Mercodia

Mall-0184 v 3.0

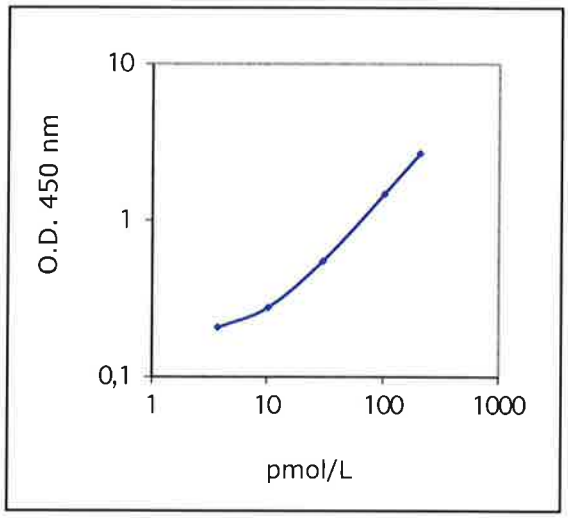
Certificate of Analysis

1. **Manufacturer**

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

2. **Description**

Catalog no:	10-1232-01
Product:	Mercodia Rat/Mouse Proinsulin ELISA
Lot no:	36756
Expiry date:	2026-11-30



Component		*Art no*	*Lot no*	*O.D. 450 nm*	*Exp. date*
Calibrator 0		20-6721	36282	0,150	2027-12-05
Calibrator 3,74	pmol/L	20-6727	36273	0,207	2027-11-21
Calibrator 10,2	pmol/L	20-6728	36274	0,277	2027-11-21
Calibrator 30,3	pmol/L	20-6729	36275	0,550	2027-11-21
Calibrator 102	pmol/L	20-6730	36276	1,471	2027-11-21
Calibrator 206	pmol/L	20-6731	36277	2,668	2027-11-21
Coated Plate		20-6738	36284		2027-12-02
Enzyme Conjugate 11X		20-6734	36298		2026-12-10
Enzyme Conjugate Buffer		20-6736	36272		2027-11-21
Wash Buffer 21X		20-6746	36724		2032-06-12
Substrate TMB		20-2629	36313		2029-02-28
Stop Solution		20-2693	36746		2032-07-01

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3. Quality control

Quality control has been performed for lot no 36756 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/Mouse Proinsulin ELISA is calibrated against an in-house reference preparation of rat proinsulin.

5. Assay method

Test procedure used is according to current Direction for Use for the product and lot.

6. Intended use

Mercodia Rat/Mouse Proinsulin ELISA provides a method for the quantitative determination of rat and mouse proinsulin, in serum, plasma, cell culture medium or cellular extracts.

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:
2025-08-21	Jonas Kvick	
Date of approval:	**Approved by:**	**Signature:**
2025-08-21	Mattias Taslov	

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