Mercodia

Mall-0184 v 3.0

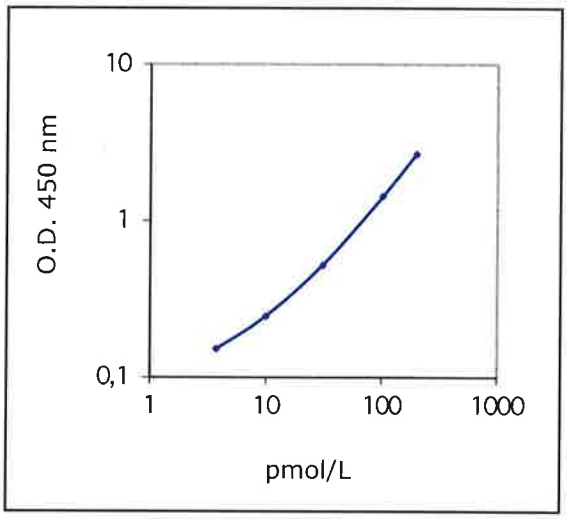
Certificate of Analysis

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:	35591
Expiry date:	2025-07-31



Component		*Art no*	*Lot no*	*O.D. 450 nm*	*Exp. date*
Calibrator 0		20-6721	35278	0,105	2026-06-02
Calibrator 3,71	pmol/L	20-6727	35287	0,152	2026-05-24
Calibrator 9,86	pmol/L	20-6728	35288	0,245	2026-05-24
Calibrator 30,4	pmol/L	20-6729	35289	0,520	2026-05-24
Calibrator 101	pmol/L	20-6730	35290	1,431	2026-05-24
Calibrator 199	pmol/L	20-6731	35291	2,663	2026-05-24
Coated Plate		20-6738	35264		2026-08-14
Enzyme Conjugate 11X		20-6734	35584		2025-08-15
Enzyme Conjugate Buffer		20-6736	35279		2026-04-28
Wash Buffer 21X		20-6746	35568		2030-09-05
Substrate TMB		20-2629	32367		2025-07-31
Stop Solution		20-2693	35523		2030-08-10

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3. Quality control

Quality control has been performed for lot no 35591 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:
2023-10-02	Elin Wernberg	EW
Date of approval:	**Approved by:**	**Signature:**
2023-10-03	Matthias H	MH

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