

AccuSet[™] HTLV-I/II Performance Panel

0820-0481 / Batch #10601056

OVERVIEW

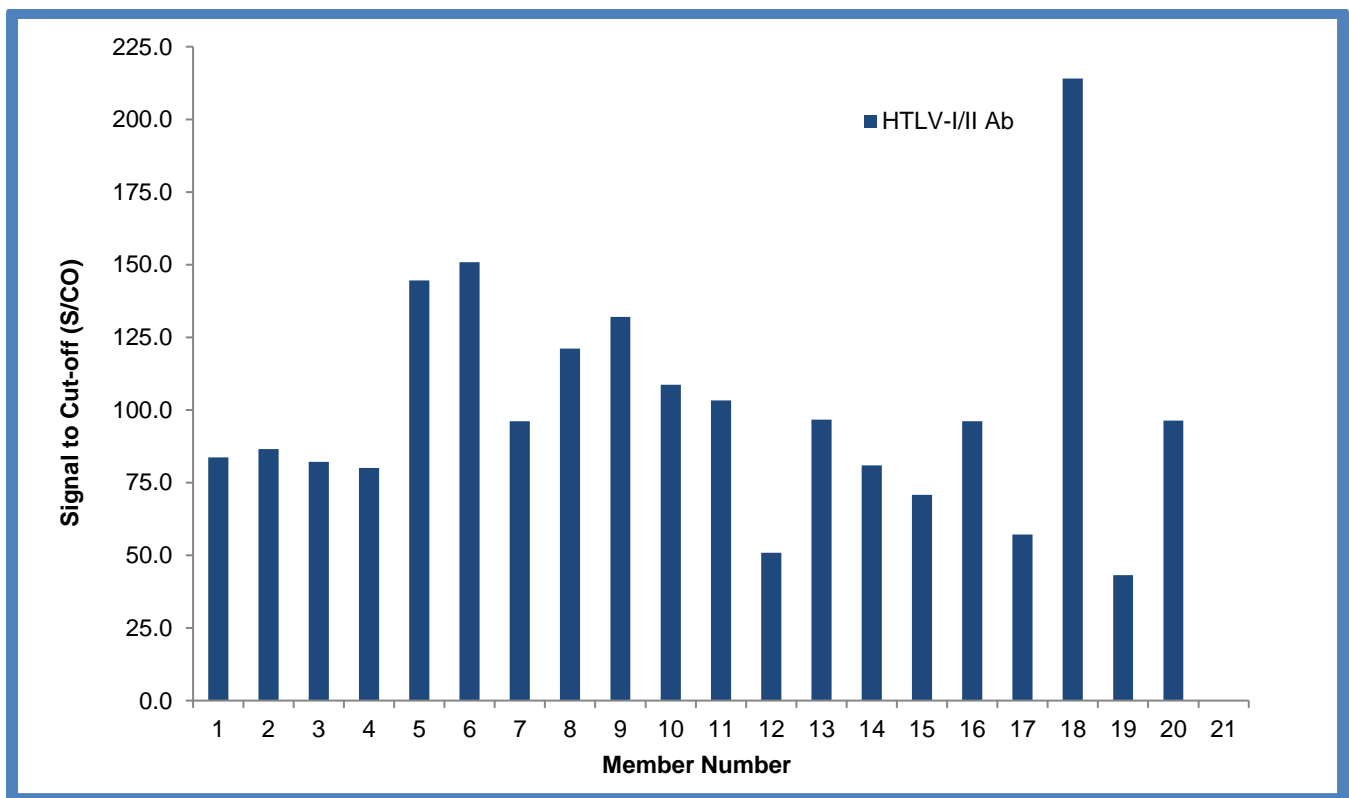
AccuSet[™] HTLV-I/II Performance Panel 0820-0481 / Batch #10601056 is a 21-member panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.2 mL). Panel members represent bleeds from multiple individuals positive for HTLV. Each sample represents a single collection event. No preservatives were added.

Test results from commercially available HTLV assays are included for characterization of the panel members. This panel of human plasma samples demonstrates reactivity ranging from negative to high positive for HTLV-I and HTLV-II antibodies. One sample is included as a non-reactive sample and is negative using all HTLV antibody 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 HTLV; all were found negative for HBsAg, anti-HIV, and anti-HCV. This does not ensure the absence of these or other human pathogens.

