

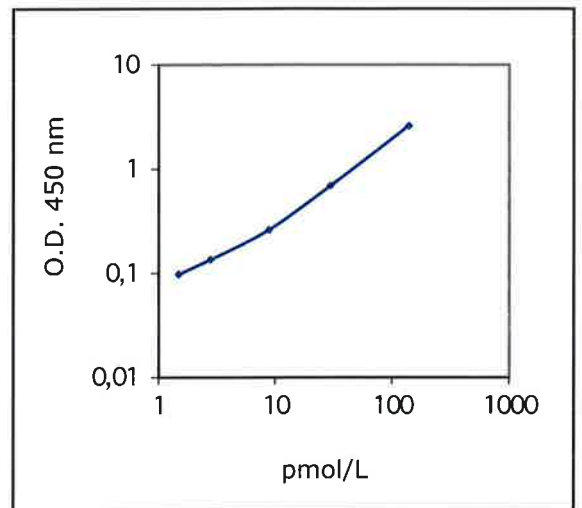
Certificate of Analysis

1. Manufacturer

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

2. Description

Catalog no: 10-1271-01
Product: MercoDia Glucagon ELISA
Lot no: 33191
Expiry date: 2024-03-31



<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	32209	0,069	2024-04-06
Calibrator 1,48 pmol/L	20-7042	32215	0,098	2024-04-27
Calibrator 2,79 pmol/L	20-7044	32216	0,136	2024-04-27
Calibrator 8,88 pmol/L	20-7046	32217	0,263	2024-04-27
Calibrator 29,9 pmol/L	20-7048	32218	0,699	2024-04-27
Calibrator 140 pmol/L	20-7050	32219	2,623	2024-04-27
Assay Buffer	20-7551	32225		2024-04-08
Coated Plate	20-7057	32207		2024-04-19
Enzyme Conjugate 11X	20-7053	32285		2024-05-20
Enzyme Conjugate Buffer	20-7055	32222		2024-04-07
Wash Buffer 21X	20-6746	32934		2028-10-18
Substrate TMB	20-2629	31053		2024-07-31
Stop Solution	20-2693	32745		2028-09-02

3. Quality control

Quality control has been performed for lot no 33191 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:

2021-09-24

Performed by:

Thomas Kj

Signature:

Date of approval:

2021-12-20

Approved by:

Elin Westberg EW

Signature: