Mercodia

Mall-0075 v 6.0

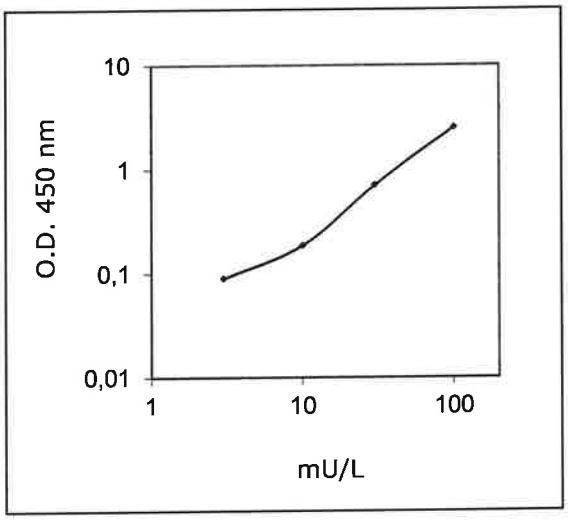
Certificate of Analysis

1. **Manufacturer**

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

2. **Description**

Catalog no: 10-1128-01
Product: Mercodia Iso Insulin ELISA
Lot no: 37511
Expiry date: 2029-08-31



Component		*Art no*	*Lot no*	*O.D. 450 nm*	*Exp. date*
Calibrator 0		20-2702	37503	0,076	2029-09-21
Calibrator 3	mU/L	20-2703	37504	0,090	2029-09-16
Calibrator 10	mU/L	20-2704	37505	0,187	2029-09-16
Calibrator 30	mU/L	20-2705	37506	0,710	2029-09-16
Calibrator 100	mU/L	20-2706	37507	2,536	2029-09-16
Coated Plate		20-2701	37508		2029-09-28
Enzyme Conjugate 11X		20-2707	37509		2029-09-08
Enzyme Conjugate Buffer		20-2708	37510		2029-09-29
Wash Buffer 21X		20-6746	37528		2033-08-28
Substrate TMB		20-2629	37312		2030-08-31
Stop Solution		20-2693	37299		2033-05-29

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

3. Quality control

Quality control has been performed for lot no 37511 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:
2026-11-05	Jonas Kvick	

Date of approval:	Approved by:	Signature:
2026-11-06	Mattias Tale	

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