

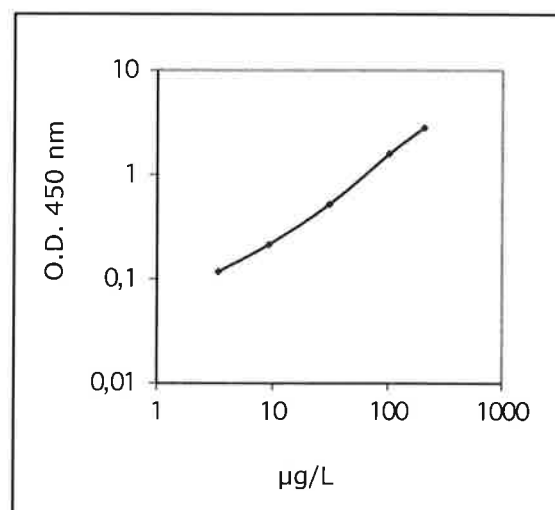
Certificate of Analysis

1. Manufacturer

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

2. Description

Catalog no: 10-1176-01
Product: Mercodia MPO ELISA
Lot no: 35775
Expiry date: 2025-03-31



Component	Art no	Lot no	O.D. 450 nm	Exp. date
Calibrator 0	20-6582	35636	0,064	2026-10-02
Calibrator 3,41 µg/L	20-5209	35642	0,117	2025-04-10
Calibrator 9,21 µg/L	20-5210	35643	0,213	2025-04-10
Calibrator 30,4 µg/L	20-5211	35644	0,519	2025-04-10
Calibrator 101 µg/L	20-5212	35645	1,577	2025-04-10
Calibrator 204 µg/L	20-5213	35646	2,812	2025-04-10
Coated Plate	20-5201	35635		2026-10-02
Assay Buffer	20-5220	35641		2026-10-10
Enzyme Conjugate 11X	20-5216	35648		2026-10-12
Enzyme Conjugate Buffer	20-5218	35638		2026-10-10
Sample Buffer	20-5208	35637		2026-10-05
Wash Buffer 21X	20-6746	35603		2030-10-09
Substrate TMB	20-2629	35551		2027-07-31
Stop Solution	20-2693	35523		2030-08-10

3. Quality control

Quality control has been performed for lot no 35775 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:

2023-11-22

Performed by:

Mattias BL

Signature:

M

Date of approval:

2023-11-22

Approved by:

Elin Wernberg

Signature:

EW