

Quality Control Certificate



Borrelia 14kDa + OspC IgM ELISA

REF RE57211	LOT EBM194	2027-11-30 YYYY-MM-DD
--------------------	-------------------	--------------------------

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	0.032	-	< 0.15	0.010
CAL B	10	0.366	0.25 (> CAL A)	0.75	0.394
CAL C	25	0.821	-	-	0.872
CAL D	100	2.500	> 1.20	-	2.667
CONTROL -	-	0.113	-	< 0.25	0.122
CONTROL +	-	1.755	> 1.00	-	1.811

*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	<8
CONTROL +	4.8	64	3.2	42	5.9	79

Kit Composition:

REF		LOT	
KEBM671A	CAL A	K705	2028-04
KEBM671B	CAL B	K705	2028-04
KEBM671C	CAL C	K705	2028-04
KEBM671D	CAL D	K705	2028-04
KEBM661	CONTROL -	K706	2028-04
KEBM651	CONTROL +	K707	2028-04
KEZZ711	MTP	K689	2028-04
KEBM541	ENZCONJ	K719	2028-04
KEBM751	DILBUF M	K673	2028-04
KIZZZ01	CONC WASHBUF	K675	2029-09
KEZZ991	TMB SUBS	K503-3	2029-04
KEZZ921	TMB STOP	K674	2029-03

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:	2026-04-27
Accepted	
This document has been produced electronically and is valid without a signature.	