

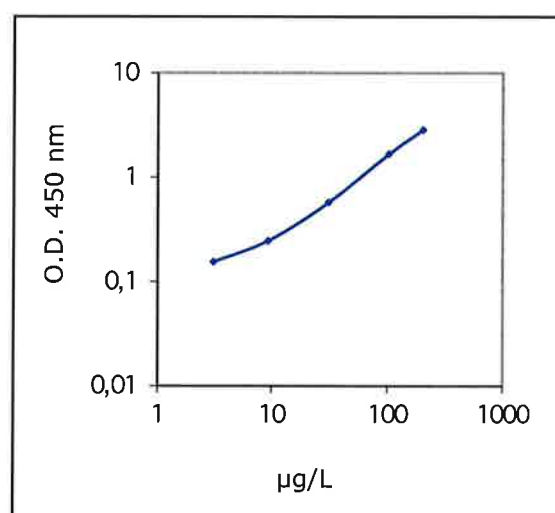
Certificate of Analysis

1. Manufacturer

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

2. Description

Catalog no: 10-1176-01
Product: Mercodia MPO ELISA
Lot no: 35224
Expiry date: 2023-12-31



Component	Art no	Lot no	O.D. 450 nm	Exp. date
Calibrator 0	20-6582	31942	0,099	2024-01-29
Calibrator 3,12 µg/L	20-5209	35142	0,155	2024-08-01
Calibrator 9,37 µg/L	20-5210	35143	0,245	2024-08-01
Calibrator 31,3 µg/L	20-5211	35144	0,573	2024-08-01
Calibrator 104 µg/L	20-5212	35145	1,673	2024-08-01
Calibrator 205 µg/L	20-5213	35146	2,848	2024-08-01
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	31053		2024-07-31
Stop Solution	20-2693	30785		2027-02-07

3. Quality control

Quality control has been performed for lot no 35224 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:

2023-03-09

Performed by:

Elin Westberg EW

Signature:

Date of approval:

2023-03-09

Approved by:

Jonas Kuf

Signature: