

CERTIFICATE

Survey of 15 May 2026

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

(R) analysis is subject to the RiliBÄK

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

Düsseldorf, 29 May 2026



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



Prof. Dr. Marc Hübner
(Adviser)

CERTIFICATE OF PARTICIPATION

Survey of 15 May 2026

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)
AB against Toxoplasma gondii IgA (semiquantitative) - other method
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

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Listing and evaluation of the results

10011570: TestLine Clinical Diagnostics s.r.o.

Survey of 15 May 2026

Adviser:

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452

Parasite Serology - Toxoplasmosis

Analyte	Sample 452A-260428	Unit	Your value	Target value	TV-Type	Lower limit	Upper limit	Deviation	Z-Score	Meets criteria	
AB against Toxoplasma gondii IgG (semiquantitative)	(2) -01		164								Sample not evaluated
	(2) -02		288								Sample not evaluated
AB against Toxoplasma gondii IgM (semiquantitative)	(2) -01		4.53								Sample not evaluated
	(2) -02		5.41								Sample not evaluated
AB against Toxoplasma gondii IgA (semiquantitative)	(1,2) -01		3.00								Sample not evaluated
	(1,2) -02		4.27								Sample not evaluated
Toxoplasma gondii IgG avidity (semiquantitative)	(1,2) -01	%	88.0								Sample not evaluated
	(1,2) -02		97.0								Sample not evaluated

Analyte	Sample 452A-260428	Your unit	Stated value	Conversion factor	Method	Manufacturer	Device	Lot number
AB against Toxoplasma gondii IgG (semiquantitative)	-01	U/ml	164	1.00	228	TT	ZY99	CL100782
	-02		288	1.00				
AB against Toxoplasma gondii IgM (semiquantitative)	-01	U/ml	4.53	1.00	228	TT	ZY99	CL100507
	-02		5.41	1.00				
AB against Toxoplasma gondii IgA (semiquantitative)	-01	U/ml	3.00	1.00	9999	TT	ZY99	CL100804
	-02		4.27	1.00				
Toxoplasma gondii IgG avidity (semiquantitative)	-01		88.0	1.00	190	TT	ZY99	0100125736
	-02		97.0	1.00				

Analyte	Sample 452A-260428	Method	Manufacturer	Device	Your specification(s)	Correct specification(s)	TV-Type	Meets criteria
AB against Toxoplasma gondii IgG (qualitative)	-01	190	TT	ZY99	positive (3)	positive (3)	gM	+
	-02				positive (3)	positive (3)	gM	+
	-01	247	TT	ZY99	positive (3)	positive (3)	gM	+
	-02				positive (3)	positive (3)	gM	+
AB against Toxoplasma gondii IgM (qualitative)	-01	190	TT	ZY99	negative (1)	negative (1)	gM	+
	-02				positive (3)	negative, borderline, positive (1,2,3)	gM	+
	-01	247	TT	ZY99	negative (1)	negative (1)	gM	+
	-02				positive (3)	negative, borderline, positive (1,2,3)	gM	+
AB against Toxoplasma gondii IgA (qualitative)	-01	190	TT	ZY99	negative (1)	negative (1)	gM	+
	-02				negative (1)	negative (1)	gM	+
	-01	247	TT	ZY99	negative (1)	negative (1)	gM	+
	-02				negative (1)	negative (1)	gM	+
Toxoplasma gondii IgG avidity (qualitative)	-01	190	TT	ZY99	high (1)	high (1)	gM	+
	-02				high (1)	high (1)	gM	+

Listing and evaluation of the results

10011570: TestLine Clinical Diagnostics s.r.o.

Survey of 15 May 2026

Analyte	Sample 452A- 260428	Method	Manu- facturer	Device	Your specification(s)	Correct specification(s)	TV- Type	Meets criteria
diagnostic comment	-01				serological evidence for a chronic (latent) infection	serological evidence for a chronic (latent) infection, serological evidence for a chronic (latent) infection, follow-up examination follow-up indicated	M	+
	-02				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	M	-

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

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

Individual summary of results

10011570: TestLine Clinical Diagnostics s.r.o.

