CERTIFICATE

Survey of 06 June 2025

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

Infection Serology - Treponema pallidum Antibodies (311):

Validity 12 months:

AB against Treponema pallidum polyvalent (qualitative) - Immunological test (ELISA) (R: B2)
AB against Treponema pallidum IgG (qualitative) - Immunological test (ELISA) (R: B2)
Treponema pallidum IgG - Immunoblot - Immunoblot (R: B2)

(R) analysis is subject to the RiliBÄK

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

DAkkS Deutsche Akkreditierungsstelle D-EP-15027-02-00

Gesellschaft zur Förderung der Qualitätssicherung in medizinischen Laboratorien e.V. INSTAND Qualitätskontrolle und Ringversuch DÜSSELDORF

Düsseldorf, 25 June 2025

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

Prof. Dr. med. K.-P. Hunfeld
(Adviser)

CERTIFICATE OF PARTICIPATION

Survey of 06 June 2025

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

Infection Serology - Treponema pallidum Antibodies (311):

AB against Treponema pallidum polyvalent (qualitative) - Immunological test (ELISA) (R: B2)
AB against Treponema pallidum IgG (qualitative) - Immunological test (ELISA) (R: B2)
AB against Treponema pallidum IgM (qualitative) - Immunological test (ELISA) (R: B2)
Treponema pallidum IgG - Immunoblot - Immunoblot (R: B2)
Treponema pallidum IgM - Immunoblot - Immunoblot (R: B2)
diagnostic comment

(R) analysis is subject to the RiliBÄK

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Düsseldorf, 25 June 2025

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(Head of Reference Institution)

Prof. Dr. med. K.-P. Hunfeld
(Adviser)

INSTAND

Listing and evaluation of the results

10011570: TestLine Clinical Diagnostics s.r.o.

Survey of 06 June 2025

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311 Infection Serology - Treponema pallidum Antibodies

Analyte	Sample	Method	Manufacturer	Device	**Your specification(s)**	Correct specification(s)	TV-Type	Meets criteria
AB against Treponema pallidum polyvalent (qualitative)	31	190	TT	ZY99	positive (3)	positive (3)	gM	+
	32				negative (1)	negative (1)	gM	+
AB against Treponema pallidum IgG (qualitative)	31	190	TT	ZY99	positive (3)	positive (3)	gM	+
	32				negative (1)	negative (1)	gM	+
AB against Treponema pallidum IgM (qualitative)	31	190	TT	ZY99	negative (1)	borderline, positive (2,3)	gM	-
	32				negative (1)	negative (1)	gM	+
Treponema pallidum IgG - Immunoblot	31	247	TT	ZY99	positive (3)	positive (3)	gM	+
	32				negative (1)	negative (1)	gM	+
Treponema pallidum IgM - Immunoblot	31	247	TT	ZY99	negative (1)	borderline, positive (3,2)	gM	-
	32				negative (1)	negative (1)	gM	+
diagnostic comment	31				serological evidence for a past (latent) infection requiring no treatment, not suitable for transfusion	serological evidence for an infection requiring treatment, not suitable for transfusion, serological evidence for an infection requiring treatment + not suitable for transfusion, serological evidence for an infection requiring treatment + follow-up recommended in 3 - 6 months after start of treatment, not suitable for transfusion + follow-up recommended in 3 - 6 months after start of treatment, serological evidence for an infection requiring treatment + not suitable for transfusion + follow-up recommended in 3 - 6 months after start of treatment	M	-
	32				no serological evidence for an infection, suitable for transfusion	no serological evidence for an infection, suitable for transfusion, no serological evidence for an infection + suitable for transfusion	M	+

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

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Individual summary of results

10011570: TestLine Clinical Diagnostics s.r.o.

Survey of 06 June 2025

311 Infection Serology - Treponema pallidum Antibodies

AB against Treponema pallidum polyvalent (qualitative) (N = 305, Rate of success: 98,7%)

Sample 31

Collective	negative (1)	positive (3)	total
ELISA, Euroimmun	1	19 •	20
ELISA, other provider	0	8 •	8
CLIA, Abbott	0	15 •	15
CLIA, DiaSorin	0	67 •	67
CLIA, Roche	0	11 •	11
CLIA, Siemens	0	16 •	16
CLIA, other provider	0	1 •	1
CMIA, Abbott	0	73 •	73
CMIA, other provider	0	4 •	4
ECLIA, Roche	0	72 •	72
ECLIA, other provider	0	2 •	2
other methods	0	16 •	16

