# AccuSet™ Toxoplasmosis Performance Panel

0820-0321 / Batch #10344475

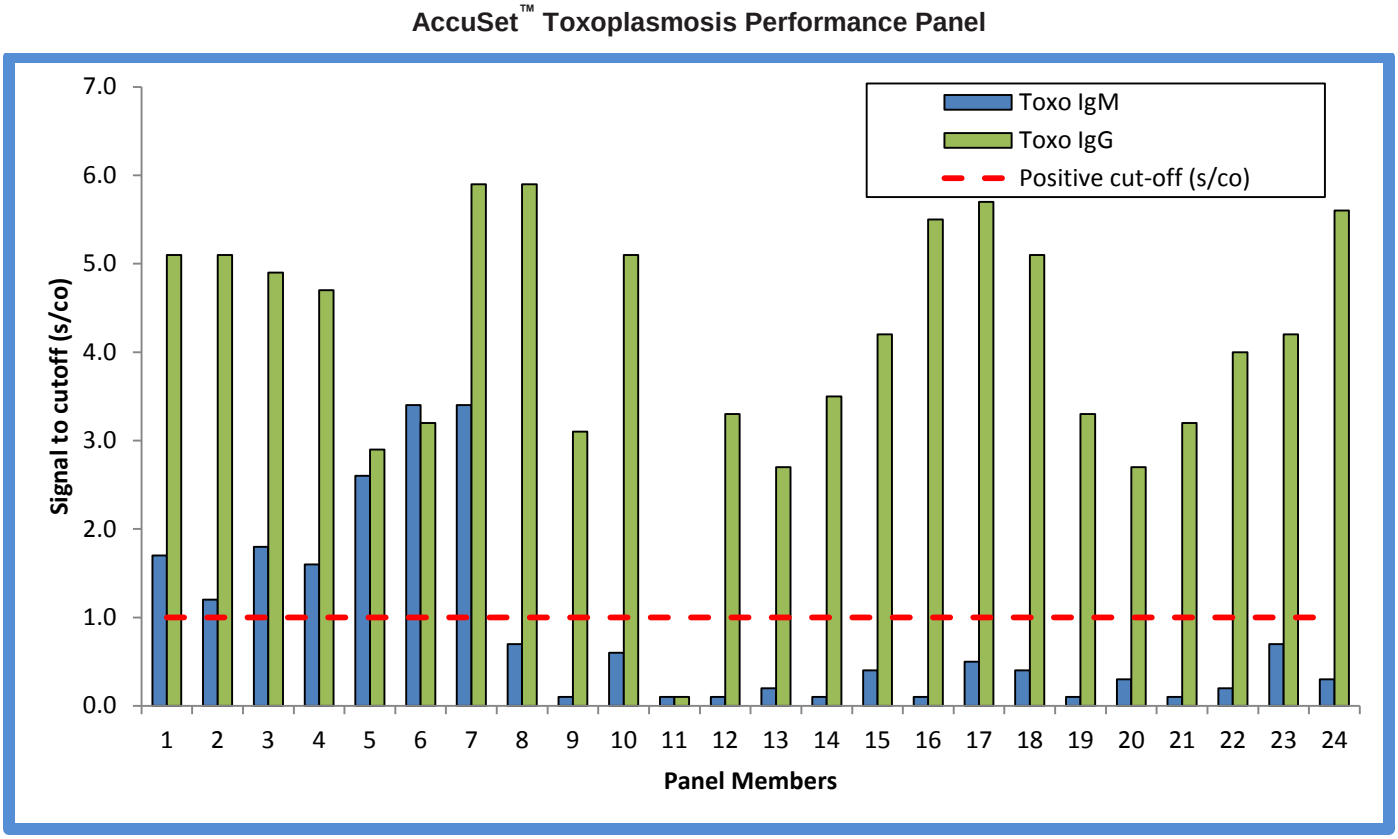
## OVERVIEW

AccuSet™ Toxoplasmosis Performance Panel (0820-0321 / Batch #10344475) is a 24-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 toxoplasmosis. Each sample represents a single collection event. No preservatives were added.

Test results from commercially-available toxoplasmosis assays are included for characterization of the panel members. This panel of human plasma samples demonstrates a range of antibody reactivity which approach the sensitivity limits for several toxoplasmosis test methods. One sample is included as a non-reactive sample and is negative for all toxoplasmosis 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: 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.




