

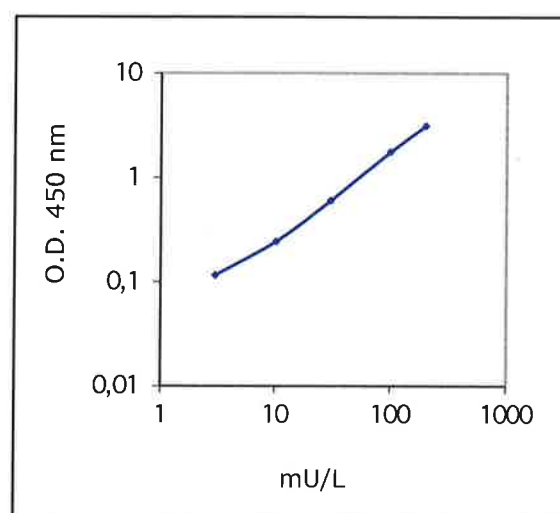
## Certificate of Analysis

### 1. Manufacturer

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

### 2. Description

Catalog no: 10-1113-10  
 Product: Mercodia Insulin ELISA  
 Lot no: 37006  
 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	0,064	2028-08-04
Calibrator 2,97 mU/L	20-2616	36765	0,116	2028-08-06
Calibrator 10,1 mU/L	20-2617	36766	0,243	2028-08-06
Calibrator 30,1 mU/L	20-2618	36767	0,599	2028-08-06
Calibrator 99,0 mU/L	20-2619	36768	1,754	2028-08-06
Calibrator 198 mU/L	20-2620	36769	3,114	2028-08-06
Coated Plate	20-2622	36873		2028-09-29
Enzyme Conjugate 11X	20-2631	36875		2028-10-21
Enzyme Conjugate Buffer	20-2630	36874		2028-09-26
Wash Buffer 21X	20-3194	36877		2032-09-22
Substrate TMB	20-3136	36451		2029-05-31
Stop Solution	20-2694	36685		2032-05-13

**3. Quality control**

Quality control has been performed for lot no 37006 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 1<sup>st</sup> 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:

2025-11-21

Performed by:

Yonas Krick

Signature:



Date of approval:

2025-11-21

Approved by:

Elin Westberg

Signature:

