

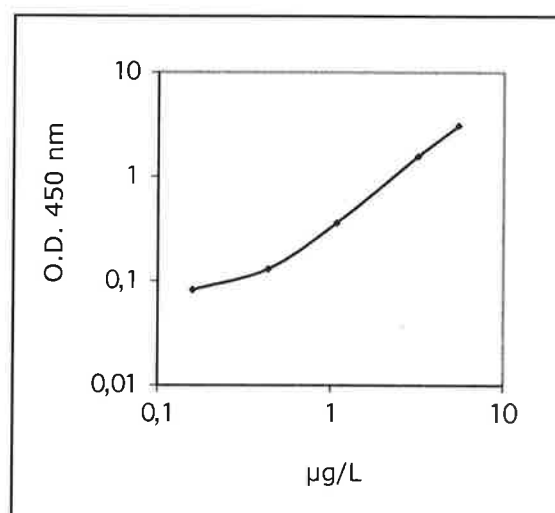
Certificate of Analysis

1. Manufacturer

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

2. Description

Catalog no: 10-1250-10
 Product: Mercodia Rat Insulin ELISA
 Lot no: 35078
 Expiry date: 2025-01-31



Component	Art no	Lot no	O.D. 450 nm	Exp. date
Calibrator 0	20-3082	33291	0,069	2025-02-03
Calibrator 0,159 µg/L	20-3116	33284	0,082	2025-02-04
Calibrator 0,436 µg/L	20-3117	33285	0,130	2025-02-04
Calibrator 1,08 µg/L	20-3118	33286	0,360	2025-02-04
Calibrator 3,17 µg/L	20-3119	33287	1,560	2025-02-04
Calibrator 5,44 µg/L	20-3120	33288	3,080	2025-02-04
Coated Plate	20-3193	33298		2027-02-14
Enzyme Conjugate 11X	20-3085	33301		2025-02-01
Enzyme Conjugate Buffer	20-3090	33294		2025-02-03
Wash Buffer 21X	20-3194	33988		2029-09-07
Substrate TMB	20-3136	33424		2026-06-30
Stop Solution	20-2694	32534		2028-06-02

3. Quality control

Quality control has been performed for lot no 35078 according to standard operating procedures at Mercodia AB, and the product is released based on fulfillment of established acceptance criteria.

4. Calibration

The Mercodia Rat Insulin ELISA is calibrated against an in-house reference preparation of rat insulin.

5. Assay method

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

6. Intended use

Mercodia Rat Insulin ELISA provides a method for the quantitative determination of rat 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:

2022-11-29

Performed by:

Jonas Ky

Signature:

Date of approval:

2022-11-29

Approved by:

Mattias Ist

Signature:

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