

OVERVIEW

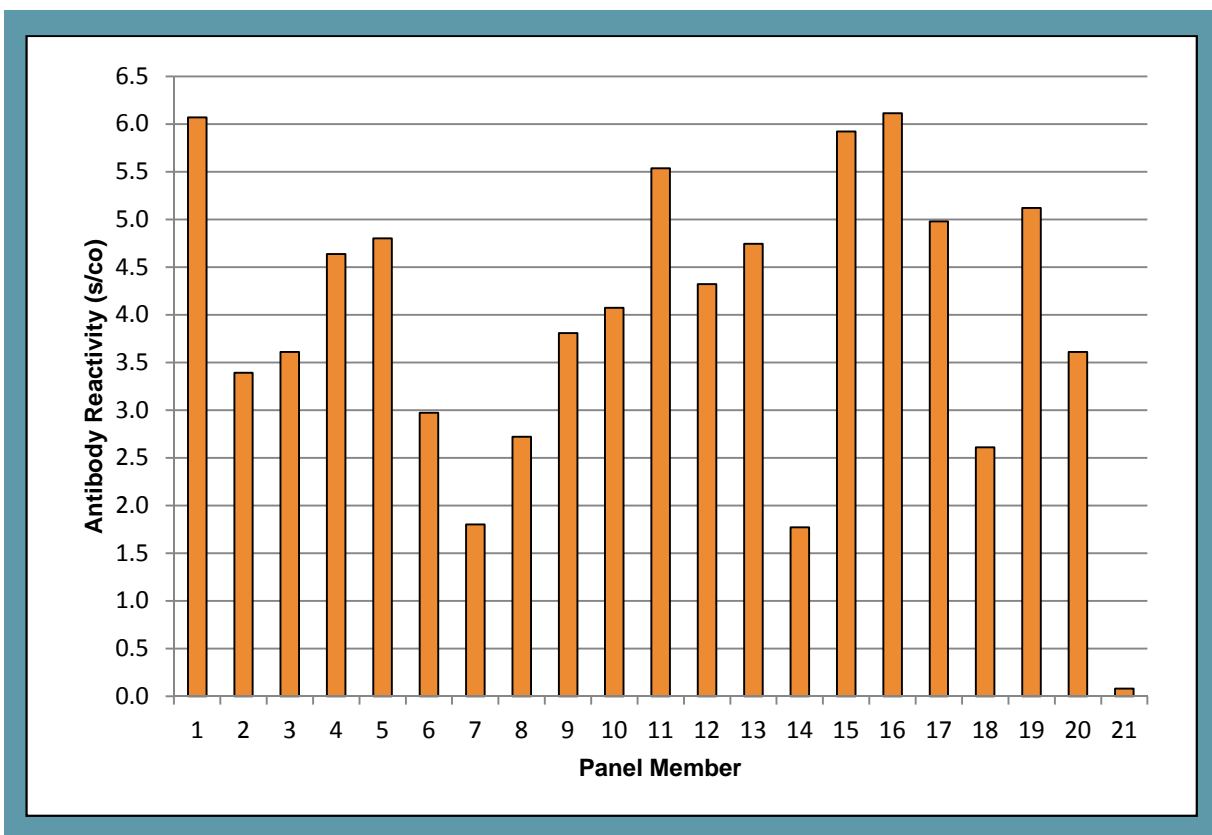
Chagas (*T. cruzi*) AccuSet™ Performance Panel (0845-0073) is a 21-member panel of undiluted, naturally occurring plasma samples. Panel members represent bleeds from multiple individuals positive for Chagas disease from varying countries of origin. Each sample represents a single collection event. No preservatives were added.

Test results from commercially-available Chagas 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 Chagas antibodies. One sample is included as a non-reactive sample and is negative for all Chagas 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.

Chagas (*T. cruzi*) AccuSet™ Mixed Titer Performance Panel



*This graph demonstrates the breadth of antibody reactivity to Trypanosoma cruzi (*T. cruzi*) amongst panel members utilizing Ortho *T. cruzi* ELISA Test System assay results.*

