

AccuSet™ HIV-1 p24 Antigen Mixed Titer Performance Panel

0800-0522 / Batch #10678323

OVERVIEW

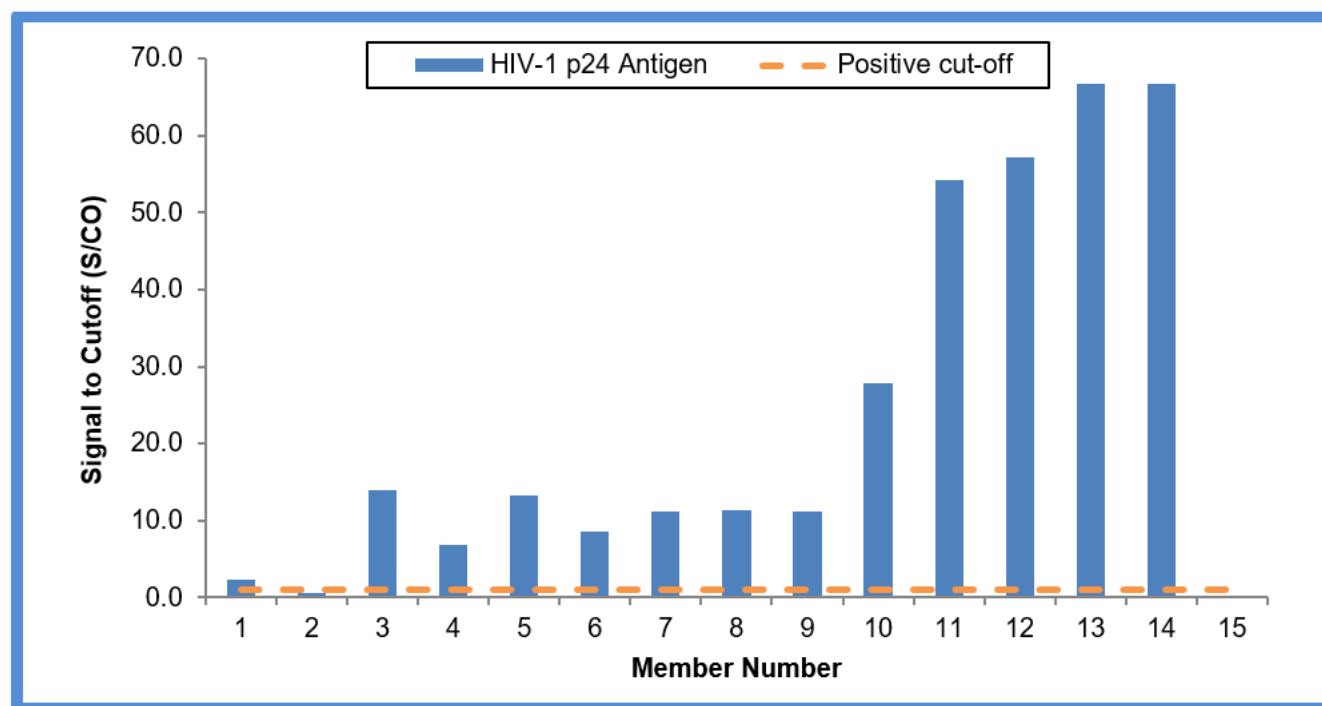
AccuSet™ HIV-1 p24 Antigen Mixed Titer Performance Panel 0800-0522 / Batch #10678323 is a 15-member validation panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.0 mL per vial). Panel members represent bleeds from multiple individuals positive for HIV-1 p24 antigen. Each sample 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 HIV-1 p24 antigen 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.

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This graph demonstrates panel member reactivity to the Perkin Elmer HIV-1 p24 Antigen EIA (HIV-1 p24 Antigen) test method.

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Panel Member Information

Panel Member	SeraCare Batch #	SeraCare Donor ID #	Bleed Date
01	10430525	BD407032	21-Mar-2019
02	BM202281	NA	25-Jul-2002
03	10481823	BD428660	07-Jan-2020
04	10430738	BD407037	06-May-2019
05	9241479	BD110026	03-Jul-2009
06	10418764	BD406215	18-Jan-2019
07	BM206240	BD102670	24-May-2006
08	10440665	BD411043	31-May-2019
09	10430739	BD407037	01-May-2019
10	10440664	BD411043	28-May-2019
11	10266892	BD328452	18-May-2016
12	10418763	BD406214	05-Dec-2018
13	10418760	BD406213	27-Dec-2018
14	10000722	NA	08-Oct-1998
15	10250896	BD319841	22-Jul-2015

NA = Not Available

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HIV RNA and HIV Antigen Assays¹