Survey of 15 May 2026

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Parasite Serology - Toxoplasmosis

AB against <i>Toxoplasma gondii</i> IgG (semiquantitative) (IU/ml, N = 300)									
Collective	Sample 452A- 260428	Target value	Target range	Participants collective			Rate (%)		
				AVG	CV	Num.	Sam.	total	
Immuno fluorescence test	-01	512	128 - 2048	453	68.9	11	90.9	90.9	
	-02	2048	512 - 8192	2746	65.7	11	100		
Immunoassays, Abbott	-01	11.5	7.36 - 15.6	11.5	5.80	51	100	100	
	-02	57.6	36.9 - 78.3	57.6	6.37	51	100		
Immunoassays, BioMerieux	-01	69.2	44.3 - 94.1	69.2	10.9	30	96.7	96.7	
	-02	340	218 - 462	340	20.6	30	100		
Immunoassays, Beckman (1)	-01	55.1	35.3 - 74.9	55.1	19.4	3			
	-02	282	180 - 384	282	9.93	3			
Immunoassays, DiaSorin	-01	43.2	27.6 - 58.8	43.2	15.3	94	96.8	91.5	
	-02	290	186 - 394	290	18.0	94	92.6		
Immunoassays, Euroimmun	-01	54.6	34.9 - 74.3	54.6	100	9	11.1	0.000	
	-02	211	135 - 287	211	91.9	9	33.3		
Immunoassays, Roche	-01	333	213 - 453	333	5.71	69	97.1	94.1	
	-02		>650 -	650	0.000	69	97.1		
Immunoassays, Siemens	-01	50.7	32.4 - 69.0	50.7	3.39	14	100	100	
	-02	189	121 - 257	189	3.01	14	100		
Immunoassays, Virion / Serion	-01	77.1	49.3 - 105	77.1	12.0	8	100	87.5	
	-02	358	229 - 487	358	32.1	8	87.5		
Immunoassays, other providers	-01		Sample not evaluated			11			
	-02		Sample not evaluated			11			
other methods (1)	-01		Sample not evaluated			1			
	-02		Sample not evaluated			1			

Graphical representation
not useful

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

Rate of success: 91,7%

AB against <i>Toxoplasma gondii</i> IgM (semiquantitative) (IU/ml, N = 259)									
Collective	Sample 452A- 260428	Target value	Target range	Participants collective			Rate (%)		
				AVG	CV	Num.	Sam.	total	
Immuno fluorescence test (1)	-01		- <64.0	32.0	80.3	4			
	-02		- <=256	72.0	193	4			
Agglutination test (ISAGA) (1)	-01		- <256	256	0.000	5			
	-02		- <=256	256	0.000	5			
Immunoassays, Abbott	-01	0.150	0.096 - 0.204	0.150	16.7	40	87.5	87.5	
	-02	0.246	0.157 - 0.335	0.246	10.2	40	92.5		
Immunoassays, BioMerieux	-01	0.727	0.465 - 0.989	0.727	16.9	19	78.9	78.9	
	-02	0.572	0.366 - 0.778	0.572	15.4	19	78.9		
Immunoassays, Beckman (1)	-01	0.805	0.515 - 1.09	0.805	2.98	2			
	-02	0.805	0.515 - 1.09	0.805	0.994	2			
Immunoassays, DiaSorin	-01		- <3.00	3.00	0.000	91	91.2	87.9	
	-02	5.36	3.43 - 7.29	5.36	9.68	91	95.6		
Immunoassays, Euroimmun (1)	-01	0.295	0.189 - 0.401	0.295	28.8	5			
	-02	1.41	0.902 - 1.92	1.41	18.9	5			
Immunoassays, Roche	-01	0.214	0.137 - 0.291	0.214	9.35	61	96.7	96.7	
	-02	0.435	0.278 - 0.592	0.435	5.52	61	98.4		
Immunoassays, Siemens	-01	0.440	0.282 - 0.598	0.440	15.7	13	92.3	92.3	
	-02	0.789	0.505 - 1.07	0.789	5.83	13	100		
Immunoassays, Virion / Serion	-01	82.4	52.7 - 112	82.4	24.6	8	100	100	
	-02	324	207 - 441	324	4.91	8	100		

