Mercodia

Mall-0056 v 6.0

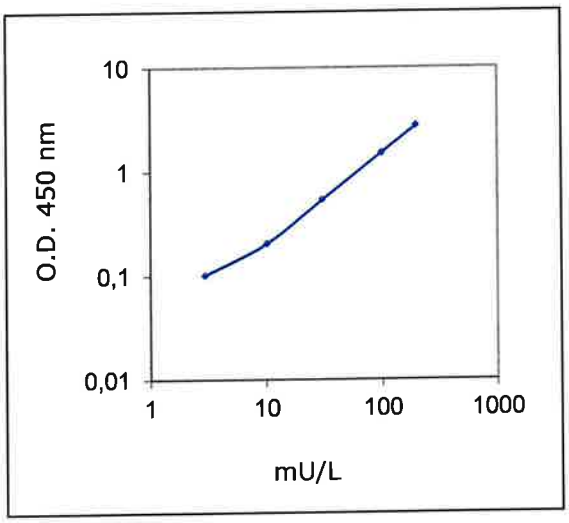
Certificate of Analysis

1. **Manufacturer**

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

2. **Description**

Catalog no: 10-1113-10
Product: Mercodia Insulin ELISA
Lot no: 37689
Expiry date: 2028-07-31



Component	*Art no*	*Lot no*	*O.D. 450 nm*	*Exp. date*
Calibrator 0	20-2615	36763	0,055	2028-08-04
Calibrator 2,97 mU/L	20-2616	36765	0,102	2028-08-06
Calibrator 10,1 mU/L	20-2617	36766	0,205	2028-08-06
Calibrator 30,1 mU/L	20-2618	36767	0,537	2028-08-06
Calibrator 99,0 mU/L	20-2619	36768	1,521	2028-08-06
Calibrator 198 mU/L	20-2620	36769	2,762	2028-08-06
Coated Plate	20-2622	37402		2029-10-05
Enzyme Conjugate 11X	20-2631	37403		2029-10-27
Enzyme Conjugate Buffer	20-2630	37404		2029-10-12
Wash Buffer 21X	20-3194	37145		2033-03-04
Substrate TMB	20-3136	37313		2030-08-31
Stop Solution	20-2694	37702		2033-11-13

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

3. Quality control

Quality control has been performed for lot no 37689 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:
2026-11-19	Elin Westberg	EW

Date of approval:	Approved by:	Signature:
2026-11-19	Jonas Kvick	

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