Mercodia

Mall-0055 v 6.0

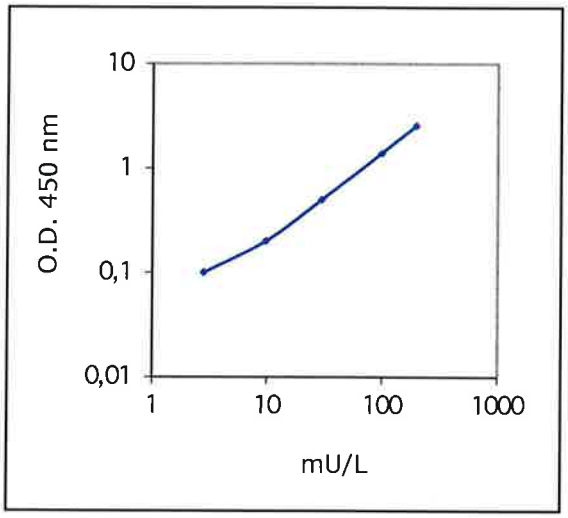
Certificate of Analysis

1. **Manufacturer**

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

2. **Description**

Catalog no: 10-1113-01
Product: Mercodia Insulin ELISA
Lot no: 36959
Expiry date: 2027-05-31



Component	*Art no*	*Lot no*	*O.D. 450 nm*	*Exp. date*
Calibrator 0	20-2615	36094	0,059	2027-06-11
Calibrator 2,86 mU/L	20-2616	36095	0,101	2027-06-05
Calibrator 9,88 mU/L	20-2617	36096	0,201	2027-06-05
Calibrator 30,1 mU/L	20-2618	36097	0,503	2027-06-05
Calibrator 99,3 mU/L	20-2619	36098	1,393	2027-06-05
Calibrator 196 mU/L	20-2620	36099	2,561	2027-06-05
Coated Plate	20-2622	36100		2027-07-01
Enzyme Conjugate 11X	20-2625	36103		2027-06-25
Enzyme Conjugate Buffer	20-2627	36093		2027-07-02
Wash Buffer 21X	20-6746	36804		2032-08-21
Substrate TMB	20-2629	36313		2029-02-28
Stop Solution	20-2693	36554		2032-03-07

Address Mercodia AB, Sylveniusgatan 8A, SE-754 50 Uppsala, Sweden
Phone +46 18 57 00 70 | **Fax** +46 18 57 00 80 | **Vat No** SE-556157510001
E-mail info@mercodia.com | **Website** www.mercodia.com

3. Quality control

Quality control has been performed for lot no 36959 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:
2025-05-22	Elin Westberg	EW

Date of approval:	Approved by:	Signature:
2025-11-03	Jonas Klick	

Address Mercodia AB, Sylveniusgatan 8A, SE-754 50 Uppsala, Sweden
Phone +46 18 57 00 70 | **Fax** +46 18 57 00 80 | **Vat No** SE-556157510001
E-mail info@mercodia.com | **Website** www.mercodia.com