Mercodia

Mall-0059 v 7.0

Certificate of Analysis

1. **Manufacturer**

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

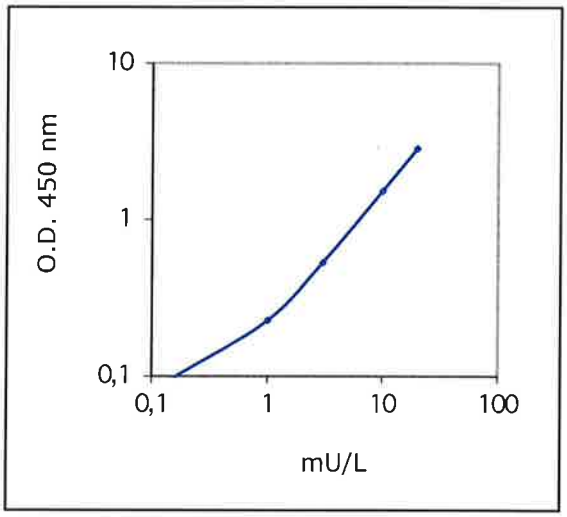
2. **Description**

Catalog no: 10-1132-01

Product: Mercodia Ultrasensitive Insulin ELISA

Lot no: 36360

Expiry date: 2026-08-31



Component	*Art no*	*Lot no*	*O.D. 450 nm*	*Exp. date*
Calibrator 0	20-6600	35571	0,073	2026-09-11
Calibrator 0,15 mU/L	20-3317	35572	0,097	2026-10-12
Calibrator 1 mU/L	20-3319	35573	0,228	2026-10-12
Calibrator 3 mU/L	20-3320	35574	0,534	2026-10-12
Calibrator 10 mU/L	20-3321	35575	1,525	2026-10-12
Calibrator 20 mU/L	20-3322	35576	2,853	2026-10-12
Coated Plate	20-6604	35569		2026-09-11
Enzyme Conjugate 11X	20-3325	35579		2026-11-16
Enzyme Conjugate Buffer	20-6602	35578		2026-09-14
Wash Buffer 21X	20-6746	36246		2031-10-10
Substrate TMB	20-2629	34163		2026-11-30
Stop Solution	20-2693	33839		2029-06-27

Address Mercodia AB, Sylveniusgatan 8A, SE-754 50 Uppsala, Sweden
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E-mail info@mercodia.com | **Website** www.mercodia.com

3. Quality control

Quality control has been performed for lot no 36360 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 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 Ultrasensitive 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:	Performed by:	Signature:
2023-12-14		

Date of approval:	Approved by:	Signature:
2024-12-13		

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