Panel Member	Roche cobas® 6800/8800 HIV-1 RNA (copies/mL)	Perkin Elmer HIV-1 p24 ELISA (S/CO)
01	1.11 x 10⁵	2.32
02	7.06 x 10²	0.60
03	4.91 x 10⁵	13.93
04	5.98 x 10⁵	6.84
05	2.16 x 10⁵	13.33
06	1.18 x 10⁶	8.63
07	2.73 x 10⁴	11.23
08	2.64 x 10⁶	11.39
09	6.10 x 10⁵	11.25
10	2.74 x 10⁶	27.82
11	4.15 x 10⁶	54.28
12	5.46 x 10⁶	57.14
13	4.40 x 10⁶	>66.67, 63.27*
14	2.84 x 10⁵	>66.67
15	TND	0.13
Test Date	10-Aug-2023	04-Aug-2023
Test Site	RL	LGC
Kit Part Code	NA	NEK050A
Kit Lot No.	NA	990-23261
Kit Exp. Date	NA	01-May-2024

¹Results 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; RL = Reference Lab; LGC = LGC Clinical Diagnostics; NA = Not Available

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HIV Antigen/Antibody Assays¹

Panel Member	Abbott ARCHITECT HIV Ag/Ab Combo (S/CO)	Abbott Alinity s HIV Ag/Ab Combo (S/CO)	Roche cobas® Elecsys HIV combi PT (COI)	Avioq HIV-1 Microelisa (S/CO)
01	52.47	47.58	42.18	3.54
02	0.37	0.35	0.50	0.24
03	32.70	40.93	86.82	4.35
04	36.75	37.77	106.30	5.85
05	6.70	7.25	3.98	0.22
06	46.75	46.70	120.15	7.31
07	44.88	41.98	24.75	1.91
08	10.87	11.46	52.89	2.91
09	32.14	30.61	29.83	2.33
10	22.56	20.67	22.55	1.74
11	266.83	237.90	158.15	3.82
12	81.95	78.82	185.55	4.21
13	66.92	64.65	96.31	3.80
14	97.64	91.38	43.31	1.04
15	0.11	0.09	0.22	0.25
Test Date	02-Aug-2023	03-Aug-2023	21-Aug-2023	02-Aug-2023
Test Site	LGC	RL	RL	LGC
Kit Part Code	2P36	NA	NA	100384
Kit Lot No.	50176BE00	51089BE00	NA	23101H
Kit Exp. Date	28-Oct-2023	07-Apr-2024	NA	04-Jul-2024

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HIV Antigen/Antibody Rapid Test¹

Alere Determine™ HIV-1/2 Ag/Ab Combo		
Panel Member	HIV Ag	HIV Ab
01	NEG	POS
02	NEG	NEG
03	NEG	POS
04	NEG	POS
05	NEG	NEG
06	NEG	POS
07	NEG	POS
08	NEG	POS
09	NEG	POS
10	NEG	POS
11	NEG	POS
12	NEG	POS
13	NEG	POS
14	POS	POS
15	NEG	NEG
Test Date		01-Aug-2023
Test Site		LGC
Kit Part Code		7D2648
Kit Lot No.		237258
Kit Exp. Date		28-Nov-2024

¹Results are reported as singlicate testing; positive/reactive results are noted in bold red.
POS = Positive; NEG = Negative; LGC = LGC Clinical Diagnostics

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HIV Confirmatory Assay¹

Bio-Rad Genetic Systems™ HIV-1 Western Blot

Panel Member	Band Pattern	HIV-1 Interpretation
01	24,55f, 160	POS
02	No Bands	NEG
03	24, 31f, 55, 160	POS
04	18f, 24, 55, 160	POS
05	No Bands	NEG
06	18, 24, 31f, 41f, 55, 65, 120, 160	POS
07	18f, 24f, 160f	IND
08	18f, 24, 31, 41f, 55, 160f	IND
09	18f, 24, 55f, 160f	IND
10	18f, 24, 31f, 41f, 55, 160f	IND
11	24, 31f, 55f, 160	POS
12	18, 24, 41f, 55, 160	POS
13	24, 55, 160	POS
14	31f, 160f	IND
15	41f	IND
Test Date	14-Sep-2023	
Test Site	LGC	
Kit Part Code	32508	
Kit Lot No.	64527588	
Kit Exp. Date	22-May-2024	

¹Results are reported as singlicate testing.

f=faint band; POS = Positive; NEG = Negative; IND = Indeterminate; LGC = LGC Clinical Diagnostics

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 CDx-Info@LGCGroup.com or by phone at 508.244.6400.