*This graph demonstrates reactivity among panel members from the Trinity Biotech Captia™ Toxo IgM and Toxo IgG assays.*

# AccuSet™ Toxoplasmosis Performance Panel

0820-0321 / Batch #10344475

## Panel Member Information

| Panel Member | SeraCare Batch # | SeraCare Donor ID # | Bleed Date |
|---|---|---|---|
| 01 | 10311431 | BD360819 | 28-Sep-2015 |
| 02 | 10311432 | BD360820 | 23-Oct-2015 |
| 03 | 10321177 | BD357329 | 06-May-2016 |
| 04 | 10321178 | BD357329 | 08-May-2016 |
| 05 | 10321179 | BD357330 | 17-Jan-2018 |
| 06 | 10321180 | BD357330 | 19-Jan-2018 |
| 07 | 10007625 | BD200224 | 30-May-2013 |
| 08 | 9259176 | BD110978 | 29-Apr-2012 |
| 09 | 10127362 | BD250523 | 11-Jun-2015 |
| 10 | 10127410 | BD250568 | 12-Jun-2015 |
| 11 | 9259496 | BD106585 | 21-May-2012 |
| 12 | 10127394 | BD250554 | 15-Jun-2015 |
| 13 | 10127482 | BD250640 | 12-Jun-2015 |
| 14 | 10127353 | BD250514 | 11-Jun-2015 |
| 15 | 10181204 | BD281977 | 06-Jan-2016 |
| 16 | 10127380 | BD250541 | 12-Jun-2015 |
| 17 | 10181175 | BD281948 | 12-Feb-2016 |
| 18 | 10127387 | BD250547 | 15-Jun-2015 |
| 19 | 10127483 | BD250641 | 12-Jun-2015 |
| 20 | 10181186 | BD281959 | 05-Feb-2016 |
| 21 | 10127501 | BD250659 | 15-Jun-2015 |
| 22 | 10181161 | BD281935 | 13-Feb-2016 |
| 23 | 10181176 | BD282088 | 12-Feb-2016 |
| 24 | 10181216 | BD281989 | 19-Feb-2016 |

# AccuSet™ Toxoplasmosis Performance Panel

0820-0321 / Batch #10344475

## Toxoplasmosis IgM

| Panel Member | Trinity Biotech Captia™ Toxoplasma gondii IgM (s/co)[1,5] | Abbott ARCHITECT Toxo IgM (INDEX)[2,5] | bioMerieux VIDAS® Toxo IgM (TV)[3,5] | DiaSorin LIAISON® Toxo IgM (AU/mL)[4,5] | Bio-Rad Platelia™ Toxo IgM (s/co)[1,5] |
|---|---|---|---|---|---|
| 01 | **1.7** | **2.6** | **1.9** | **12.9** | **2.8** |
| 02 | **1.2** | **1.9** | **2.0** | **16.1** | **3.1** |
| 03 | **1.8** | **1.4** | **2.8** | **75.7** | **3.3** |
| 04 | **1.6** | **1.2** | **2.8** | **68.1** | **3.2** |
| 05 | **2.6** | **4.0** | **2.7** | **71.1** | **3.3** |
| 06 | **3.4** | **2.8** | **2.3** | **45.7** | **2.9** |
| 07 | **3.4** | **1.0** | **1.0** | **11.5** | **1.7** |
| 08 | 0.7 | **0.8** | 0.3 | <3.0 | 0.8 |
| 09 | 0.1 | 0.1 | 0.1 | <3.0 | 0.0 |
| 10 | 0.6 | 0.1 | 0.2 | 6.7 | 0.2 |
| 11 | 0.1 | 0.1 | 0.1 | <3.0 | 0.0 |
| 12 | 0.1 | 0.1 | 0.0 | <3.0 | 0.0 |
| 13 | 0.2 | 0.3 | 0.5 | <3.0 | **1.1** |
| 14 | 0.1 | 0.1 | 0.1 | <3.0 | 0.0 |
| 15 | 0.4 | 0.4 | 0.5 | 3.1 | 0.8 |
| 16 | 0.1 | 0.2 | 0.3 | <3.0 | 0.6 |
| 17 | 0.5 | 0.1 | 0.2 | <3.0 | 0.2 |
| 18 | 0.4 | 0.1 | 0.1 | <3.0 | 0.0 |
| 19 | 0.1 | 0.1 | 0.1 | <3.0 | 0.0 |
| 20 | 0.3 | 0.0 | 0.0 | <3.0 | 0.0 |
| 21 | 0.1 | 0.0 | 0.1 | <3.0 | 0.0 |
| 22 | 0.2 | 0.1 | 0.1 | 3.3 | 0.0 |
| 23 | 0.7 | 0.1 | 0.2 | <3.0, 3.5[6] | 0.1 |
| 24 | 0.3 | 0.1 | 0.1 | <3.0 | 0.0 |
| Test Date | 22-May-2018 | 28-May-2018 | 23-May-2018 | 23-May-2018 | 24-May-2018 |
| Test Site | SC | RL | RL | RL | SC |
| Kit Part Code | 2325160 | 6C20-25 | NA | NA | 26211 |
| Kit Lot No. | 2325160-085 | 84166L100 | 1006192440 | NA | 7F0035 |
| Kit Exp. Date | 31-Mar-2019 | 27-Nov-2018 | 09-Oct-2018 | NA | 15-Oct-2018 |
| Kit Regulatory Status | IVD/CE | IVD/CE | IVD | IVD/CE | IVD/CE |

