

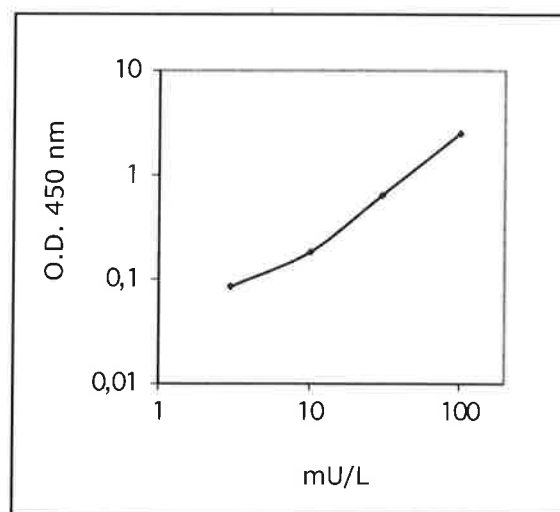
Certificate of Analysis

1. Manufacturer

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

2. Description

Catalog no: 10-1128-01
 Product: Mercodia Iso Insulin ELISA
 Lot no: 36201
 Expiry date: 2025-09-30



<i>Component</i>	<i>Art no</i>	<i>Lot no</i>	<i>O.D. 450 nm</i>	<i>Exp. date</i>
Calibrator 0	20-2702	36241	0,071	2025-10-02
Calibrator 3 mU/L	20-2703	36237	0,085	2025-10-03
Calibrator 10 mU/L	20-2704	36238	0,182	2025-10-03
Calibrator 30 mU/L	20-2705	36239	0,640	2025-10-03
Calibrator 100 mU/L	20-2706	36240	2,498	2025-10-03
Coated Plate	20-2701	36242		2025-10-06
Enzyme Conjugate 11X	20-2707	36212		2027-06-18
Enzyme Conjugate Buffer	20-2708	35995		2027-06-13
Wash Buffer 21X	20-6746	35603		2030-10-09
Substrate TMB	20-2629	33423		2026-06-30
Stop Solution	20-2693	33839		2029-06-27

3. Quality control

Quality control has been performed for lot no 36201 according to standard operating procedures at Mercodia AB, and the product is released based on fulfillment of established acceptance criteria.

4. Calibration

The Mercodia Insulin ELISA is calibrated against 1st International Reference Preparation 66/304.

5. Assay method

Test procedure used is according to current Direction for Use for the product and lot.

6. Intended use

Mercodia Insulin ELISA provides a method for the quantitative determination of insulin 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:

2024-09-27

Performed by:

Jonas Krick

Signature:

[Signature]

Date of approval:

2024-09-27

Approved by:

Elin Westberg

Signature:

EW