Mercodia
Mall-0065 v 7.0

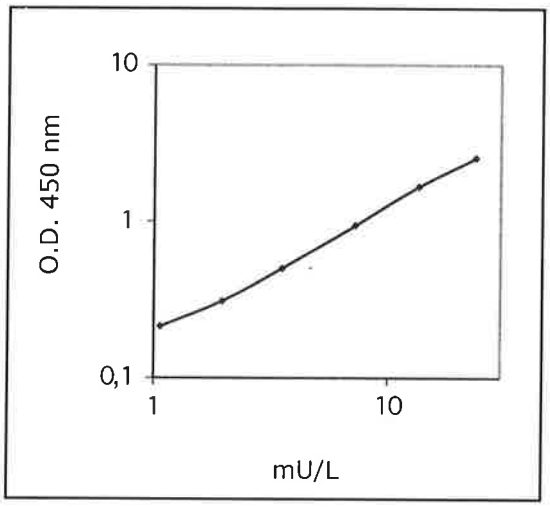
Certificate of Analysis

1. **Manufacturer**

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

2. **Description**

Catalog no: 10-1143-01
Product: Mercodia Oxidized LDL ELISA
Lot no: 36699
Expiry date: 2027-02-28



Component	*Art no*	*Lot no*	*O.D. 450 nm*	*Exp. date*
Calibrator 0	20-4113	36535	0,103	2027-03-17
Calibrator 1 1,07 mU/L	20-4114	36527	0,214	2027-03-20
Calibrator 2 1,97 mU/L	20-4115	36528	0,309	2027-03-20
Calibrator 3 3,55 mU/L	20-4116	36529	0,501	2027-03-20
Calibrator 4 7,26 mU/L	20-4117	36530	0,942	2027-03-20
Calibrator 5 13,5 mU/L	20-4118	36531	1,669	2027-03-20
Calibrator 6 23,5 mU/L	20-7553	36534	2,537	2027-03-20
Coated Plate	20-4120	36726		2027-06-09
Assay Buffer	20-4135	36537		2027-04-04
Enzyme Conjugate 15X	20-4123	36547		2027-04-03
Enzyme Conjugate Buffer	20-4133	36536		2027-04-23
Control (L)	20-4127	36532		2027-03-20
Control (H)	20-4131	36533		2027-03-20
Sample Buffer 4X	20-4137	36538		2027-04-16
Wash Buffer 21X	20-6746	36608		2032-04-07
Substrate TMB	20-2629	36313		2029-02-28
Stop Solution	20-2693	36554		2032-03-07

Quality Control Serum	*Assigned range (mU/l)*	*Results (mU/l)*	*Calculated Concentration (x 6561, U/l)*
Control (L)	2,77 - 4,81	3,62	23,8
Control (H)	7,97 - 15,8	11,0	72,2

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

3. **Quality control**

Quality control has been performed for lot no 36699 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:
2025-06-23	Matthias H	
Date of approval:	**Approved by:**	**Signature:**
2025-06-24	Elin Westberg	EW

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