

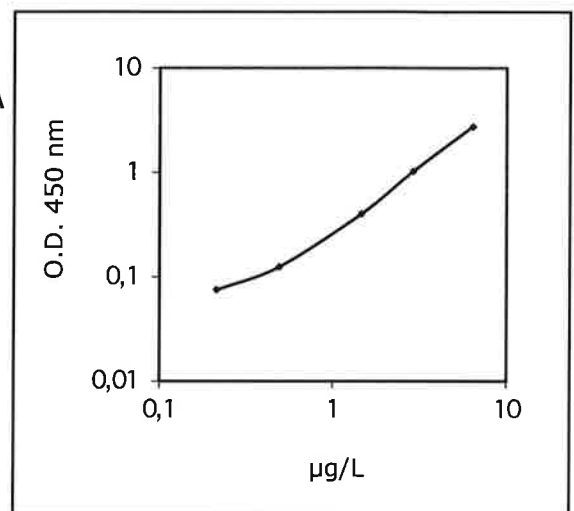
Certificate of Analysis

1. Manufacturer

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

2. Description

Catalog no: 10-1247-10
 Product: Merckodia Mouse Insulin ELISA
 Lot no: 35609
 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	0,068	2026-02-17
Calibrator 0,212 µg/L	20-3150	35154	0,075	2026-03-09
Calibrator 0,486 µg/L	20-3151	35155	0,124	2026-03-09
Calibrator 1,46 µg/L	20-3152	35156	0,399	2026-03-09
Calibrator 2,93 µg/L	20-3153	35157	1,022	2026-03-09
Calibrator 6,41 µg/L	20-3154	35158	2,739	2026-03-09
Coated Plate	20-3193	35150		2028-03-13
Enzyme Conjugate 11X	20-3267	35161		2026-03-21
Enzyme Conjugate Buffer	20-3270	35222		2026-03-13
Wash Buffer 21X	20-3194	35428		2030-08-14
Substrate TMB	20-3136	33424		2026-06-30
Stop Solution	20-2694	33469		2029-03-17

3. Quality control

Quality control has been performed for lot no 35609 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 EW

Signature:

Date of approval:

2023-09-21

Approved by:

Mattias Johansson MJ

Signature: