

# Quality Control Certificate



## Borrelia 14kDa + OspC IgM ELISA

<b>REF</b> RE57211	<b>LOT</b> EBM193	<b>2026-08-31</b> YYYY-MM-DD
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### Final Release Results:

	Conc. U/mL	Measured value OD	manual		e.g. automated/DSX
			Acceptable range* lower limit OD	upper limit OD	Measured value OD
CAL A	2	0.010	-	< 0.15	0.010
CAL B	10	0.339	0.25 (> CAL A)	0.75	0.327
CAL C	25	0.817	-	-	0.718
CAL D	100	2.592	> 1.20	-	2.274
CONTROL -	-	0.093	-	< 0.25	0.094
CONTROL +	-	1.944	> 1.00	-	1.723

\*During automated procedure the optical densities of calibrators and controls may rise due to temperature and specific device conditions.  
In case of none conformance with the OD ranges stated on the QC Certificate please contact IBL-International or use the validation criteria only!

Validation criteria (manual/automated)						
	Measured value		Acceptable range			
	Cut-off Index	Conc. U/mL	lower limit Cut-off Index	Conc. U/mL	upper limit Cut-off Index	Conc. U/mL
CONTROL -	0.3	4	-	-	< 0.6	<7
CONTROL +	5.7	70	3.7	46	6.9	86

### Kit Composition:

<b>REF</b>		<b>LOT</b>	
KEBM671A	CAL A	L555	2026-09
KEBM671B	CAL B	L555	2026-09
KEBM671C	CAL C	L555	2026-09
KEBM671D	CAL D	L555	2026-09
KEBM661	CONTROL -	L556	2026-09
KEBM651	CONTROL +	L557	2026-09
KEZZ711	MTP	L544	2026-09
KEBM541	ENZCONJ	L558	2026-09
KEBM751	DILBUF M	L525	2026-08
KIZZZ01	CONC WASHBUF	L459	2028-01
KEZZ991	TMB SUBS	L541	2027-10
KEZZ921	TMB STOP	L296	2027-04

All reagents of this kit containing human serum or plasma have been tested and were found negative for HIV I/II, HBsAg and HCV.

Valid edition of the instructions for use: 2024-11

This product has been tested successfully by the Quality Control Department and was released for sale according to the existing specifications.

Verified by: T. Borchert

Validation date: 2025-11-18

# Accepted

This document has been produced electronically and is valid without a signature.



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