Mercodia

Mall-0379 v2.0

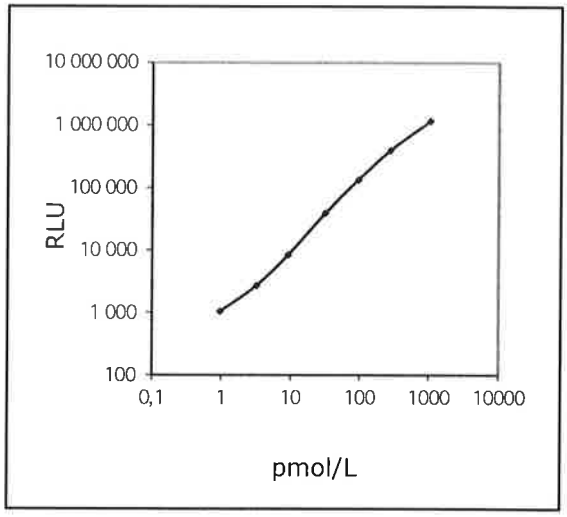
Certificate of Analysis

1. **Manufacturer**

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

2. **Description**

Catalog no: 10-1278-01
Product: Mercodia Total GLP-1 NL-ELISA
Lot no: 35965
Expiry date: 2027-01-31



Component	*Art no*	*Lot no*	*RLU*	*Exp. date*
Calibrator 0	20-7259	35881	459	2027-02-05
Calibrator 0,958 pmol/L	20-7266	35873	1048	2027-02-16
Calibrator 3,18 pmol/L	20-7267	35874	2684	2027-02-16
Calibrator 9,13 pmol/L	20-7268	35875	8308	2027-02-16
Calibrator 31,6 pmol/L	20-7269	35876	38976	2027-02-16
Calibrator 95,1 pmol/L	20-7270	35877	134110	2027-02-16
Calibrator 278 pmol/L	20-7271	35878	399041	2027-02-16
Calibrator 1030 pmol/L	20-7299	35879	1158791	2027-02-16
Coated Plate	20-7277	35868		2027-02-12
Enzyme Conjugate 11X	20-7275	35882		2027-02-20
Enzyme Conjugate Buffer	20-7273	35880		2027-02-06
Wash Buffer 21X	20-6746	35948		2031-02-27
Substrate Reagent A	20-7300	35950		2027-02-19
Substrate Reagent B	20-7301	35951		2027-02-19

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3. Quality control

Quality control has been performed for lot no 35965 according to standard operating procedures at Mercodia AB, and the product is released based on fulfillment of established acceptance criteria.

4. Calibration

Mercodia Total GLP-1 NL-ELISA is calibrated against an in-house reference preparation of GLP-1 (9-36)amide.

5. Assay method

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

6. Intended use

Mercodia Total GLP-1 ELISA provides a method for the quantitative determination of Total GLP-1 in EDTA-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 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:
2024-03-19	Jonas Krick	

Date of approval:	Approved by:	Signature:
2024-03-27	Mathias H	

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