QUALITY CONTROL CERTIFICATE

EIA Borrelia recombinant IgM (192)

IVD CE

Diagnostic kit *in vitro* according to the Directive 98/79/EC on in vitro diagnostic medical device.

Catalogue code	BrM192	**Batch**	0100067424	**Expiry date**	2022-11
Date of Analysis	8.9.2021	**Laboratory**	TestLine	**Operator**	Krejčová
Analysis number	149252	**Evaluation**	Company Standard	**Conclusion**	APPROVED

Results of Tested Batch

Parameter	Abbr.	Validity Range $A_{(450)}$	OD $A_{(450)}$	Evaluation
Blank	BL	< 0.150	**0.044**	Passed
U/ml	Cal 1	< 0.5 × A(Cal 2)	**0.050**	Passed
CUT-OFF (Calibrator 2) 20 U/ml	Cal 2	0,150 - 0,900	**0.507**	Passed
U/ml	Cal 3	> 1.5 × A(Cal 2)	**2.041**	Passed

Quality Specification under Company Standard

EIA Borrelia recombinant IgM (192)	**Value**
Diagnostic specificity	97.3 %
Diagnostic sensitivity	99.1 %
Intra-assay (VC)	3.43 %
Inter-assay (VC)	6.42 %
Homogeneity (VC)	3.64 %
Attainable level of combined uncertainty (VC)	7.99 %

Hereby, the product of the above batch is <u>RELEASED</u> to distribution.

Date: 08.09.2021

Signature: .....

Head of Quality Control Department

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