Mercodia
Mall-0065 v 7.0

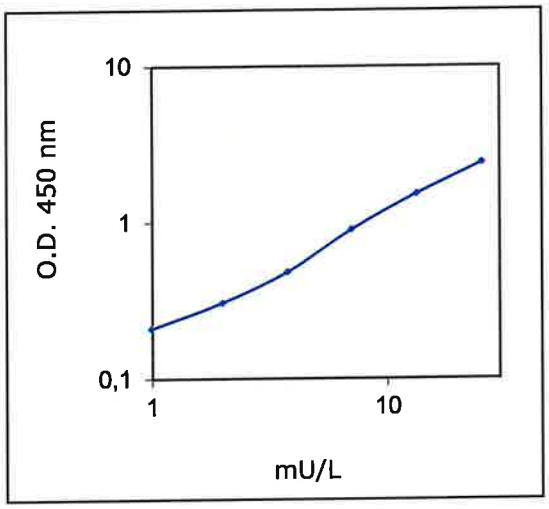
Certificate of Analysis

1. **Manufacturer**

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

2. **Description**

Catalog no: 10-1143-01
Product: Mercodia Oxidized LDL ELISA
Lot no: 37397
Expiry date: 2028-10-31



Component	*Art no*	*Lot no*	*O.D. 450 nm*	*Exp. date*
Calibrator 0	20-4113	36999	0,087	2028-11-24
Calibrator 1 1,08 mU/L	20-4114	36990	0,218	2028-12-05
Calibrator 2 1,98 mU/L	20-4115	36991	0,324	2028-12-05
Calibrator 3 3,69 mU/L	20-4116	36992	0,546	2028-12-05
Calibrator 4 6,88 mU/L	20-4117	36993	0,931	2028-12-05
Calibrator 5 12,8 mU/L	20-4118	36994	1,536	2028-12-05
Calibrator 6 25,3 mU/L	20-7553	36995	2,656	2028-12-05
Coated Plate	20-4120	36988		2028-11-24
Assay Buffer	20-4135	37000		2028-11-25
Enzyme Conjugate 15X	20-4123	37004		2028-12-03
Enzyme Conjugate Buffer	20-4133	37003		2028-12-03
Control (L)	20-4127	36996		2028-12-05
Control (H)	20-4131	36997		2028-12-05
Sample Buffer 4X	20-4137	37001		2028-12-11
Wash Buffer 21X	20-6746	36958		2032-12-03
Substrate TMB	20-2629	36313		2029-02-28
Stop Solution	20-2693	37299		2033-05-29

Quality Control Serum	*Assigned range (mU/l)*	*Results (mU/l)*	*Calculated Concentration (x 6561, U/l)*
Control (L)	2,91 - 5,05	3,86	25,3
Control (H)	8,17 - 16,2	12,2	80,0

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

3. **Quality control**

Quality control has been performed for lot no 37397 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:
2026-02-04	Elin Wernby	EW
Date of approval:	**Approved by:**	**Signature:**
2026-07-06	Matthias Lf	

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