AccuSet™ HIV-1/2
Mixed Titer Performance Panel
0800-0664 / Batch #10819618

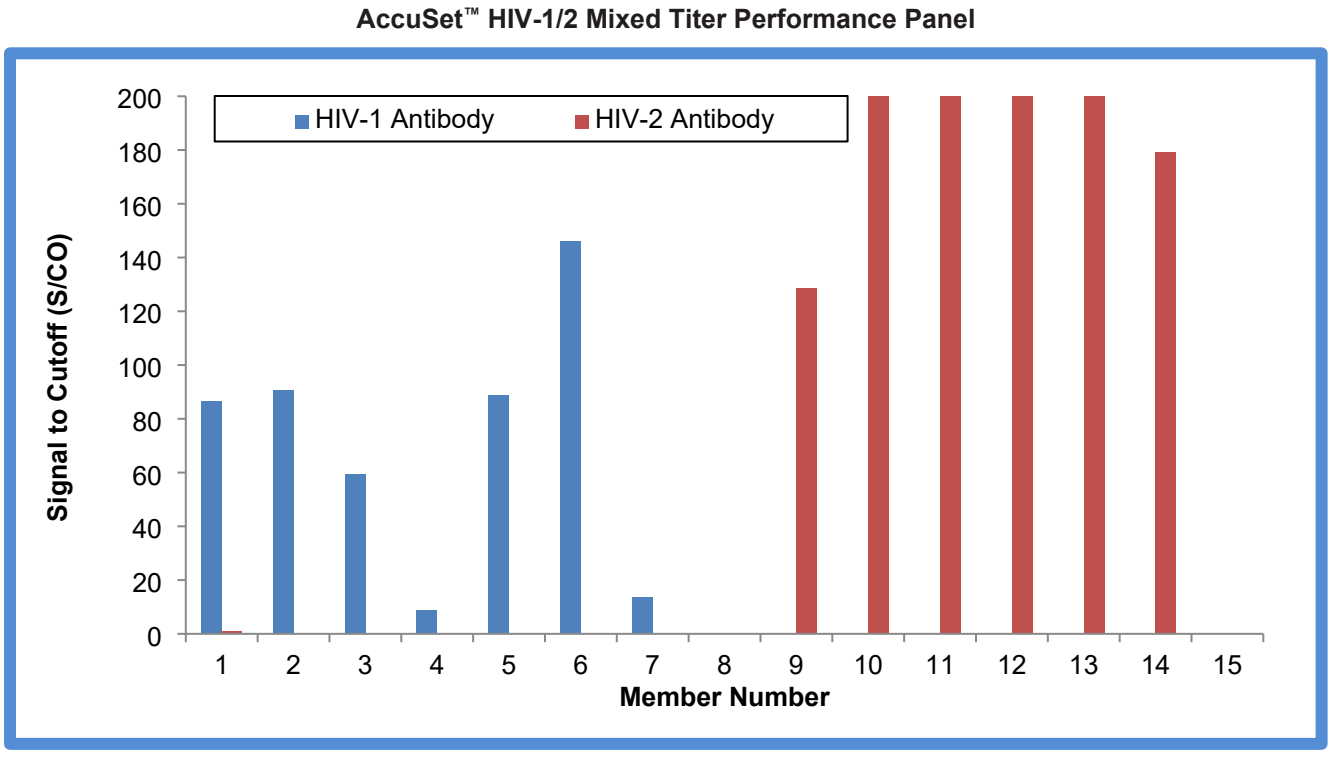
OVERVIEW

AccuSet™ HIV-1/2 Mixed Titer Performance Panel 0800-0664 / Batch #10819618 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 for HIV-1 and HIV-2. 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.



This graph demonstrates panel member reactivity to the Bio-Rad BioPlex® 2200 System HIV-1 Antibody and HIV-2 antibody test methods. Values greater or equal to 1.0 are positive/reactive.

