

CERTIFICATE

Survey of 06 June 2025

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

Infection Serology - Helicobacter pylori Antibodies (334):

Validity 12 months:

AB against Helicobacter pylori IgG (qualitative) - Immunological test (CLIA)

AB against Helicobacter pylori IgG (qualitative) - Immunological test (ELISA)

AB against Helicobacter pylori IgA (qualitative) - Immunological test (CLIA)

AB against Helicobacter pylori IgA (qualitative) - Immunological test (ELISA)

AB against Helicobacter pylori IgG - Immunoblot

AB against Helicobacter pylori IgA - Immunoblot

diagnostic comment

(R) analysis is subject to the RiliBÄK

Customer:

10011570

TestLine Clinical Diagnostics s.r.o.

Krizikova 188/68

61200 Brno



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 - Helicobacter pylori Antibodies (334):

AB against Helicobacter pylori IgG (qualitative) - Immunological test (CLIA)
AB against Helicobacter pylori IgG (qualitative) - Immunological test (ELISA)
AB against Helicobacter pylori IgG (semiquantitative) - Immunological test (CLIA)
AB against Helicobacter pylori IgA (qualitative) - Immunological test (CLIA)
AB against Helicobacter pylori IgA (qualitative) - Immunological test (ELISA)
AB against Helicobacter pylori IgA (semiquantitative) - Immunological test (CLIA)
AB against Helicobacter pylori IgG - Immunoblot
AB against Helicobacter pylori IgA - Immunoblot
diagnostic comment

(R) analysis is subject to the RiliBÄK

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(Head of Reference Institution)



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

Listing and evaluation of the results

10011570: TestLine Clinical Diagnostics s.r.o.

Survey of 06 June 2025

Adviser:

Prof. Dr. med. K.-P. Hunfeld

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Infection Serology - Helicobacter pylori Antibodies

Analyte	Sam- ple	Unit	Your value	Target value	TV- Type	Lower limit	Upper limit	Deviation	Z-Score	Meets criteria	
AB against Helicobacter pylori IgG (semiquantitative)	(2) 31		1.54								Sample not evaluated
	(2) 32		331								Sample not evaluated
AB against Helicobacter pylori IgA (semiquantitative)	(1,2) 31		1.74								Sample not evaluated
	(1,2) 32		4.87								Sample not evaluated

Analyte	Sam- ple	Your unit	Stated value	Conversion factor	Method	Manu- facturer	Device	Lot number
AB against Helicobacter pylori IgG (semiquantitative)	31	U/ml	1.54	1.00	228	TT	ZY99	CL100472
	32		331	1.00				
AB against Helicobacter pylori IgA (semiquantitative)	31	U/ml	1.74	1.00	228	TT	ZY99	CL100498
	32		4.87	1.00				

Analyte	Sam- ple	Method	Manu- facturer	Device	Your specification(s)	Correct specification(s)	TV- Type	Meets criteria
AB against Helicobacter pylori IgG (qualitative)	31	190	TT	ZY99	negative (1)	negative (1)	gM	+
	32				positive (3)	positive (3)	gM	+
	31	228	TT	ZY99	negative (1)	negative (1)	gM	+
	32				positive (3)	positive (3)	gM	+
AB against Helicobacter pylori IgA (qualitative)	31	190	TT	ZY99	negative (1)	negative (1)	gM	+
	32				negative (1)	negative (1)	gM	+
	31	228	TT	ZY99	negative (1)	negative (1)	gM	+
	32				negative (1)	negative (1)	gM	+
AB against Helicobacter pylori IgG - Immunoblot	31		TT	ZY99	negative (1)	negative (1)	gM	+
	32				positive (3)	positive (3)	gM	+
AB against Helicobacter pylori IgA - Immunoblot	31		TT	ZY99	negative (1)	negative (1)	gM	+
	32				negative (1)	negative (1)	gM	+
diagnostic comment	31				no evidence for infection (1)	no evidence for infection (1)	M	+
	32				Serological evidence for infection (2)	Serological evidence for infection, Serological evidence for infection + further diagnostic analysis recommended ((2,3),2)	M	+

** BRAVO **

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

(2) Semiquantitative results are collected for scientific reasons only and are therefore not certified.

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.

