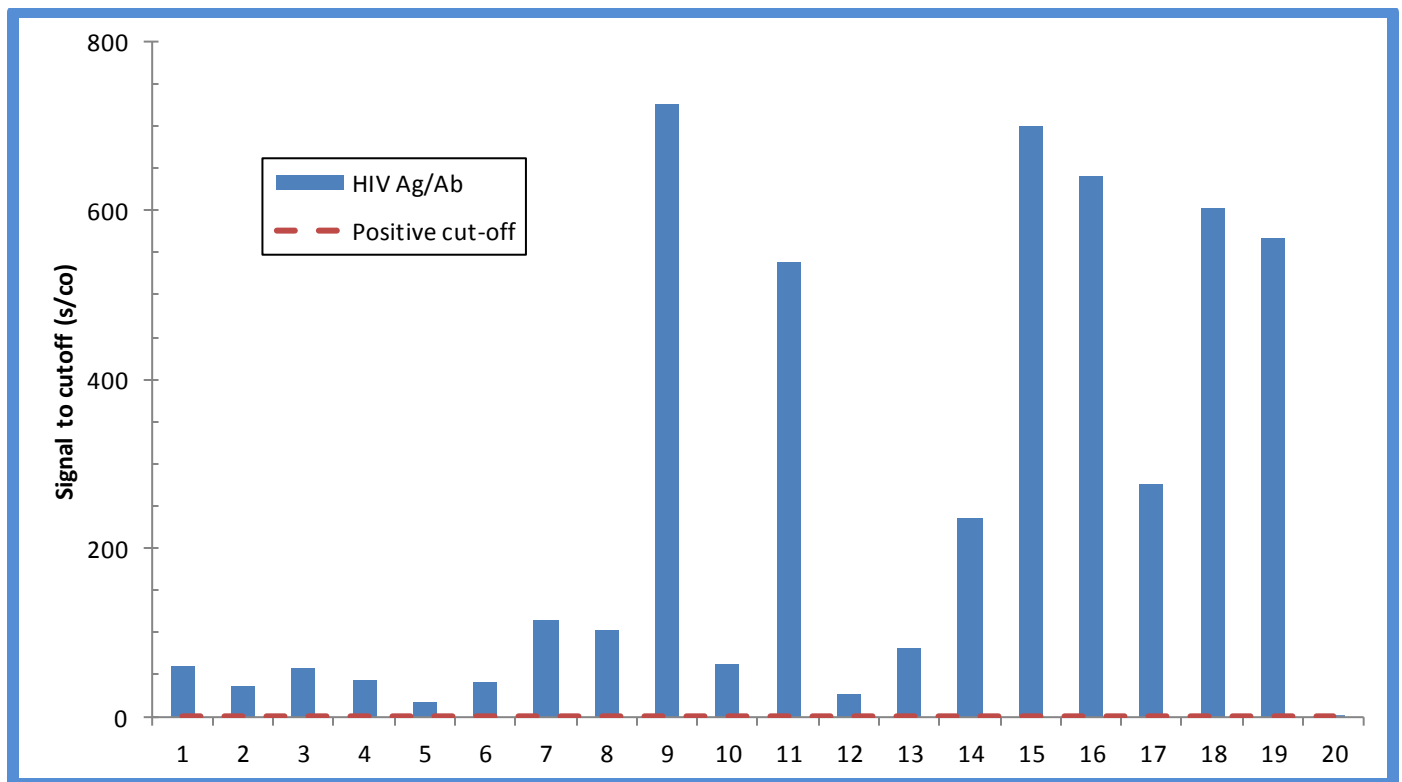
AccuSet™ HIV-1 Mixed Titer Performance Panel (0800-0436) is a 20-member panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.0 mL per vial). Panel members represent bleeds from multiple individuals positive for antibodies to HIV. Each sample represents a single collection event. 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. 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 Mixed Titer Performance Panel



This graph demonstrates the relative titer amongst panel members with the Abbott ARCHITECT HIV Antigen/Antibody Combo test method.

