

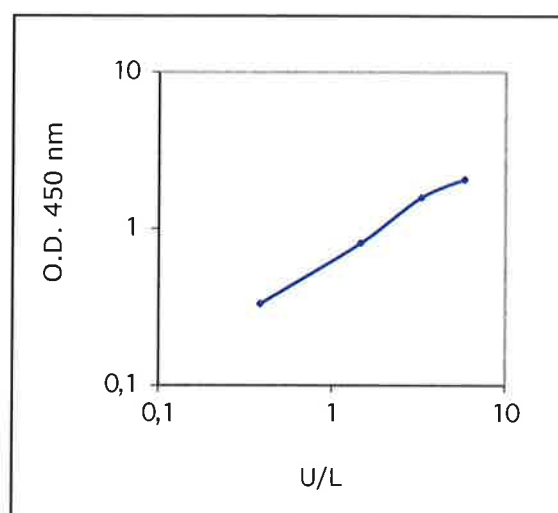
Certificate of Analysis

1. Manufacturer

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

2. Description

Catalog no: 10-1106-01
 Product: Mercodia Lp(a) ELISA
 Lot no: 35610
 Expiry date: 2026-07-31



<i>Component</i>	<i>Art no</i>	<i>Lot no</i>	<i>O.D. 450 nm</i>	<i>Exp. date</i>
Calibrator 0	20-2513	35447	0,098	2026-08-07
Calibrator 0,381 U/L	20-2514	35443	0,332	2026-08-16
Calibrator 1,46 U/L	20-2515	35444	0,811	2026-08-16
Calibrator 3,29 U/L	20-2516	35445	1,587	2026-08-16
Calibrator 5,82 U/L	20-2517	35446	2,072	2026-08-16
Coated Plate	20-2519	35440		2026-08-07
Enzyme Conjugate 11X	20-2533	35450		2026-08-17
Enzyme Conjugate Buffer	20-2524	35448		2026-08-11
Pretreatment Solution	20-2124	35441		2026-08-18
Sample Buffer 5X	20-2530	35442		2026-08-17
Wash Buffer 21X	20-6746	35568		2030-09-05
Substrate TMB	20-2629	34163		2026-11-30
Stop Solution	20-2693	35523		2030-08-10

3. Quality control

Quality control has been performed for lot no 35610 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:

2023-10-03

Performed by:

Elin Westberg

Signature:

EW

Date of approval:

2023-10-03

Approved by:

Malin Sjö

Signature:

MS