Mercodia

Mall-0076 v 8.0

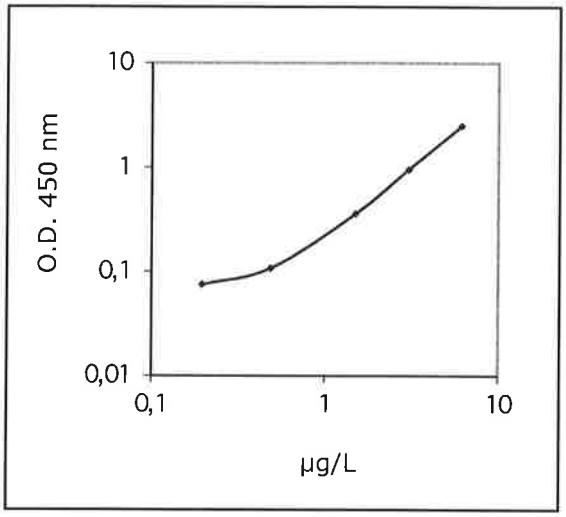
Certificate of Analysis

1. **Manufacturer**

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

2. **Description**

Catalog no:	10-1247-01
Product:	Mercodia Mouse Insulin ELISA
Lot no:	36523
Expiry date:	2027-12-31



Component	*Art no*	*Lot no*	*O.D. 450 nm*	*Exp. date*
Calibrator 0	20-3262	36363	0,062	2028-01-16
Calibrator 0,196 µg/L	20-3150	36364	0,075	2028-01-08
Calibrator 0,489 µg/L	20-3151	36365	0,107	2028-01-08
Calibrator 1,49 µg/L	20-3152	36366	0,356	2028-01-08
Calibrator 3,01 µg/L	20-3153	36367	0,946	2028-01-08
Calibrator 6,09 µg/L	20-3154	36368	2,483	2028-01-08
Coated Plate	20-3193	36373		2030-01-13
Enzyme Conjugate 11X	20-3266	36375		2028-01-08
Enzyme Conjugate Buffer	20-3269	36369		2028-01-10
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

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

3. Quality control

Quality control has been performed for lot no 36523 according to standard operating procedures at Mercodia AB, and the product is released based on fulfillment of established acceptance criteria.

4. Calibration

The Mercodia Mouse Insulin ELISA is calibrated against an in-house reference preparation of mouse insulin.

5. Assay method

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

6. Intended use

Mercodia Mouse Insulin ELISA provides a method for the quantitative determination of mouse 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:
2025-03-12	Matthias H	MH
Date of approval:	**Approved by:**	**Signature:**
2025-03-12	Elin Westberg	EW

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