

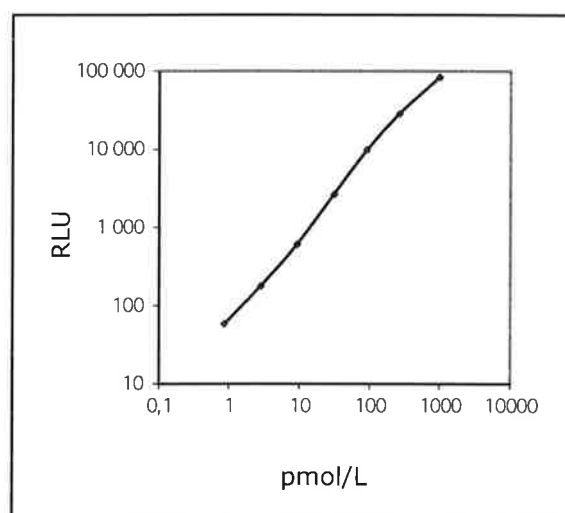
Certificate of Analysis

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: 34076
 Expiry date: 2025-04-30



<i>Component</i>	<i>Art no</i>	<i>Lot no</i>	<i>RLU</i>	<i>Exp. date</i>
Calibrator 0	20-7259	33815	20	2025-08-08
Calibrator 0,851 pmol/L	20-7266	33823	58	2025-08-11
Calibrator 2,81 pmol/L	20-7267	33824	178	2025-08-11
Calibrator 9,20 pmol/L	20-7268	33825	609	2025-08-11
Calibrator 30,8 pmol/L	20-7269	33826	2657	2025-08-11
Calibrator 90,6 pmol/L	20-7270	33827	9817	2025-08-11
Calibrator 263 pmol/L	20-7271	33828	28549	2025-08-11
Calibrator 991 pmol/L	20-7299	33829	83865	2025-08-11
Coated Plate	20-7277	33812		2025-08-22
Enzyme Conjugate 11X	20-7275	33836		2025-09-06
Enzyme Conjugate Buffer	20-7273	33834		2025-08-11
Wash Buffer 21X	20-6746	33635		2029-05-20
Substrate Reagent A	20-7300	33583		2025-05-11
Substrate Reagent B	20-7301	33584		2025-05-11

3. Quality control

Quality control has been performed for lot no 34076 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:

2022-09-22

Performed by:

Mattias St

Signature:

M

Date of approval:

2022-09-26

Approved by:

Tomas K

Signature:

K