

AccuSet™ Chagas (*T. cruzi*)

Performance Panel

0845-0201 / Batch #10408819

OVERVIEW

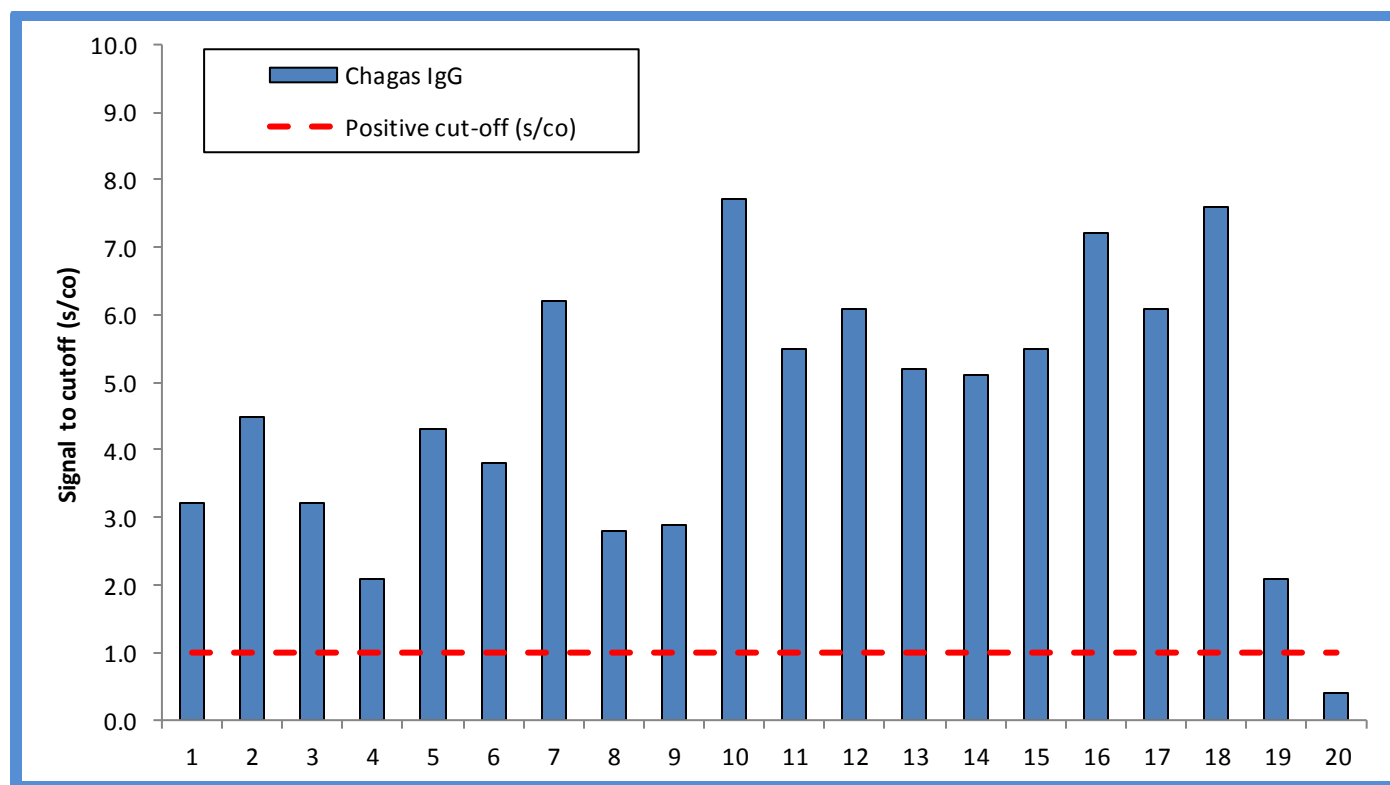
AccuSet™ Chagas (*Trypanosoma cruzi*) Performance Panel 0845-0201 / Batch #10408819 is a 20-member validation panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.0 mL per vial). Panel members represent bleeds from multiple individuals positive for antibodies to Chagas (*T. cruzi*). Each sample represents a single collection event. No preservatives were added.

Test results from commercially available chagas (*T. cruzi*) assays are included for characterization of the panel members. This panel of human plasma samples demonstrates a range of antibody reactivities for several chagas test methods. One sample is included as a non-reactive sample and is negative for all chagas test methods performed.

For Research Use Only. Not for use in diagnostic procedures. Data are offered for informational purposes. SeraCare Life Sciences does not claim that others can duplicate test results exactly.

CAUTION: Potentially infectious materials. Follow Universal Precautions. The units that make up this panel were tested and found negative for anti-HIV-1/2, HBsAg and anti-HCV. This does not ensure the absence of these or other human pathogens.