# AccuSet™ HIV-1 Mixed Titer Performance Panel

0800-0436 / Batch 10447000

## Panel Member Information

Panel Member	SeraCare Batch #	SeraCare Donor ID #	Bleed Date
01	9253902	BD111102	04-JUL-2000
02	10418766	BD406217	27-SEP-2018
03	10430531	BD407035	22-MAR-2019
04	10430534	BD407035	24-MAR-2019
05	10430738	BD407037	06-MAY-2019
06	10266924	BD328464	30-OCT-2015
07	BM217425	BD104207	22-MAR-2007
08	10418768	BD406218	29-NOV-2018
09	9117876	BD110620	NA
10	9226376	BD106191	23-JAN-2008
11	9226471	NA	22-FEB-2007
12	9251513	BD111003	05-JUL-2000
13	10266902	BD328456	29-OCT-2015
14	BM206402	BD102915	25-AUG-2006
15	BM206404	BD102916	30-AUG-2006
16	BM206410	BD102907	18-SEP-2006
17	9230844	BD106688	05-MAY-2008
18	BM217852	NA	NA
19	BM217853	NA	NA
20	9192330	NA	NA

NA = Not Available

# AccuSet™ HIV-1 Mixed Titer Performance Panel

0800-0436 / Batch 10447000

## HIV RNA and Antigen

Panel Member	Roche cobas® HIV-1 cobas® 6800 (cp/mL) <sup>1,3</sup>	Perkin Elmer HIV-1 p24 ELISA (s/co) <sup>2,3</sup>
01	<b>27,000</b>	<b>1.5</b>
02	<b>24,350</b>	0.2
03	<b>107,500</b>	0.98
04	<b>88,700</b>	0.8
05	<b>523,500</b>	<b>2.8</b>
06	<b>264,000</b>	0.7
07	<b>1,215</b>	0.2
08	<b>1,165</b>	0.1
09	<b>7,660</b>	<b>1.7</b>
10	<b>194</b>	0.1
11	<b>2,245</b>	0.4
12	<b>44, TND<sup>4</sup></b>	0.1
13	<b>10,700</b>	0.1
14	<b>406</b>	0.3
15	<b>4,510</b>	0.1
16	<b>737</b>	0.1
17	TND	0.1
18	TND	0.1
19	TND	0.1
20	TND	0.2
Test Date	09-DEC-2019	05-DEC-2019
Test Site	RL	SC
Kit Part Code	NA	NEK050A
Kit Lot No.	NA	990-19403
Kit Exp. Date	NA	01-AUG-2020

<sup>1</sup>Results are reported as copies per milliliter (cp/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 the mean result of duplicate testing, except where noted.

<sup>4</sup>Individual results are presented. The assay cut-off is 20 cp/mL.

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

# AccuSet™ HIV-1 Mixed Titer Performance Panel

0800-0436 / Batch 10447000

## HIV Antigen / Antibody

Panel Member	Abbott ARCHITECT HIV Ag/Ab Combo (s/co) <sup>1,3</sup>	Siemens ADVIA Centaur® HIV Ag/Ab Combo (Index) <sup>2,3</sup>	Ortho VITROS® HIV c (s/co) <sup>1,3</sup>	Roche Elecsys combi PT (s/co) <sup>1,3</sup>
01	<b>59.5</b>	<b>4.6</b>	<b>18.7</b>	<b>126.0</b>
02	<b>36.5</b>	<b>11.5</b>	<b>4.9</b>	<b>12.3</b>
03	<b>57.2</b>	<b>4.5</b>	<b>3.5</b>	<b>23.0</b>
04	<b>44.6</b>	<b>4.0</b>	<b>3.9</b>	<b>32.0</b>
05	<b>18.0</b>	<b>7.2</b>	<b>13.9</b>	<b>123.2</b>
06	<b>42.7</b>	<b>5.3</b>	<b>17.0</b>	<b>275.9</b>
07	<b>115.1</b>	<b>10.0</b>	<b>50.3</b>	<b>383.4</b>
08	<b>104.1</b>	<b>9.8</b>	<b>31.9</b>	<b>97.7</b>
09	<b>726.4</b>	<b>&gt;12.0<sup>4</sup></b>	<b>201.5</b>	<b>129.0</b>
10	<b>61.8</b>	<b>&gt;12.0<sup>4</sup></b>	<b>72.4</b>	<b>278.5</b>
11	<b>538.5</b>	<b>&gt;12.0<sup>4</sup></b>	<b>209.0</b>	<b>475.2</b>
12	<b>26.8</b>	<b>8.8</b>	<b>31.3</b>	<b>220.3</b>
13	<b>82.1</b>	<b>7.3</b>	<b>43.0</b>	<b>244.3</b>
14	<b>236.8</b>	<b>&gt;12.0<sup>4</sup></b>	<b>238.5</b>	<b>71.1</b>
15	<b>700.3</b>	<b>&gt;12.0<sup>4</sup></b>	<b>233.5</b>	<b>207.7</b>
16	<b>641.5</b>	<b>&gt;12.0<sup>4</sup></b>	<b>204.0</b>	<b>715.7</b>
17	<b>275.9</b>	<b>&gt;12.0<sup>4</sup></b>	<b>118.5</b>	<b>2843.0</b>
18	<b>602.1</b>	<b>&gt;12.0<sup>4</sup></b>	<b>180.5</b>	<b>1387.5</b>
19	<b>567.9</b>	<b>&gt;12.0<sup>4</sup></b>	<b>184.0</b>	<b>1261.0</b>
20	0.1	0.1	0.1	0.4
Test Date	05-DEC-2019	09-DEC-2019	08-DEC-2019, 14-DEC-2019, 15-DEC-2019; 18-DEC-2019	19-DEC-2019
Test Site	SC	RL	RL	RL
Kit Part Code	2P36	NA	NA	NA
Kit Lot No.	07190BE00	117223	0059;0140	NA
Kit Exp. Date	19-MAY-2020	12-JUN-2020	07-SEP-2020; 07-NOV-2020	NA

