Mercodia

Mall-0070 v 9.0

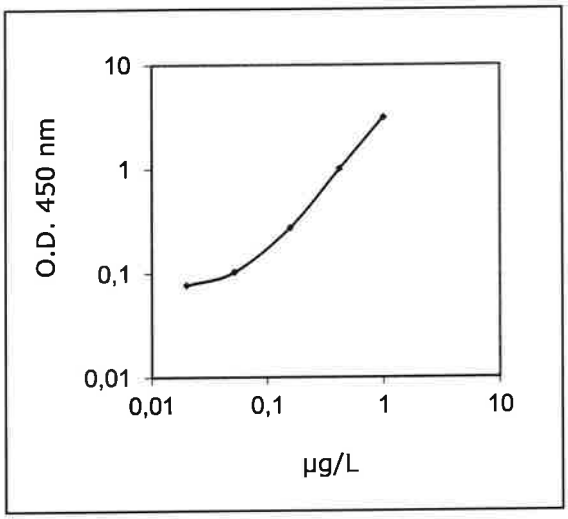
Certificate of Analysis

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:	37369
Expiry date:	2029-08-31



Component		*Art no*	*Lot no*	*O.D. 450 nm*	*Exp. date*
Calibrator 0		20-3166	37359	0,069	2029-09-23
Calibrator 0,020	µg/L	20-3169	37360	0,077	2029-09-17
Calibrator 0,052	µg/L	20-3172	37361	0,103	2029-09-17
Calibrator 0,157	µg/L	20-3175	37362	0,274	2029-09-17
Calibrator 0,417	µg/L	20-3178	37363	1,009	2029-09-17
Calibrator 0,991	µg/L	20-3181	37364	3,153	2029-09-17
Coated Plate		20-3193	37365		2031-09-21
Enzyme Conjugate 11X		20-3139	37366		2029-09-15
Enzyme Conjugate Buffer		20-3191	37618		2029-09-29
Wash Buffer 21X		20-6746	37528		2033-08-28
Substrate TMB		20-2629	37312		2030-08-31
Stop Solution		20-2693	37299		2033-05-29

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

3. Quality control

Quality control has been performed for lot no 37369 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:
2026-10-27	Jonas Krick	
Date of approval:	**Approved by:**	**Signature:**
2026-10-27	Elin Westberg	

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