

# HIV-1 Worldwide AccuSet™ Performance Panel

0800-0492 / Batch #10536933

## OVERVIEW

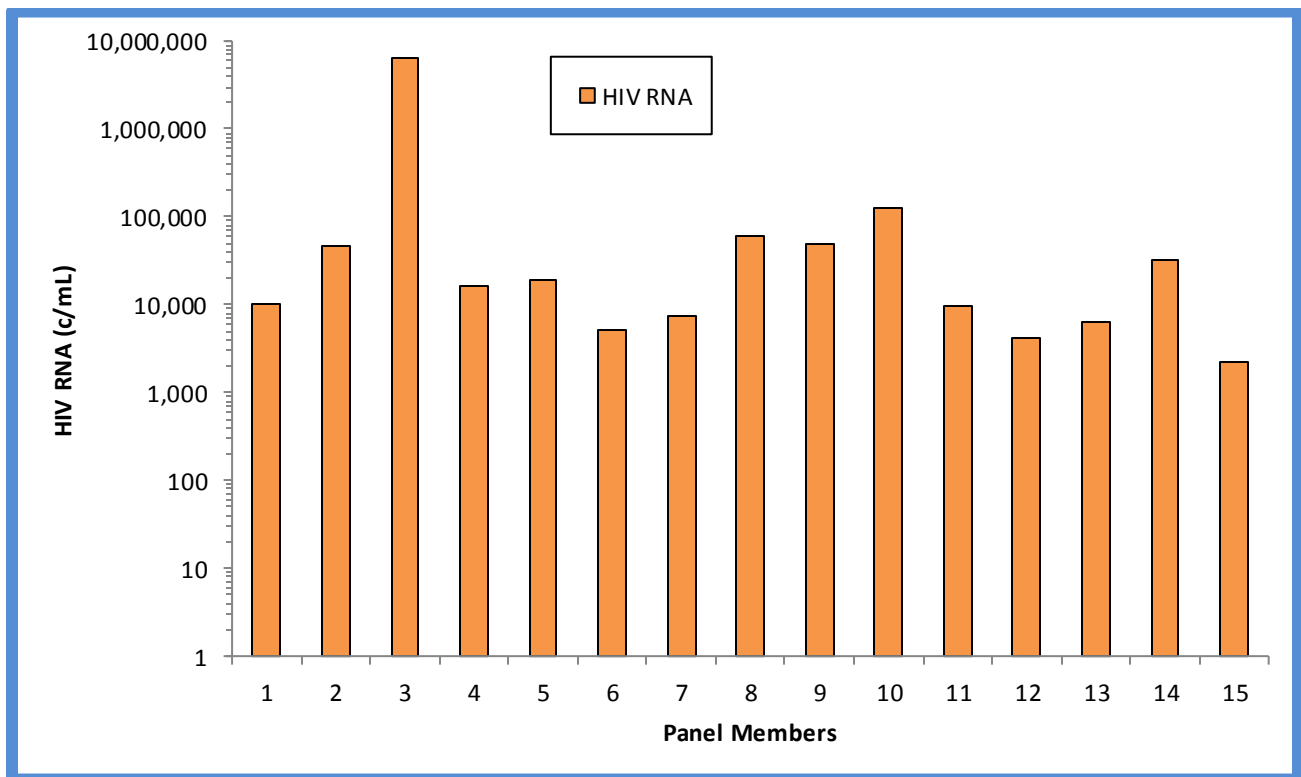
HIV-1 Worldwide AccuSet™ Performance Panel (0800-0492) is a 15-member validation panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.0 mL per vial). Panel members consist of 8 distinct varieties of HIV genotypes, including several circulating recombinant forms and mixed subtypes. Represented in this panel are genotypes B, BF, BG, CPX, C, CRF01\_AE, CRF02\_AG, and F1.

This panel consists of members tested for HIV-1 RNA, 4<sup>th</sup> generation screening tests for Ag/Ab, HIV p24 antigen, and anti-HIV-1, using a variety of commercially available test methods, including rapid and confirmatory test methods. Genotypes were determined using commercially available HIV RNA sequencing methods.

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 and found negative for HBsAg and anti-HCV. This does not ensure the absence of these or other human pathogens.

**HIV-1 Worldwide AccuSet™ Performance Panel**



*This graph demonstrates HIV antibody/antigen reactivity amongst panel members utilizing test results from the Roche COBAS® Ampliprep/COBAS® TaqMan® test method.*

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## Panel Member Information

Panel Member	SeraCare Batch #	Genotype <sup>1,2</sup>	Country of Origin
01	10440650	B	US
02	10440666	B	US
03	10440665	B	US
04	10461715	B	Honduras
05	10408558	BF	Spain
06	10408559	BG	Spain
07	10408554	C	Spain
08	10422492	C	France
09	10447377	C	India
10	10447375	C	India
11	10408555	CPX	Spain
12	10408552	CRF01_AE	Spain
13	9222221	CRF02_AG	NA
14	10430532	CRF02_AG	US
15	10408557	F1	Spain

<sup>1</sup>Genotypes were classified at regional reference labs using commercially available HIV RNA sequencing methods.

<sup>2</sup>If the genome contains sequences originating from more than two subtypes, the letters are replaced by "CPX", denoting "complex".

NA = Not Available

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## HIV RNA<sup>3</sup>

Panel Member	Roche COBAS® Ampliprep/COBAS® TaqMan® HIV-1 Test (c/mL) <sup>1,2</sup>
	01
02	<b>45731</b>
03	<b>6278531</b>
04	<b>16273</b>
05	<b>19367</b>
06	<b>5165</b>
07	<b>7497</b>
08	<b>61522</b>
09	<b>49694</b>
10	<b>128701</b>
11	<b>9699</b>
12	<b>4184</b>
13	<b>6483</b>
14	<b>32947</b>
15	<b>2178</b>
Test Date	14-19-Jan-2021
Test Site	RL
Kit Part Code	NA
Kit Lot No.	G17518
Kit Exp. Date	30-Nov-2021

<sup>1</sup>Results are reported as the mean result of duplicate testing.

<sup>2</sup>Results are reported as copies per mL (c/mL); positive/reactive results are noted in bold red.  
RL = Reference Lab; NA = Not Available.

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## HIV Antigen and Antibody<sup>3</sup>

Panel Member	Siemens ADVIA Centaur HIV 1/O/2 (INDEX) <sup>1,2</sup>	Abbott ARCHITECT HIV Ag/Ab Combo (s/co) <sup>1,3</sup>	Perkin Elmer Alliance HIV-1 p24 Antigen (s/co) <sup>1,3</sup>	Avioq HIV-1 Microelisa System (s/co) <sup>1,3</sup>
01	<b>8.43</b>	<b>66.0</b>	0.176	<b>6.14</b>
02	<b>&gt;12.00</b>	<b>10.1</b>	<b>1.737</b>	<b>3.87</b>
03	<b>&gt;12.00</b>	<b>11.8</b>	<b>8.448</b>	<b>4.41</b>
04	<b>&gt;12.00</b>	<b>1166.4</b>	<b>1.614</b>	<b>9.42</b>
05	<b>&gt;12.00</b>	<b>66.2</b>	0.193	<b>8.08</b>
06	<b>&gt;12.00</b>	<b>172.7</b>	0.202	<b>8.57</b>
07	<b>&gt;12.00</b>	<b>296.2</b>	0.184	<b>8.90</b>
08	<b>7.51</b>	<b>177.1</b>	0.237	<b>8.09</b>
09	<b>&gt;12.00</b>	<b>969.5</b>	0.123	<b>9.64</b>
10	<b>&gt;12.00</b>	<b>655.7</b>	0.140	<b>10.07</b>
11	<b>&gt;12.00</b>	<b>727.8</b>	0.229	<b>9.49</b>
12	<b>&gt;12.00</b>	<b>146.4</b>	<b>1.526</b>	<b>8.69</b>
13	<b>&gt;12.00</b>	<b>1084.7</b>	0.395	<b>9.81</b>
14	<b>5.38</b>	<b>39.1</b>	0.298	<b>7.64</b>
15	<b>11.85, &gt;12.00</b>	<b>49.7</b>	0.132	<b>7.24</b>
Test Date	15-Jan-2021	13-Jan-2021	19-Jan-2021	13-Jan-2021
Test Site	RL	SC	SC	SC
Kit Part Code	NA	2P36	NEK050A	100384
Kit Lot No.	117270	22232BE00	990-20321	20103H
Kit Exp. Date	23-May-2021	08-Jul-2021	07-Jul-2021	17-Nov-2021

<sup>1</sup>Results are reported as the mean result of duplicate testing.

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

<sup>3</sup>Results are reported as signal to cut-off (s/co); positive/reactive results are noted in bold red.

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

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## HIV Confirmatory and Rapid Testing

Panel Member	Bio-Rad Western Blot Band Pattern <sup>1</sup>	Bio-Rad Western Blot Result <sup>1</sup>
01	<b>24, 55, 160</b>	<b>POS</b>
02	<b>24, 55, 160</b>	<b>POS</b>
03	<b>24, f41, 55, f160</b>	IND
04	<b>18, 24, 31, 41, 55, 65, 120, 160</b>	<b>POS</b>
05	<b>f18, 24, 31, 41, 51, 55, 65, f120, 160</b>	<b>POS</b>
06	<b>24, 31, f41, 55, 65, f120, 160</b>	<b>POS</b>
07	<b>24, 31, 41, 51, 55, 65, f120, 160</b>	<b>POS</b>
08	<b>24, 31, f41, 55, f65, f120, 160</b>	<b>POS</b>
09	<b>18, 24, 31, 41, 51, 55, 65, 120, 160</b>	<b>POS</b>
10	<b>18, 24, 31, 41, 51, 55, 65, 120, 160</b>	<b>POS</b>
11	<b>f18, 24, 31, 41, 51, 55, 65, 120, 160</b>	<b>POS</b>
12	<b>f18, 31, 55, 65, f120, 160</b>	IND
13	<b>f18, 24, 31, 41, 51, 55, 65, 120, 160</b>	<b>POS</b>
14	<b>24, 55, 65, 160</b>	<b>POS</b>
15	<b>24, f41, 55, 160</b>	<b>POS</b>
Test Date	18-Jan-2021	
Test Site	SC	
Kit Part Code	32508	
Kit Lot No.	64351891	
Kit Exp. Date	18-Jun-2021	

<sup>1</sup>Results are reported as the result of singlicate testing, and positive/reactive results are noted in bold red.  
f = Faint band; POS = Positive result; IND = Indeterminate result  
SC = SeraCare Life Sciences;

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.