

Anti-*Toxoplasma gondii* Mixed Titer Performance Panel PTT202

DATA SHEET

OVERVIEW

Anti-*Toxoplasma gondii* Mixed Titer Performance Panel PTT202 is a 21-member panel of undiluted, naturally-occurring plasma samples collected between 2002 and 2012 from donors in the United States. No preservatives were added.

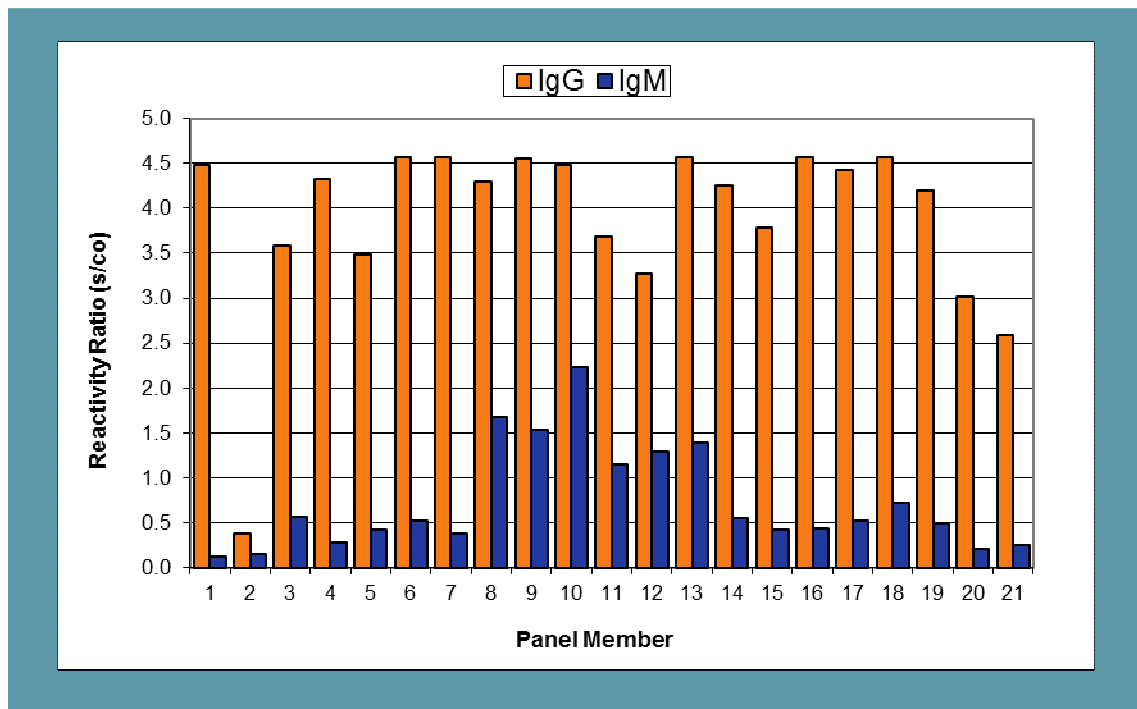
Test results from commercially-available anti-*Toxoplasma gondii* IgG, IgM, and IgG avidity assays are included. Twenty panel members are positive for IgG antibodies to *Toxoplasma gondii*, with varying levels of reactivity for IgM antibodies. One panel member is negative for anti-*Toxoplasma gondii* antibodies by all methods tested.

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: Follow Universal Precautions. All panel members were found non-reactive for HBsAg, anti-HIV, and anti-HCV. This does not ensure the absence of these or other human pathogens.

For assistance, contact SeraCare Technical Support at 508.244.6400.

ANTI-TOXOPLASMA GONDII MIXED TITER PERFORMANCE PANEL PTT202



This graph demonstrates the breadth of antibody reactivity among PTT202 panel members using Trinity Biotech CAPTIA™.

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Anti-Toxo IgG Assays

Panel Member	Bleed Date	Abbott ARCHITECT® Toxo IgG ¹	DiaSorin LIAISON® Toxo IgG ¹	Trinity Biotech CAPTIA™ Toxo gondii IgG ³	bioMerieux VIDAS® Toxo IgG ⁴
PTT202-01	17 Jan 11	71.40	>500.00	4.48	239.00
PTT202-02	08 May 09	0.00	<3.00	0.39	0.00
PTT202-03	13 Jan 11	11.65	148.50	3.58	85.00
PTT202-04	16 Feb 05	17.30	>500.00	4.33	128.50
PTT202-05	04 Sep 11	5.40	87.40	3.48	59.50
PTT202-06	12 Nov 09	87.30	>500.00	4.57	>300.00
PTT202-07	12 Oct 02	4.95	>500.00	4.57	178.00
PTT202-08	13 Jan 11	30.25	>500.00	4.30	>300.00
PTT202-09	14 Aug 04	135.05	>500.00	4.55	>300.00
PTT202-10	22 Nov 11	83.75	>500.00	4.48	280.00
PTT202-11	02 Feb 12	9.05	209.00	3.69	112.00
PTT202-12	29 Nov 11	20.95	283.00	3.27	120.00
PTT202-13	23 Nov 11	39.50	>500.00	4.57	>300.00
PTT202-14	14 Oct 11	4.25	235.50	4.26	134.50
PTT202-15	14 Oct 11	6.75	113.50	3.78	76.50
PTT202-16	06 Jun 11	29.40	>500.00	4.57	189.00
PTT202-17	06 Jun 11	19.20	312.50	4.43	155.00
PTT202-18	06 Jun 11	5.70	>500.00	4.57	173.00
PTT202-19	14 Oct 11	5.45	253.00	4.19	104.00
PTT202-20	11 Jul 09	4.05	70.20	3.02	56.50
PTT202-21	04 Apr 09	2.10 ²	19.85	2.59	26.00
Test Date		10 Apr 13	08 Apr 13	18 Mar 13	13 May 13
Test Site		RL	RL	SC	RL
Kit Part Code		6C19-25	310700	2325100	NA
Kit Lot No.		23047LI00, 25219LI00	034044	2325100-553	1001706590
Kit Exp. Date		22 Oct 13, 15 Jan 14	16 Jul 13	30 Jun 14	09 Aug 13
Kit Regulatory Status		IVD/CE	IVD	CE	IVD

