Mercodia
Mall-0065 v 7.0

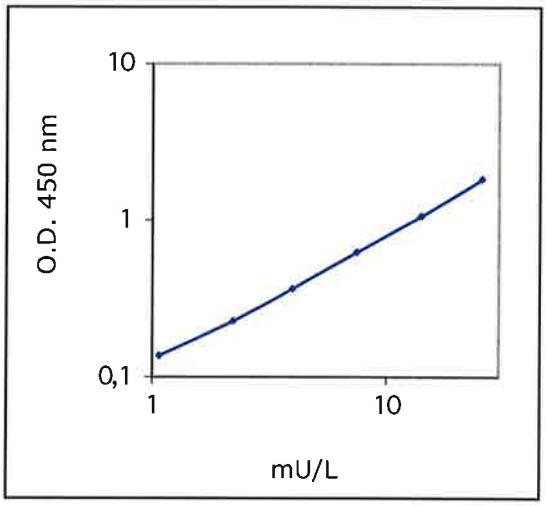
Certificate of Analysis

1. **Manufacturer**

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

2. **Description**

Catalog no: 10-1143-01
Product: Mercodia Oxidized LDL ELISA
Lot no: 35513
Expiry date: 2025-04-30



Component	*Art no*	*Lot no*	*O.D. 450 nm*	*Exp. date*
Calibrator 0	20-4113	35381	0,061	2025-06-15
Calibrator 1 1,08 mU/L	20-4114	35369	0,137	2025-05-16
Calibrator 2 2,25 mU/L	20-4115	35370	0,228	2025-05-16
Calibrator 3 4,04 mU/L	20-4116	35371	0,367	2025-05-16
Calibrator 4 7,54 mU/L	20-4117	35372	0,627	2025-05-16
Calibrator 5 14,1 mU/L	20-4118	35373	1,063	2025-05-16
Calibrator 6 25,6 mU/L	20-7553	35376	1,831	2025-05-16
Coated Plate	20-4120	35377		2025-05-22
Assay Buffer	20-4135	35382		2025-06-14
Enzyme Conjugate 15X	20-4123	35385		2025-06-28
Enzyme Conjugate Buffer	20-4133	35380		2025-06-14
Control (L)	20-4127	35374		2025-05-16
Control (H)	20-4131	35375		2025-05-16
Sample Buffer 4X	20-4137	35379		2025-05-29
Wash Buffer 21X	20-6746	35429		2030-06-01
Substrate TMB	20-2629	34163		2026-11-30
Stop Solution	20-2693	35136		2030-01-23

Quality Control Serum	*Assigned range (mU/l)*	*Results (mU/l)*	*Calculated Concentration (x 6561, U/l)*
Control (L)	3,94 – 6,86	5,90	38,7
Control (H)	8,71 – 17,3	14,2	93,2

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

3. Quality control

Quality control has been performed for lot no 35513 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:
2023-08-18		
Date of approval:	Approved by:	Signature:
2023-08-22		

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