Mercodia

Mall-0068 v 8.0

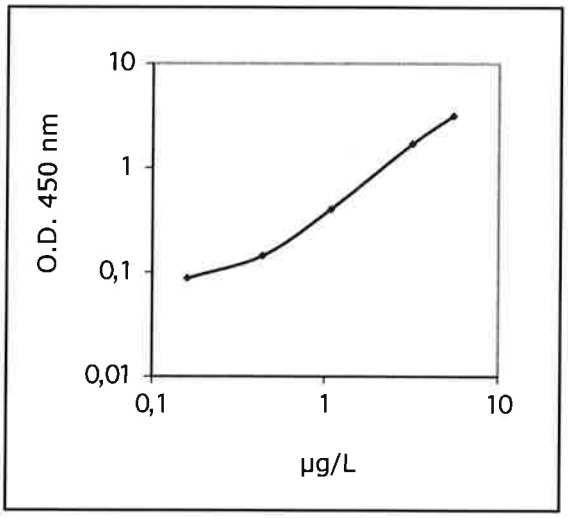
Certificate of Analysis

1. **Manufacturer**

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

2. **Description**

Catalog no:	10-1250-01
Product:	Mercodia Rat Insulin ELISA
Lot no:	35930
Expiry date:	2025-01-31



Component		*Art no*	*Lot no*	*O.D. 450 nm*	*Exp. date*
Calibrator 0		20-3082	33291	0,066	2025-02-03
Calibrator 0,159	µg/L	20-3116	33284	0,087	2025-02-04
Calibrator 0,436	µg/L	20-3117	33285	0,143	2025-02-04
Calibrator 1,08	µg/L	20-3118	33286	0,401	2025-02-04
Calibrator 3,17	µg/L	20-3119	33287	1,694	2025-02-04
Calibrator 5,44	µg/L	20-3120	33288	3,152	2025-02-04
Coated Plate		20-3193	33296		2027-02-07
Enzyme Conjugate 11X		20-3084	33300		2025-02-01
Enzyme Conjugate Buffer		20-3087	33293		2025-02-03
Wash Buffer 21X		20-6746	31141		2027-05-05
Substrate TMB		20-2629	32367		2025-07-31
Stop Solution		20-2693	35772		2030-11-16

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

3. Quality control

Quality control has been performed for lot no 35930 according to standard operating procedures at Mercodia AB, and the product is released based on fulfillment of established acceptance criteria.

4. Calibration

The Mercodia 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 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:
2022-04-28	Jonas Kvick	

Date of approval:	Approved by:	Signature:
2024-02-19	Elin Wernberg	EW

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