¹Immunoassay results are reported as the mean result of duplicate testing expressed as International Units per mL (IU/mL). Results in red are considered reactive/positive.

²Sample results with a unit value equal to 1.6 – <3.0 IU/mL are considered grayzone and may contain low levels of IgG.

³Immunoassay results are reported as the mean result of duplicate testing expressed as a sample to cut-off value (S/CO). Results in red are considered reactive/positive.

⁴Immunoassay results are reported as the mean result of duplicate testing expressed as a relative fluorescence value (RFV) in International Units per mL (IU/mL). Results in red are considered reactive/positive.

RL = Reference Lab; SC = SeraCare

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NA = Not Available

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Anti-Toxo IgM Assays

Panel Member	Abbott ARCHITECT® Toxo IgM ¹	DiaSorin LIAISON® Toxo IgM ²	Trinity Biotech CAPTIA™ Toxo gondii IgM ¹	bioMerieux VIDAS® Toxo IgM ⁴	BioRad PLATELIA™ Toxo IgM ¹
PTT202-01	0.12	<3.00	0.13	0.07	0.08
PTT202-02	0.09	<3.00	0.15	0.09	0.14
PTT202-03	0.23	<3.00	0.57	0.25	0.89
PTT202-04	0.08	<3.00	0.29	0.08	0.16
PTT202-05	0.09	<3.00	0.43	0.08	0.09
PTT202-06	0.09	<3.00	0.53	0.08	0.60
PTT202-07	0.08	<3.00	0.39	0.05	0.08
PTT202-08	2.94	46.80	1.68	4.03	6.79
PTT202-09	2.73	34.85	1.54	3.52	6.36
PTT202-10	3.42	55.45	2.23	3.75	6.80
PTT202-11	2.63	14.95	1.15	2.94	6.60
PTT202-12	4.24	12.10	1.30	3.11	6.80
PTT202-13	2.06	22.20	1.39	3.32	6.70
PTT202-14	2.73	9.45 ³	0.55	4.19	6.80
PTT202-15	0.12	<3.00	0.43	0.10	0.12
PTT202-16	0.10	<3.00	0.44	0.06	0.07
PTT202-17	1.08	<3.00	0.53	0.44	1.24
PTT202-18	0.52	<3.00	0.73	0.33	1.63
PTT202-19	0.21	<3.00	0.49	0.29	0.78
PTT202-20	0.15	<3.00	0.21	0.29	0.95
PTT202-21	0.09	<3.00	0.25	0.09	0.08
Test Date	10 Apr 13	08 Apr 13	26 Apr 13	13 May 13	18 Mar 13
Test Site	RL	RL	SC	RL	SC
Kit Part Code	6C20-25	310710	2325160	NA	26211
Kit Lot No.	24272LI00	024022	2325160-053	1001629600	2F0020
Kit Exp. Date	03 Dec 13	14 Jan 14	30 Apr 13	28 Jul 13	15 Aug 13
Kit Regulatory Status	IVD/CE	IVD	CE	IVD	IVD

¹Immunoassay results are reported as the mean result of duplicate testing expressed as a sample to cut-off value (S/CO). Results in red are considered reactive/positive.

²Immunoassay results are reported as the mean result of duplicate testing expressed as Arbitrary Units per mL (AU/mL). Results in red are considered reactive/positive.

³Sample results with a unit value equal to 8.00 – 9.90 AU/mL are considered equivocal.

⁴Immunoassay results are reported as the mean result of duplicate testing expressed as a relative fluorescence value (RFV). Results in red are considered reactive/positive.

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Anti-Toxo IgG Avidity Assay

Panel Member	bioMerieux VIDAS [®] Toxo IgG Avidity ¹
PTT202-01	0.49
PTT202-02	NA
PTT202-03	0.59
PTT202-04	0.57
PTT202-05	0.49
PTT202-06	0.51
PTT202-07	0.47
PTT202-08	0.19
PTT202-09	0.23
PTT202-10	0.20
PTT202-11	0.27
PTT202-12	0.24
PTT202-13	0.24
PTT202-14	0.51
PTT202-15	0.52
PTT202-16	0.58
PTT202-17	0.40
PTT202-18	0.55
PTT202-19	0.59
PTT202-20	0.40
PTT202-21	0.50
Test Date	13 May 13
Test Site	RL
Kit Part Code	NA
Kit Lot No.	1001664540
Kit Exp. Date	21 Oct 13
Kit Regulatory Status	IVD

¹Immunoassay results are reported as the mean result of duplicate testing expressed as a relative fluorescence value (RFV). Results in red are considered reactive/positive.

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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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