Mercodia
Mall-0065 v 7.0

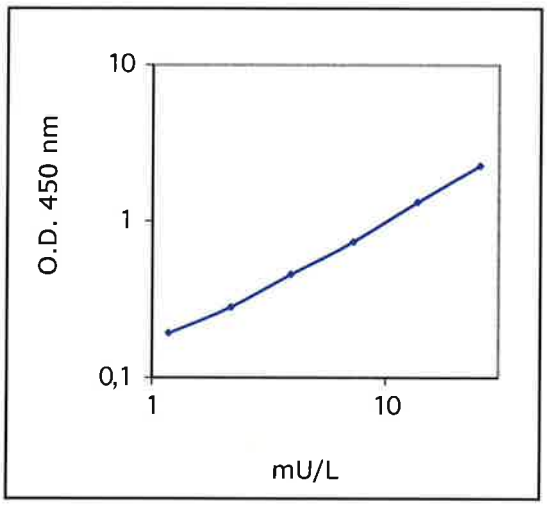
Certificate of Analysis

1. **Manufacturer**

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

2. **Description**

Catalog no: 10-1143-01
Product: Mercodia Oxidized LDL ELISA
Lot no: 36503
Expiry date: 2026-08-31



Component	*Art no*	*Lot no*	*O.D. 450 nm*	*Exp. date*
Calibrator 0	20-4113	36196	0,086	2026-09-20
Calibrator 1 1,18 mU/L	20-4114	36186	0,193	2026-09-05
Calibrator 2 2,17 mU/L	20-4115	36187	0,283	2026-09-05
Calibrator 3 3,91 mU/L	20-4116	36188	0,459	2026-09-05
Calibrator 4 7,25 mU/L	20-4117	36189	0,741	2026-09-05
Calibrator 5 13,6 mU/L	20-4118	36190	1,329	2026-09-05
Calibrator 6 25,1 mU/L	20-7553	36193	2,273	2026-09-05
Coated Plate	20-4120	36198		2026-09-09
Assay Buffer	20-4135	36194		2026-09-27
Enzyme Conjugate 15X	20-4123	36202		2026-09-25
Enzyme Conjugate Buffer	20-4133	36195		2026-09-12
Control (L)	20-4127	36191		2026-09-05
Control (H)	20-4131	36192		2026-09-05
Sample Buffer 4X	20-4137	36197		2026-09-11
Wash Buffer 21X	20-6746	36361		2031-12-18
Substrate TMB	20-2629	34163		2026-11-30
Stop Solution	20-2693	36245		2031-10-22

Quality Control Serum	*Assigned range (mU/l)*	*Results (mU/l)*	*Calculated Concentration (x 6561, U/l)*
Control (L)	3,26 - 5,68	4,52	29,7
Control (H)	9,11 - 18,1	14,7	96,4

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3. Quality control

Quality control has been performed for lot no 36503 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:
2024-11-19	Elin Westberg	EW
Date of approval:	**Approved by:**	**Signature:**
2025-02-05	Mattias H	MH

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