

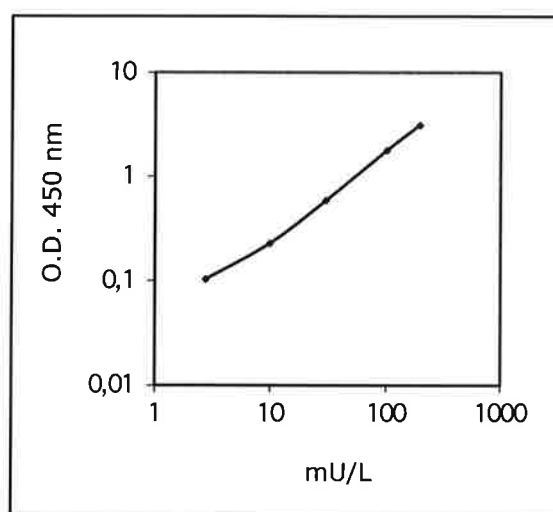
Certificate of Analysis

1. Manufacturer

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

2. Description

Catalog no: 10-1113-01
 Product: MercoDia Insulin ELISA
 Lot no: 36069
 Expiry date: 2026-03-31



<i>Component</i>	<i>Art no</i>	<i>Lot no</i>	<i>O.D. 450 nm</i>	<i>Exp. date</i>
Calibrator 0	20-2615	35331	0,052	2026-04-19
Calibrator 2,77 mU/L	20-2616	35334	0,104	2026-04-17
Calibrator 9,89 mU/L	20-2617	35335	0,229	2026-04-17
Calibrator 29,9 mU/L	20-2618	35336	0,593	2026-04-17
Calibrator 101 mU/L	20-2619	35337	1,795	2026-04-17
Calibrator 195 mU/L	20-2620	35338	3,121	2026-04-17
Coated Plate	20-2622	35332		2026-05-08
Enzyme Conjugate 11X	20-2625	35347		2026-04-18
Enzyme Conjugate Buffer	20-2627	35339		2026-04-26
Wash Buffer 21X	20-6746	35948		2031-02-27
Substrate TMB	20-2629	34163		2026-11-30
Stop Solution	20-2693	35947		2031-02-23

3. Quality control

Quality control has been performed for lot no 36069 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:

2023-06-12

Performed by:

Jonas Kvick

Signature:



Date of approval:

2024-05-20

Approved by:

Eli Westberg

Signature:

