Mercodia

Mall-0078 v 9.0

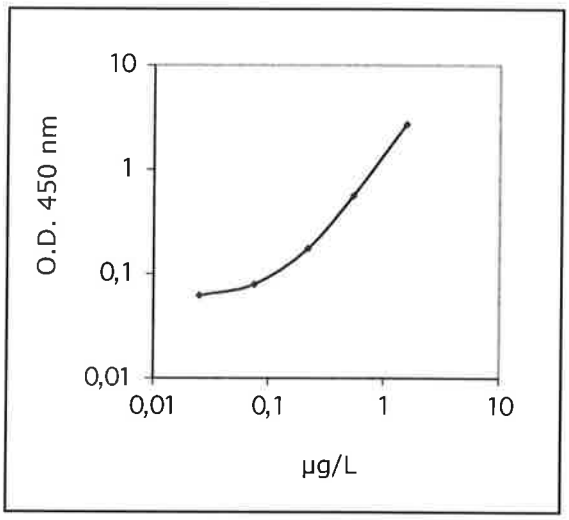
Certificate of Analysis

1. **Manufacturer**

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

2. **Description**

Catalog no:	10-1249-01
Product:	Mercodia Ultrasensitive Mouse Insulin ELISA
Lot no:	36312
Expiry date:	2027-04-30



Component	*Art no*	*Lot no*	*O.D. 450 nm*	*Exp. date*
Calibrator 0	20-3242	36039	0,056	2027-04-30
Calibrator 0,025 µg/L	20-3148	36040	0,062	2027-05-03
Calibrator 0,075 µg/L	20-3149	36041	0,079	2027-05-03
Calibrator 0,219 µg/L	20-3236	36042	0,174	2027-05-03
Calibrator 0,538 µg/L	20-3237	36043	0,557	2027-05-03
Calibrator 1,55 µg/L	20-3238	36044	2,704	2027-05-03
Coated Plate	20-3193	36045		2029-05-13
Enzyme Conjugate 11X	20-3246	36049		2027-05-14
Enzyme Conjugate Buffer	20-3249	36038		2027-05-03
Wash Buffer 21X	20-6746	35948		2031-02-27
Substrate TMB	20-2629	35551		2027-07-31
Stop Solution	20-2693	33839		2029-06-27

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

3. Quality control

Quality control has been performed for lot no 36312 according to standard operating procedures at Mercodia AB, and the product is released based on fulfillment of established acceptance criteria.

4. Calibration

The Mercodia Ultrasensitive 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 Ultrasensitive 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:
2024-07-15	Mattias H	

Date of approval:	Approved by:	Signature:
2024-10-30	Tjonas Kvick	

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