

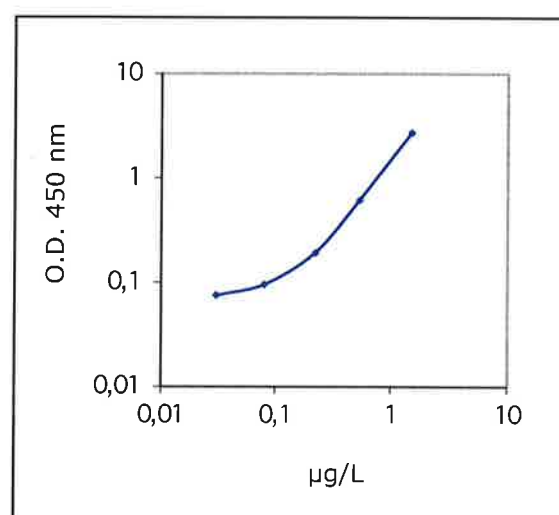
Certificate of Analysis

1. Manufacturer

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

2. Description

Catalog no: 10-1249-01
Product: Mercodia Ultrasensitive
Mouse Insulin ELISA
Lot no: 35600
Expiry date: 2024-10-31



Component	Art no	Lot no	O.D. 450 nm	Exp. date
Calibrator 0	20-3242	33018	0,068	2024-11-15
Calibrator 0,030 µg/L	20-3148	33007	0,075	2024-11-18
Calibrator 0,079 µg/L	20-3149	33008	0,095	2024-11-18
Calibrator 0,221 µg/L	20-3236	33009	0,192	2024-11-18
Calibrator 0,532 µg/L	20-3237	33010	0,614	2024-11-18
Calibrator 1,48 µg/L	20-3238	33011	2,705	2024-11-18
Coated Plate	20-3193	33014		2026-11-15
Enzyme Conjugate 11X	20-3246	33326		2025-01-27
Enzyme Conjugate Buffer	20-3249	33165		2024-11-30
Wash Buffer 21X	20-6746	35568		2030-09-05
Substrate TMB	20-2629	32367		2025-07-31
Stop Solution	20-2693	33839		2029-06-27

3. Quality control

Quality control has been performed for lot no 35600 according to standard operating procedures at Mercodia AB, and the product is released based on fulfillment of established acceptance criteria.

4. Calibration

The Mercodia Ultrasensitive 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 Ultrasensitive 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:

2022-02-17

Performed by:

Elin Wernberg EW

Signature:

Date of approval:

2023-09-28

Approved by:

Mattias El

Signature: