

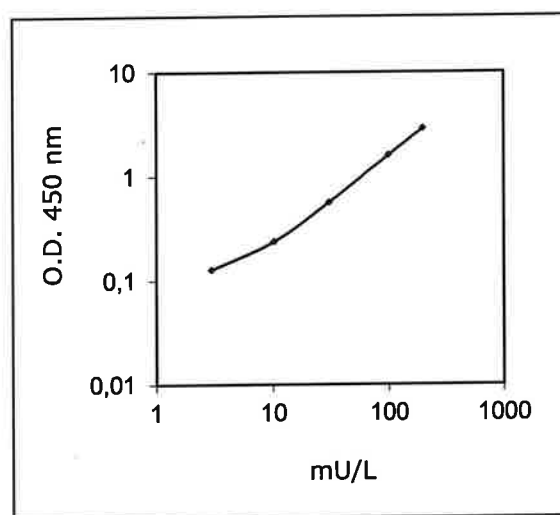
Certificate of Analysis

1. Manufacturer

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

2. Description

Catalog no: 10-1113-01
Product: Mercodia Insulin ELISA
Lot no: 37396
Expiry date: 2028-07-31



<i>Component</i>	<i>Art no</i>	<i>Lot no</i>	<i>O.D. 450 nm</i>	<i>Exp. date</i>
Calibrator 0	20-2615	36763	0,080	2028-08-04
Calibrator 2,97 mU/L	20-2616	36765	0,128	2028-08-06
Calibrator 10,1 mU/L	20-2617	36766	0,238	2028-08-06
Calibrator 30,1 mU/L	20-2618	36767	0,568	2028-08-06
Calibrator 99,0 mU/L	20-2619	36768	1,600	2028-08-06
Calibrator 198 mU/L	20-2620	36769	2,887	2028-08-06
Coated Plate	20-2622	36762		2028-08-11
Enzyme Conjugate 11X	20-2625	36771		2028-08-14
Enzyme Conjugate Buffer	20-2627	36764		2028-08-05
Wash Buffer 21X	20-6746	36804		2032-08-21
Substrate TMB	20-2629	36313		2029-02-28
Stop Solution	20-2693	37299		2033-05-29

3. Quality control

Quality control has been performed for lot no 37396 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:

2025-10-02

Performed by:

Jonas Kvick

Signature:

Jonas Kvick

Date of approval:

2026-07-06

Approved by:

Elin Westberg

Signature:

Elin Westberg