

AccuSet™ HIV-1/2 Mixed Titer Performance Panel

0800-0580 / Batch #10662446

OVERVIEW

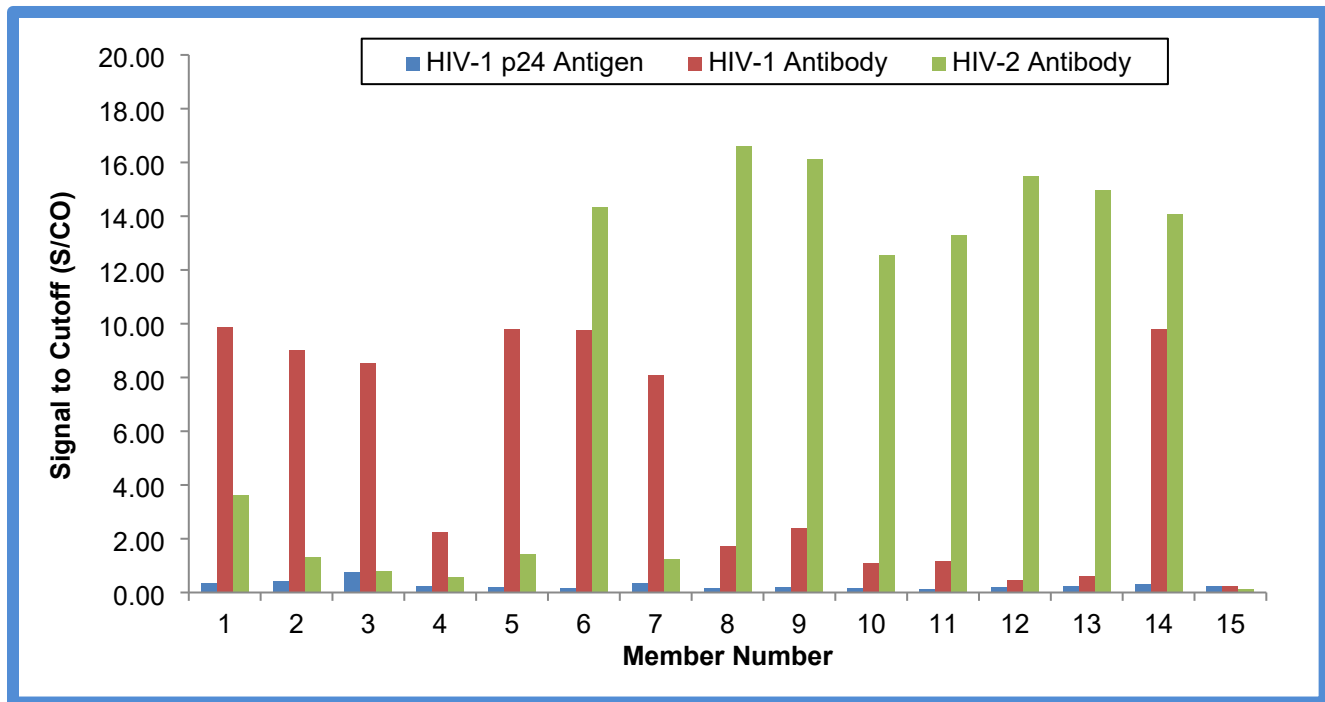
AccuSet™ HIV-1/2 Mixed Titer Performance Panel 0800-0580 / Batch #10662446 is a 15-member validation panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.0 mL per vial). Panel members represent bleeds from multiple individuals positive for HIV. Each sample represents a single 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[™] 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) ¹	Abbott Alinity m HIV-1 RNA (copies/mL) ¹	Perkin Elmer HIV-1 p24 ELISA (S/CO) ¹
01	6910	6537	0.37
02	10020	7681	0.44
03	198 , TND*	TND, BLD*	0.75
04	2700	1773	0.23
05	37 , TND*	TND	0.21
06	111	51	0.17
07	3395	1968	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	19200	21450	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

