Mercodia
Mall-0676 v 1.0

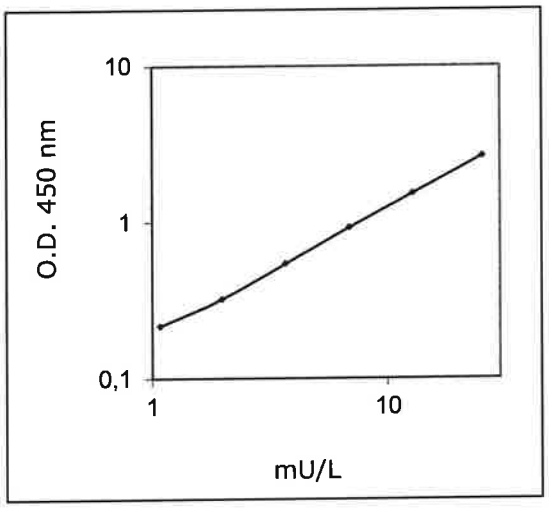
Certificate of Analysis

1. **Manufacturer**

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

2. **Description**

Catalog no: 10-1143-03
Product: Mercodia Oxidized LDL ELISA
Lot no: 37698
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	37311		2033-06-18
Substrate TMB	20-2629	36313		2029-02-28
Stop Solution	20-2693	37095		2033-02-16

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

Address Mercodia AB, Sylveniusgatan 8A, SE-754 50 Uppsala, Sweden
Phone +46 18 57 00 70 | **Fax** +46 18 57 00 80 | **Vat No** SE-556157510001
E-mail info@mercodia.com | **Website** www.mercodia.com

3. **Quality control**

Quality control has been performed for lot no 37698 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**

Mercodia is ISO 13485 certified, demonstrating compliance with the international quality management system standard for medical devices. This product is supplied for research use only and is not intended for use as an in vitro diagnostic (IVD) medical device.

10. **Names and signatures of certifying officers**

Date of analysis:	Performed by:	Signature:
2026-02-04	Elin Westberg	EW

Date of approval:	Approved by:	Signature:
2026-10-28	Jonas Klick	JK

Address Mercodia AB, Sylveniusgatan 8A, SE-754 50 Uppsala, Sweden
Phone +46 18 57 00 70 | **Fax** +46 18 57 00 80 | **Vat No** SE-556157510001
E-mail info@mercodia.com | **Website** www.mercodia.com