

Quality Control Certificate



Haemophilus influenzae B IgG ELISA

REF 30217458**LOT** IHIB144U **2028-05-31**
YYYY-MM-DD

Final Release Results:

	Concentration µg/mL	manual		
		Measured value OD	Acceptable range*	OD/ODmax
CAL 1	0.10	0.147	< 0.500	5%
CAL 2	0.17	0.238		9%
CAL 3	0.50	0.538		20%
CAL 4	1.40	1.259		46%
CAL 5	4.00	2.733	> 1.000	100%

*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 found µg/mL	Validation criteria (manual/automated)		
		lower limit µg/mL	target µg/mL	upper limit µg/mL
CONTROL LL	0.52	0.38	0.54	0.70
CONTROL HL	1.32	0.96	1.37	1.79

Kit Composition:

REF		LOT		REF		LOT	
KIHIB11	MTP	K758	2030-04	KIZZZ71	TMB STOP	K774	2029-04
KIHIB41	ENZCONJ CONC	K771	2028-05				
KIHIB51	CAL 1-5	K768	2029-04				
KIHIB61	CONTROL LL	K769	2029-04				
KIHIB71	CONTROL HL	K770	2029-04				
KIHIB81	DILBUF	K772	2029-04				
KIZZZ01	CONC WASHBUF	K773	2029-10				
KEZZ991	TMB SUBS	K503-3	2029-04				

Valid edition of the instructions for use: V2025-11

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: 2026-07-30

Accepted

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

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