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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	10496667	BD436230	08-Nov-2019
04	10538049	BD459676	03-Jan-2020
05	10242376	BD316775	14-Sep-2016
06	9253079	NA	NA
07	10497506	BD436958	23-Dec-2019
08	10671138	BD406473	10-Mar-2013
09	10671140	BD519646	07-Jun-2022
10	10682062	BD524993	07-Jul-2013
11	10682126	BD519646	12-Apr-2023
12	10802044	BD568121	19-Apr-2025
13	10806950	BD524993	11-Jan-2015
14	10809145	BD570652	22-Sep-2025
15	10360918	BD345631	10-Aug-2017

NA = Not Available

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HIV RNA and HIV Antigen Assays[1]

Panel Member	Roche cobas® 6800/8800 HIV-1 RNA (copies/mL)	Revvity HIV-1 p24 ELISA (S/CO)
01	**8.51E+03**	0.37
02	**7.37E+03**	0.67
03	**6.74E+02**	0.37
04	**2.65E+03**	0.34
05	**2.01E+04**	0.35
06	**2.00E+02**	0.40
07	**8.23E+03**	0.58
08	TND	0.35
09	TND	0.31
10	TND	0.40
11	TND	0.33
12	TND	0.36
13	TND	0.33
14	TND	0.44
15	TND	0.40
Test Date	20-Aug-2026 21-Aug-2026	26-Aug-2026
Test Site	RL	LGC
Kit Part Code	NA	NEK050A
Kit Lot No.	NA	990-25055
Kit Exp. Date	NA	01-Oct-2026

[1]Results are reported as the mean result of duplicate testing; positive/reactive results are noted in bold red.
TND = Target Not Detected; LGC = LGC Clinical Diagnostics; RL = Reference Lab; NA = Not Available

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HIV Antigen/Antibody Assays[1]

Panel Member	Abbott ARCHITECT HIV Ag/Ab Combo (S/CO)	Abbott Alinity s HIV Ag/Ab Combo (S/CO)	Abbott Alinity i HIV Combo Next (S/CO)	Siemens ADVIA Centaur® HIV Ag/Ab Combo (Index)
01	**1152.77**	**1027.86**	**658.12**	**>12.00**
02	**883.85**	**826.88**	**466.97**	**>12.00**
03	**67.24**	**64.28**	**50.84**	**5.53**
04	**5.44**	**6.44**	**18.50**	**4.67**
05	**75.93**	**76.20**	**47.32**	**9.90**
06	**1092.30**	**984.79**	**555.09**	**>12.00**
07	**17.68**	**17.87**	**33.92**	**4.53**
08	**194.45**	**273.61**	**268.45**	**>12.00**
09	**63.06**	**79.36**	**105.93**	**>12.00**
10	**190.70**	**256.63**	**271.13**	**>12.00**
11	**125.59**	**164.93**	**221.01**	**>12.00**
12	**169.17**	**205.13**	**227.60**	**>12.00**
13	**202.22**	**272.02**	**275.78**	**>12.00**
14	**98.07**	**118.39**	**113.65**	**>12.00**
15	0.20	0.08	0.11	<0.05
Test Date	18-Aug-2026	19-Aug-2026	11-Sep-2026	20-Aug-2026
Test Site	LGC	RL	RL	RL
Kit Part Code	2P36	NA	06Q86-22	NA
Kit Lot No.	88096BE00	83027MM00	81306FZ00	88624832
Kit Exp. Date	20-Feb-2027	27-Dec-2026	02-Oct-2026	18-Jan-2027

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HIV Antigen / HIV Antibody Assays[1]

		Bio-Rad BioPlex® 2200 System HIV Ag/Ab			
Panel Member	Avioq HIV-1 Microelisa (S/CO)	HIV-1 Ab	HIV-1 p24 Ag	HIV-2 Ab	HIV-1/2 Ag/Ab
01	**9.02**	**86.41**	**1.18**	0.94	**86.41**
02	**9.17**	**90.62**	0.36	0.24	**90.62**
03	**5.11**	**59.30**	0.17	0.06	**59.30**
04	**3.27**	**8.92**	0.18	0.07	**8.92**
05	**7.35**	**88.67**	0.19	0.10	**88.67**
06	**9.34**	**145.86**	0.26	0.12	**145.86**
07	**4.32**	**13.65**	0.15	0.08	**13.65**
08[2]	0.70	-	-	-	-
09	0.61	0.07	0.12	**128.60**	**128.60**
10	0.84	0.26	0.63	**>200.00**	**>200.00**
11	**3.30**	0.68*	0.36*	**>200.00***	**>200.00***
12	**1.13**	0.10	0.16	**>200.00**	**>200.00**
13	0.59	0.10	0.50	**>200.00**	**>200.00**
14	**2.26**	0.08	0.16	**179.15**	**179.15**
15	0.28	0.05	0.14	0.07	0.14
Test Date	19-Aug-2026	28-Aug-2026 10-Sep-2026			
Test Site	LGC	RL			
Kit Part Code	100384	NA			
Kit Lot No.	25101H	302000			
Kit Exp. Date	13-Jul-2027	24-Oct-2026			

