

CERTIFICATE

Survey of 16 May 2025

You have fulfilled the requirements of the External Quality Assessment with the following analysis

Parasite Serology - Toxoplasmosis (452):

Validity 12 months:

AB against *Toxoplasma gondii* IgG (qualitative) - Immunoblot (R: B2)

AB against *Toxoplasma gondii* IgG (qualitative) - Immunological test (ELISA) (R: B2)

AB against *Toxoplasma gondii* IgM (qualitative) - Immunoblot (R: B2)

AB against *Toxoplasma gondii* IgM (qualitative) - Immunological test (ELISA) (R: B2)

AB against *Toxoplasma gondii* IgA (qualitative) - Immunological test (ELISA) (R: B2)

diagnostic comment

(R) analysis is subject to the RiliBÄK

Customer:
10011570
TestLine Clinical Diagnostics s.r.o.
Krizikova 188/68
61200 Brno



Düsseldorf, 05 June 2025



Prof. Dr. med. Michael Spannagl
(Head of Reference Institution)



Prof. Dr. Marc Hübner
(Adviser)

CERTIFICATE OF PARTICIPATION

Survey of 16 May 2025

You have participated in the External Quality Assessment with the following analysis

Parasite Serology - Toxoplasmosis (452):

AB against Toxoplasma gondii IgG (qualitative) - Immunoblot (R: B2)
AB against Toxoplasma gondii IgG (qualitative) - Immunological test (ELISA) (R: B2)
AB against Toxoplasma gondii IgG (semiquantitative) - Immunological test (CLIA)
AB against Toxoplasma gondii IgM (qualitative) - Immunoblot (R: B2)
AB against Toxoplasma gondii IgM (qualitative) - Immunological test (ELISA) (R: B2)
AB against Toxoplasma gondii IgM (semiquantitative) - Immunological test (CLIA)
AB against Toxoplasma gondii IgA (qualitative) - Immunoblot (R: B2)
AB against Toxoplasma gondii IgA (qualitative) - Immunological test (ELISA) (R: B2)
Toxoplasma gondii IgG avidity (qualitative) - Immunological test (ELISA) (R: B2)
Toxoplasma gondii IgG avidity (semiquantitative) - Immunological test (ELISA)
diagnostic comment

(R) analysis is subject to the RiliBÄK

Customer:
10011570
TestLine Clinical Diagnostics s.r.o.
Krizikova 188/68
61200 Brno



Düsseldorf, 05 June 2025



Prof. Dr. med. Michael Spannagl
(Head of Reference Institution)



Prof. Dr. Marc Hübner
(Adviser)

Listing and evaluation of the results

10011570: TestLine Clinical Diagnostics s.r.o.

Survey of 16 May 2025

Adviser:

Prof. Dr. Marc Hübner

Universitätsklinikum Bonn

Institut für Medizinische Mikrobiologie,
Immunologie und Parasitologie (IMMIP)

Venusberg-Campus 1

53127 Bonn

Tel.: +49-228-287-19177

Mail: huebner@uni-bonn.de

452

Parasite Serology - Toxoplasmosis

Analyte	Sam- ple	Unit	Your value	Target value	TV- Type	Lower limit	Upper limit	Deviation	Z-Score	Meets criteria	
AB against Toxoplasma gondii IgG (semiquantitative)	(1)	31	165								Sample not evaluated
	(1)	32	132								Sample not evaluated
AB against Toxoplasma gondii IgM (semiquantitative)	(1)	31	102								Sample not evaluated
	(1)	32	10.1								Sample not evaluated
Toxoplasma gondii IgG avidity (semiquantitative)	(1,2)	31	71.0								Sample not evaluated
	(1,2)	32	85.0								Sample not evaluated

Analyte	Sam- ple	Your unit	Stated value	Conversion factor	Method	Manu- facturer	Device	Lot number
AB against Toxoplasma gondii IgG (semiquantitative)	31	U/ml	165	1.00	228	TT	ZY99	CL100493
	32		132	1.00				
AB against Toxoplasma gondii IgM (semiquantitative)	31	U/ml	102	1.00	228	TT	ZY99	0200124735
	32		10.1	1.00				
Toxoplasma gondii IgG avidity (semiquantitative)	31		71.0	1.00	190	TT	ZY99	0100121260
	32		85.0	1.00				

