

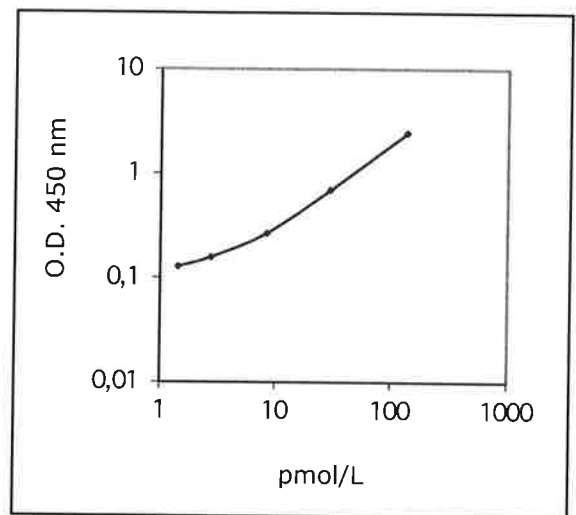
Certificate of Analysis

1. Manufacturer

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

2. Description

Catalog no: 10-1271-01
 Product: MercoDia Glucagon ELISA
 Lot no: 35567
 Expiry date: 2026-03-31



<i>Component</i>	<i>Art no</i>	<i>Lot no</i>	<i>O.D. 450 nm</i>	<i>Exp. date</i>
Calibrator 0	20-7040	35253	0,098	2026-05-02
Calibrator 1,43 pmol/L	20-7042	35255	0,128	2026-04-25
Calibrator 2,75 pmol/L	20-7044	35256	0,157	2026-04-25
Calibrator 8,37 pmol/L	20-7046	35257	0,266	2026-04-25
Calibrator 29,7 pmol/L	20-7048	35258	0,689	2026-04-25
Calibrator 136 pmol/L	20-7050	35259	2,434	2026-04-25
Assay Buffer	20-7551	35262		2026-05-16
Coated Plate	20-7057	35462		2026-06-12
Enzyme Conjugate 11X	20-7053	35261		2026-06-20
Enzyme Conjugate Buffer	20-7055	35252		2026-05-23
Wash Buffer 21X	20-6746	35429		2030-06-01
Substrate TMB	20-2629	34163		2026-11-30
Stop Solution	20-2693	35523		2030-08-10

3. Quality control

Quality control has been performed for lot no 35567 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 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 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:

2023-09-01 Ellin Westberg EW

Date of approval: Approved by: Signature:

2023-09-04 Jonas Kjick [Signature]