

OVERVIEW

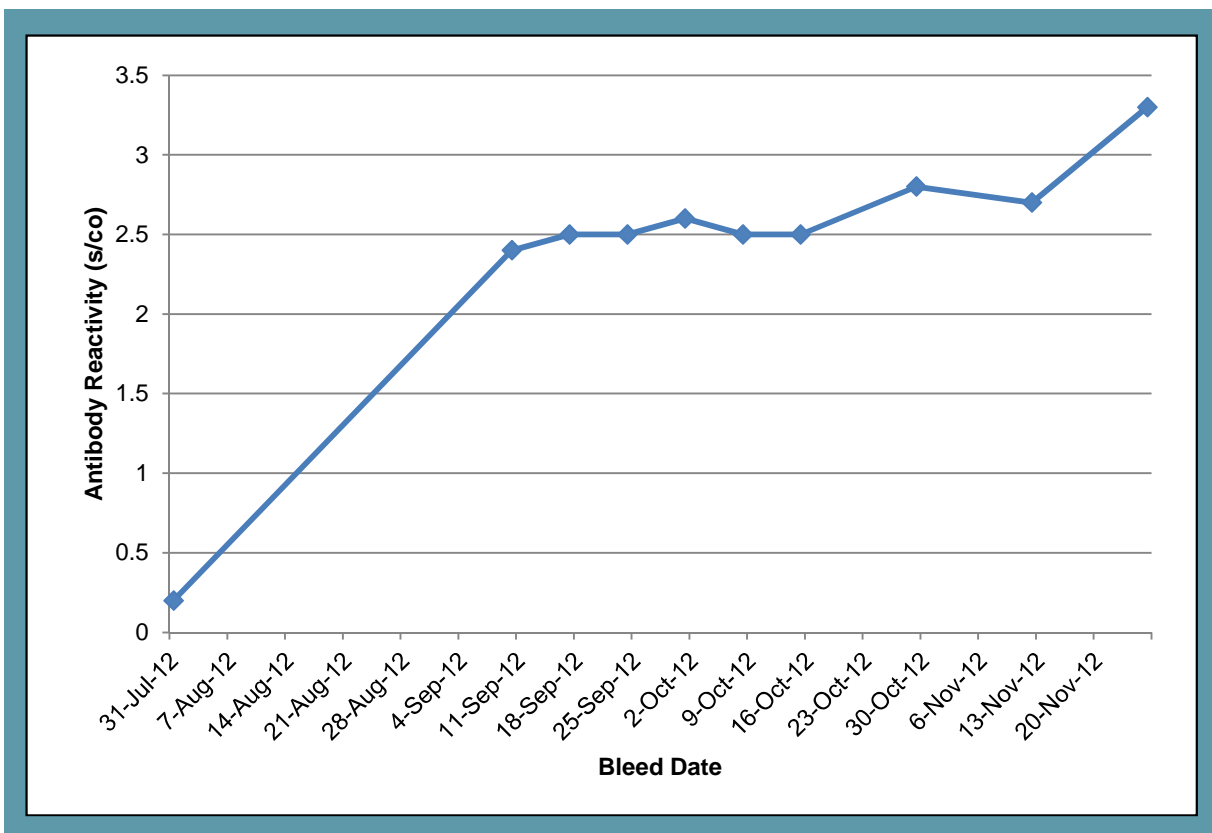
Chagas (*T. cruzi*) AccuVert™ Seroconversion Panel (0615-0038) is a 10-member panel of undiluted, naturally occurring plasma samples. Panel members represent serial bleeds collected from a single individual over the course of 118 days during the development of a Chagas infection and subsequent response. 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 a change in expression from negative to positive for Chagas antibody during the development and progression of a Chagas infection.

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.

Expression of Chagas (*T. cruzi*) Antibodies during Progression of Infection



*This graph demonstrates the development and progression of an early Chagas (*T. cruzi*) infection from a single individual. Antibody reactivity was measured using the Ortho *T. cruzi* ELISA Test System. Lines connecting data points are not indicative of antibody reactivity between bleed dates.*

Chagas (T. cruzi) AccuVert™ Seroconversion Panel

0615-0038

DATA SHEET

Chagas Antibody

Panel Member	Bleed Date	Days Since 1 st Bleed	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	31-Jul-12	0	0.2	0.1	0.1	0.5
02	10-Sep-12	41	2.4	1.6	5.2	4.0
03	17-Sep-12	48	2.5	1.6	5.4	4.0
04	24-Sep-12	55	2.5	1.9	5.3	3.9
05	01-Oct-12	62	2.6	1.9	5.5	3.9
06	08-Oct-12	69	2.5	2.2	5.8	4.0
07	15-Oct-12	76	2.5	2.1	5.4	4.1
08	29-Oct-12	90	2.8	3.2	6.2	4.3
09	12-Nov-12	104	2.7	3.0	6.2	4.2
10	26-Nov-12	118	3.3	4.6	7.0	4.8
Test Date			20-Feb-14	03-Apr-14	09-Apr-14	05-May-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

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 three replicates for member 1 and six replicates for members 2 – 10. SC = SeraCare; RL = Reference Lab; NA = Not Available; IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking

Chagas Antibody

Panel Member	Bleed Date	Days Since 1 st Bleed	Weiner Chagatest ELISA recombinante v. 4.0 ^{1,2}	Quest Chagas Screen Immunoassay ²	Quest Chagas RIPA ^{2,3}
01	31-Jul-12	0	0.1	Non-Reactive	N/A
02	10-Sep-12	41	7.4	Reactive	Positive
03	17-Sep-12	48	7.4	Reactive	Positive
04	24-Sep-12	55	7.4	Reactive	Positive
05	01-Oct-12	62	7.3	Reactive	Positive
06	08-Oct-12	69	7.2	Reactive	Positive
07	15-Oct-12	76	7.0	Reactive	Positive
08	29-Oct-12	90	7.2	Reactive	Positive
09	12-Nov-12	104	7.2	Reactive	Positive
10	26-Nov-12	118	7.8	Reactive	Positive
Test Date			05-May-14	02-Apr-14	02-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



Chagas (T. cruzi) AccuVert™ Seroconversion Panel

0615-0038

DATA SHEET

Chagas IgM Antibody

Panel Member	Bleed Date	Days Since 1 st Bleed	ARUP T. cruzi IgM Antibody IFA ¹
01	31-Jul-12	0	<1:16
02	10-Sep-12	41	1:1024
03	17-Sep-12	48	1:64
04	24-Sep-12	55	1:128
05	01-Oct-12	62	1:256
06	08-Oct-12	69	1:64
07	15-Oct-12	76	1:128
08	29-Oct-12	90	1:64
09	12-Nov-12	104	1:64
10	26-Nov-12	118	1:32
Test Date			01-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 each panel member correlated with the same result.
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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