Analyte	Sam- ple	Method	Manu- facturer	Device	Your specification(s)	Correct specification(s)	TV- Type	Meets criteria
AB against Toxoplasma gondii IgG (qualitative)	31	190	TT	ZY99	positive (3)	positive (3)	gM	+
	32				positive (3)	positive (3)	gM	+
	31	247	TT	ZY99	positive (3)	positive (3)	gM	+
	32				positive (3)	positive (3)	gM	+
AB against Toxoplasma gondii IgM (qualitative)	31	190	TT	ZY99	positive (3)	positive (3)	gM	+
	32				negative (1)	negative (1)	gM	+
	31	247	TT	ZY99	positive (3)	positive (3)	gM	+
	32				negative (1)	negative (1)	gM	+
AB against Toxoplasma gondii IgA (qualitative)	31	190	TT	ZY99	positive (3)	positive (3)	gM	+
	32				negative (1)	negative (1)	gM	+
	31	247	TT	ZY99	positive (3)	positive (3)	gM	+
	32				borderline (2)	negative (1)	gM	-
Toxoplasma gondii IgG avidity (qualitative)	31	190	TT	ZY99	high (1)	low (2)	gM	-
	32				high (1)	high, intermediate, low (1,3,2)	gM	+
diagnostic comment	31				serological evidence for an acute infection	serological evidence for an acute infection, serological evidence for an acute infection, follow-up examination indicated	M	+
	32				serological evidence for a chronic (latent) infection	serological evidence for a chronic (latent) infection, serological evidence for a chronic (latent) infection, follow-up examination indicated	M	+

(1) In general, no certificate is issued for this parameter in this EQA scheme.

(2) In individual cases is a statistically valid valuation with consensus value not given, because size of the collective < 8 values.

Additional information on the evaluation is available for download in the RV-Online system in the column "Report".

Individual summary of results

10011570: TestLine Clinical Diagnostics s.r.o.

Survey of 16 May 2025

452

Parasite Serology - Toxoplasmosis

AB against <i>Toxoplasma gondii</i> IgG (semiquantitative) (IU/ml, N = 294)									
Collective	Sam- ple	Target value	Target range	Participants collective			Rate (%)		
				AVG	CV	Num.	Sam.	total	
Immuno fluorescence test	31	8192	2048 - 32768	8040	96.4	12	83.3	81.8	
	32	2048	512 - 8192	2691	74.1	12	91.7		
Immunoassays, Abbott	31	236	151 - 321	236	36.8	56	75.0	75.0	
	32	30.8	19.7 - 41.9	30.8	6.07	56	98.2		
Immunoassays, BioMerieux	31	218	140 - 296	218	18.7	26	92.3	80.8	
	32	286	183 - 389	286	32.0	26	84.6		
Immunoassays, Beckman (1)	31	226	145 - 307	226	28.0	5			
	32	411	263 - 559	411	33.6	5			
Immunoassays, DiaSorin	31	246	157 - 335	246	19.1	86	94.2	89.5	
	32	206	132 - 280	206	18.5	86	93.0		
Immunoassays, Euroimmun (1)	31	362	232 - 492	362	115	7			
	32	320	205 - 435	320	106	7			
Immunoassays, Roche	31	716	458 - 974	716	18.7	69	92.8	42.4	
	32	1812	650 - 2464	1812	64.5	69	43.5		
Immunoassays, Siemens	31	933	597 - 1269	933	0.000	16	100	100	
	32	260	166 - 354	260	6.77	16	100		
Immunoassays, Virion / Serion	31	236	151 - 321	236	21.4	10	90.0	90.0	
	32	233	149 - 317	233	18.5	10	90.0		
Immunoassays, other providers	31		Sample not evaluated			10			
	32		Sample not evaluated			10			
without method (1)	31		Sample not evaluated			1			
	32		Sample not evaluated			1			

(1) In individual cases is a statistically valid valuation with consensus value not given, because size of the collective < 8 values.

