

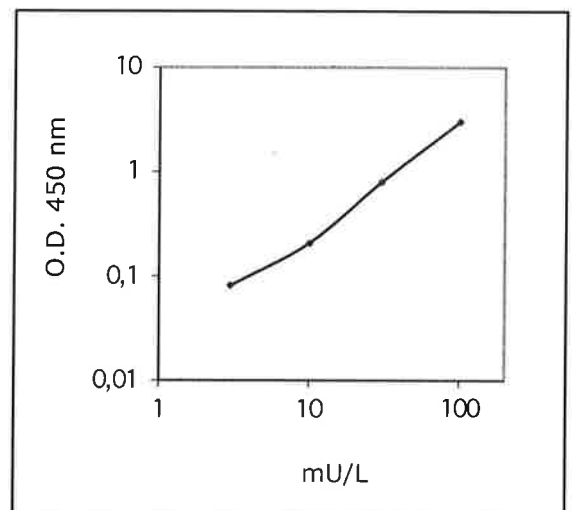
Certificate of Analysis

1. Manufacturer

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

2. Description

Catalog no: 10-1128-01
 Product: MercoDia Iso Insulin ELISA
 Lot no: 35079
 Expiry date: 2024-11-30



<i>Component</i>	<i>Art no</i>	<i>Lot no</i>	<i>O.D. 450 nm</i>	<i>Exp. date</i>
Calibrator 0	20-2702	33104	0,065	2024-12-02
Calibrator 3 mU/L	20-2703	33092	0,081	2024-12-03
Calibrator 10 mU/L	20-2704	33093	0,206	2024-12-03
Calibrator 30 mU/L	20-2705	33094	0,797	2024-12-03
Calibrator 100 mU/L	20-2706	33095	3,011	2024-12-03
Coated Plate	20-2701	33100		2024-12-06
Enzyme Conjugate 11X	20-2707	33107		2025-01-18
Enzyme Conjugate Buffer	20-2708	33102		2024-12-02
Wash Buffer 21X	20-6746	32551		2028-06-21
Substrate TMB	20-2629	32367		2025-07-31
Stop Solution	20-2693	32745		2028-09-02

3. Quality control

Quality control has been performed for lot no 35079 according to standard operating procedures at Mercodia AB, and the product is released based on fulfillment of established acceptance criteria.

4. Calibration

The Mercodia Insulin ELISA is calibrated against 1st International Reference Preparation 66/304.

5. Assay method

Test procedure used is according to current Direction for Use for the product and lot.

6. Intended use

Mercodia Insulin ELISA provides a method for the quantitative determination of insulin in serum or plasma.

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:
<u>2022-02-04</u>	<u>Mattias Lot</u>	<u>[Signature]</u>

Date of approval:	Approved by:	Signature:
<u>2022-11-30</u>	<u>Jonas King</u>	<u>[Signature]</u>