Mercodia

Mall-0080 v 7.0

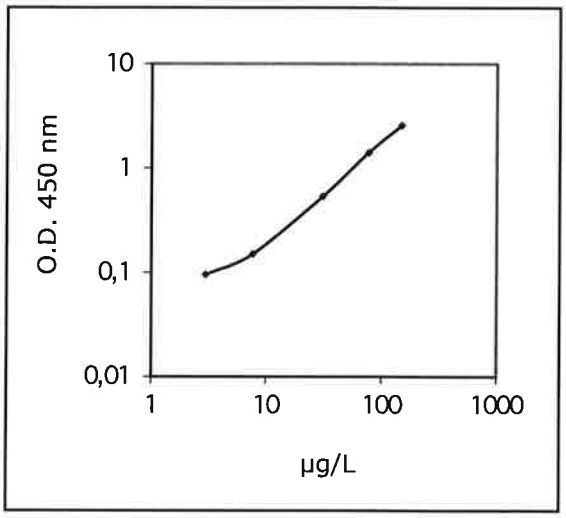
Certificate of Analysis

1. **Manufacturer**

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

2. **Description**

Catalog no:	10-1145-01
Product:	Mercodia High Range Rat Insulin ELISA
Lot no:	36488
Expiry date:	2027-01-31



Component		*Art no*	*Lot no*	*O.D. 450 nm*	*Exp. date*
Calibrator 0		20-3621	33380	0,081	2027-02-24
Calibrator 2,99	µg/L	20-3611	33386	0,095	2027-03-10
Calibrator 7,64	µg/L	20-3612	33387	0,149	2027-03-10
Calibrator 30,9	µg/L	20-3613	33388	0,534	2027-03-10
Calibrator 76,5	µg/L	20-3614	33389	1,403	2027-03-10
Calibrator 148	µg/L	20-3615	33390	2,557	2027-03-10
Coated Plate		20-3193	33378		2027-02-21
Enzyme Conjugate 11X		20-3619	33396		2027-02-24
Enzyme Conjugate Buffer		20-3625	33393		2027-02-25
Wash Buffer 21X		20-6746	36361		2031-12-18
Substrate TMB		20-2629	35551		2027-07-31
Stop Solution		20-2693	36245		2031-10-22

Address Mercodia AB, Sylveniusgatan 8A, SE-754 50 Uppsala, Sweden
Phone +46 18 57 00 70 | **Fax** +46 18 57 00 80 | **Vat No** SE-556157510001
E-mail info@mercodia.com | **Website** www.mercodia.com

3. Quality control

Quality control has been performed for lot no 36488 according to standard operating procedures at Mercodia AB, and the product is released based on fulfillment of established acceptance criteria.

4. Calibration

The Mercodia High Range 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 High Range 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:
2025-02-13	Jonas Kvick	

Date of approval:	Approved by:	Signature:
2025-02-14	Elin Westberg	EW

Address Mercodia AB, Sylveniusgatan 8A, SE-754 50 Uppsala, Sweden
Phone +46 18 57 00 70 | **Fax** +46 18 57 00 80 | **Vat No** SE-556157510001
E-mail info@mercodia.com | **Website** www.mercodia.com