AccuSet™ Chagas Performance Panel



This graph demonstrates reactivity amongst panel members from the Hemagen® Chagas Kit test system.

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Panel Member Information

Panel Member	SeraCare Batch #	SeraCare Donor ID #	Bleed Date
01	9214485	NA	NA
02	9215945	NA	22-Jun-2007
03	9216202	NA	03-Aug-2006
04	9216204	NA	12-Jun-2006
05	9216207	NA	15-Jun-2006
06	9216212	NA	11-May-2006
07	9219223	NA	NA
08	9221856	NA	NA
09	10028470	NA	23-Aug-2013
10	10028471	NA	12-Sep-2013
11	10244280	BD316793	10-Nov-2015
12	10244281	BD316794	02-Nov-2015
13	10244285	BD316798	14-Apr-2015
14	10320093	BD354082	08-May-2016
15	10320094	BD354083	06-Jun-2017
16	10320097	BD354086	27-May-2016
17	10027197	BD200578	NA
18	10320106	BD357010	16-Feb-2017
19	9203925	NA	NA
20	9256935	BD381422	NA

NA = Not Available

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Chagas IgM, Chagas IgG

Panel Member	Chagas IgM by Immunofluorescence ¹	Abbott ARCHITECT Chagas (s/co) ^{2,3}	Abbott PRISM Chagas (s/co) ^{2,3}	Hemagen® Chagas Kit (s/co) ^{2,3}
01	<1:16	8.4	7.0	3.2
02	<1:16	7.4	4.7	4.5
03	1:64	9.9	8.3	3.2
04	<1:16	0.7	0.2	2.1
05	<1:16	7.0	5.4	4.3
06	<1:16	6.0	NT	3.8
07	<1:16	11.7	5.6	6.2
08	<1:16	2.3	0.6	2.8
09	<1:16	7.5	4.9	2.9
10	<1:16	14.1	17.7	7.7
11	1:16	11.5	7.8	5.5
12	1:64	10.9	8.0	6.1
13	<1:16	12.1	9.8	5.2
14	<1:16	12.6	11.5	5.1
15	<1:16	12.0	10.0	5.5
16	<1:16	11.4	7.0	7.2
17	<1:16	11.6	11.9	6.1
18	1:32	14.6	11.8	7.6
19	<1:16	2.5	1.7	2.1
20	<1:16	0.1	0.2	0.4
Test Date	26-Apr-2019	29-Apr-2019	20-Apr-2019 03-May-2019	19-Apr-2019
Test Site	RL	RL	RL	SC
Kit Part Code	NA	2P2535	NA	66101L
Kit Lot No.	NA	94409LI00	NA	8CL1801
Kit Exp. Date	NA	19-Oct-2019	NA	31-Oct-2019

¹Results are reported as an endpoint dilution ratio; positive/reactive results are noted in bold red.

²Results are reported as a signal to cutoff ratio (s/co); positive/reactive results are noted in bold red.

³Results are reported as the mean result of duplicate testing.

NT = Not Tested, due to unknown sample interference, this member was unable to be detected on the Abbott PRISM Chagas assay from two consecutive runs.

NA = Not Available

SC = SeraCare; RL = Reference Lab

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Chagas IgG

Panel Member	Ortho <i>T. cruzi</i> ELISA Test System (s/co) ^{1,2}	BioKit bioelisa Chagas (s/co) ^{1,2}	Wiener Labs Chagatest ELISA recombinante v4.0 (s/co) ^{1,2}
01	2.5	5.5	6.3
02	3.4	1.5	5.5
03	2.4	5.0	7.2
04	0.4	0.1	1.1
05	3.2	4.9	6.6
06	2.0	2.0	4.9
07	4.0	7.4	8.1
08	1.0	0.9 ³	2.1
09	1.9	5.3	3.5
10	5.3	8.2	9.2
11	4.0	8.0	7.1
12	4.0	7.5	7.9
13	3.6	6.2	9.8
14	4.7	7.9	9.4
15	4.0	6.7	8.0
16	4.6	7.3	9.4
17	3.9	5.7	9.0
18	5.3	7.9	9.6
19	2.0	2.3	1.7
20	0.0	0.1	0.0
Test Date	21-Apr-2019	29-Apr-2019	22-Apr-2019
Test Site	RL	RL	SC
Kit Part Code	NA	3000-1236	1293257
Kit Lot No.	CRU238	B30860	1811274570
Kit Exp. Date	25-Jun-2019	22-Jul-2019	30-Nov-2019

¹Results are reported as a signal to cutoff ratio (s/co); positive/reactive results are noted in bold red.²Results are reported as the mean result of duplicate testing.³Results are reported within the assay's equivocal/grayzone range.

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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 info@seracare.com or
 by phone at 508.244.6400.