Mercodia

Mall-0058 v 5.0

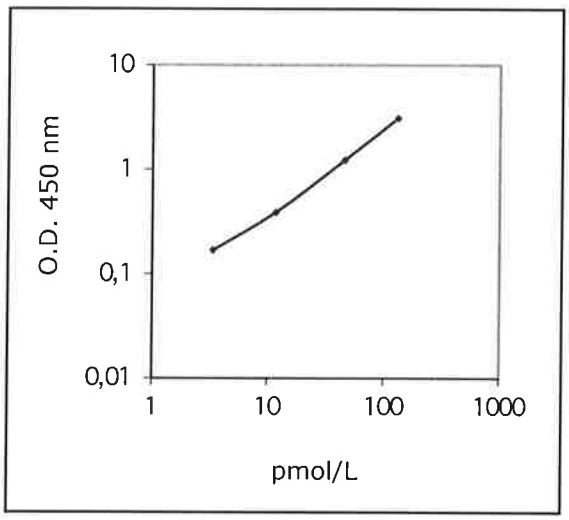
Certificate of Analysis

1. **Manufacturer**

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

2. **Description**

Catalog no: 10-1118-01
Product: Mercodia Proinsulin ELISA
Lot no: 36735
Expiry date: 2026-08-31



Component	*Art no*	*Lot no*	*O.D. 450 nm*	*Exp. date*
Calibrator 0	20-3013	36217	0,075	2026-09-30
Calibrator 3,36 pmol/L	20-3014	36221	0,168	2026-09-24
Calibrator 11,7 pmol/L	20-3015	36222	0,386	2026-09-24
Calibrator 45,8 pmol/L	20-3016	36223	1,228	2026-09-24
Calibrator 131 pmol/L	20-3017	36224	3,110	2026-09-24
Coated Plate	20-3019	36226		2026-11-04
Assay Buffer	20-3024	36229		2026-09-27
Enzyme Conjugate 21X	20-3022	36704		2027-05-28
Enzyme Conjugate Buffer	20-3028	36228		2026-10-16
Wash Buffer 21X	20-6746	36361		2031-12-18
Substrate TMB	20-2629	36313		2029-02-28
Stop Solution	20-2693	34128		2029-09-19

Address Mercodia AB, Sylveniusgatan 8A, SE-754 50 Uppsala, Sweden
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E-mail info@mercodia.com | **Website** www.mercodia.com

3. Quality control

Quality control has been performed for lot no 36735 according to standard operating procedures at Mercodia AB, and the product is released based on fulfillment of established acceptance criteria.

4. Calibration

The Mercodia Proinsulin ELISA is calibrated against the International Reference Reagent for human proinsulin, IRR 84/611.

5. Assay method

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

6. Intended use

Mercodia Proinsulin ELISA provides a method for the quantitative determination of proinsulin 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:
2025-06-24	Jonas Kvick	

Date of approval:	Approved by:	Signature:
2025-06-24		

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