Graphical representation
not useful



Collective	Sample 452A-260428	Target value	Target range	Participants collective			Rate (%)	
				AVG	CV	Num.	Sam.	total
Immunoassays, other providers	-01		Sample not evaluated			10		
	-02		Sample not evaluated			10		
other methods (1)	-01		Sample not evaluated			2		
	-02		Sample not evaluated			2		

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

AB against <i>Toxoplasma gondii</i> IgA (semiquantitative) (IU/ml, N = 25)								
Collective	Sample 452A-260428	Target value	Target range	Participants collective			Rate (%)	
				AVG	CV	Num.	Sam.	total
Agglutination test (ISAGA) (1)	-01		- <16.0	16.0	0.000	6		
	-02		- <16.0	16.0	0.000	6		
ELISA, Euroimmun	-01	0.126	0.081 - 0.171	0.126	66.7	10	30.0	30.0
	-02	0.481	0.308 - 0.654	0.481	21.0	10	90.0	
ELISA other providers	-01		Sample not evaluated			8		
	-02		Sample not evaluated			8		
other methods (1)	-01		Sample not evaluated			1		
	-02		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: 50%

Graphical representation not useful

Toxoplasma gondii IgG avidity (semiquantitative) (% , N = 95)								
Collective	Sample 452A-260428	Target value	Target range	Participants collective			Rate (%)	
				AVG	CV	Num.	Sam.	total
Abbott (1)	-01	78.0	49.9 - 106	78.0	1.81	7		
	-02	82.3	52.7 - 112	82.3	3.34	7		
BioMerieux	-01	58.0	37.1 - 78.9	58.0	7.05	23	100	100
	-02	56.3	36.0 - 76.6	56.3	7.58	23	100	
Diasorin	-01	52.6	33.7 - 71.5	52.6	13.6	42	92.9	76.2
	-02	47.9	30.7 - 65.1	47.9	29.4	42	83.3	
Euroimmun (1)	-01	74.3	47.6 - 101	74.3	17.8	5		
	-02	81.8	52.4 - 111	81.8	17.2	5		
Roche (1)	-01	90.5	57.9 - 123	90.5	0.351	6		
	-02	88.0	56.3 - 120	88.0	0.732	6		
Virion / Serion (1)	-01	61.6	39.4 - 83.8	61.6	7.74	5		
	-02	64.4	41.2 - 87.6	64.4	4.47	5		
other providers (1)	-01		Sample not evaluated			7		
	-02		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: 86,4%

Graphical representation not useful



AB against *Toxoplasma gondii* IgG (qualitative) (N = 318, Rate of success: 100%)

Sample 452A-260428-01

Collective	positive (3)	total
Immuno fluorescence test	8 ●	8
Immunoblot	22 ●	22
Immunoassays, Abbott	52 ●	52
Immunoassays, BioMerieux	31 ●	31
Immunoassays, DiaSorin	86 ●	86
Immunoassays, Euroimmun	10 ●	10
Immunoassays, Roche	69 ●	69
Immunoassays, Siemens	13 ●	13
Immunoassays, Virion / Serion	9 ●	9
Immunoassays, other providers	15 ●	15
other methods	3 ●	3

Sample 452A-260428-02

Collective	positive (3)	total
Immuno fluorescence test	8 ●	8
Immunoblot	22 ●	22
Immunoassays, Abbott	52 ●	52
Immunoassays, BioMerieux	31 ●	31
Immunoassays, DiaSorin	86 ●	86
Immunoassays, Euroimmun	10 ●	10
Immunoassays, Roche	69 ●	69
Immunoassays, Siemens	13 ●	13
Immunoassays, Virion / Serion	9 ●	9
Immunoassays, other providers	15 ●	15
other methods	3 ●	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* IgM (qualitative) (N = 307, Rate of success: 99%)

