Quality Control Certificate

Haemophilus influenzae B IgG ELISA

REF	LOT	
30217458	IHIB139	2026-10-31 YYYY-MM-DD

Final Release Results:

	Concentration µg/mL	manual Measured value OD	Acceptable range*	OD/ODmax
CAL 1	0.09	0.089	< 0.500	4%
CAL 2	0.15	0.126		6%
CAL 3	0.60	0.415		20%
CAL 4	1.90	1.179		58%
CAL 5	5.40	2.045	> 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	0.39	0.26	0.37	0.48
CONTROL HL	1.32	0.90	1.28	1.67

Kit Composition:

REF		LOT	
KIHIB11	MTP	L664	2028-10
KIHIB41	ENZCONJ CONC	L684	2026-10
KIHIB51	CAL 1-5	L666	2027-10
KIHIB61	CONTROL LL	L667	2027-10
KIHIB71	CONTROL HL	L668	2027-10
KIHIB81	DILBUF	L672	2027-10
KIZZZ01	CONC WASHBUF	L686	2028-04
KEZZ991	TMB SUBS	L663	2027-10

REF		LOT	
KIZZZ71	TMB STOP	L205	2027-03

Valid edition of the instructions for use: V2015-07 (01)

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

Verified by: M.Dries

Accepted

Validation date: 2024-12-12

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

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