

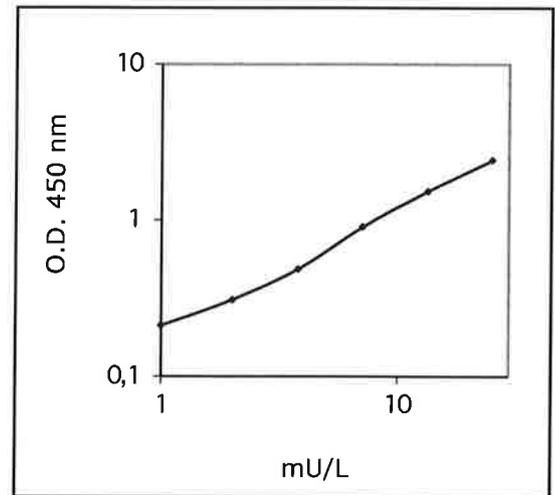
Certificate of Analysis

1. Manufacturer

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

2. Description

Catalog no: 10-1143-01
 Product: Mercodia Oxidized LDL ELISA
 Lot no: 37060
 Expiry date: 2028-10-31



<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	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	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)	2,91 - 5,05	3,86	25,3
Control (H)	8,17 - 16,2	12,2	80,0

3. Quality control

Quality control has been performed for lot no 37060 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:
<u>2026-02-04</u>	<u>Elin Westberg</u>	<u>EW</u>
Date of approval:	Approved by:	Signature:
<u>2026-02-16</u>	<u>Mattias JF</u>	<u>MJ</u>