Mercodia
Developing diagnostics

Mall-0070 v 8.0

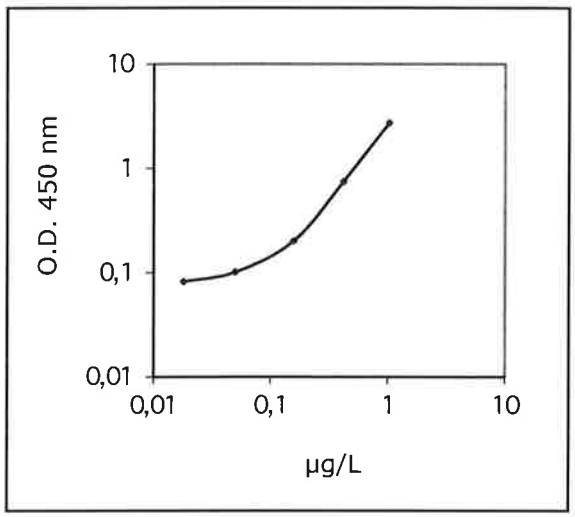
Certificate of Analysis

1. **Manufacturer**

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

2. **Description**

Catalog no:	10-1251-01
Product:	Mercodia Ultrasensitive Rat Insulin ELISA
Lot no:	32776
Expiry date:	2024-05-31



Component		*Art no*	*Lot no*	*O.D. 450 nm*	*Exp. date*
Calibrator 0		20-3166	32480	0,077	2024-06-02
Calibrator 0,018	µg/L	20-3169	32486	0,082	2024-06-03
Calibrator 0,050	µg/L	20-3172	32487	0,101	2024-06-03
Calibrator 0,157	µg/L	20-3175	32488	0,201	2024-06-03
Calibrator 0,415	µg/L	20-3178	32489	0,746	2024-06-03
Calibrator 1,02	µg/L	20-3181	32490	2,723	2024-06-03
Coated Plate		20-3193	32506		2026-05-24
Enzyme Conjugate 11X		20-3139	32772		2024-08-26
Enzyme Conjugate Buffer		20-3191	32492		2024-06-04
Wash Buffer 21X		20-6746	32551		2028-06-21
Substrate TMB		20-2629	31053		2024-07-31
Stop Solution		20-2693	32372		2028-04-22

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

3. Quality control

Quality control has been performed for lot no 32776 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 Rat Insulin ELISA is calibrated against an in-house reference preparation of rat insulin.

5. Assay method

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

6. Intended use

Mercodia Ultrasensitive Rat Insulin ELISA provides a method for the quantitative determination of rat 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:
2021-09-22	Mattias Jäder	

Date of approval:	Approved by:	Signature:
2021-09-22	Jonas Lantz	

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