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Infection Serology - Helicobacter pylori Antibodies

AB against Helicobacter pylori IgG (semiquantitative) (N = 162)								
Collective	Sam- ple	Target value	Target range	Participants collective			Rate (%)	
				AVG	CV	Num.	Sam.	total
ELISA	31		Sample not evaluated			117		
	32		Sample not evaluated			117		
CLIA	31		Sample not evaluated			40		
	32		Sample not evaluated			40		
other methods	(1) 31		Sample not evaluated			6		
	32		Sample not evaluated			6		

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

Graphical representation
not useful

AB against Helicobacter pylori IgA (semiquantitative) (N = 97)								
Collective	Sam- ple	Target value	Target range	Participants collective			Rate (%)	
				AVG	CV	Num.	Sam.	total
ELISA	31		Sample not evaluated			92		
	32		Sample not evaluated			92		
CLIA (1)	31		Sample not evaluated			5		
	32		Sample not evaluated			5		

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

Graphical representation
not useful

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Infection Serology - Helicobacter pylori Antibodies

AB against Helicobacter pylori IgG (qualitative) (N = 185, Rate of success: 100%)

Sample 31		
Collective	negative (1)	total
ELISA, DiaSorin	5 ●	5
ELISA, Euroimmun	48 ●	48
ELISA, Mikrogen	13 ●	13
ELISA, Orgentec	11 ●	11
ELISA, Virion \ Serion	31 ●	31
ELISA, Virotech	5 ●	5
ELISA, other providers	9 ●	9
CLIA, DiaSorin	20 ●	20
CLIA, Vircell	10 ●	10
CLIA, other providers	11 ●	11
Immuno fluorescence	3 ●	3
Immunochromatography	7 ●	7
other methods	12 ●	12

Sample 32		
Collective	positive (3)	total
ELISA, DiaSorin	5 ●	5
ELISA, Euroimmun	48 ●	48
ELISA, Mikrogen	13 ●	13
ELISA, Orgentec	11 ●	11
ELISA, Virion \ Serion	31 ●	31
ELISA, Virotech	5 ●	5
ELISA, other providers	9 ●	9
CLIA, DiaSorin	20 ●	20
CLIA, Vircell	10 ●	10
CLIA, other providers	11 ●	11
Immuno fluorescence	3 ●	3
Immunochromatography	7 ●	7
other methods	12 ●	12

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

AB against Helicobacter pylori IgA (qualitative) (N = 108, Rate of success: 94,4%)

Sample 31

Collective	negative (1)	total
ELISA, Euroimmun	40 ●	40
ELISA, Mikrogen	11 ●	11
ELISA, Orgentec	7 ●	7
ELISA, Virion \ Serion	27 ●	27
ELISA, Virotech	6 ●	6
ELISA, other providers	7 ●	7
CLIA, all providers	7 ●	7
other methods	3 ●	3

Sample 32

Collective	negative (1)	borderline (2)	positive (3)	total
ELISA, Euroimmun	40 ●	0	0	40
ELISA, Mikrogen	11 ●	0	0	11
ELISA, Orgentec	7 ●	0	0	7
ELISA, Virion \ Serion	25 ●	1	1	27
ELISA, Virotech	6 ●	0	0	6
ELISA, other providers	6 ●	0	0	6
CLIA, all providers	5 ●	1	1	7
other methods	2 ●	0	1	3

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

AB against Helicobacter pylori IgG - Immunoblot (N = 90, Rate of success: 98,9%)

Sample 31

Collective	negative (1)	total
Euroimmun	14 ●	14
Mikrogen	37 ●	37
Viramed	31 ●	31
Virotech	1 ●	1
other providers	6 ●	6

Sample 32

Collective	positive (3)	total
Euroimmun	14 ●	14
Mikrogen	37 ●	37
Viramed	32 ●	32
Virotech	1 ●	1
other providers	6 ●	6

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

AB against Helicobacter pylori IgA - Immunoblot (N = 72, Rate of success: 90,3%)

Sample 31

Collective	negative (1)	positive (3)	total
Euroimmun	13 ●	0	13
Mikrogen	27 ●	0	27
Viramed	23 ●	4	27
other providers	4 ●	0	4

Sample 32

Collective	negative (1)	borderline (2)	total
Euroimmun	12 ●	1	13
Mikrogen	27 ●	0	27
Viramed	28 ●	0	28
other providers	3 ●	1	4

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

diagnostic comment (N = 144, Rate of success: 93,1%)

Sample 31

Collective	no evidence for infection (1)	Serological evidence for infection (2)	further diagnostic analysis recommended (3)	total
all providers	141 ●	2	4	147

Sample 32

Collective	no evidence for infection (1)	Serological evidence for infection (2)	further diagnostic analysis recommended (3)	Serological evidence for infection, further diagnostic analysis recommended (2, 3)	total
all providers	2	52 ●	4	86 ●	144

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