

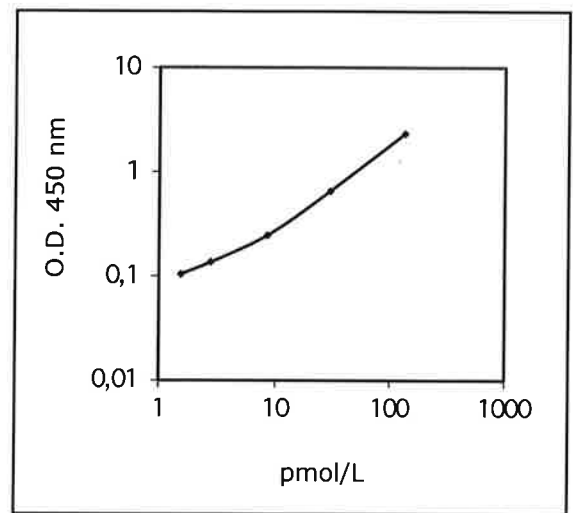
Certificate of Analysis

1. Manufacturer

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

2. Description

Catalog no: 10-1271-01
 Product: Mercodia Glucagon ELISA
 Lot no: 35430
 Expiry date: 2025-05-31



<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	33679	0,075	2025-06-10
Calibrator 1,54 pmol/L	20-7042	33685	0,104	2025-06-30
Calibrator 2,77 pmol/L	20-7044	33686	0,136	2025-06-30
Calibrator 8,49 pmol/L	20-7046	33687	0,246	2025-06-30
Calibrator 29,6 pmol/L	20-7048	33688	0,652	2025-06-30
Calibrator 135 pmol/L	20-7050	33689	2,327	2025-06-30
Assay Buffer	20-7551	33700		2025-06-15
Coated Plate	20-7057	33677		2025-06-27
Enzyme Conjugate 11X	20-7053	33762		2025-08-30
Enzyme Conjugate Buffer	20-7055	33693		2025-06-16
Wash Buffer 21X	20-6746	35178		2030-02-03
Substrate TMB	20-2629	33423		2026-06-30
Stop Solution	20-2693	35136		2030-01-23

3. Quality control

Quality control has been performed for lot no 35430 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:

2022-09-16

Performed by:

Jonas Kung

Signature:

Date of approval:

2023-05-31

Approved by:

Mattias Jön

Signature: