

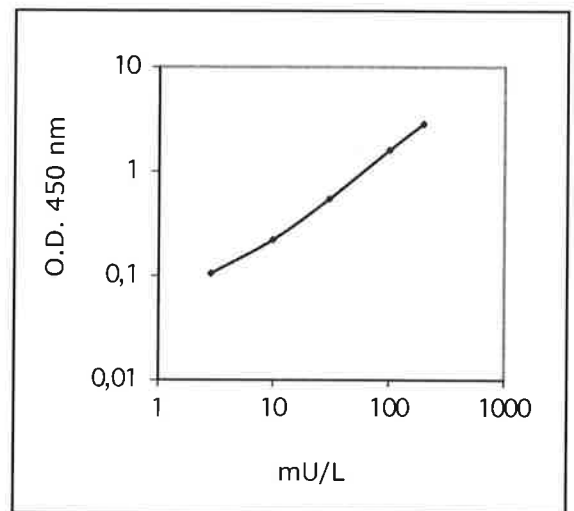
## *Certificate of Analysis*

### 1. Manufacturer

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

### 2. Description

Catalog no: 10-1113-10  
 Product: MercoDia Insulin ELISA  
 Lot no: 36467  
 Expiry date: 2027-05-31



<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	36094	0,057	2027-06-11
Calibrator 2,86 mU/L	20-2616	36095	0,105	2027-06-05
Calibrator 9,88 mU/L	20-2617	36096	0,220	2027-06-05
Calibrator 30,1 mU/L	20-2618	36097	0,541	2027-06-05
Calibrator 99,3 mU/L	20-2619	36098	1,589	2027-06-05
Calibrator 196 mU/L	20-2620	36099	2,849	2027-06-05
Coated Plate	20-2622	36321		2027-11-11
Enzyme Conjugate 11X	20-2631	36324		2027-11-19
Enzyme Conjugate Buffer	20-2630	36320		2027-11-18
Wash Buffer 21X	20-3194	36357		2031-12-06
Substrate TMB	20-3136	35552		2027-07-31
Stop Solution	20-2694	36168		2031-08-15

### 3. Quality control

Quality control has been performed for lot no 36467 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:

2024-12-09

Performed by:

Matthias H

Signature:



Date of approval:

2025-01-27

Approved by:

Elin Worsberg

Signature:

EW