

Quality Control Certificate



Haemophilus influenzae B IgG ELISA

REF RE56351

LOT IHIB142

2027-04-30
YYYY-MM-DD

Final Release Results:

| | Concentration µg/mL | manual | | |
|-------|------------------------|-------------------------|----------------------|----------|
| | | Measured value OD | Acceptable range* | OD/ODmax |
| CAL 1 | 0.09 | 0.096 | < 0.500 | 3% |
| CAL 2 | 0.17 | 0.145 | | 5% |
| CAL 3 | 0.60 | 0.534 | | 19% |
| CAL 4 | 1.80 | 1.475 | | 53% |
| CAL 5 | 5.00 | 2.762 | > 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 | 0.53 | 0.35 | 0.50 | 0.65 |
| CONTROL HL | 1.19 | 0.86 | 1.23 | 1.59 |

Kit Composition:

| REF | | LOT | | REF | | LOT | |
|---------|--------------|------|---------|---------|----------|------|---------|
| KIHIB11 | MTP | L991 | 2029-04 | KIZZZ71 | TMB STOP | L969 | 2028-04 |
| KIHIB41 | ENZCONJ CONC | L964 | 2027-04 | | | | |
| KIHIB51 | CAL 1-5 | L965 | 2028-04 | | | | |
| KIHIB61 | CONTROL LL | L966 | 2028-04 | | | | |
| KIHIB71 | CONTROL HL | L967 | 2028-04 | | | | |
| KIHIB81 | DILBUF | L974 | 2028-04 | | | | |
| KIZZZ01 | CONC WASHBUF | L968 | 2028-10 | | | | |
| KEZZ991 | TMB SUBS | L919 | 2028-06 | | | | |

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: Dr. Spangenberg

Validation date: 2025-06-19

Accepted

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



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