Mercodia

Mall-0056 v 6.0

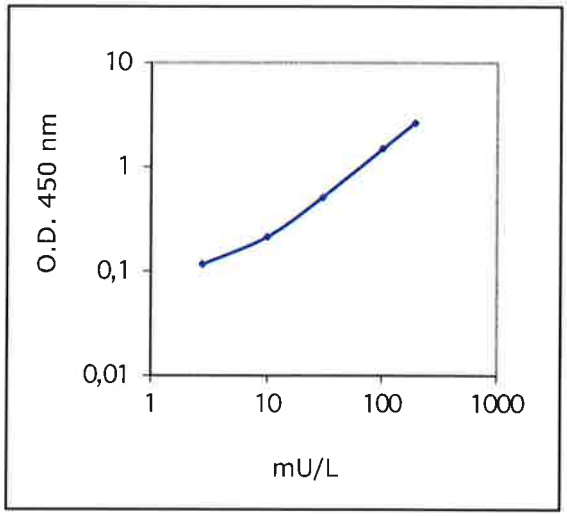
Certificate of Analysis

1. **Manufacturer**

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

2. **Description**

Catalog no: 10-1113-10
Product: Mercodia Insulin ELISA
Lot no: 36037
Expiry date: 2026-03-31



Component	*Art no*	*Lot no*	*O.D. 450 nm*	*Exp. date*
Calibrator 0	20-2615	35331	0,060	2026-04-19
Calibrator 2,77 mU/L	20-2616	35334	0,117	2026-04-17
Calibrator 9,89 mU/L	20-2617	35335	0,214	2026-04-17
Calibrator 29,9 mU/L	20-2618	35336	0,514	2026-04-17
Calibrator 101 mU/L	20-2619	35337	1,505	2026-04-17
Calibrator 195 mU/L	20-2620	35338	2,662	2026-04-17
Coated Plate	20-2622	35657		2026-11-20
Enzyme Conjugate 11X	20-2631	35656		2026-10-19
Enzyme Conjugate Buffer	20-2630	35655		2026-10-24
Wash Buffer 21X	20-3194	36018		2031-04-10
Substrate TMB	20-3136	35552		2027-07-31
Stop Solution	20-2694	35522		2030-08-11

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E-mail info@mercodia.com | **Website** www.mercodia.com

3. Quality control

Quality control has been performed for lot no 36037 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:
2023-12-12	Elin Westberg	EW
Date of approval:	**Approved by:**	**Signature:**
2024-04-25	Jonas Kvick	

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