

Quality Control Certificate



MuSK-Ab ELISA

REF RE51021	LOT EMU149	2027-05-31 YYYY-MM-DD
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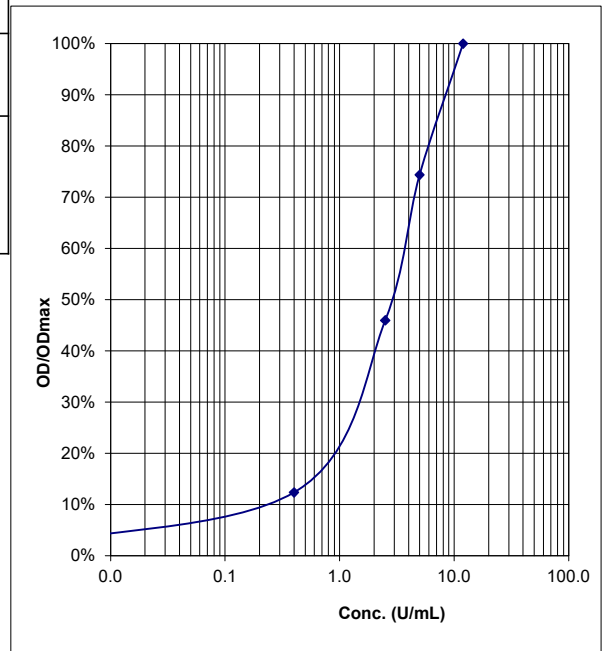
Final Release Results:

	Concentration U/mL	manual			e.g. automated/ Evolyzer
		Measured value OD	Range	OD/ODmax	Measured value OD
CAL A	0	0.034	≤ 0.100	1%	0.041
CAL B	0.4	0.305	-	12%	0.257
CAL C	2.5	1.136	-	46%	0.985
CAL D	5	1.838	-	74%	1.540
CAL E	12	2.471	>1.000	100%	2.097

*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 +	3.0	2.1	3.0	3.9
CONTROL -	0.1			<0.4

Validation criteria				
	COV found	Acceptable range		
	COV	lower limit COV	target COV	upper limit COV
CONTROL +	4.3	3.0	4.2	5.5
CONTROL -	0.4			<0.8



Kit Composition:

REF		LOT	
KEMU511	MTP	K134	2027-05
KEMU541	ENZCONJ CONC	K239	2027-06
KEMU521	ANTISERUM	K229	2027-06
KEMU751	ASSAYBUF	K225	2027-06
KEMU611	CAL A-E	K230	2027-06
KEMU651	CONTROL +	K231	2027-06
KEMU661	CONTROL -	K232	2027-06

REF		LOT	
KEZZ961	PNPP SUBS	K180	2027-09
KEZZ951	PNPP STOP	K189	2028-05
KIZZ01	WASHBUF CONC	K198	2028-12

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: 2025-07-21

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