Mercodia

Mall-0104 v 7.0

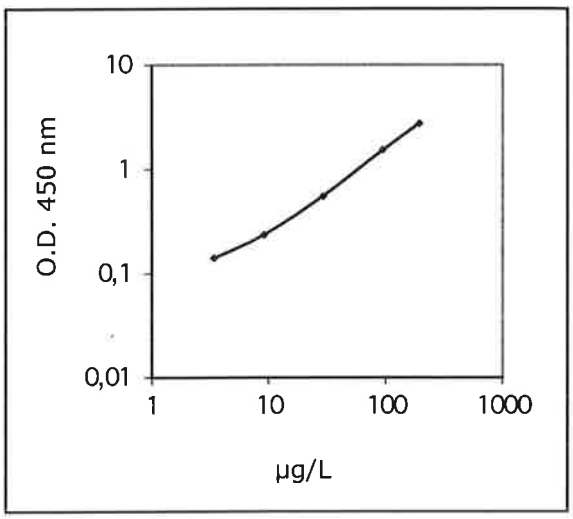
Certificate of Analysis

1. **Manufacturer**

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

2. **Description**

Catalog no: 10-1176-01
Product: Mercodia MPO ELISA
Lot no: 33735
Expiry date: 2023-06-30



Component	*Art no*	*Lot no*	*O.D. 450 nm*	*Exp. date*
Calibrator 0	20-6582	31942	0,090	2024-01-29
Calibrator 3,41 µg/L	20-5209	33210	0,140	2023-07-12
Calibrator 9,13 µg/L	20-5210	33211	0,234	2023-07-12
Calibrator 29,1 µg/L	20-5211	33212	0,548	2023-07-12
Calibrator 94,1 µg/L	20-5212	33213	1,526	2023-07-12
Calibrator 194 µg/L	20-5213	33214	2,739	2023-07-12
Coated Plate	20-5201	31933		2024-02-08
Assay Buffer	20-5220	31938		2024-01-28
Enzyme Conjugate 11X	20-5216	31944		2024-02-16
Enzyme Conjugate Buffer	20-5218	31936		2024-01-28
Sample Buffer	20-5208	31940		2024-01-27
Wash Buffer 21X	20-6746	31676		2027-11-03
Substrate TMB	20-2629	29655		2023-07-31
Stop Solution	20-2693	30785		2027-02-07

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

3. **Quality control**

Quality control has been performed for lot no 33735 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:
2022-03-03	Matthias Ingelsson	

Date of approval:	Approved by:	Signature:
2022-05-24	Johan Kylsberg	

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