Mercodia
Mall-0065 v 7.0

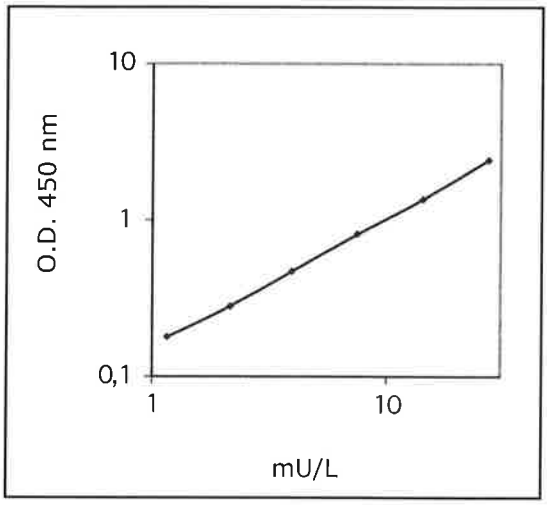
Certificate of Analysis

1. **Manufacturer**

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

2. **Description**

Catalog no: 10-1143-01
Product: Mercodia Oxidized LDL ELISA
Lot no: 36090
Expiry date: 2026-01-31



Component	*Art no*	*Lot no*	*O.D. 450 nm*	*Exp. date*
Calibrator 0	20-4113	35928	0,073	2026-02-19
Calibrator 1 1,16 mU/L	20-4114	35936	0,179	2026-03-01
Calibrator 2 2,15 mU/L	20-4115	35937	0,281	2026-03-01
Calibrator 3 3,95 mU/L	20-4116	35938	0,470	2026-03-01
Calibrator 4 7,54 mU/L	20-4117	35939	0,813	2026-03-01
Calibrator 5 14,2 mU/L	20-4118	35940	1,358	2026-03-01
Calibrator 6 26,7 mU/L	20-7553	35943	2,418	2026-03-01
Coated Plate	20-4120	35927		2026-03-11
Assay Buffer	20-4135	35931		2026-03-12
Enzyme Conjugate 15X	20-4123	35944		2026-03-13
Enzyme Conjugate Buffer	20-4133	35932		2026-03-13
Control (L)	20-4127	35941		2026-03-01
Control (H)	20-4131	35942		2026-03-01
Sample Buffer 4X	20-4137	35935		2026-02-28
Wash Buffer 21X	20-6746	36055		2031-05-07
Substrate TMB	20-2629	35551		2027-07-31
Stop Solution	20-2693	35947		2031-02-23

Quality Control Serum	*Assigned range (mU/l)*	*Results (mU/l)*	*Calculated Concentration (x 6561, U/l)*
Control (L)	3,27-5,69	4,67	30,6
Control (H)	10,1-20,1	14,6	95,8

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

3. Quality control

Quality control has been performed for lot no 36090 according to standard operating procedures at Mercodia AB, and the product is released based on fulfillment of established acceptance criteria.

4. Calibration

No international reference is at date available. The Mercodia Oxidized LDL ELISA is calibrated in relative arbitrary units against an in house reference preparation.

5. Assay method

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

6. Intended use

Mercodia Oxidized LDL ELISA provides a method for the quantitative determination of oxidized low density lipoproteins (oxidized LDL) in human blood 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 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:
2024-06-24	Mattias [illegible]	

Date of approval:	Approved by:	Signature:
2024-07-01	Jonas Krick	

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