Sample 32

Collective	negative (1)	borderline (2)	positive (3)	total
ELISA, Euroimmun	19 •	0	1	20
ELISA, other provider	8 •	0	0	8
CLIA, Abbott	14 •	0	1	15
CLIA, DiaSorin	67 •	0	0	67
CLIA, Roche	11 •	0	0	11
CLIA, Siemens	16 •	0	0	16
CLIA, other provider	1 •	0	0	1
CMIA, Abbott	73 •	0	0	73
CMIA, other provider	4 •	0	0	4
ECLIA, Roche	71 •	0	1	72
ECLIA, other provider	2 •	0	0	2
other methods	15 •	1	0	16

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

AB against Treponema pallidum IgG (qualitative) (N = 74, Rate of success: 97,3%)

Sample 31

Collective	positive (3)	total
ELISA, Euroimmun	24 •	24
ELISA, Mikrogen	11 •	11
ELISA, other provider	8 •	8
CLIA	14 •	14
other methods	17 •	17

Sample 32

Collective	negative (1)	positive (3)	total
ELISA, Euroimmun	24 •	0	24
ELISA, Mikrogen	11 •	0	11
ELISA, other provider	8 •	0	8
CLIA	12 •	2	14
other methods	17 •	0	17

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

AB against Treponema pallidum IgM (qualitative) (N = 69, Rate of success: 85,5%)

Sample 31

Collective	negative (1)	borderline (2)	positive (3)	total
ELISA, Euroimmun	3	6 •	28 •	37
ELISA, Mikrogen	0	0 •	22 •	22
ELISA, other provider	4	1 •	1 •	6
other methods	2	1 •	1 •	4

Sample 32

Collective	negative (1)	total
ELISA, Euroimmun	37 •	37
ELISA, Mikrogen	22 •	22
ELISA, other provider	6 •	6
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

Treponema pallidum IgG - Immunoblot (N = 181, Rate of success: 97,8%)

Sample 31

Collective	positive (3)	total
Immunoblot, Euroimmun	6	6
Immunoblot, Mikrogen	26	26
Immunoblot, Viramed	38	38
Immunoblot, Virotech	3	3
Immunoblot other provider	8	8
Westernblot	9	9
Line Blot, Euroimmun	8	8
Line Blot, Mikrogen	54	54
Line Blot, Viramed	5	5
Line Blot, Virotech	11	11
Line Blot, other provider	4	4
other methods	9	9

Sample 32

Collective	negative (1)	total
Immunoblot, Euroimmun	6	6
Immunoblot, Mikrogen	26	26
Immunoblot, Viramed	38	38
Immunoblot, Virotech	3	3
Immunoblot other provider	7	7
Westernblot	9	9
Line Blot, Euroimmun	8	8
Line Blot, Mikrogen	52	52
Line Blot, Viramed	5	5
Line Blot, Virotech	10	10
Line Blot, other provider	4	4
other methods	9	9

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

Treponema pallidum IgM - Immunoblot (N = 185, Rate of success: 94,6%)

Sample 31

Collective	negative (1)	borderline (2)	positive (3)	total
Immunoblot, Euroimmun	0	0	5	5
Immunoblot, Mikrogen	0	10	18	28
Immunoblot, Viramed	1	30	9	40
Immunoblot, Virotech	0	0	3	3
Immunoblot other provider	1	0	6	7
Westernblot	2	3	3	8
Line Blot, Euroimmun	0	0	8	8
Line Blot, Mikrogen	0	22	38	60
Line Blot, Viramed	1	3	1	5
Line Blot, Virotech	0	0	11	11
other methods	0	6	4	10

Sample 32

Collective	negative (1)	positive (3)	total
Immunoblot, Euroimmun	5	0	5
Immunoblot, Mikrogen	28	0	28
Immunoblot, Viramed	40	0	40
Immunoblot, Virotech	3	0	3
Immunoblot other provider	5	0	5
Westernblot	8	0	8
Line Blot, Euroimmun	7	1	8
Line Blot, Mikrogen	59	0	59
Line Blot, Viramed	5	0	5
Line Blot, Virotech	10	0	10
other methods	10	0	10

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

diagnostic comment (N = 274, Rate of success: 89,1%)

Sample 31

Collective	serological evidence for an infection requiring treatment, not suitable for transfusion, follow-up recommended in 3 - 6 months after start of treatment	serological evidence for an infection requiring treatment, not suitable for transfusion	serological evidence for an infection requiring treatment	not suitable for transfusion	others	total
all methods	146	40	33	23	26	268

Sample 32

Collective	no serological evidence for an infection, suitable for transfusion	no serological evidence for an infection	suitable for transfusion	questionable result, follow-up recommended in approx. 2 weeks, no serological evidence for an infection	others	total
all methods	200	61	10	2	1	274

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