Mercodia
Mall-0065 v 7.0

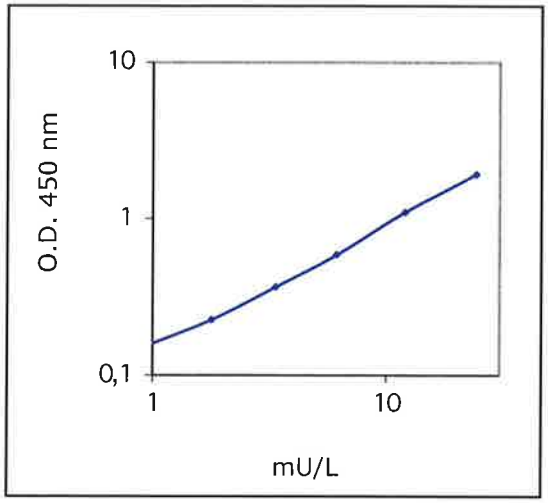
Certificate of Analysis

1. **Manufacturer**

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

2. **Description**

Catalog no: 10-1143-01
Product: Mercodia Oxidized LDL ELISA
Lot no: 36232
Expiry date: 2025-09-30



Component	*Art no*	*Lot no*	*O.D. 450 nm*	*Exp. date*
Calibrator 0	20-4113	35613	0,073	2025-10-23
Calibrator 1 0,987 mU/L	20-4114	35616	0,159	2025-10-19
Calibrator 2 1,78 mU/L	20-4115	35617	0,226	2025-10-19
Calibrator 3 3,36 mU/L	20-4116	35618	0,367	2025-10-19
Calibrator 4 6,13 mU/L	20-4117	35619	0,589	2025-10-19
Calibrator 5 12,0 mU/L	20-4118	35620	1,102	2025-10-19
Calibrator 6 23,9 mU/L	20-7553	35623	1,926	2025-10-19
Coated Plate	20-4120	35614		2025-10-09
Assay Buffer	20-4135	35612		2025-10-13
Enzyme Conjugate 15X	20-4123	35626		2025-11-01
Enzyme Conjugate Buffer	20-4133	35611		2025-10-10
Control (L)	20-4127	35621		2025-10-19
Control (H)	20-4131	35622		2025-10-19
Sample Buffer 4X	20-4137	35624		2025-10-18
Wash Buffer 21X	20-6746	31449		2027-09-16
Substrate TMB	20-2629	35551		2027-07-31
Stop Solution	20-2693	29914		2026-06-12

Quality Control Serum	*Assigned range (mU/l)*	*Results (mU/l)*	*Calculated Concentration (x 6561, U/l)*
Control (L)	3,11-5,41	4,22	27,7
Control (H)	8,78-17,4	13,3	87,3

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

3. **Quality control**

Quality control has been performed for lot no 36232 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:
2023-12-20	Elin Westberg	EW
Date of approval:	**Approved by:**	**Signature:**
2024-09-17	Matthias H	

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