Chagas (T. cruzi) AccuSet™ Performance Panel

0845-0073

DATA SHEET

Chagas Antibody

Panel Member	Country of Origin	Ortho T. cruzi ELISA Test System ^{1,2,5}	Abbott PRISM Chagas ^{1,2,6}	Abbott ARCHITECT Chagas ^{1,3,5}	Hemagen® Chagas Kit EIA ^{1,4,5}
01	NA	6.1	3.6	10.7	7.3
02	Mexico	3.4	5.0	6.8	4.0
03	Mexico	3.6	6.4	7.5	4.8
04	Mexico	4.6	9.9	8.7	5.1
05	Mexico	4.8	8.7	7.8	5.6
06	Mexico	3.0	3.8	6.0	3.6
07	Argentina	1.8	4.4	4.9	2.2
08	Argentina	2.7	5.9	5.9	3.1
09	USA	3.8	8.4	8.0	3.9
10	USA	4.1	9.2	10.4	4.8
11	NA	5.5	8.6	7.7	6.5
12	Mexico	4.3	5.9	7.3	4.8
13	USA	4.7	14.3	10.6	5.4
14	NA	1.8	1.8	3.4	2.3
15	El Salvador	5.9	10.5	10.5	6.5
16	NA	6.1	9.7	10.1	6.7
17	NA	5.0	8.9	6.5	5.4
18	NA	2.6	1.6	5.5	4.1
19	NA	5.1	8.0	9.6	6.0
20	NA	3.6	5.5	7.2	4.3
21	NA	0.1	0.1	0.1	0.2
Test Date		25-Mar-14	03-Apr-14	09-Apr-14	16-Apr-14
Test Site		SC	RL	RL	SC
Kit Part Code		6901968	NA	2P25-35	66101
Kit Lot No.		CRU215	NA	36136LI00	4CB0801
Kit Exp Date		09-Aug-14	NA	09-Dec-14	31-May-15
Kit Regulatory Status		IVD/CE	IVD	IVD	IVD/CE

¹Results are reported as a signal to cut-off value (s/co). Positive/reactive results are noted in bold red. ²Signal to cut-off values greater than 1.0 are considered positive/reactive. ³Signal to cut-off values greater than or equal to 1.0 are considered positive/reactive. ⁴Signal to cut-off values greater than 1.1 are considered positive/reactive. ⁵Results are reported as the mean result of duplicate testing. ⁶Results are reported as the mean result of six replicates for members 1 – 20 and two replicates for member 21.

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



Chagas (T. cruzi) AccuSet™ Performance Panel

0845-0073

DATA SHEET

Chagas Antibody

Panel Member	Country of Origin	Weiner Chagatest ELISA ^{1,2}	Quest Chagas Screen Immunoassay ²	Quest Chagas RIPA ^{2,3}
01	NA	9.0	Reactive	Positive
02	Mexico	4.5	Reactive	Positive
03	Mexico	4.5	Reactive	Positive
04	Mexico	6.4	Reactive	Positive
05	Mexico	5.6	Reactive	Positive
06	Mexico	5.3	Reactive	Positive
07	Argentina	1.7	Reactive	Positive
08	Argentina	2.6	Reactive	Positive
09	USA	5.4	Reactive	Positive
10	USA	6.5	Reactive	Positive
11	NA	6.8	Reactive	Positive
12	Mexico	5.3	Reactive	Positive
13	USA	8.2	Reactive	Positive
14	NA	1.7	Reactive	Positive
15	El Salvador	8.9	Reactive	Positive
16	NA	8.8	Reactive	Positive
17	NA	7.0	Reactive	Positive
18	NA	7.1	Reactive	Positive
19	NA	9.4	Reactive	Positive
20	NA	7.6	Reactive	Positive
21	NA	0.1	Non-Reactive	NA
Test Date		05-May-14	03-Apr-14	03-Apr-14
Test Site		SC	RL	RL
Kit Part Code		1293257	NA	NA
Kit Lot No.		1311124050	NA	NA
Kit Exp Date		30-Nov-14	NA	NA
Kit Regulatory Status		IVD/CE	NA	NA

¹Results are reported as a signal to cut-off value (s/co). Signal to cut-off values greater than 1.1 are considered positive/reactive and are noted in bold red.

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

³Reactive members from the initial Quest Chagas Screen Immunoassay were reflexed to the Chagas RIPA.

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

DATA SHEET

Chagas IgM Antibody

Panel Member	Country of Origin	ARUP T. cruzi IgM Antibody IFA ¹
01	NA	<1:16
02	Mexico	<1:16
03	Mexico	<1:16
04	Mexico	<1:16
05	Mexico	<1:16
06	Mexico	<1:16
07	Argentina	<1:16
08	Argentina	<1:16
09	USA	<1:16
10	USA	<1:16
11	NA	<1:16
12	Mexico	<1:16
13	USA	<1:16
14	NA	<1:16
15	El Salvador	1:64/1:16
16	NA	<1:16
17	NA	<1:16
18	NA	1:64/1:512
19	NA	<1:16
20	NA	<1:16
21	NA	<1:16
Test Date		03-Apr-14
Test Site		RL
Kit Part Code		NA
Kit Lot No.		NA
Kit Exp Date		NA
Kit Regulatory Status		ASR

¹Results are reported as an antibody titer. Values 1:16 or greater are considered positive for IgM antibodies to *Trypanosoma cruzi* and are noted in bold red. Duplicate testing was performed; replicates for panel members 1 – 14, 16, 17, 19 – 21 correlated with the same negative result. Members 15 and 18 are positive for IgM antibodies. Results for both replicates are provided.

NA = Not Available; RL = Reference Lab; ASR = Analyte Specific Reagent

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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