[1]Results are reported as a signal to cutoff ratio (s/co); positive/reactive results are noted in bold red.
[2]Results are reported as an index value; positive/reactive results are noted in bold red.
[3]Results are reported as a test value (TV); positive/reactive results are noted in bold red.
[4]Results are reported as an arbitrary unit (AU/mL); positive/reactive results are noted in bold red.
[5]Results are reported as the mean result of duplicate testing.
[6]Results are reported as individual replicates.
SC = SeraCare; RL = Reference Lab; NA = Not Available
IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking

# AccuSet™ Toxoplasmosis Performance Panel

0820-0321 / Batch #10344475

## Toxoplasmosis IgG

| Panel Member | Abbott ARCHITECT Toxo IgG (IU/mL)[1,3] | bioMerieux VIDAS® Toxo IgG II (IU/mL)[1,3] | DiaSorin LIAISON® Toxo IgG (IU/mL)[1,3] | Trinity Biotech Captia™ Toxoplasma gondii IgG (s/co)[2,3] |
|---|---|---|---|---|
| 01 | **19.3** | **135.5** | **70.2** | **5.1** |
| 02 | **65.2** | **281.0** | **125.0** | **5.1** |
| 03 | **122.0** | **263.5** | **207.5** | **4.9** |
| 04 | **104.4** | **269.5** | **190.0** | **4.7** |
| 05 | **24.3** | **43.0** | **32.8** | **2.9** |
| 06 | **24.9** | **45.5** | **34.1** | **3.2** |
| 07 | **171.7** | **>300** | **282.5** | **5.9** |
| 08 | **24.0** | **141.0** | **132.5** | **5.9** |
| 09 | **4.8** | **29.0** | **19.3** | **3.1** |
| 10 | **19.3** | **192.0** | **73.4** | **5.1** |
| 11 | 0.0 | 0.0 | 0.0 | 0.1 |
| 12 | **7.9** | **36.0** | **19.4** | **3.3** |
| 13 | **1.8** | **18.5** | **19.0** | **2.7** |
| 14 | **5.9** | **41.5** | **34.7** | **3.5** |
| 15 | **14.3** | **76.5** | **40.4** | **4.2** |
| 16 | **38.1** | **126.5** | **116.5** | **5.5** |
| 17 | **66.7** | **>300** | **200.0** | **5.7** |
| 18 | **20.3** | **176.5** | **98.8** | **5.1** |
| 19 | **7.6** | **40.0** | **30.0** | **3.3** |
| 20 | 1.2 | **16.5** | **10.6** | **2.7** |
| 21 | **6.3** | **39.0** | **35.6** | **3.2** |
| 22 | **8.9** | **66.5** | **36.2** | **4.0** |
| 23 | **21.1** | **88.0** | **46.6** | **4.2** |
| 24 | **42.8** | **>300** | **148.0** | **5.6** |
| Test Date | 28-May-2018 | 22-May-2018 | 23-May-2018 | 22-May-2018 |
| Test Site | RL | RL | RL | SC |
| Kit Part Code | 6C19-25 | NA | NA | 2325100 |
| Kit Lot No. | 84096L100 | 1006162530 | NA | 2325100-580 |
| Kit Exp. Date | 19-Dec-2018 | 28-Oct-2018 | NA | 31-May-2019 |
| Kit Regulatory Status | IVD/CE | IVD | IVD | IVD/CE |

[1]Results are reported as international units (IU/mL); positive/reactive results are noted in bold red.
[2]Results are reported as a signal to cutoff ratio (s/co); positive/reactive results are noted in bold red.
[3]Results are reported as the mean result of duplicate testing.
SC = SeraCare; RL = Reference Lab; NA = Not Available
IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking

**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.**