

CERTIFICATE

Survey of 27 June 2025

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

Virus Immunology - Tick-Borne Encephalitis (TBE/FSME) Virus (Ab) (358):

Validity 12 months:

Anti-TBE/FSME virus IgG

Anti-TBE/FSME virus IgG - avidity

Anti-TBE/FSME virus IgM

(R) analysis is subject to the RiliBÄK

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



Düsseldorf, 16 July 2025



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



Dr. Axel Schubert
(Adviser)

CERTIFICATE OF PARTICIPATION

Survey of 27 June 2025

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

Virus Immunology - Tick-Borne Encephalitis (TBE/FSME) Virus (Ab) (358):

Anti-TBE/FSME virus IgG

Anti-TBE/FSME virus IgG - avidity

Anti-TBE/FSME virus IgM

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(Head of Reference Institution)



Dr. Axel Schubert
(Adviser)



Listing and evaluation of the results

10011570: TestLine Clinical Diagnostics s.r.o.

Survey of 27 June 2025

Adviser:

Dr. Axel Schubert
INSTAND e.V.
Ubierstraße 20
40223 Düsseldorf

Tel.: +49 211-15 92 13 720
Mail: schubert@instand-ev.de

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Virus Immunology - Tick-Borne Encephalitis (TBE/FSME) Virus (Ab)

Anti-TBE/FSME virus IgG

+

Name of test	Unit	Method	Manufacturer				
CLIA TBE Virus IgG		Immunological test (CLIA) (228)	TEST-LINE (TT)				
Result (qual)	Sample 358A- 250610	Your specification(s)	Correct specification(s)		TV- Type		Meets criteria
	-01 -02	positive (3) positive (3)	positive (3) positive (3)		SV SV		+ +
Name of test	Unit	Method	Manufacturer				
CLIA TBE Virus IgG	U/ml	Immunological test (CLIA) (228)	TEST-LINE (TT)				
Result (quant)	Sample 358A- 250610	Your value	Lower limit	Upper limit	TV- Type	Target value	Meets criteria
	-01 -02	76.3 66.6					
Result (qual)	Sample 358A- 250610	Your specification(s)	Correct specification(s)		TV- Type		Meets criteria
	-01 -02	positive (3) positive (3)	positive (3) positive (3)		SV SV		+ +

Anti-TBE/FSME virus IgG - avidity

+

Name of test	Unit	Method	Manufacturer			
EIA TBE Virus IgG Avidität		Immunological test (ELISA) (190)	TEST-LINE (TT)			
Result (qual)	Sample 358A- 250610	Your specification(s)	Correct specification(s)	TV- Type		Meets criteria
	-01	high (1)	high (1)	SV		+
	-02	high (1)	high (1)	SV		+
Avidity in percent	Sample 358A- 250610	Your value				
	-01	78.0				
	-02	69.0				

Anti-TBE/FSME virus IgM

+

Name of test	Unit	Method	Manufacturer			
CLIA TBE Virus IgM		Immunological test (CLIA) (228)	TEST-LINE (TT)			
Result (qual)	Sample 358A- 250610	Your specification(s)	Correct specification(s)	TV- Type		Meets criteria
	-01	negative (1)	negative (1)	SV		+
	-02	negative (1)	negative (1)	SV		+

Listing and evaluation of the results

10011570: TestLine Clinical Diagnostics s.r.o.

Survey of 27 June 2025

Anti-TBE/FSME virus IgM

+

Name of test	Unit	Method	Manufacturer				
CLIA TBE Virus IgM	U/ml	Immunological test (CLIA) (228)	TEST-LINE (TT)				
Result (quant)	Sample 358A- 250610	Your value	Lower limit	Upper limit	TV- Type	Target value	Meets criteria
(1)	-01	31.1					
	-02	17.3					
Result (qual)	Sample 358A- 250610	Your specification(s)	Correct specification(s)		TV- Type		Meets criteria
(1)	-01	positive (3)	negative (1)		SV		
	-02	negative (1)	negative (1)		SV		+

(1) This result is not considered for the certificate, because results of further tests / for further gene regions are evaluated as "correct" for all evaluated samples.

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