Mercodia

Mall-0275 v2.0

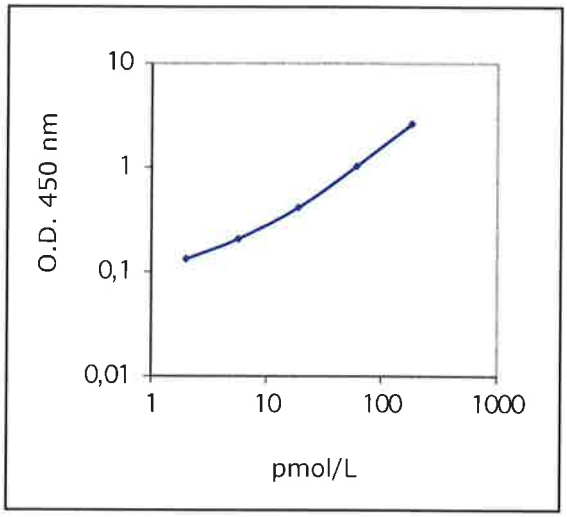
Certificate of Analysis

1. **Manufacturer**

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

2. **Description**

Catalog no: 10-1281-01
Product: Mercodia Glucagon ELISA – 10 µL
Lot no: 35570
Expiry date: 2025-10-31



Component	*Art no*	*Lot no*	*O.D. 450 nm*	*Exp. date*
Calibrator 0	20-7141	34202	0,105	2025-11-02
Calibrator 2,01 pmol/L	20-7147	34191	0,134	2026-01-10
Calibrator 5,68 pmol/L	20-7148	34192	0,208	2026-01-10
Calibrator 18,8 pmol/L	20-7149	34193	0,416	2026-01-10
Calibrator 60,3 pmol/L	20-7150	34194	1,035	2026-01-10
Calibrator 183 pmol/L	20-7151	34195	2,640	2026-01-10
Coated Plate	20-7057	34209		2025-10-31
Enzyme Conjugate 11X	20-7156	35038		2025-11-03
Enzyme Conjugate Buffer	20-7153	34200		2025-11-04
Wash Buffer 21X	20-6746	35429		2030-06-01
Substrate TMB	20-2629	33423		2026-06-30
Stop Solution	20-2693	34128		2029-09-19

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3. Quality control

Quality control has been performed for lot no 35570 according to standard operating procedures at Mercodia AB, and the product is released based on fulfillment of established acceptance criteria.

4. Calibration

Mercodia Glucagon ELISA – 10 µL is calibrated against WHO 1st international reference preparation 69/194.

5. Assay method

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

6. Intended use

Mercodia Glucagon ELISA – 10 µL provides a method for the quantitative determination of glucagon 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 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:
2023-03-01	Elin Wernberg	EW

Date of approval:	Approved by:	Signature:
2023-08-30	Jonas Krick	

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