

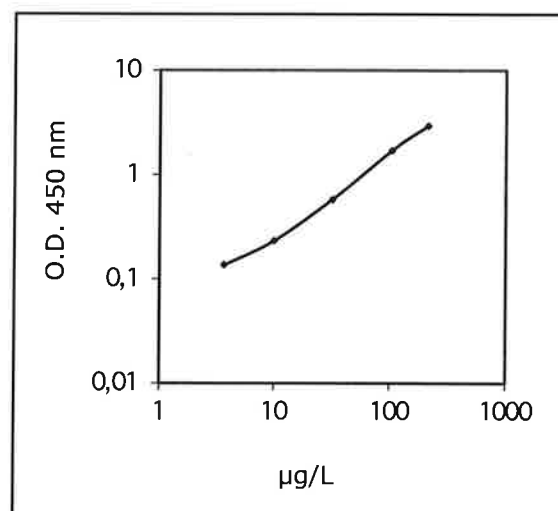
Certificate of Analysis

1. Manufacturer

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

2. Description

Catalog no: 10-1176-01
 Product: Mercodia MPO ELISA
 Lot no: 37048
 Expiry date: 2027-03-31



<i>Component</i>	<i>Art no</i>	<i>Lot no</i>	<i>O.D. 450 nm</i>	<i>Exp. date</i>
Calibrator 0	20-6582	36906	0,077	2028-10-20
Calibrator 3,64 µg/L	20-5209	36893	0,136	2027-04-22
Calibrator 9,94 µg/L	20-5210	36894	0,231	2027-04-22
Calibrator 31,9 µg/L	20-5211	36895	0,576	2027-04-22
Calibrator 104 µg/L	20-5212	36896	1,700	2027-04-22
Calibrator 213 µg/L	20-5213	36897	2,931	2027-04-22
Coated Plate	20-5201	36891		2028-10-13
Assay Buffer	20-5220	36905		2028-10-16
Enzyme Conjugate 11X	20-5216	36904		2028-11-20
Enzyme Conjugate Buffer	20-5218	36892		2028-10-10
Sample Buffer	20-5208	36898		2028-10-02
Wash Buffer 21X	20-6746	36804		2032-08-21
Substrate TMB	20-2629	36313		2029-02-28
Stop Solution	20-2693	36746		2032-07-01

3. Quality control

Quality control has been performed for lot no 37048 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:

2026-01-08

Performed by:

Jonas Krick

Signature:

Date of approval:

2026-01-08

Approved by:

Elin Westberg

Signature:

EW