Mercodia

Mall-0075 v 6.0

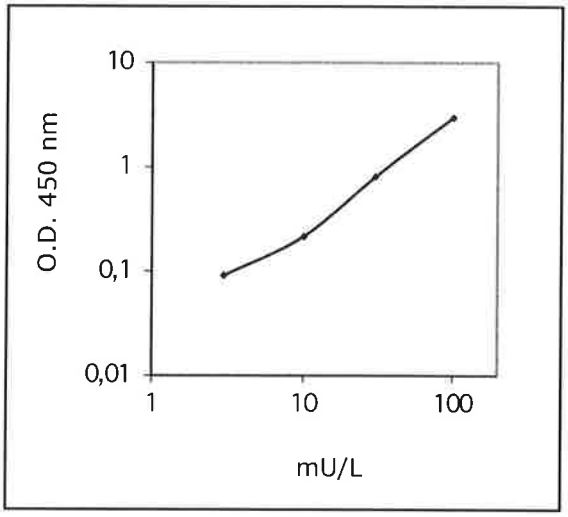
Certificate of Analysis

1. **Manufacturer**

Mercodia AB, Sylveniusgatan 8A, 754 50 Uppsala, SWEDEN

2. **Description**

Catalog no: 10-1128-01
Product: Mercodia Iso Insulin ELISA
Lot no: 36559
Expiry date: 2027-04-30



Component	*Art no*	*Lot no*	*O.D. 450 nm*	*Exp. date*
Calibrator 0	20-2702	35994	0,069	2027-05-29
Calibrator 3 mU/L	20-2703	35996	0,091	2027-06-19
Calibrator 10 mU/L	20-2704	35997	0,215	2027-06-19
Calibrator 30 mU/L	20-2705	35998	0,805	2027-06-19
Calibrator 100 mU/L	20-2706	35999	2,960	2027-06-19
Coated Plate	20-2701	36362		2028-03-03
Enzyme Conjugate 11X	20-2707	36000		2027-06-18
Enzyme Conjugate Buffer	20-2708	35995		2027-06-13
Wash Buffer 21X	20-6746	36422		2031-12-30
Substrate TMB	20-2629	36313		2029-02-28
Stop Solution	20-2693	36245		2031-10-22

Address Mercodia AB, Sylveniusgatan 8A, SE-754 50 Uppsala, Sweden
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E-mail info@mercodia.com | **Website** www.mercodia.com

3. Quality control

Quality control has been performed for lot no 36559 according to standard operating procedures at Mercodia AB, and the product is released based on fulfillment of established acceptance criteria.

4. Calibration

The Mercodia Insulin ELISA is calibrated against 1st International Reference Preparation 66/304.

5. Assay method

Test procedure used is according to current Direction for Use for the product and lot.

6. Intended use

Mercodia Insulin ELISA provides a method for the quantitative determination of insulin in serum or plasma.

7. Storage and handling

Recommended storage of kit is 2-8°C.
Storage of unused or diluted kit components is stated in the Direction for Use.

8. Hazardous information

Please refer to the Material Safety Data Sheet for hazard identification.

9. Quality standard documentation

The Mercodia Quality System fulfills the QSR and the requirements for the European CE mark, the Directive 98/79/CE on *in vitro* diagnostic medical devices. Mercodia is ISO 13485 certified, for compliance with the International Quality Management System for medical devices.

10. Names and signatures of certifying officers

Date of analysis:	Performed by:	Signature:
2025-04-14	Dalan Arabaci	DA

Date of approval:	Approved by:	Signature:
2025-04-17	Elin Westberg	EW

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