

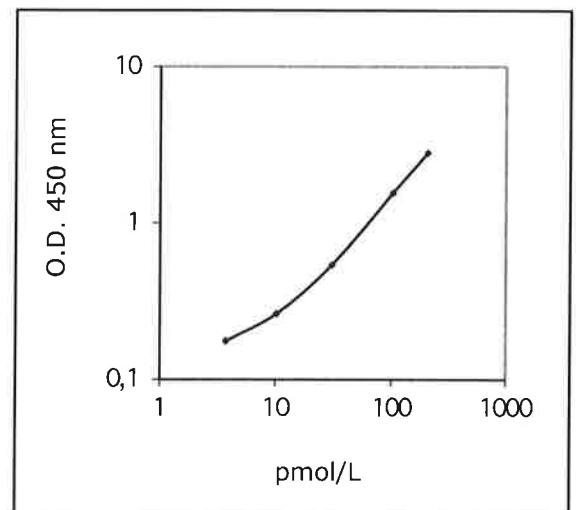
## *Certificate of Analysis*

### 1. Manufacturer

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

### 2. Description

Catalog no: 10-1232-01  
 Product: Merckodia Rat/Mouse  
           Proinsulin ELISA  
 Lot no: 36433  
 Expiry date: 2026-11-30



<i>Component</i>	<i>Art no</i>	<i>Lot no</i>	<i>O.D. 450 nm</i>	<i>Exp. date</i>
Calibrator 0	20-6721	36282	0,121	2027-12-05
Calibrator 3,74 pmol/L	20-6727	36273	0,176	2027-11-21
Calibrator 10,2 pmol/L	20-6728	36274	0,263	2027-11-21
Calibrator 30,3 pmol/L	20-6729	36275	0,539	2027-11-21
Calibrator 102 pmol/L	20-6730	36276	1,554	2027-11-21
Calibrator 206 pmol/L	20-6731	36277	2,808	2027-11-21
Coated Plate	20-6738	36284		2027-12-02
Enzyme Conjugate 11X	20-6734	36298		2026-12-10
Enzyme Conjugate Buffer	20-6736	36272		2027-11-21
Wash Buffer 21X	20-6746	36361		2031-12-18
Substrate TMB	20-2629	34163		2026-11-30
Stop Solution	20-2693	34128		2029-09-19

### 3. Quality control

Quality control has been performed for lot no 36433 according to standard operating procedures at Mercodia AB, and the product is released based on fulfillment of established acceptance criteria.

### 4. Calibration

The Mercodia Rat/Mouse Proinsulin ELISA is calibrated against an in-house reference preparation of rat proinsulin.

### 5. Assay method

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

### 6. Intended use

Mercodia Rat/Mouse Proinsulin ELISA provides a method for the quantitative determination of rat and mouse proinsulin, in serum, plasma, cell culture medium or cellular extracts.

### 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:

2025-01-21

Performed by:

Eira Lindqvist

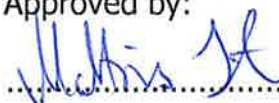
Signature:



Date of approval:

2025-01-24

Approved by:



Signature:

