Mercodia

Mall-0058 v 5.0

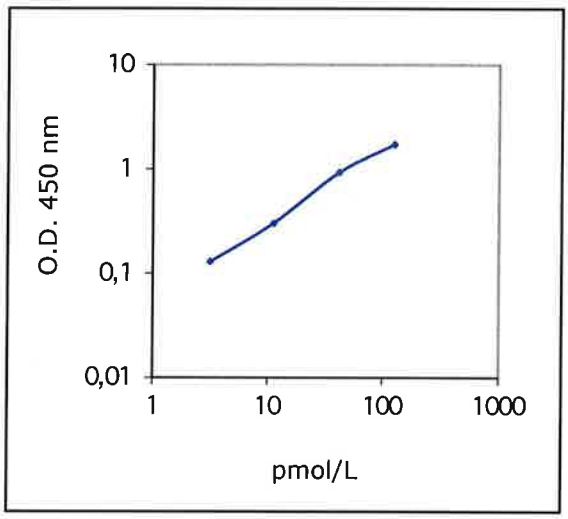
Certificate of Analysis

1. **Manufacturer**

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

2. **Description**

Catalog no: 10-1118-01
Product: Mercodia Proinsulin ELISA
Lot no: 36323
Expiry date: 2026-04-30



Component	*Art no*	*Lot no*	*O.D. 450 nm*	*Exp. date*
Calibrator 0	20-3013	36060	0,059	2026-05-08
Calibrator 3,15 pmol/L	20-3014	36056	0,130	2026-05-16
Calibrator 11,2 pmol/L	20-3015	36057	0,302	2026-05-16
Calibrator 41,7 pmol/L	20-3016	36058	0,931	2026-05-16
Calibrator 126 pmol/L	20-3017	36059	2,414	2026-05-16
Coated Plate	20-3019	36063		2026-06-10
Assay Buffer	20-3024	36061		2026-05-08
Enzyme Conjugate 21X	20-3022	36066		2026-06-13
Enzyme Conjugate Buffer	20-3028	36062		2026-05-31
Wash Buffer 21X	20-6746	31676		2027-11-03
Substrate TMB	20-2629	33423		2026-06-30
Stop Solution	20-2693	29914		2026-06-12

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E-mail info@mercodia.com | **Website** www.mercodia.com

3. Quality control

Quality control has been performed for lot no 36323 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:
2024-08-07	Elin Wernby	EW
Date of approval:	**Approved by:**	**Signature:**
2024-11-08	Matthias H	MH

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