

## OVERVIEW

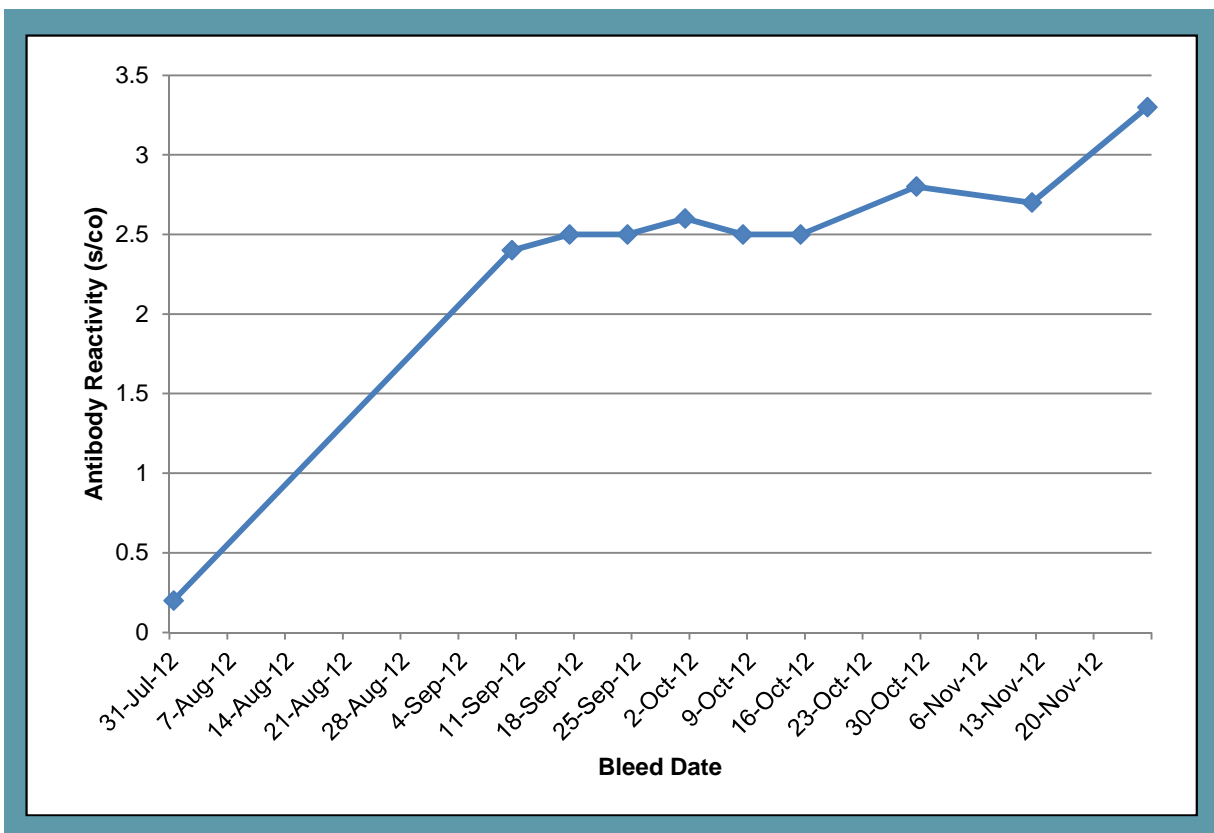
Chagas (*T. cruzi*) AccuVert™ Seroconversion Panel (0615-0038) is a 10-member panel of undiluted, naturally occurring plasma samples. Panel members represent serial bleeds collected from a single individual over the course of 118 days during the development of a Chagas infection and subsequent response. 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 <sup>st</sup> Bleed | Ortho T. cruzi ELISA Test System <sup>1,2,5</sup> | Abbott PRISM Chagas <sup>1,2,6</sup> | Abbott ARCHITECT Chagas <sup>1,3,5</sup> | Hemagen® Chagas Kit EIA <sup>1,4,5</sup> |
|-----------------------|------------|----------------------------------|---|--------------------------------------|--|--|
| 01                    | 31-Jul-12  | 0                                | 0.2   | 0.1                                  | 0.1                                      | 0.5                                      |
| 02                    | 10-Sep-12  | 41                               | <b>2.4</b>  | <b>1.6</b>                           | <b>5.2</b>                               | <b>4.0</b>                               |
| 03                    | 17-Sep-12  | 48                               | <b>2.5</b>  | <b>1.6</b>                           | <b>5.4</b>                               | <b>4.0</b>                               |
| 04                    | 24-Sep-12  | 55                               | <b>2.5</b>  | <b>1.9</b>                           | <b>5.3</b>                               | <b>3.9</b>                               |
| 05                    | 01-Oct-12  | 62                               | <b>2.6</b>  | <b>1.9</b>                           | <b>5.5</b>                               | <b>3.9</b>                               |
| 06                    | 08-Oct-12  | 69                               | <b>2.5</b>  | <b>2.2</b>                           | <b>5.8</b>                               | <b>4.0</b>                               |
| 07                    | 15-Oct-12  | 76                               | <b>2.5</b>  | <b>2.1</b>                           | <b>5.4</b>                               | <b>4.1</b>                               |
| 08                    | 29-Oct-12  | 90                               | <b>2.8</b>  | <b>3.2</b>                           | <b>6.2</b>                               | <b>4.3</b>                               |
| 09                    | 12-Nov-12  | 104                              | <b>2.7</b>  | <b>3.0</b>                           | <b>6.2</b>                               | <b>4.2</b>                               |
| 10                    | 26-Nov-12  | 118                              | <b>3.3</b>  | <b>4.6</b>                           | <b>7.0</b>                               | <b>4.8</b>                               |
| 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                                      |