[1]Results are reported as the mean result of duplicate testing; positive/reactive results are noted in bold red.
[2]Unable to result due to instrument error.
*Individual result reported due to instrument error on one of the replicates.
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HIV-1/2 Supplemental Assay[1]

	Bio-Rad Geenius™ HIV-1/2 Supplemental Assay			
Panel Member	**HIV-1 Result**	**HIV-2 Result**	**Positive Bands**	
01	**POS**	NEG	160, 41, 24, 31	
02	**POS**	NEG	160, 41, 24, 31	
03	**POS**	NEG	160, 41, 24	
04	**POS**	NEG	160, 41, 24	
05	**POS**	NEG	160, 41, 24	
06	**POS**	NEG	160, 41, 24, 31	
07	**POS**	NEG	160, 41, 24, 31	
08	NEG	**POS**	140, 36, 31	
09	NEG	**POS**	140, 36, 31	
10	NEG	**POS**	140, 36, 31	
11	**POS** (Cross-Reactivity)	**POS**	140, 160, 36, 41, 31	
12	NEG	**POS**	140, 36, 24	
13	NEG	**POS**	140, 36, 31	
14*	IND	IND	Rep 1	36, 24, 31
	NEG	**POS**	Rep 2	140, 36, 24, 31
15	NEG	NEG	-	
Test Date		20-Aug-2026 21-Sep-2026 29-Sep2026		
Test Site		RL		
Kit Part Code		NA		
Kit Lot No.		5M0104		
Kit Exp. Date		22-Apr-2027		

[1]Results are reported as singlicate testing; positive/reactive results are noted in bold red.
*Two replicates tested for panel member 14. Individual replicates reported due to result variability.
RL = Reference Lab; NA = Not Available; POS = Positive; NEG = Negative; IND = Indeterminate

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HIV Confirmatory Assay[1]

		INNOGENETICS® INNO-LIA™ HIV I/II Score						
		Band Results						
Panel Member	HIV-1/2 Antibody Interpretation	sgp120	gp41	p31	p24	p17	sgp105	gp36
01	**HIV-1 POS**	3+	4+	3+	3+	4+	-	-
02	**HIV-1 POS**	2+	3+	2+	3+	3+	-	-
03	**HIV-1 POS**	-	3+	2+	3+	1+	-	-
04	**HIV-1 POS**	1+	2+	-	3+	2+	-	-
05	**HIV-1 POS**	-	3+	2+	2+	2+	-	-
06	**HIV-1 POS**	2+	3+	2+	3+	3+	-	-
07	**HIV-1 POS**	2+	3+	-	2+	2+	-	
08	**HIV-2 POS**	-	-	3+	-	-	3+	3+
09	IND	-	-	2+	+/-	-	-	2+
10	**HIV-2 POS**	-	-	2+	1+	-	3+	3+
11	**HIV-2 POS**	-	-	3+	1+	-	1+	3+
12	**HIV-2 POS**	-	-	1+	3+	-	2+	3+
13	**HIV-2 POS**	-	-	2+	+/-	-	3+	3+
14	**HIV-2 POS**	-	-	-	3+	-	1+	3+
15	NEG	-	-	-	-	-	-	-
Test Date		28-Aug-2026						
Test Site		RL						
Kit Part Code		NA						
Kit Lot No.		299265						
Kit Exp. Date		31-May-2027						

[1]Results are reported as singlicate testing; positive/reactive results are noted in bold red.
POS = Positive; NEG = Negative; IND = Indeterminate
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.