

Quality Control Certificate



Borrelia + VisE IgG ELISA

REF RE57201	LOT EBV191	2027-11-30 YYYY-MM-DD
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Final Release Results:

	Conc. U/mL	Measured value OD	manual		e.g. automated/DSX Measured value OD
			Acceptable range*		
			lower limit OD	upper limit OD	
CAL A	2	0.009	-	< 0.15	0.012
CAL B	10	0.446	0.10 (> CAL A)	0.55	0.401
CAL C	50	0.973	-	-	0.931
CAL D	200	2.340	> 1.20	-	2.558
CONTROL -	-	0.090	-	< 0.15	0.079
CONTROL +	-	2.050	> 1.00	-	2.158

*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		upper limit	
			Cut-off Index	Conc. U/mL	Cut-off Index	Conc. U/mL
CONTROL -	0.2	3	-	-	<0.4	<5
CONTROL +	4.6	160	3.2	117	6.0	217

Kit Composition:

REF		LOT	
KEBV671A	CAL A	K681	2028-03
KEBV671B	CAL B	K681	2028-03
KEBV671C	CAL C	K681	2028-03
KEBV671D	CAL D	K681	2028-03
KEBV661	CONTROL -	K682	2028-03
KEBV651	CONTROL +	K683	2028-03
KEBV511	MTP	K669	2028-03
KEBV541	ENZCONJ	K699	2028-03
KEBV751	DILBUF	K672	2028-03
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: 2026-04-29

Accepted

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