

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

0800-0580 / Batch #10662446

### OVERVIEW

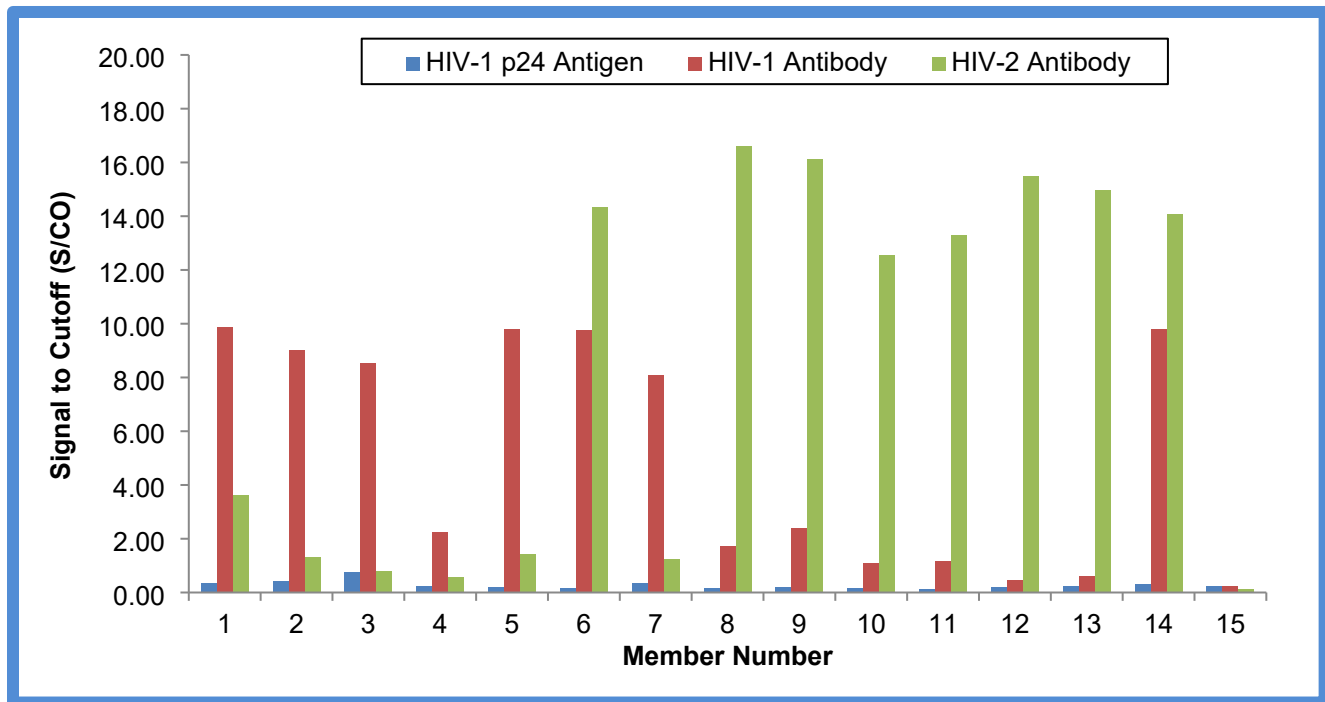
AccuSet™ HIV-1/2 Mixed Titer Performance Panel 0800-0580 / Batch #10662446 is a 15-member validation panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.0 mL per vial). Panel members represent bleeds from multiple individuals positive for HIV. Each sample represents a single 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. LGC 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; all were found negative for anti-HCV and HBsAg. This does not ensure the absence of these or other human pathogens.

AccuSet™ HIV-1/2 Mixed Titer Performance Panel



This graph demonstrates panel member reactivity to the Perkin Elmer HIV-1 p24 Antigen EIA (HIV-1 p24 Antigen), Avioq HIV-1 microelisa (HIV-1 Antibody), and the Bio-Rad GS HIV-2 EIA (HIV-2 Antibody) test methods. Values greater than 1.0 are positive/reactive.

