

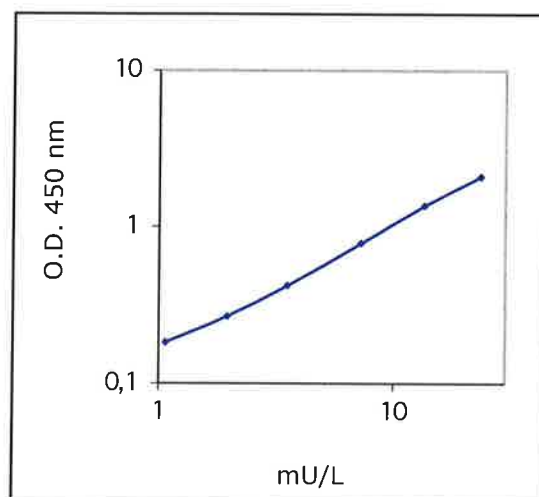
Certificate of Analysis

1. Manufacturer

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

2. Description

Catalog no: 10-1143-01
 Product: Mercodia Oxidized LDL ELISA
 Lot no: 36700
 Expiry date: 2027-02-28



<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	36535	0,082	2027-03-17
Calibrator 1 1,07 mU/L	20-4114	36527	0,183	2027-03-20
Calibrator 2 1,97 mU/L	20-4115	36528	0,268	2027-03-20
Calibrator 3 3,55 mU/L	20-4116	36529	0,421	2027-03-20
Calibrator 4 7,26 mU/L	20-4117	36530	0,787	2027-03-20
Calibrator 5 13,5 mU/L	20-4118	36531	1,371	2027-03-20
Calibrator 6 23,5 mU/L	20-7553	36534	2,094	2027-03-20
Coated Plate	20-4120	36727		2027-06-23
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	36724		2032-06-12
Substrate TMB	20-2629	36313		2029-02-28
Stop Solution	20-2693	36746		2032-07-01

<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)	2,77-4,81	3,70	24,3
Control (H)	7,97-15,8	12,2	80,0

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3. Quality control

Quality control has been performed for lot no 36700 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:

2025-08-11

Performed by:

Elin Westberg

Signature:

EW

Date of approval:

2025-08-13

Approved by:

Jonas Krick

Signature: