

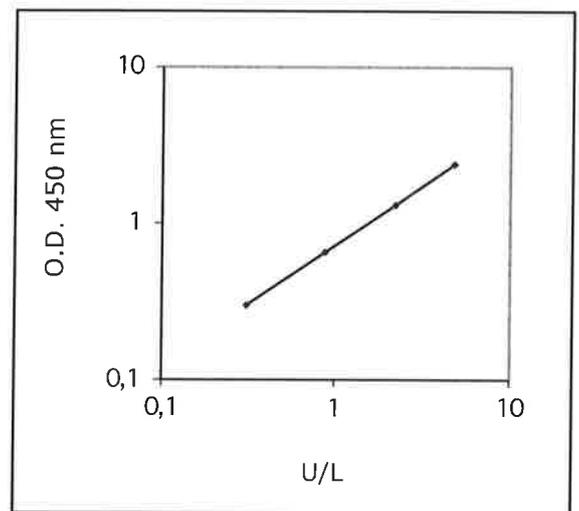
Certificate of Analysis

1. Manufacturer

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

2. Description

Catalog no: 10-1106-01
 Product: Mercodia Lp(a) ELISA
 Lot no: 37166
 Expiry date: 2028-09-30



<i>Component</i>	<i>Art no</i>	<i>Lot no</i>	<i>O.D. 450 nm</i>	<i>Exp. date</i>
Calibrator 0	20-2513	36930	0,116	2028-10-22
Calibrator 0,306 U/L	20-2514	36933	0,299	2028-11-18
Calibrator 0,877 U/L	20-2515	36934	0,655	2028-11-18
Calibrator 2,22 U/L	20-2516	36935	1,307	2028-11-18
Calibrator 4,81 U/L	20-2517	36936	2,393	2028-11-18
Coated Plate	20-2519	36932		2029-01-19
Enzyme Conjugate 11X	20-2533	36941		2028-12-16
Enzyme Conjugate Buffer	20-2524	36939		2028-10-22
Pretreatment Solution	20-2124	36931		2028-10-22
Sample Buffer 5X	20-2530	36938		2028-10-27
Wash Buffer 21X	20-6746	36958		2032-12-03
Substrate TMB	20-2629	36313		2029-02-28
Stop Solution	20-2693	37095		2033-02-16

3. Quality control

Quality control has been performed for lot no 37166 according to standard operating procedures at MercoDia AB, and the product is released based on fulfillment of established acceptance criteria.

4. Calibration

The MercoDia Lp(a) ELISA is calibrated against a highly purified, fully validated, commercial Lp(a) preparation.

5. Assay method

Test procedure used is according to current Direction for Use for the product and lot.

6. Intended use

MercoDia Lp(a) ELISA provides a method for the quantitative determination of human Lp(a) in 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 Material 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:

2026-03-05

Performed by:

Mathias J

Signature:

MJ

Date of approval:

2026-03-05

Approved by:

Jonas Kvick

Signature:

JK