AccuSet[™] HTLV-I/II Performance Panel



This graph demonstrates the antibody reactivity to HTLV-I and HTLV-II amongst panel members utilizing Abbott ARCHITECT rHTLV-I/II assay results.

AccuSet[™] HTLV-I/II
 Performance Panel
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Panel Member Information

Panel Member	SeraCare Batch #	SeraCare Donor ID #	Bleed Date
01	9266029	BD110979	3-Feb-13
02	9267750	BD111454	9-May-13
03	9268356	BD111489	13-Jun-13
04	9268434	BD111490	20-Jun-13
05	10007053	BD111491	2-Aug-13
06	10007045	BD200054	5-Aug-13
07	10242385	BD316782	17-Feb-16
08	10386193	BD392612	17-Nov-17
09	10544883	BD463908	23-Nov-20
10	10544889	BD463914	23-Aug-19
11	9144417	BD110648	8-Jan-00
12	9254188	BD110972	9-Sep-11
13	9254447	BD110977	28-Sep-11
14	9254602	BD110991	29-Jul-11
15	9255995	BD111197	19-Dec-11
16	10080098	BD221177	10-Oct-14
17	9130522	BD448579	18-Apr-01
18	10544880	BD463905	5-Feb-20
19	10544882	BD463907	13-Nov-20
20	BM216730	NA	6-Jul-01
21	9249938	BD448580	28-Aug-08

NA = Not Available

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HTLV-I/II Antibody

Panel Member	Abbott Alinity s HTLV-I/II (s/co) ¹	Abbott ARCHITECT rHTLV-I/II (s/co) ¹	DiaSorin LIAISON XL MUREX recHTLV-I/II (s/co) ¹	Avioq HTLV-I/II Microelisa System (s/co) ¹
01	115.0	83.7	125.0	8.4
02	114.7	86.5	115.0	6.9
03	109.7	82.1	110.0	9.2
04	106.3	80.1	120.0	6.4
05	244.8	144.6	130.0	9.1
06	242.9	150.8	130.0	9.2
07	160.2	96.1	135.0	9.1
08	192.1	121.1	190.0	8.7
09	176.9	132.0	130.0	9.0
10	164.1	108.7	160.0	9.4
11	154.2	103.3	130.0	9.3
12	64.6	50.9	95.5	4.6
13	138.3	96.7	125.0	3.2
14	124.7	80.9	110.0	9.1
15	93.8	70.8	100.0	7.6
16	163.7	96.1	140.0	5.6
17	67.6	57.1	110.0	7.4
18	279.3	214.0	220.0	9.2
19	56.6	43.2	69.0	5.5
20	150.9	96.3	150.0	4.5
21	0.2	0.1	0.3	0.1
Test Date	22-JAN-2022	25-JAN-2022	20-JAN-2022	21-JAN-2022
Test Site	RL	RL	SC	SC
Kit Part Code	NA	6L61-35	310270	500192
Kit Lot No.	30145BE00	32362BE00	170023	21021
Kit Exp. Date	1-AUG-2022	19-AUG-2022	25-JAN-2022	29-OCT-2023

