Mercodia

Mall-0070 v 9.0

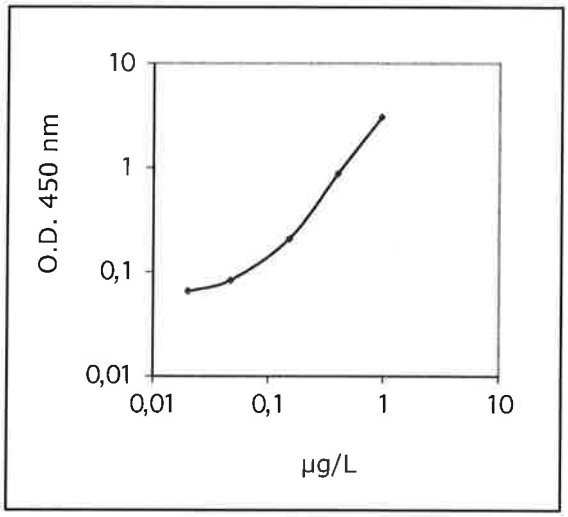
Certificate of Analysis

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:	35920
Expiry date:	2026-11-30



Component		*Art no*	*Lot no*	*O.D. 450 nm*	*Exp. date*
Calibrator 0		20-3166	35800	0,060	2026-12-12
Calibrator 0,020	µg/L	20-3169	35801	0,065	2026-12-14
Calibrator 0,047	µg/L	20-3172	35804	0,083	2026-12-14
Calibrator 0,152	µg/L	20-3175	35805	0,207	2026-12-14
Calibrator 0,410	µg/L	20-3178	35806	0,875	2026-12-14
Calibrator 0,951	µg/L	20-3181	35807	3,033	2026-12-14
Coated Plate		20-3193	35810		2028-12-18
Enzyme Conjugate 11X		20-3139	35811		2027-01-17
Enzyme Conjugate Buffer		20-3191	35802		2026-12-13
Wash Buffer 21X		20-6746	35568		2030-09-05
Substrate TMB		20-2629	35551		2027-07-31
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 35920 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:
2024-02-23	Jonas Kvick	

Date of approval:	Approved by:	Signature:
2024-02-23	Mattias St	

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