

AccuSet™ HIV-1 Worldwide Performance Panel

0800-0492 / Batch #10536933

OVERVIEW

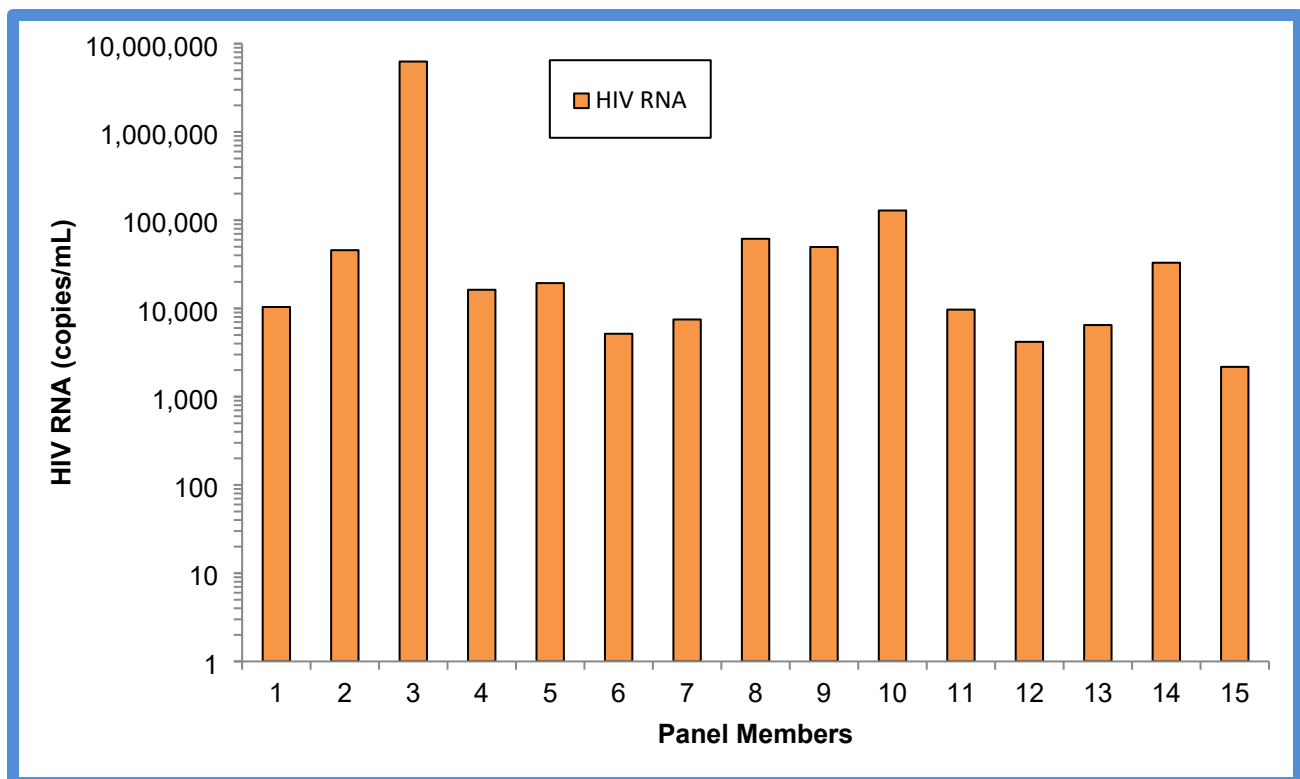
HIV-1 Worldwide AccuSet™ Performance Panel (0800-0492) / Batch #10536933 is a 15-member validation panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.0 mL per vial). Panel members consist of 8 distinct varieties of HIV genotypes, including several circulating recombinant forms 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, 4th 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. LGC 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 ^{1,2}	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

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

²If 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 and HIV Antigen Assays¹

Panel Member	Roche COBAS® Ampliprep/COBAS® TaqMan® HIV-1 Test (copies/mL)	Perkin Elmer Alliance HIV-1 p24 Antigen (s/co)
	01	10384
02	45731	1.737
03	6278531	8.448
04	16273	1.614
05	19367	0.193
06	5165	0.202
07	7497	0.184
08	61522	0.237
09	49694	0.123
10	128701	0.140
11	9699	0.229
12	4184	1.526
13	6483	0.395
14	32947	0.298
15	2178	0.132
Test Date	14-19-Jan-2021	19-Jan-2021
Test Site	RL	LGC
Kit Part Code	NA	NEK050A
Kit Lot No.	G17518	990-20321
Kit Exp. Date	30-Nov-2021	07-Jul-2021

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

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HIV Antigen/Antibody and HIV Antibody Assays¹

Panel Member	Siemens ADVIA Centaur HIV 1/O/2 (INDEX)	Abbott ARCHITECT HIV Ag/Ab Combo (s/co)	Abbott Alinity i HIV Combo Next (s/co)	Avioq HIV-1 Microelisa System
01	8.43	66.0	33.18	6.14
02	>12.00	10.1	16.83	3.87
03	>12.00	11.8	18.74	4.41
04	>12.00	1166.4	522.62	9.42
05	>12.00	66.2	48.64	8.08
06	>12.00	172.7	69.54	8.57
07	>12.00	296.2	101.49	8.90
08	7.51	177.1	61.56	8.09
09	>12.00	969.5	420.12	9.64
10	>12.00	655.7	333.54	10.07
11	>12.00	727.8	326.89	9.49
12	>12.00	146.4	55.19	8.69
13	>12.00	1084.7	428.52	9.81
14	5.38	39.1	30.52	7.64
15	11.85, >12.00	49.7	38.69	7.24
Test Date	15-Jan-2021	13-Jan-2021	02-Dec-2025	13-Jan-2021
Test Site	RL	LGC	RL	LGC
Kit Part Code	NA	2P36	6Q86	100384
Kit Lot No.	117270	22232BE00	81648FZ00	20103H
Kit Exp. Date	23-May-2021	08-Jul-2021	02-Oct-2026	17-Nov-2021

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

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HIV Confirmatory Assay¹

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

¹Results 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

LGC = LGC SeraCare

The package insert for this panel can be found at www.seracare.com.

A printed copy of the package insert or data sheet may be requested by email at info@seracare.com or by phone at 508.244.6400.