AccuSet<sup>™</sup> HIV-1/2  
 Mixed Titer Performance Panel  
 0800-0580 / Batch #10662446

**Panel Member Information**

Panel Member	SeraCare Batch #	SeraCare Donor ID #	Bleed Date
01	9251702	BD111022	03-Mar-2000
02	9251703	BD111032	22-Jan-2002
03	10000787	NA	NA
04	10538049	BD459676	03-Jan-2020
05	9148147	BD110746	19-Nov-1987
06	9253079	NA	NA
07	9253899	BD111048	22-Jul-2000
08	10431584	BD409489	30-Jan-2019
09	10431587	BD409489	02-Apr-2019
10	10594654	BD110417	13-Feb-2019
11	10594655	BD110417	15-Feb-2019
12	10624540	BD406473	17-Apr-2011
13	10624547	BD406473	05-Aug-2012
14	10654826	BD513677	22-Aug-2017
15	10310079	BD349121	05-Jun-2017

NA = Not Available

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## HIV RNA and HIV Antigen Assays

Panel Member	Roche cobas® 6800/8800 HIV-1 RNA (copies/mL) <sup>1</sup>	Abbott Alinity m HIV-1 RNA (copies/mL) <sup>1</sup>	Perkin Elmer HIV-1 p24 ELISA (S/CO) <sup>1</sup>
01	<b>6910</b>	<b>6537</b>	0.37
02	<b>10020</b>	<b>7681</b>	0.44
03	<b>198</b> , TND*	TND, BLD*	0.75
04	<b>2700</b>	<b>1773</b>	0.23
05	<b>37</b> , TND*	TND	0.21
06	<b>111</b>	<b>51</b>	0.17
07	<b>3395</b>	<b>1968</b>	0.35
08	TND	TND	0.18
09	TND	TND	0.20
10	TND	TND	0.18
11	TND	TND	0.14
12	TND	TND	0.20
13	TND	TND	0.23
14	<b>19200</b>	<b>21450</b>	0.31
15	TND	TND	0.24
Test Date	26-May-2023	24-May-2023	25-May-2023
Test Site	RL	RL	LGC
Kit Part Code	NA	NA	NEK050A
Kit Lot No.	NA	381277	990-23151
Kit Exp. Date	NA	28-Apr-2024	01-Dec-2023

<sup>1</sup>Results are reported as the mean result of duplicate testing; positive/reactive results are noted in bold red.

\*Interpretation variability; individual replicates reported.

TND = Target Not Detected; BLD = Below Limit of Detection; LGC = LGC Clinical Diagnostics

RL = Reference Lab; NA = Not Available

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## HIV Antigen/Antibody Assays