<sup>1</sup>Results are reported as a signal to cut-off value (s/co). Positive/reactive results are noted in bold red. <sup>2</sup>Signal to cut-off values greater than 1.0 are considered positive/reactive. <sup>3</sup>Signal to cut-off values greater than or equal to 1.0 are considered positive/reactive. <sup>4</sup>Signal to cut-off values greater than 1.1 are considered positive/reactive. <sup>5</sup>Results are reported as the mean result of duplicate testing. <sup>6</sup>Results 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 <sup>st</sup> Bleed | Weiner Chagatest ELISA recombinante v. 4.0 <sup>1,2</sup> | Quest Chagas Screen Immunoassay <sup>2</sup> | Quest Chagas RIPA <sup>2,3</sup> |
|-----------------------|------------|----------------------------------|---|--|----------------------------------|
| 01                    | 31-Jul-12  | 0                                | 0.1   | Non-Reactive                                 | N/A                              |
| 02                    | 10-Sep-12  | 41                               | <b>7.4</b>  | <b>Reactive</b>                              | <b>Positive</b>                  |
| 03                    | 17-Sep-12  | 48                               | <b>7.4</b>  | <b>Reactive</b>                              | <b>Positive</b>                  |
| 04                    | 24-Sep-12  | 55                               | <b>7.4</b>  | <b>Reactive</b>                              | <b>Positive</b>                  |
| 05                    | 01-Oct-12  | 62                               | <b>7.3</b>  | <b>Reactive</b>                              | <b>Positive</b>                  |
| 06                    | 08-Oct-12  | 69                               | <b>7.2</b>  | <b>Reactive</b>                              | <b>Positive</b>                  |
| 07                    | 15-Oct-12  | 76                               | <b>7.0</b>  | <b>Reactive</b>                              | <b>Positive</b>                  |
| 08                    | 29-Oct-12  | 90                               | <b>7.2</b>  | <b>Reactive</b>                              | <b>Positive</b>                  |
| 09                    | 12-Nov-12  | 104                              | <b>7.2</b>  | <b>Reactive</b>                              | <b>Positive</b>                  |
| 10                    | 26-Nov-12  | 118                              | <b>7.8</b>  | <b>Reactive</b>                              | <b>Positive</b>                  |
| 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                               |

<sup>1</sup>Results 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.

<sup>2</sup>Results are reported as the mean result of duplicate testing. <sup>3</sup>Reactive 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 <sup>st</sup> Bleed | ARUP T. cruzi IgM Antibody IFA <sup>1</sup> |
|-----------------------|------------|----------------------------------|---|
| 01                    | 31-Jul-12  | 0                                | <1:16                                       |
| 02                    | 10-Sep-12  | 41                               | <b>1:1024</b>                               |
| 03                    | 17-Sep-12  | 48                               | <b>1:64</b>                                 |
| 04                    | 24-Sep-12  | 55                               | <b>1:128</b>                                |
| 05                    | 01-Oct-12  | 62                               | <b>1:256</b>                                |
| 06                    | 08-Oct-12  | 69                               | <b>1:64</b>                                 |
| 07                    | 15-Oct-12  | 76                               | <b>1:128</b>                                |
| 08                    | 29-Oct-12  | 90                               | <b>1:64</b>                                 |
| 09                    | 12-Nov-12  | 104                              | <b>1:64</b>                                 |
| 10                    | 26-Nov-12  | 118                              | <b>1:32</b>                                 |
| Test Date             |            |                                  | 01-Apr-14                                   |
| Test Site             |            |                                  | RL  |
| Kit Part Code         |            |                                  | NA  |
| Kit Lot No.           |            |                                  | NA  |
| Kit Exp Date          |            |                                  | NA  |
| Kit Regulatory Status |            |                                  | ASR   |

<sup>1</sup>Results 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](http://www.seracare.com)

A printed copy of the Package Insert or Data Sheet may be requested by email at [info@seracare.com](mailto:info@seracare.com), or by phone at 508.244.6400

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