<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 an Index; positive/reactive results are noted in bold red.

<sup>3</sup>Results are reported as the mean result of duplicate testing.

<sup>4</sup>Result is off-scale.

NA = Not Available; SC = SeraCare; RL = Reference Lab

# AccuSet™ HIV-1 Mixed Titer Performance Panel

0800-0436 / Batch 10447000

## HIV Antibody

Panel Member	Bio-Rad Genetic Systems™ HIV-1/HIV-2 Plus O EIA (s/co) <sup>1,2,5</sup>	Avioq HIV-1 Microelisa (s/co) <sup>1,2,5</sup>	OraSure OraQuick® HIV Rapid Antibody Test <sup>5</sup>
01	<b>13.9<sup>3</sup></b>	<b>7.4</b>	<b>POS</b>
02	<b>13.9<sup>3</sup></b>	<b>6.1<sup>4</sup></b>	<b>POS</b>
03	<b>13.9<sup>3</sup></b>	<b>4.9<sup>4</sup></b>	<b>POS</b>
04	<b>13.9<sup>3</sup></b>	<b>6.5</b>	<b>POS</b>
05	<b>13.9<sup>3</sup></b>	<b>7.2</b>	<b>POS</b>
06	<b>13.9<sup>3</sup></b>	<b>8.2</b>	<b>POS</b>
07	<b>13.9<sup>3</sup></b>	<b>8.3</b>	<b>POS</b>
08	<b>13.9<sup>3</sup></b>	<b>7.4</b>	<b>POS</b>
09	<b>13.9<sup>3</sup></b>	<b>10.3</b>	<b>POS</b>
10	<b>13.9<sup>3</sup></b>	<b>9.1</b>	<b>POS</b>
11	<b>13.9<sup>3</sup></b>	<b>10.3</b>	<b>POS</b>
12	<b>13.9<sup>3</sup></b>	<b>8.4</b>	<b>POS</b>
13	<b>13.9<sup>3</sup></b>	<b>8.6</b>	<b>POS</b>
14	<b>13.9<sup>3</sup></b>	<b>10.5</b>	<b>POS</b>
15	<b>13.9<sup>3</sup></b>	<b>10.5</b>	<b>POS</b>
16	<b>13.9<sup>3</sup></b>	<b>10.6</b>	<b>POS</b>
17	<b>13.9<sup>3</sup></b>	<b>10.0</b>	<b>POS</b>
18	<b>13.9<sup>3</sup></b>	<b>10.2</b>	<b>POS</b>
19	<b>13.9<sup>3</sup></b>	<b>10.1</b>	<b>POS</b>
20	0.1	0.3	NEG
Test Date	05-DEC-2019	05-DEC-2019, 09-DEC-2019	05-DEC-2019
Test Site	SC	SC	SC
Kit Part Code	32588	100384	1001.0079
Kit Lot No.	148PBB-05	18105H	0006672847
Kit Exp. Date	31-MAR-2020	11-JUN-2020	30-NOV-2021

<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, except where noted.

<sup>3</sup>Result is off-scale.

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

<sup>5</sup>Positive/reactive results are noted in bold red.

SC = SeraCare; POS = Positive; NEG = Negative

# AccuSet™ HIV-1 Mixed Titer Performance Panel

0800-0436 / Batch 10447000

## Anti-HIV Confirmatory<sup>1</sup>

Panel Member	Bio-Rad GS HIV-1 Western Blot	Result	Innogenetics INNO-LIA™ HIV /II Score	Result
	Band Pattern		Band Pattern	
01	24, 55, 160	<b>HIV-1 POS</b>	f17, 24, 41, f120	<b>HIV-1 POS</b>
02	f18, 24, 55, 160	<b>HIV-1 POS</b>	17, 24, 41, 120	<b>HIV-1 POS</b>
03	f18, 24, 55, 160	<b>HIV-1 POS</b>	24, 41	<b>HIV-1 POS</b>
04	f18, 24, 55, 160	<b>HIV-1 POS</b>	24, 41	<b>HIV-1 POS</b>
05	f18, 24, 55, 160	<b>HIV-1 POS</b>	17, 24, 41	<b>HIV-1 POS</b>
06	18, 24, 55, 160	<b>HIV-1 POS</b>	17, 24, 41, 120	<b>HIV-1 POS</b>
07	f18, 24, f31, 55, f65, 160	<b>HIV-1 POS</b>	17, 24, 31, 41, 120	<b>HIV-1 POS</b>
08	f18, 24, 55, 160	<b>HIV-1 POS</b>	17, 24, 41	<b>HIV-1 POS</b>
09	f18, 24, 31, 41, 55, 65, 120, 160	<b>HIV-1 POS</b>	17, 24, 31, 41, 120	<b>HIV-1 POS</b>
10	f18, 24, 31, f41, 55, 65, 160	<b>HIV-1 POS</b>	17, 24, 31, 41, 120	<b>HIV-1 POS</b>
11	18, 24, 31, 41, 55, 65, 120, 160	<b>HIV-1 POS</b>	17, 24, 31, 41, 120	<b>HIV-1 POS</b>
12	f18, 24, 31, f41, 55, 160	<b>HIV-1 POS</b>	17, 24, 41, 120	<b>HIV-1 POS</b>
13	f18, 24, 31, f41, 55, f65, 160	<b>HIV-1 POS</b>	17, 24, 31, 41, 120	<b>HIV-1 POS</b>
14	18, 24, 31, 41, 55, 65, 120, 160	<b>HIV-1 POS</b>	17, 24, 31, 41, 120	<b>HIV-1 POS</b>
15	18, 24, 31, 41, 55, 65, 120, 160	<b>HIV-1 POS</b>	17, 24, 31, 41, 120	<b>HIV-1 POS</b>
16	18, 24, 31, 41, 55, 65, 120, 160	<b>HIV-1 POS</b>	17, 24, 31, 41, 120	<b>HIV-1 POS</b>
17	f18, 24, 41, f55, f65, 120, 160	<b>HIV-1 POS</b>	17, 24, 41, 120	<b>HIV-1 POS</b>
18	18, 24, 31, 41, 55, 65, 120, 160	<b>HIV-1 POS</b>	17, 24, 31, 41, 120	<b>HIV-1 POS</b>
19	18, 24, 31, 41, 55, 65, 120, 160	<b>HIV-1 POS</b>	17, 24, 31, 41, 120	<b>HIV-1 POS</b>
20	No Bands	NEG	No Bands	NEG
Test Date	17-DEC-2019		19-DEC-2019	
Test Site	SC		RL	
Kit Part Code	32508		NA	
Kit Lot No.	64250342		406155	
Kit Exp. Date	28-MAR-2020		30-JUN-2020	

<sup>1</sup>Positive/reactive results are noted in bold red.

f = faint; POS = Positive; NEG = Negative; SC = SeraCare; RL = Reference Lab; 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.