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

AccuSet™ HTLV-I/II Performance Panel

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HTLV-I/II Confirmatory

INNOGENETICS® INNO-LIA™ HTLV-I/II Score¹

Panel Member	HTLV-I/II Antibody Interpretation	Band Results						
		gp21 I/II	gp46 I/II	gp46 I	gp46 II	p19 I/II	p19 I	p24 I/II
01	HTLV-I POS	2+	2+	2+	-	2+	2+	2+
02	HTLV-I POS	2+	2+	2+	-	2+	2+	2+
03	HTLV-I POS	2+	2+	2+	-	2+	2+	2+
04	HTLV-I POS	2+	2+	2+	-	2+	1+	1+
05	HTLV-I POS	3+	2+	2+	-	3+	2+	2+
06	HTLV-I POS	3+	2+	2+	+/-	3+	2+	2+
07	HTLV-I POS	2+	2+	2+	-	2+	2+	2+
08	HTLV-I POS	2+	2+	2+	-	2+	2+	2+
09	HTLV-I POS	2+	2+	2+	-	2+	2+	2+
10	HTLV-I POS	2+	2+	2+	-	2+	2+	2+
11	HTLV-II POS	2+	2+	-	2+	2+	-	3+
12	IND	2+	-	-	-	2+	-	2+
13	IND	2+	+/-	-	-	-	-	-
14	HTLV-II POS	2+	2+	-	2+	2+	-	2+
15	HTLV-II POS	2+	2+	-	2+	2+	-	2+
16	HTLV-II POS	2+	2+	-	2+	-	-	-
17	HTLV-II POS	2+	1+	-	2+	1+	-	2+
18	HTLV-II POS	2+	2+	-	2+	2+	-	2+
19	HTLV-II POS	2+	2+	-	2+	-	-	1+
20	HTLV-II POS	2+	2+	-	2+	-	-	-
21	HTLV-I/II NEG	-	-	-	-	-	-	-
Test Date		2-FEB-2022						
Test Site		RL						
Kit Part Code		80541						
Kit Lot No.		408881						
Kit Exp. Date		31-AUG-2022						

¹Results are reported as singlicate testing; positive/reactive results are noted in bold red.

RL = Reference Lab; POS = Positive; NEG = Negative; IND = Indeterminate

AccuSet™ HTLV-I/II Performance Panel

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HTLV-I/II Confirmatory (continued)

MP Diagnostics HTLV Blot 2.4 Western Blot¹

Panel Member	HTLV-I/II Antibody Interpretation	Band Results										
		GD21	gp46	p19	p24	p26	p28	p32	p36	p53	rgp46I	gp46 II
01	HTLV-I POS	3+	3+	3+	2+	1+	1+	1+	2+	2+	3+	-
02	HTLV-I POS	3+	1+	3+	2+	1+	1+	+/-	1+	1+	3+	-
03	HTLV-I POS	3+	+/-	3+	3+	1+	+/-	1+	2+	1+	1+	-
04	HTLV-I POS	3+	1+	3+	2+	1+	1+	+/-	1+	1+	3+	-
05	HTLV-I POS	3+	3+	3+	3+	3+	3+	3+	3+	3+	3+	-
06	HTLV-I POS	3+	3+	3+	3+	3+	3+	3+	3+	3+	3+	-
07	HTLV-I POS	3+	2+	3+	3+	1+	1+	2+	2+	2+	3+	-
08	HTLV-I POS	3+	3+	3+	3+	3+	3+	3+	3+	3+	3+	-
09	HTLV-I POS	3+	3+	3+	3+	3+	3+	3+	3+	3+	3+	-
10	HTLV-I POS	3+	2+	3+	3+	3+	3+	3+	3+	2+	3+	-
11	HTLV-II POS	3+	-	2+	3+	-	-	-	3+	3+	-	3+
12	HTLV-II POS	2+	+/-	-	2+	-	-	-	-	+/-	-	1+
13	HTLV-II POS	3+	-	-	1+	-	-	-	-	-	-	1+
14	HTLV-II POS	3+	-	-	3+	-	-	-	+/-	-	-	3+
15	HTLV-II POS	2+	-	2+	3+	-	-	-	+/-	-	-	3+
16	HTLV-II POS	3+	-	-	1+	-	-	-	-	-	-	2+
17	HTLV-II POS	2+	-	+/-	2+	-	-	-	-	-	-	2+
18	HTLV-II POS	3+	-	-	3+	-	-	+/-	1+	+/-	-	3+
19	HTLV-II POS	2+	-	-	2+	-	-	-	-	-	-	2+
20	HTLV-II POS	3+	-	-	2+	-	-	-	-	-	-	3+
21	HTLV-I/II NEG	-	-	-	-	-	-	-	-	-	-	-
Test Date	28-JAN-2022											
Test Site	SC											
Kit Part Code	0711088036											
Kit Lot No.	AK1009											
Kit Exp. Date	1-DEC-2022											

¹Results are reported as singlicate testing; positive/reactive results are noted in bold red.

SC=SeraCare; POS = Positive; NEG = Negative

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.