

Quality Control Certificate



MuSK-Ab ELISA

REF RE51021	LOT EMU150	2027-11-30 YYYY-MM-DD
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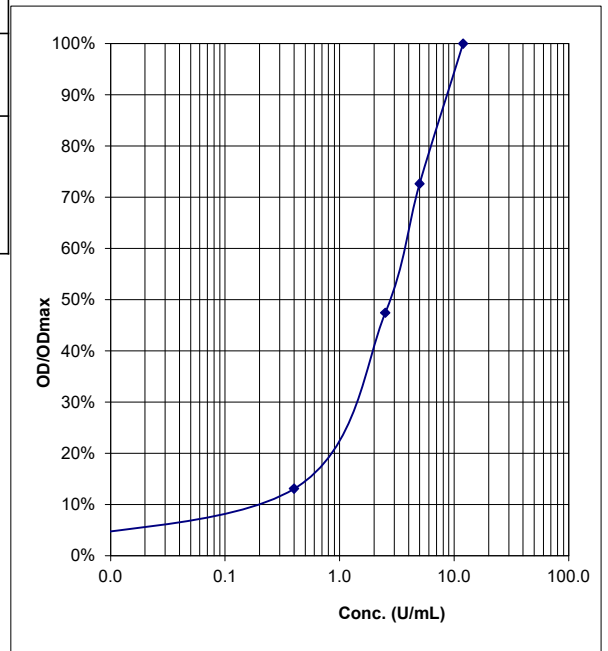
Final Release Results:

	Concentration U/mL	manual			e.g. automated/ Evolyzer
		Measured value OD	Range	OD/ODmax	Measured value OD
CAL A	0	0.040	≤ 0.100	2%	0.073
CAL B	0.4	0.331	-	13%	0.268
CAL C	2.5	1.201	-	47%	1.212
CAL D	5	1.840	-	73%	1.993
CAL E	12	2.532	>1.000	100%	2.252

*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!

	Concentration	Acceptable range		
	found U/mL	lower limit U/mL	target U/mL	upper limit U/mL
CONTROL +	2.8	2.0	2.9	3.8
CONTROL -	0.1			<0.4

Validation criteria				
	COV found	Acceptable range		
	COV	lower limit COV	target COV	upper limit COV
CONTROL +	4.0	2.8	4.1	5.3
CONTROL -	0.4			<0.8



Kit Composition:

REF		LOT	
KEMU511	MTP	K552	2028-01
KEMU541	ENZCONJ CONC	K546	2028-02
KEMU521	ANTISERUM	K547	2028-01
KEMU751	ASSAYBUF	K548	2028-01
KEMU611	CAL A-E	K549	2028-01
KEMU651	CONTROL +	K550	2028-01
KEMU661	CONTROL -	K551	2028-01

REF		LOT	
KEZZ961	PNPP SUBS	K492-2	2027-11
KEZZ951	PNPP STOP	K520	2028-12
KIZZZ01	WASHBUF CONC	K521	2029-06

Valid edition of the instructions for use: 2023-03

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

Verified by: Dr. Spangenberg

Accepted

Validation date: 2026-03-30

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



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