Sample 452A-260428-01

Collective	negative (1)	borderline (2)	positive (3)	total
Immuno fluorescence test	4 ●	0	0	4
Immunoblot	19 ●	0	0	19
Immunoassays, Abbott	50 ●	0	0	50
Immunoassays, BioMerieux	24 ●	1	1	26
Immunoassays, DiaSorin	91 ●	0	0	91
Immunoassays, Euroimmun	9 ●	0	0	9
Immunoassays, Roche	67 ●	0	0	67
Immunoassays, Siemens	13 ●	0	0	13
Immunoassays, Virion / Serion	9 ●	0	0	9
Immunoassays, other providers	13 ●	0	0	13
M.363, R.AX	1 ●	0	0	1
Agglutination test (ISAGA)	2 ●	0	0	2
other methods	3 ●	0	0	3

Sample 452A-260428-02

Collective	negative (1)	positive (3)	borderline (2)	total
Immuno fluorescence test	3 ●	1 ●	0 ●	4
Immunoblot	3 ●	16 ●	0 ●	19
Immunoassays, Abbott	50 ●	0 ●	0 ●	50
Immunoassays, BioMerieux	25 ●	1 ●	0 ●	26
Immunoassays, DiaSorin	84 ●	1 ●	6 ●	91
Immunoassays, Euroimmun	0 ●	8 ●	1 ●	9
Immunoassays, Roche	66 ●	0 ●	0 ●	66
Immunoassays, Siemens	13 ●	0 ●	0 ●	13
Immunoassays, Virion / Serion	0 ●	2 ●	7 ●	9
Immunoassays, other providers	9 ●	3 ●	1 ●	13
M.363, R.AX	1 ●	0 ●	0 ●	1
Agglutination test (ISAGA)	1 ●	1 ●	0 ●	2
other methods	2 ●	1 ●	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 = 35, Rate of success: 97,1%)
Sample 452A-260428-01

Collective	negative (1)	total
Agglutination test (ISAGA)	6 ●	6
Immunoblot	6 ●	6
ELISA, Euroimmun	11 ●	11
ELISA	12 ●	12

Sample 452A-260428-02

Collective	negative (1)	borderline (2)	total
Agglutination test (ISAGA)	6 ●	0	6
Immunoblot	6 ●	0	6
ELISA, Euroimmun	11 ●	0	11
ELISA	11 ●	1	12

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 = 107, Rate of success: 91,6%)
Sample 452A-260428-01

Collective	high (1)	intermediate (3)	low (2)	not done (98)	total
Abbott	6 ●	0	0	0	6
BioMerieux	29 ●	1	0	0	30
Diasorin	39 ●	1	1	0	41
Euroimmun	4 ●	0	0	1	5
Roche	7 ●	0	0	0	7
Virion / Serion	5 ●	0	0	0	5
Mikrogen	7 ●	0	0	0	7
other providers	6 ●	0	0	0	6

Sample 452A-260428-02

Collective	high (1)	intermediate (3)	low (2)	not done (98)	total
Abbott	6 ●	0	0	0	6
BioMerieux	29 ●	1	0	0	30
Diasorin	36 ●	3	1	1	41
Euroimmun	5 ●	0	0	0	5
Roche	7 ●	0	0	0	7
Virion / Serion	5 ●	0	0	0	5
Mikrogen	7 ●	0	0	0	7
other providers	6 ●	0	0	0	6

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

diagnostic comment (N = 241, Rate of success: 94,2%)
Sample 452A-260428-01

Collective	serological evidence for a chronic (latent) infection	serological evidence for a chronic (latent) infection, follow-up examination follow-up indicated	no serological evidence for an infection	serological evidence for an acute infection	others	total
all providers	212 ●	19 ●	6	2	1	240

Sample 452A-260428-02

Collective	serological evidence for a chronic (latent) infection	serological evidence for a chronic (latent) infection, follow-up examination follow-up indicated	serological evidence for an acute infection, follow-up examination indicated	no serological evidence for an infection	others	total
all providers	163 ●	58 ●	11 ●	5	4	241

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