Mercodia

Mall-0268 v2.0

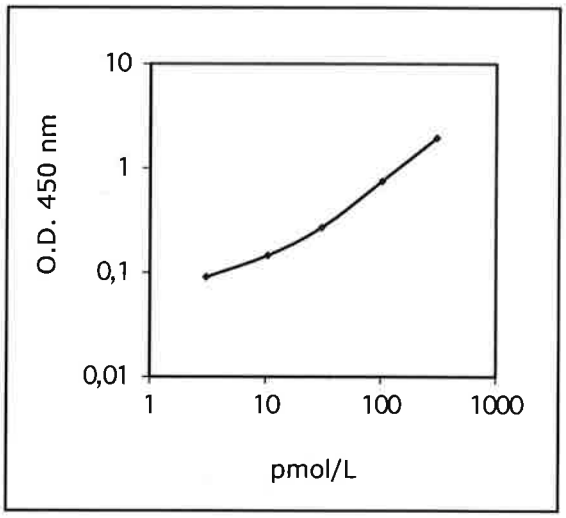
Certificate of Analysis

1. **Manufacturer**

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

2. **Description**

Catalog no: 10-1273-01
Product: Mercodia Glicentin ELISA
Lot no: 35899
Expiry date: 2026-09-30



Component	*Art no*	*Lot no*	*O.D. 450 nm*	*Exp. Date*
Calibrator 0	20-7072	35499	0,074	2026-10-13
Calibrator 2,87 pmol/L	20-7073	35501	0,090	2026-11-09
Calibrator 9,91 pmol/L	20-7074	35502	0,145	2026-11-09
Calibrator 29,6 pmol/L	20-7075	35503	0,269	2026-11-09
Calibrator 98,6 pmol/L	20-7076	35504	0,749	2026-11-09
Calibrator 299 pmol/L	20-7077	35505	1,939	2026-11-09
Coated Plate	20-7080	35495		2026-10-30
Assay Buffer	20-7092	35498		2026-10-13
Enzyme Conjugate 11X	20-7078	35506		2026-12-06
Enzyme Conjugate Buffer	20-7079	35497		2026-10-19
Wash Buffer 21X	20-6746	35704		2030-11-14
Substrate TMB	20-2629	34163		2026-11-30
Stop Solution	20-2693	35772		2030-11-16

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

3. Quality control

Quality control has been performed for lot no 35899 according to standard operating procedures at Mercodia AB, and the product is released based on fulfillment of established acceptance criteria.

4. Calibration

Mercodia Glicentin ELISA is calibrated against an in-house reference preparation of human Glicentin, validated with amino analysis and HPLC-UV LC-MS/MS.

5. Assay method

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

6. Intended use

Mercodia Glicentin ELISA provides a method for the quantitative determination of human glicentin in EDTA-plasma, serum and cell culture medium.

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 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:
2024-02-21	Elin Westberg	EW

Date of approval:	Approved by:	Signature:
2024-02-27	Jonas Klinck	

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