



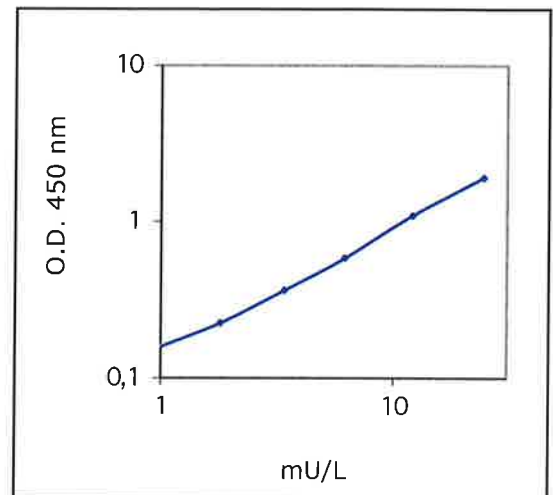
Certificate of Analysis

1. Manufacturer

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

2. Description

Catalog no: 10-1143-01
 Product: Mercodia Oxidized LDL ELISA
 Lot no: 35792
 Expiry date: 2025-09-30



<i>Component</i>	<i>Art no</i>	<i>Lot no</i>	<i>O.D. 450 nm</i>	<i>Exp. date</i>
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	35704		2030-11-14
Substrate TMB	20-2629	35551		2027-07-31
Stop Solution	20-2693	35772		2030-11-16

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

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3. Quality control

Quality control has been performed for lot no 35792 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:

2023-12-20

Performed by:

Elin Wernberg

Signature:

Elin Wernberg

Date of approval:

2023-01-11

Approved by:

Mattias J. L.

Signature:

Mattias J. L.