

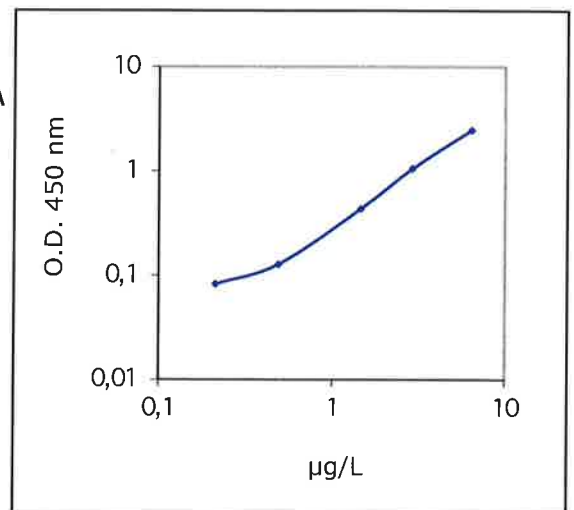
Certificate of Analysis

1. Manufacturer

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

2. Description

Catalog no: 10-1247-01
 Product: MercoDia Mouse Insulin ELISA
 Lot no: 36421
 Expiry date: 2026-01-31



<i>Component</i>	<i>Art no</i>	<i>Lot no</i>	<i>O.D. 450 nm</i>	<i>Exp. date</i>
Calibrator 0	20-3262	35152	0,072	2026-02-17
Calibrator 0,212 µg/L	20-3150	35154	0,083	2026-03-09
Calibrator 0,486 µg/L	20-3151	35155	0,128	2026-03-09
Calibrator 1,46 µg/L	20-3152	35156	0,436	2026-03-09
Calibrator 2,93 µg/L	20-3153	35157	1,061	2026-03-09
Calibrator 6,41 µg/L	20-3154	35158	2,472	2026-03-09
Coated Plate	20-3193	35149		2028-03-06
Enzyme Conjugate 11X	20-3266	35160		2026-03-21
Enzyme Conjugate Buffer	20-3269	35221		2026-03-13
Wash Buffer 21X	20-6746	36246		2031-10-10
Substrate TMB	20-2629	34163		2026-11-30
Stop Solution	20-2693	36245		2031-10-22

3. Quality control

Quality control has been performed for lot no 36421 according to standard operating procedures at MercoDia AB, and the product is released based on fulfillment of established acceptance criteria.

4. Calibration

The MercoDia Mouse Insulin ELISA is calibrated against an in-house reference preparation of mouse insulin.

5. Assay method

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

6. Intended use

MercoDia Mouse Insulin ELISA provides a method for the quantitative determination of mouse 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:

2023-05-12

Performed by:

Elin Westberg

Signature:

EW

Date of approval:

2025-01-03

Approved by:

Jonas Krick

Signature:

JK