Mercodia

Mall-0080 v 7.0

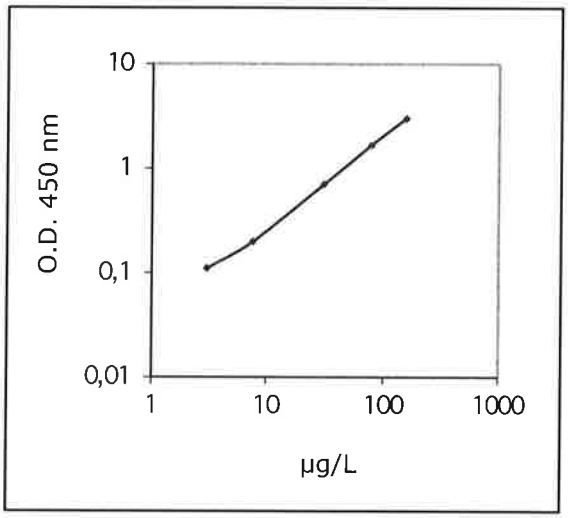
Certificate of Analysis

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:	36719
Expiry date:	2029-02-28



Component		*Art no*	*Lot no*	*O.D. 450 nm*	*Exp. date*
Calibrator 0		20-3621	36680	0,081	2030-05-07
Calibrator 3,05	µg/L	20-3611	36675	0,110	2030-05-21
Calibrator 7,61	µg/L	20-3612	36676	0,198	2030-05-21
Calibrator 30,9	µg/L	20-3613	36677	0,704	2030-05-21
Calibrator 77,5	µg/L	20-3614	36678	1,663	2030-05-21
Calibrator 154	µg/L	20-3615	36679	2,999	2030-05-21
Coated Plate		20-3193	36683		2030-05-12
Enzyme Conjugate 11X		20-3619	36684		2030-05-07
Enzyme Conjugate Buffer		20-3625	36681		2030-05-20
Wash Buffer 21X		20-6746	36724		2032-06-12
Substrate TMB		20-2629	36313		2029-02-28
Stop Solution		20-2693	34128		2029-09-19

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3. Quality control

Quality control has been performed for lot no 36719 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:
2025-07-01	Jonas Kvick	

Date of approval:	Approved by:	Signature:
2025-07-01	Mattias H	

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