Rate of success: 73,1%

Graphical representation
not useful

AB against <i>Toxoplasma gondii</i> IgM (semiquantitative) (IU/ml, N = 266)									
Collective	Sam- ple	Target value	Target range	Participants collective			Rate (%)		
				AVG	CV	Num.	Sam.	total	
Immuno fluorescence test (1)	31	256	64.0 - 1024	256	0.000	5			
	32		- <64.0	19.0	154	5			
Agglutination test (ISAGA) (1)	31	1024	256 - 4096	2262	102	6			
	32		- <256	133	114	6			
Immunoassays, Abbott	31	2.54	1.63 - 3.45	2.54	8.27	46	95.7	89.1	
	32	0.204	0.131 - 0.277	0.204	9.31	46	89.1		
Immunoassays, BioMerieux	31	2.35	1.50 - 3.20	2.35	4.94	21	100	95.2	
	32	0.208	0.133 - 0.283	0.208	8.17	21	95.2		
Immunoassays, Beckman (1)	31	14.6	9.34 - 19.9	14.6	12.4	4			
	32	0.980	0.627 - 1.33	0.980	11.3	4			
Immunoassays, DiaSorin	31	47.4	30.3 - 64.5	47.4	10.7	83	98.8	92.8	
	32	3.61	2.31 - 4.91	3.61	30.2	83	94.0		
Immunoassays, Euroimmun (1)	31	5.53	3.54 - 7.52	5.53	14.9	5			
	32	0.630	0.403 - 0.857	0.630	24.6	5			
Immunoassays, Roche	31	3.46	2.21 - 4.71	3.46	11.9	62	96.8	90.0	
	32	0.354	0.227 - 0.481	0.354	14.1	62	90.3		
Immunoassays, Siemens	31	7.01	4.49 - 9.53	7.01	6.80	15	100	100	
	32	0.741	0.474 - 1.01	0.741	12.6	15	100		
Immunoassays, Virion / Serion	31	1806	1156 - 2456	1806	24.0	10	90.0	70.0	
	32		- <=100	100	0.000	10	80.0		

Graphical representation
not useful

Collective	Sam- ple	Target value	Target range	Participants collective			Rate (%)	
				AVG	CV	Num.	Sam.	total
Immunoassays, other providers	31		Sample not evaluated			9		
	32		Sample not evaluated			9		
other methods (1)	31		Sample not evaluated			1		
	32		Sample not evaluated			1		
without method (1)	31		Sample not evaluated			1		
	32		Sample not evaluated			1		

(1) In individual cases is a statistically valid valuation with consensus value not given, because size of the collective < 8 values.

Toxoplasma gondii IgG avidity (semiquantitative) (% , N = 90)									
Collective	Sam- ple	Target value	Target range	Participants collective			Rate (%)		
				AVG	CV	Num.	Sam.	total	
Abbott (1)	31	31.2	20.0 - 42.4	31.2	30.9	7			
	32	85.8	54.9 - 117	85.8	1.90	7			
BioMerieux	31	5.95	3.81 - 8.09	5.95	18.5	21	95.2	95.2	
	32	34.3	22.0 - 46.6	34.3	12.1	21	100		
Diasorin	31	8.26	5.29 - 11.2	8.26	15.9	39	94.9	89.7	
	32	58.7	37.6 - 79.8	58.7	16.5	39	94.9		
Euroimmun (1)	31	21.7	13.9 - 29.5	21.7	36.1	5			
	32	42.1	26.9 - 57.3	42.1	19.3	5			
Roche (1)	31	51.8	33.2 - 70.4	51.8	2.55	6			
	32	44.0	28.2 - 59.8	44.0	2.66	6			
Virion / Serion (1)	31	29.8	19.1 - 40.5	29.8	11.2	5			
	32	30.2	19.3 - 41.1	30.2	25.4	5			
other providers (1)	31		Sample not evaluated			7			
	32		Sample not evaluated			7			

(1) In individual cases is a statistically valid valuation with consensus value not given, because size of the collective < 8 values.

Rate of success: 88%

Graphical representation
not useful

452

Parasite Serology - Toxoplasmosis

AB against Toxoplasma gondii IgG (qualitative) (N = 314, Rate of success: 99,7%)

Sample 31

Collective	positive (3)	total
Immuno fluorescence test	8 ●	8
Immunoblot	24 ●	24
Immunoassays, Abbott	54 ●	54
Immunoassays, BioMerieux	29 ●	29
Immunoassays, DiaSorin	79 ●	79
Immunoassays, Euroimmun	8 ●	8
Immunoassays, Roche	64 ●	64
Immunoassays, Siemens	15 ●	15
Immunoassays, Virion / Serion	10 ●	10
Immunoassays, other providers	18 ●	18
other methods	4 ●	4
without method	1 ●	1