Panel Member	Abbott ARCHITECT HIV Ag/Ab Combo (S/CO) <sup>1</sup>	Abbott Alinity s HIV Ag/Ab Combo (S/CO) <sup>1</sup>	Abbott Alinity i HIV Combo Next (S/CO) <sup>1</sup>	Roche cobas® Elecys HIV combi PT (COI) <sup>1</sup>	Ortho VITROS HIV Combo (S/CO) <sup>1</sup>
01	<b>1562.64</b>	<b>1314.13</b>	<b>627.80</b>	<b>324.85</b>	<b>174.00</b>
02	<b>1170.22</b>	<b>1056.09</b>	<b>444.92</b>	<b>695.40</b>	<b>244.50</b>
03	<b>322.35</b>	<b>263.04</b>	<b>76.83</b>	<b>1486.50</b>	<b>134.50</b>
04	<b>5.32</b>	<b>5.94</b>	<b>17.74</b>	<b>53.92</b>	<b>9.24</b>
05	<b>1329.03</b>	<b>1189.98</b>	<b>546.37</b>	<b>247.55</b>	<b>221.00</b>
06	<b>1397.44</b>	<b>1226.74</b>	<b>502.71</b>	<b>429.05</b>	<b>220.00</b>
07	<b>289.53</b>	<b>268.41</b>	<b>90.40</b>	<b>834.00</b>	<b>114.00</b>
08	<b>196.97</b>	<b>187.48</b>	<b>248.89</b>	<b>204.25</b>	<b>47.25</b>
09	<b>200.76</b>	<b>194.96</b>	<b>251.50</b>	<b>201.65</b>	<b>47.35</b>
10	<b>182.40</b>	<b>167.94</b>	<b>219.18</b>	<b>2045.50</b>	<b>60.60</b>
11	<b>183.41</b>	<b>166.48</b>	<b>222.89</b>	<b>1710.50</b>	<b>62.70</b>
12	<b>238.02</b>	<b>224.65</b>	<b>279.02</b>	<b>362.15</b>	<b>50.35</b>
13	<b>231.67</b>	<b>216.97</b>	<b>267.78</b>	<b>396.90</b>	<b>53.55</b>
14	<b>1216.83</b>	<b>1001.33</b>	<b>499.96</b>	<b>784.10</b>	<b>636.50</b>
15	0.29	0.24	0.21	<b>1.71</b>	0.20
Test Date	19-May-2023	23-May-2023	02-Dec-2025	22-June-2023	31-May-2023
Test Site	LGC	RL	RL	RL	RL
Kit Part Code	2P36	NA	6Q86	NA	NA
Kit Lot No.	48531BE00	49068BE00	81648FZ00	NA	560
Kit Exp. Date	11-Sep-2023	26-Dec-2023	02-Oct-2026	NA	27-Feb-2024

<sup>1</sup>Results are reported as the mean result of duplicate testing; positive/reactive results are noted in bold red.  
LGC = LGC Clinical Diagnostics; RL = Reference Lab; NA = Not Available

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

0800-0580 / Batch #10662446

## HIV Antigen/Antibody Assays

Panel Member	Siemens Advia Centaur® HIV Ag/Ab Combo (Index) <sup>1</sup>	Avioq HIV-1 Microelisa (S/CO) <sup>1</sup>	Bio-Rad GS HIV-2 EIA (S/CO) <sup>1</sup>	Alere Determine™ HIV-1/2 Ag/Ab Combo <sup>2</sup>	
				HIV Ag	HIV Ab
01	>12.00, >12.00*	<b>9.88</b>	<b>3.64</b>	NEG	<b>POS</b>
02	>12.00, >12.00*	<b>9.04</b>	<b>1.32</b>	NEG	<b>POS</b>
03	>12.00, >12.00*	<b>8.52</b>	0.80	NEG	<b>POS</b>
04	<b>5.23</b>	<b>2.24</b>	0.56	NEG	<b>POS</b>
05	>12.00, >12.00*	<b>9.82</b>	<b>1.43</b>	NEG	<b>POS</b>
06	>12.00, >12.00*	<b>9.77</b>	<b>14.34</b>	NEG	<b>POS</b>
07	<b>10.05</b>	<b>8.08</b>	<b>1.24</b>	NEG	<b>POS</b>
08	>12.00, >12.00*	<b>1.75</b>	<b>16.63</b>	NEG	<b>POS</b>
09	>12.00, >12.00*	<b>2.39</b>	<b>16.14</b>	NEG	<b>POS</b>
10	>12.00, >12.00*	<b>1.10</b>	<b>12.56</b>	NEG	<b>POS</b>
11	>12.00, >12.00*	<b>1.17</b>	<b>13.31</b>	NEG	<b>POS</b>
12	>12.00, >12.00*	0.47	<b>15.49</b>	NEG	<b>POS</b>
13	>12.00, >12.00*	0.60	<b>14.96</b>	NEG	<b>POS</b>
14	>12.00, >12.00*	<b>9.82</b>	<b>14.08</b>	NEG	<b>POS</b>
15	0.25	0.25	0.11	NEG	NEG
Test Date	24-May-2023	24-May-2023	23-May-2023	19-May-2023	
Test Site	RL	LGC	LGC	LGC	
Kit Part Code	NA	100384	32536	7D2648	
Kit Lot No.	94239334	22101H	183TY1-05	235354	
Kit Exp. Date	25-Nov-2023	22-Aug-2023	02-Aug-2023	28-Oct-2024	

<sup>1</sup>Results are reported as the mean result of duplicate testing; positive/reactive results are noted in bold red.

<sup>2</sup>Results are reported as singlicate testing; positive/reactive results are noted in bold red.

\*Individual results reported.

POS = Positive; NEG = Negative; RL = Reference Lab; LGC = LGC Clinical Diagnostics; NA = Not Available

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## HIV-1/2 Supplemental Assay

### Bio-Rad Geenius™ HIV-1/2 Supplemental Assay<sup>1</sup>

Panel Member	HIV-1 Result	HIV-2 Result	Positive Bands
01	<b>POS</b>	NEG	24, 31, 41, 160
02	<b>POS</b>	NEG	24, 31, 41, 160
03	<b>POS</b>	NEG	24, 31, 41, 160
04	<b>POS</b>	NEG	24, 41, 160
05	<b>POS</b>	NEG	24, 31, 41, 160
06	<b>POS</b>	NEG	24, 31, 41, 160
07	<b>POS</b>	NEG	24, 41, 160
08	GRAY	<b>POS</b>	31, 36, 41, 140
09	GRAY	<b>POS</b>	31, 36, 41, 140
10	NEG	<b>POS</b>	31, 36, 140
11	NEG	<b>POS</b>	31, 36, 140
12	NEG	<b>POS</b>	31, 36, 140
13	NEG	<b>POS</b>	31, 36, 140
14	<b>POS</b>	NEG	24, 31, 41, 140, 160
15	NEG	NEG	-
Test Date	01-June-2023		
Test Site	RL		
Kit Part Code	NA		
Kit Lot No.	2C0064		
Kit Exp. Date	23-Feb-2024		

<sup>1</sup>Results are reported as singlicate testing; positive/reactive results are noted in bold red.  
RL = Reference Lab; NA = Not Available; POS = Positive; NEG = Negative; GRAY = Indeterminate

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

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## HIV Confirmatory Assay

### INNOGENETICS® INNO-LIA™ HIV I/II Score<sup>1</sup>

#### Band Results

Panel Member	HIV-1/2 Antibody	sgp120	gp41	p31	p24	p17	sgp105	gp36
	Interpretation							
01	<b>POS</b>	2+	3+	2+	3+	3+	-	-
02	<b>POS</b>	2+	3+	2+	3+	2+	-	-
03	<b>POS</b>	2+	3+	2+	3+	2+	-	-
04	<b>POS</b>	1+	2+	-	2+	2+	-	-
05	<b>POS</b>	3+	3+	2+	2+	2+	-	-
06	<b>POS</b>	2+	3+	2+	3+	3+	-	-
07	<b>POS</b>	3+	3+	2+	2+	2+	-	-
08	<b>POS</b>	-	-	2+	2+	2+	3+	3+
09	<b>POS</b>	-	-	2+	2+	2+	3+	3+
10	<b>POS</b>	-	-	2+	1+	-	2+	2+
11	<b>POS</b>	-	-	2+	1+	-	2+	2+
12	<b>POS</b>	-	-	3+	1+	-	3+	2+
13	<b>POS</b>	-	-	2+	1+	-	3+	3+
14	<b>POS</b>	2+	3+	2+	3+	3+	1+	-
15	NEG	-	-	-	-	-	-	-
Test Date				12-Jun-2023				
Test Site				RL				
Kit Part Code				NA				
Kit Lot No.				410799				
Kit Exp. Date				30-Apr-2024				

<sup>1</sup>Results are reported as singlicate testing; positive/reactive results are noted in bold red.

POS = Positive; NEG = Negative

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 [CDx-Info@LGCGroup.com](mailto:CDx-Info@LGCGroup.com) or  
by phone at 508.244.6400.