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; 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) ¹	Abbott Alinity s HIV Ag/Ab Combo (S/CO) ¹	Roche cobas® Elecsys HIV combi PT (COI) ¹	Ortho VITROS HIV Combo (S/CO) ¹
01	1562.64	1314.13	324.85	174.00
02	1170.22	1056.09	695.40	244.50
03	322.35	263.04	1486.50	134.50
04	5.32	5.94	53.92	9.24
05	1329.03	1189.98	247.55	221.00
06	1397.44	1226.74	429.05	220.00
07	289.53	268.41	834.00	114.00
08	196.97	187.48	204.25	47.25
09	200.76	194.96	201.65	47.35
10	182.40	167.94	2045.50	60.60
11	183.41	166.48	1710.50	62.70
12	238.02	224.65	362.15	50.35
13	231.67	216.97	396.90	53.55
14	1216.83	1001.33	784.10	636.50
15	0.29	0.24	1.71	0.20
Test Date	19-May-2023	23-May-2023	22-June-2023	31-May-2023
Test Site	LGC	RL	RL	RL
Kit Part Code	2P36	NA	NA	NA
Kit Lot No.	48531BE00	49068BE00	NA	560
Kit Exp. Date	11-Sep-2023	26-Dec-2023	NA	27-Feb-2024

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HIV Antigen/Antibody Assays

Panel Member	Siemens	Avioq	Bio-Rad GS	Alere Determine™	
	Advia Centaur® HIV Ag/Ab Combo (Index) ¹			HIV-1 Microelisa (S/CO) ¹	HIV-2 EIA (S/CO) ¹
				HIV Ag	HIV Ab
01	>12.00, >12.00*	9.88	3.64	NEG	POS
02	>12.00, >12.00*	9.04	1.32	NEG	POS
03	>12.00, >12.00*	8.52	0.80	NEG	POS
04	5.23	2.24	0.56	NEG	POS
05	>12.00, >12.00*	9.82	1.43	NEG	POS
06	>12.00, >12.00*	9.77	14.34	NEG	POS
07	10.05	8.08	1.24	NEG	POS
08	>12.00, >12.00*	1.75	16.63	NEG	POS
09	>12.00, >12.00*	2.39	16.14	NEG	POS
10	>12.00, >12.00*	1.10	12.56	NEG	POS
11	>12.00, >12.00*	1.17	13.31	NEG	POS
12	>12.00, >12.00*	0.47	15.49	NEG	POS
13	>12.00, >12.00*	0.60	14.96	NEG	POS
14	>12.00, >12.00*	9.82	14.08	NEG	POS
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	

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

²Results 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 Assay¹

Panel Member	HIV-1 Result	HIV-2 Result	Positive Bands
01	POS	NEG	24, 31, 41, 160
02	POS	NEG	24, 31, 41, 160
03	POS	NEG	24, 31, 41, 160
04	POS	NEG	24, 41, 160
05	POS	NEG	24, 31, 41, 160
06	POS	NEG	24, 31, 41, 160
07	POS	NEG	24, 41, 160
08	GRAY	POS	31, 36, 41, 140
09	GRAY	POS	31, 36, 41, 140
10	NEG	POS	31, 36, 140
11	NEG	POS	31, 36, 140
12	NEG	POS	31, 36, 140
13	NEG	POS	31, 36, 140
14	POS	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		

¹Results 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

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HIV Confirmatory Assay

INNOGENETICS® INNO-LIA™ HIV I/II Score¹

Band Results

Panel Member	HIV-1/2 Antibody	sgp120	gp41	p31	p24	p17	sgp105	gp36
	Interpretation							
01	POS	2+	3+	2+	3+	3+	-	-
02	POS	2+	3+	2+	3+	2+	-	-
03	POS	2+	3+	2+	3+	2+	-	-
04	POS	1+	2+	-	2+	2+	-	-
05	POS	3+	3+	2+	2+	2+	-	-
06	POS	2+	3+	2+	3+	3+	-	-
07	POS	3+	3+	2+	2+	2+	-	-
08	POS	-	-	2+	2+	2+	3+	3+
09	POS	-	-	2+	2+	2+	3+	3+
10	POS	-	-	2+	1+	-	2+	2+
11	POS	-	-	2+	1+	-	2+	2+
12	POS	-	-	3+	1+	-	3+	2+
13	POS	-	-	2+	1+	-	3+	3+
14	POS	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				

¹Results 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.

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.