Sample 32

Collective	negative (1)	positive (3)	total
Immuno fluorescence test	0	8 ●	8
Immunoblot	0	24 ●	24
Immunoassays, Abbott	0	54 ●	54
Immunoassays, BioMerieux	0	29 ●	29
Immunoassays, DiaSorin	0	79 ●	79
Immunoassays, Euroimmun	0	8 ●	8
Immunoassays, Roche	1	63 ●	64
Immunoassays, Siemens	0	15 ●	15
Immunoassays, Virion / Serion	0	10 ●	10
Immunoassays, other providers	0	18 ●	18
other methods	0	4 ●	4
without method	0	1 ●	1

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective

AB against *Toxoplasma gondii* IgM (qualitative) (N = 311, Rate of success: 96,5%)

Sample 31

Collective	positive (3)	negative (1)	total
Immuno fluorescence test	5 ●	0	5
Immunoblot	21 ●	1	22
Immunoassays, Abbott	51 ●	0	51
Immunoassays, BioMerieux	28 ●	0	28
Immunoassays, DiaSorin	83 ●	0	83
Immunoassays, Euroimmun	8 ●	0	8
Immunoassays, Roche	63 ●	1	64
Immunoassays, Siemens	15 ●	0	15
Immunoassays, Virion / Serion	11 ●	0	11
Immunoassays, other providers	17 ●	0	17
M.363, R.AX	1 ●	0	1
Agglutination test (ISAGA)	3 ●	0	3
other methods	3 ●	0	3

Sample 32

Collective	negative (1)	positive (3)	borderline (2)	total
Immuno fluorescence test	5 ●	0	0	5
Immunoblot	22 ●	0	0	22
Immunoassays, Abbott	51 ●	0	0	51
Immunoassays, BioMerieux	28 ●	0	0	28
Immunoassays, DiaSorin	82 ●	0	1	83
Immunoassays, Euroimmun	7 ●	0	1	8
Immunoassays, Roche	62 ●	2	0	64
Immunoassays, Siemens	15 ●	0	0	15
Immunoassays, Virion / Serion	10 ●	1	0	11
Immunoassays, other providers	12 ●	4	1	17
M.363, R.AX	1 ●	0	0	1
Agglutination test (ISAGA)	3 ●	0	0	3
other methods	3 ●	0	0	3

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective

AB against *Toxoplasma gondii* IgA (qualitative) (N = 37, Rate of success: 83,8%)

Sample 31

Collective	positive (3)	borderline (2)	negative (1)	total
Agglutination test (ISAGA)	7 ●	0	0	7
Immunoblot	2 ●	3	2	7
ELISA, Euroimmun	10 ●	0	0	10
ELISA	13 ●	0	0	13

Sample 32

Collective	negative (1)	borderline (2)	total
Agglutination test (ISAGA)	7 ●	0	7
Immunoblot	6 ●	1	7
ELISA, Euroimmun	10 ●	0	10
ELISA	13 ●	0	13

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective

Toxoplasma gondii IgG avidity (qualitative) (N = 106, Rate of success: 90,6%)

Sample 31

Collective	high (1)	intermediate (3)	low (2)	total
Abbott	0	0	7 ●	7
BioMerieux	0	0	27 ●	27
Diasorin	0	0	40 ●	40
Euroimmun	0	0	5 ●	5
Roche	0	0	7 ●	7
Virion / Serion	0	0	5 ●	5
Mikrogen	0	2	6 ●	8
other providers	2	1	4 ●	7

Sample 32

Collective	high (1)	intermediate (3)	low (2)	not done (98)	total
Abbott	6 ●	0 ●	0 ●	1	7
BioMerieux	21 ●	6 ●	0 ●	0	27
Diasorin	38 ●	1 ●	0 ●	1	40
Euroimmun	0 ●	2 ●	2 ●	1	5
Roche	0 ●	0 ●	5 ●	0	5
Virion / Serion	0 ●	1 ●	4 ●	0	5
Mikrogen	8 ●	0 ●	0 ●	0	8
other providers	5 ●	2 ●	0 ●	0	7

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective

diagnostic comment (N = 234, Rate of success: 92,3%)

Sample 31

Collective	serological evidence for an acute infection	serological evidence for a chronic (latent) infection	serological evidence for an acute infection, follow-up examination indicated	serological evidence for a chronic (latent) infection, follow-up examination follow-up indicated	total
all providers	116 ●	2	109 ●	6	233

Sample 32

Collective	no serological evidence for an infection	serological evidence for a chronic (latent) infection	serological evidence for an acute infection, follow-up examination indicated	serological evidence for a chronic (latent) infection, follow-up examination follow-up indicated	total
all providers	7	193 ●	3	31 ●	234

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective