

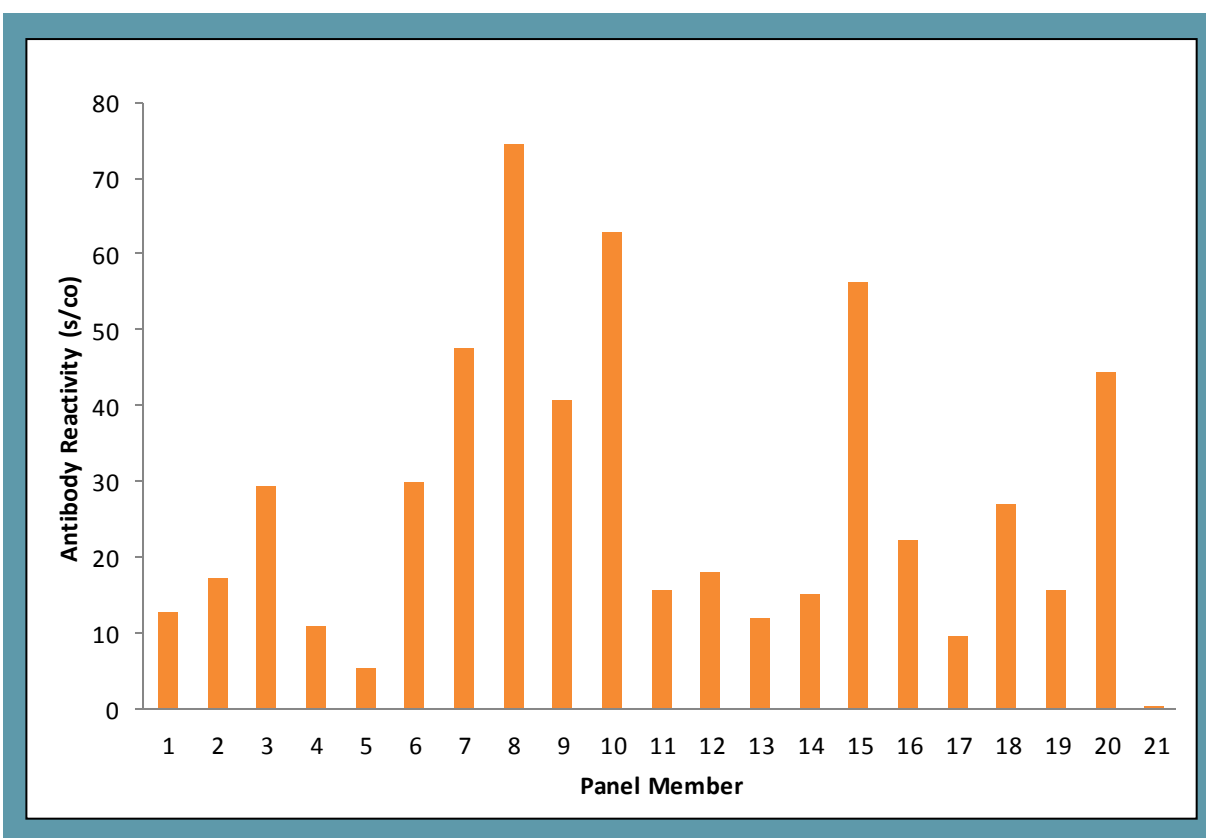
OVERVIEW

HTLV I/II Mixed Titer AccuSet™ Performance Panel (0820-0192) is a 21-member panel of undiluted, naturally occurring plasma samples. 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 antibody 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 provided for informational purposes. SeraCare Life Sciences does not claim that others can duplicate test results exactly.

CAUTION: Potentially infectious materials. Follow Universal Precautions. All panel members were found negative for HBsAg, anti-HIV, and anti-HCV.

HTLV I/II Mixed Titer AccuSet™ Performance Panel

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

DATA SHEET

HTLV I/II Antibody

Panel Member	Abbott ARCHITECT® HTLV-I/HTLV-II (s/co) ^{1,2}	Abbott PRISM HTLV-1/HTLV-11 (s/co) ¹	AVIOQ® HTLV-I/II Microelisa System (s/co) ¹	DiaSorin Murex® HTLV I + II (s/co) ^{1,2}
01	84.1	12.8	3.5	>11.4
02	72.3	17.4	7.9	>11.4
03	82.2	29.4	8.3	>11.4
04	74.6	11.0	5.0	>11.4
05	50.2	5.3	5.2	>11.4
06	84.0	29.9	8.4	>11.4
07	97.7	47.7	7.5	>11.4
08	134.2	74.5	8.5	>11.4
09	101.0	40.7	8.6	>11.4
10	120.3	63.0	8.8	>11.4
11	59.8	15.6	5.6	>11.4
12	61.4	18.1	7.3	>11.4
13	63.9	11.9	4.1	>11.4
14	89.0	15.2	3.7	>11.4
15	101.2	56.2	8.7	>11.4
16	46.0	22.4	3.9	>11.4
17	92.0	9.7	2.8	>11.4
18	73.0	27.0	8.6	>11.4
19	56.1	15.8	7.0	>11.4
20	99.1	44.5	7.5	>11.4
21	0.1	0.3	NR	0.3
Test Date	22-Aug-14	22-Aug-14	22-Aug-14	02-Sep-14
Test Site	RL	RL	RL	SC
Kit Part Code	NA	NA	NA	GE81
Kit Lot No.	40019L100	NA	NA	D221910
Kit Exp Date	05-May-15	NA	NA	30-Nov-14
Kit Regulatory Status	IVD/CE	IVD	IVD/CE	IVD/CE

¹Results are reported as a signal to cut-off value (s/co). Signal to cut-off values greater than or equal to 1.0 are considered positive/reactive and are noted in bold red.

²Results are reported as the mean result of duplicate testing.

NR = Non-Reactive

SC = SeraCare; RL = Reference Lab; NA = Not Available; IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking

DATA SHEET

HTLV I/II Confirmatory

Panel Member	MP Diagnostics	MP Diagnostics
	HTLV Blot 2.4 Western Blot	HTLV Blot 2.4 Western Blot Band Pattern
01	HTLV-I	GD21, p19, p24, p26, p28, p36, rgp46-I
02	HTLV-I	GD21, p19, p24, p26, p28, p32, p36, rgp46-I
03	HTLV-I ¹	GD21, p19, p24, p26, p28, p32, p36
04	HTLV-I	GD21, p19, p24, p26, p28, p32, rgp46-I
05	HTLV-I	GD21, p19, p24, p26, p28, p32, rgp46-I
06	HTLV-I	GD21, p19, p24, p26, p28, p32, rgp46-I
07	HTLV-I	GD21, p19, p24, p26, p28, p32, rgp46-I
08	HTLV-I	GD21, gp46, p19, p24, p26, p28, p32, p36, p53, rgp46-I
09	HTLV-I	GD21, p19, p24, p26, p28, p32, p36, rgp46-I
10	HTLV-I	GD21, gp46, p19, p24, p26, p28, p32, p36, p53, rgp46-I
11	HTLV-I	GD21, p19, p24, rgp46-I
12	HTLV-II	GD21, p24, rgp46-II
13	HTLV-II	GD21, p24, rgp46-II
14	HTLV-II	GD21, p24, p53, rgp46-I, rgp46-II
15	HTLV-II	GD21, p19, p24, p28, p32, p36, rgp46-II
16	HTLV-II ²	BD21, p24, rgp46-II
17	HTLV-II ²	BD21, p24, rgp46-II
18	HTLV-II	BD21, p24, rgp46-II
19	HTLV-II	BD21, p19, p24, rgp46-II
20	HTLV-II	BD21, p19, p24, p36, rgp46-II
21	NEG	No Bands
Test Date	18-Aug-14	18-Aug-14
Test Site	SC	SC
Kit Part Code	11082-036	11082-036
Kit Lot No.	AK3018	AK3018
Kit Exp Date	5/1/2015	5/1/2015
Kit Regulatory Status	IVD/CE	IVD/CE

¹Member 3 was found to be weak positive for HTLV-I.

²Members 16 and 17 were found to be weak positive for HTLV-II.

HTLV-I = HTLV-I Seropositive; HTLV-II = HTLV-II Seropositive; NEG = Negative

SC = SeraCare; IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking

DATA SHEET

HTLV I/II Confirmatory

Panel Member	HTLV-I/II IFA	Innogenetics INNO-LIA® HTLV I/II Score ¹	HTLV I/II RIPA
01	HTLV-I	HTLV-I	Reactive
02	HTLV-I	HTLV-I	Reactive
03	HTLV-I	HTLV-I	Reactive
04	HTLV-I	HTLV-I	Reactive
05	HTLV-I	HTLV-I	Reactive
06	HTLV-I	HTLV-I	Reactive
07	HTLV-I	HTLV-I	Reactive
08	HTLV-I	HTLV-I	Reactive
09	HTLV-I	HTLV-I	Reactive
10	HTLV-I	HTLV-I	Reactive
11	HTLV-I	HTLV-I	Reactive
12	HTLV-II	HTLV-II	Reactive
13	HTLV-II	HTLV	Reactive
14	HTLV-II	HTLV-II	Reactive
15	HTLV-II	HTLV-II	Reactive
16	HTLV-II	HTLV	Reactive
17	HTLV-II	IND	Reactive
18	HTLV-II	HTLV-II	Reactive
19	HTLV-II	HTLV-II	Reactive
20	HTLV-II	HTLV-II	Reactive
21	NR	NEG	NR
Test Date	18-Sep-14	06-Oct-14	18-Sep-14
Test Site	RL	RL	RL
Kit Part Code	NA	NA	NA
Kit Lot No.	NA	NA	NA
Kit Exp Date	NA	NA	NA
Kit Regulatory Status	NA	I/D/CE	NA

¹Results are reported as the mean result of duplicate testing.

HTLV-I = HTLV-I Seropositive; HTLV-II = HTLV-II Seropositive; HTLV = HTLV Seropositive

NR = Non-Reactive; IND = Indeterminate; NEG = Negative

RL = Reference Lab; NA = Not Available; IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking

The Package Insert for this panel in PDF form 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

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