Mercodia

Mall-0672 v 1.0

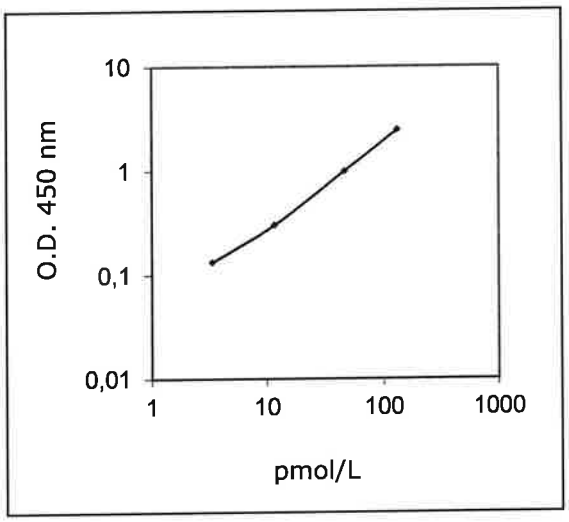
Certificate of Analysis

1. **Manufacturer**

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

2. **Description**

Catalog no:	10-1118-03
Product:	Mercodia Proinsulin ELISA
Lot no:	37694
Expiry date:	2027-04-30



Component	*Art no*	*Lot no*	*O.D. 450 nm*	*Exp. date*
Calibrator 0	20-3013	36614	0,059	2027-06-02
Calibrator 3,35 pmol/L	20-3014	36615	0,133	2027-05-16
Calibrator 11,6 pmol/L	20-3015	36616	0,303	2027-05-16
Calibrator 46,0 pmol/L	20-3016	36617	0,991	2027-05-16
Calibrator 131 pmol/L	20-3017	36618	2,472	2027-05-16
Coated Plate	20-3019	36609		2027-06-13
Assay Buffer	20-3024	36613		2027-06-17
Enzyme Conjugate 21X	20-3022	36949		2027-11-25
Enzyme Conjugate Buffer	20-3028	36612		2027-05-28
Wash Buffer 21X	20-6746	37311		2033-06-18
Substrate TMB	20-2629	36313		2029-02-28
Stop Solution	20-2693	37095		2033-02-16

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

3. Quality control

Quality control has been performed for lot no 37694 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

Mercodia is ISO 13485 certified, demonstrating compliance with the international quality management system standard for medical devices. This product is supplied for research use only and is not intended for use as an in vitro diagnostic (IVD) medical device.

10. Names and signatures of certifying officers

Date of analysis:	Performed by:	Signature:
2026-01-16	Mattias Jade	MJ
Date of approval:	**Approved by:**	**Signature:**
2026-10-28	Elin Westberg	EW

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