Mercodia

Mall-0059 v 7.0

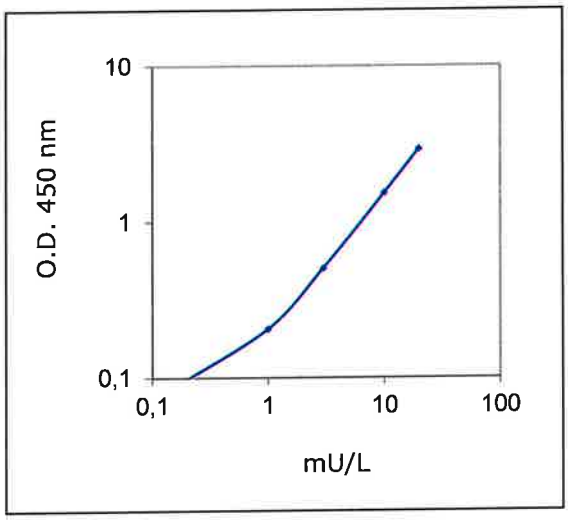
Certificate of Analysis

1. Manufacturer

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

2. Description

Catalog no:	10-1132-01
Product:	Mercodia Ultrasensitive Insulin ELISA
Lot no:	37598
Expiry date:	2029-02-28



Component	*Art no*	*Lot no*	*O.D. 450 nm*	*Exp. Date*
Calibrator 0	20-6600	37139	0,063	2029-03-26
Calibrator 0,15 mU/L	20-3317	37134	0,085	2029-03-11
Calibrator 1 mU/L	20-3319	37135	0,203	2029-03-11
Calibrator 3 mU/L	20-3320	37136	0,498	2029-03-11
Calibrator 10 mU/L	20-3321	37137	1,508	2029-03-11
Calibrator 20 mU/L	20-3322	37138	2,882	2029-03-11
Coated Plate	20-6604	37133		2029-03-16
Enzyme Conjugate 11X	20-3325	37142		2029-03-05
Enzyme Conjugate Buffer	20-6602	37140		2029-03-17
Wash Buffer 21X	20-6746	37311		2033-06-18
Substrate TMB	20-2629	36313		2029-02-28
Stop Solution	20-2693	37095		2033-02-16

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E-mail info@mercodia.com | **Website** www.mercodia.com

3. Quality control

Quality control has been performed for lot no 37598 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:
2026-04-27	Mattias Sat	MM

Date of approval:	Approved by:	Signature:
2026-09-17	Elin Westberg	EW

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