Mercodia

Mall-0058 v 5.0

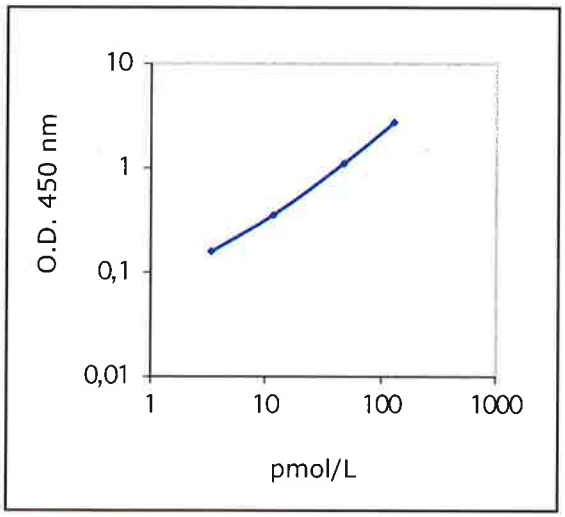
Certificate of Analysis

1. **Manufacturer**

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

2. **Description**

Catalog no: 10-1118-01
Product: Mercodia Proinsulin ELISA
Lot no: 35327
Expiry date: 2025-01-31



Component	*Art no*	*Lot no*	*O.D. 450 nm*	*Exp. date*
Calibrator 0	20-3013	35164	0,077	2025-03-01
Calibrator 3,37 pmol/L	20-3014	35169	0,159	2025-02-20
Calibrator 11,6 pmol/L	20-3015	35170	0,355	2025-02-20
Calibrator 46,5 pmol/L	20-3016	35171	1,108	2025-02-20
Calibrator 127 pmol/L	20-3017	35172	2,744	2025-02-20
Coated Plate	20-3019	35153		2025-03-20
Assay Buffer	20-3024	35174		2025-03-02
Enzyme Conjugate 21X	20-3022	35176		2025-03-14
Enzyme Conjugate Buffer	20-3028	35173		2025-03-03
Wash Buffer 21X	20-6746	35178		2030-02-03
Substrate TMB	20-2629	33423		2026-06-30
Stop Solution	20-2693	35136		2030-01-23

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 35327 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:
2023-04-13	Elin Westberg	EW
Date of approval:	**Approved by:**	**Signature:**
2023-04-13	Mathias Ståhlbrandt	MS

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