

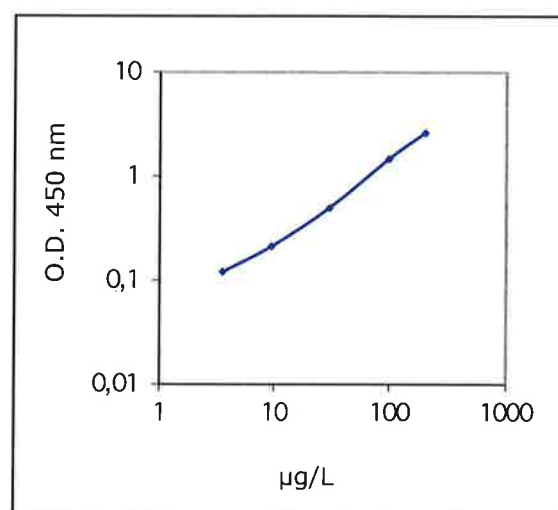
Certificate of Analysis

1. Manufacturer

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

2. Description

Catalog no: 10-1176-01
Product: Mercodia MPO ELISA
Lot no: 36638
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	36361		2031-12-18
Substrate TMB	20-2629	35551		2027-07-31
Stop Solution	20-2693	31476		2027-09-21

3. Quality control

Quality control has been performed for lot no 36638 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:

2024-12-16

Performed by:

Elin Westberg

Signature:

EW

Date of approval:

2025-04-07

Approved by:

Jonas Krich

Signature:

JK