Mercodia

Mall-0064 v 7.0

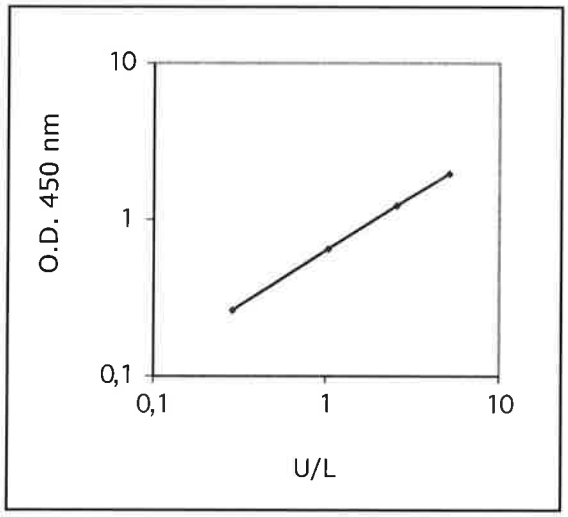
Certificate of Analysis

1. **Manufacturer**

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

2. **Description**

Catalog no: 10-1106-01
Product: Mercodia Lp(a) ELISA
Lot no: 36372
Expiry date: 2027-03-31



Component	*Art no*	*Lot no*	*O.D. 450 nm*	*Exp. date*
Calibrator 0	20-2513	35972	0,101	2027-04-03
Calibrator 0,288 U/L	20-2514	35973	0,263	2027-04-04
Calibrator 1,03 U/L	20-2515	35974	0,648	2027-04-04
Calibrator 2,55 U/L	20-2516	35975	1,229	2027-04-04
Calibrator 5,11 U/L	20-2517	35976	1,958	2027-04-04
Coated Plate	20-2519	36184		2027-08-20
Enzyme Conjugate 11X	20-2533	35979		2027-04-11
Enzyme Conjugate Buffer	20-2524	35971		2027-04-05
Pretreatment Solution	20-2124	35977		2027-04-03
Sample Buffer 5X	20-2530	35978		2027-04-05
Wash Buffer 21X	20-6746	36246		2031-10-10
Substrate TMB	20-2629	35551		2027-07-31
Stop Solution	20-2693	33839		2029-06-27

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3. Quality control

Quality control has been performed for lot no 36372 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:	Performed by:	Signature:
2024-09-05	Jonas Kvick	

Date of approval:	Approved by:	Signature:
2024-12-09	Elin Westberg	EW

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