

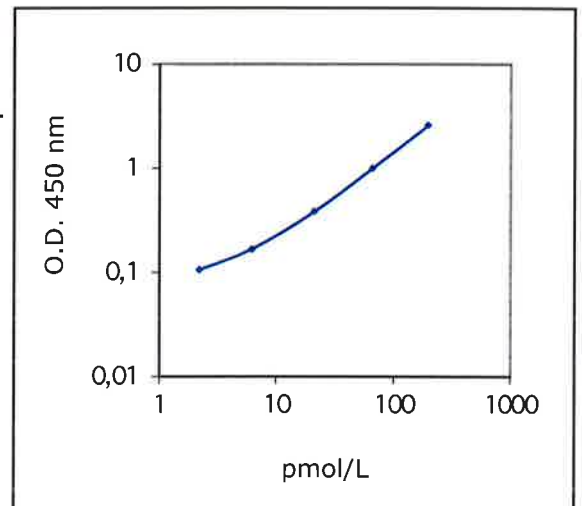
Certificate of Analysis

1. Manufacturer

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

2. Description

Catalog no: 10-1281-01
 Product: Merckodia Glucagon ELISA – 10 µL
 Lot no: 33984
 Expiry date: 2024-07-31



<i>Component</i>	<i>Art no</i>	<i>Lot no</i>	<i>O.D. 450 nm</i>	<i>Exp. date</i>
Calibrator 0	20-7141	32949	0,073	2024-10-19
Calibrator 2,18 pmol/L	20-7147	32942	0,106	2024-10-26
Calibrator 6,15 pmol/L	20-7148	32943	0,167	2024-10-26
Calibrator 20,9 pmol/L	20-7149	32944	0,383	2024-10-26
Calibrator 65,2 pmol/L	20-7150	32945	0,998	2024-10-26
Calibrator 194 pmol/L	20-7151	32946	2,579	2024-10-26
Coated Plate	20-7057	32936		2024-11-01
Enzyme Conjugate 11X	20-7156	32953		2024-10-20
Enzyme Conjugate Buffer	20-7153	32951		2024-10-28
Wash Buffer 21X	20-6746	33635		2029-05-20
Substrate TMB	20-2629	31053		2024-07-31
Stop Solution	20-2693	33452		2027-03-07

3. Quality control

Quality control has been performed for lot no 33984 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 – 10 µL 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 – 10 µL 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:

2022-01-12



Date of approval: Approved by: Signature:

2022-08-29

