

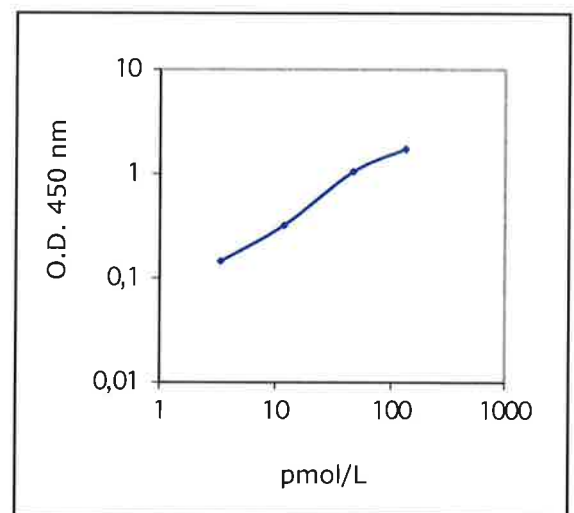
## *Certificate of Analysis*

### 1. Manufacturer

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

### 2. Description

Catalog no: 10-1118-01  
 Product: MercoDia Proinsulin ELISA  
 Lot no: 36552  
 Expiry date: 2026-08-31



| <i>Component</i>        | <i>Art no</i> | <i>Lot no</i> | <i>O.D. 450 nm</i> | <i>Exp. date</i> |
|-------------------------|---------------|---------------|--------------------|------------------|
| Calibrator 0            | 20-3013       | 36217         | 0,069              | 2026-09-30       |
| Calibrator 3,36 pmol/L  | 20-3014       | 36221         | 0,145              | 2026-09-24       |
| Calibrator 11,7 pmol/L  | 20-3015       | 36222         | 0,319              | 2026-09-24       |
| Calibrator 45,8 pmol/L  | 20-3016       | 36223         | 1,051              | 2026-09-24       |
| Calibrator 131 pmol/L   | 20-3017       | 36224         | 2,602              | 2026-09-24       |
| Coated Plate            | 20-3019       | 36226         |                    | 2026-11-04       |
| Assay Buffer            | 20-3024       | 36229         |                    | 2026-09-27       |
| Enzyme Conjugate 21X    | 20-3022       | 36230         |                    | 2026-10-16       |
| Enzyme Conjugate Buffer | 20-3028       | 36228         |                    | 2026-10-16       |
| Wash Buffer 21X         | 20-6746       | 36361         |                    | 2031-12-18       |
| Substrate TMB           | 20-2629       | 35551         |                    | 2027-07-31       |
| Stop Solution           | 20-2693       | 36245         |                    | 2031-10-22       |

### 3. Quality control

Quality control has been performed for lot no 36552 according to standard operating procedures at Mercodia AB, and the product is released based on fulfillment of established acceptance criteria.

### 4. Calibration

The Mercodia Proinsulin ELISA is calibrated against the International Reference Reagent for human proinsulin, IRR 84/611.

### 5. Assay method

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

### 6. Intended use

Mercodia Proinsulin ELISA provides a method for the quantitative determination of proinsulin 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:

2024-12-11

Performed by:

Elin Westberg

Signature:

EW

Date of approval:

2025-03-03

Approved by:

Göran Krich

Signature:

GK