Mercodia

Mall-0104 v 7.0

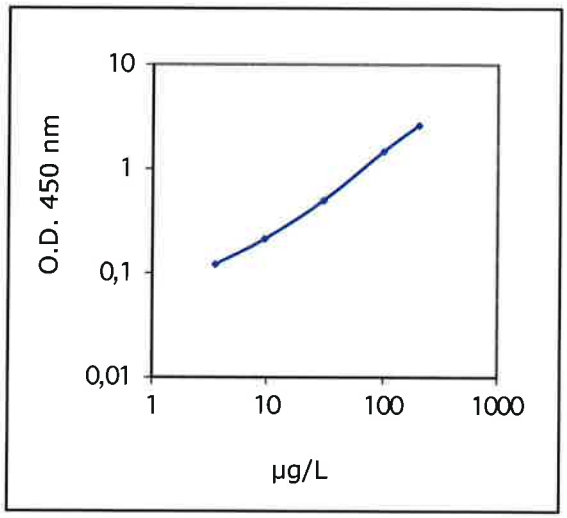
Certificate of Analysis

1. **Manufacturer**

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

2. **Description**

Catalog no: 10-1176-01
Product: Mercodia MPO ELISA
Lot no: 36297
Expiry date: 2026-03-31



Component		*Art no*	*Lot no*	*O.D. 450 nm*	*Exp. date*
Calibrator 0		20-6582	36286	0,067	2027-11-01
Calibrator 3,55	µg/L	20-5209	36287	0,121	2026-04-25
Calibrator 9,47	µg/L	20-5210	36288	0,212	2026-04-25
Calibrator 30,2	µg/L	20-5211	36289	0,496	2026-04-25
Calibrator 98,5	µg/L	20-5212	36290	1,464	2026-04-25
Calibrator 200	µg/L	20-5213	36291	2,607	2026-04-25
Coated Plate		20-5201	36293		2027-11-25
Assay Buffer		20-5220	36294		2027-10-22
Enzyme Conjugate 11X		20-5216	36296		2027-11-21
Enzyme Conjugate Buffer		20-5218	36295		2027-10-25
Sample Buffer		20-5208	36319		2027-11-14
Wash Buffer 21X		20-6746	36246		2031-10-10
Substrate TMB		20-2629	35551		2027-07-31
Stop Solution		20-2693	36245		2031-10-22

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E-mail info@mercodia.com | **Website** www.mercodia.com

3. Quality control

Quality control has been performed for lot no 36297 according to standard operating procedures at Mercodia AB, and the product is released based on fulfillment of established acceptance criteria.

4. Calibration

The Mercodia MPO ELISA is calibrated against a highly purified, fully validated, commercial MPO preparation.

5. Assay method

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

6. Intended use

Mercodia MPO ELISA provides a method for the quantitative determination of human MPO 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:
2024-12-16	Ellen Westberg	EW

Date of approval:	Approved by:	Signature:
2024-12-16	Jonas Kvick	

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