

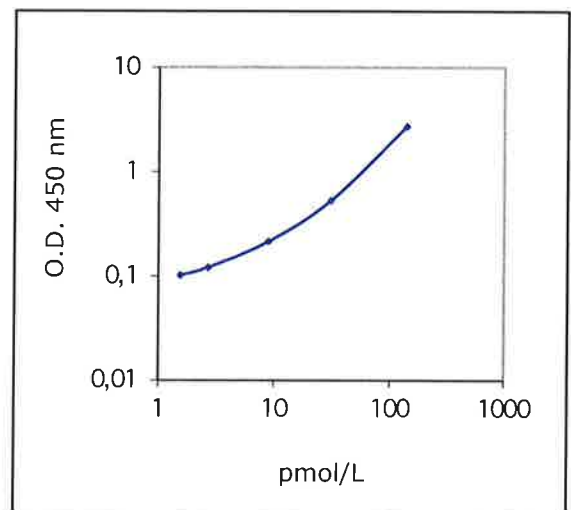
Certificate of Analysis

1. Manufacturer

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

2. Description

Catalog no: 10-1271-01
 Product: MercoDia Glucagon ELISA
 Lot no: 36136
 Expiry date: 2027-04-30



<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	36022	0,075	2027-06-14
Calibrator 1,55 pmol/L	20-7042	36024	0,102	2027-05-07
Calibrator 2,71 pmol/L	20-7044	36025	0,121	2027-05-07
Calibrator 8,85 pmol/L	20-7046	36026	0,214	2027-05-07
Calibrator 30,4 pmol/L	20-7048	36027	0,526	2027-05-07
Calibrator 138 pmol/L	20-7050	36028	1,963	2027-05-07
Assay Buffer	20-7551	36023		2027-06-13
Coated Plate	20-7057	36029		2027-05-27
Enzyme Conjugate 11X	20-7053	36032		2027-06-11
Enzyme Conjugate Buffer	20-7055	36031		2027-06-13
Wash Buffer 21X	20-6746	36055		2031-05-07
Substrate TMB	20-2629	35551		2027-07-31
Stop Solution	20-2693	35947		2031-02-23

3. Quality control

Quality control has been performed for lot no 36136 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:

2024-08-16

Performed by:

Elin Westberg

Signature:

EW

Date of approval:

2024-08-19

Approved by:

Mattias H

Signature:

MH