

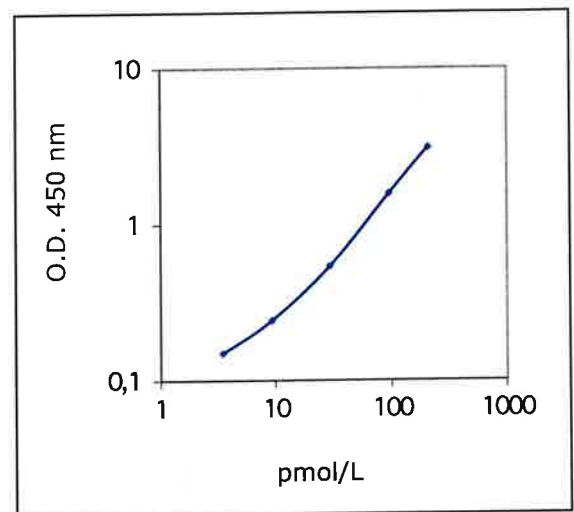
Certificate of Analysis

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: 37167
Expiry date: 2028-02-29



<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	37035	0,095	2029-01-15
Calibrator 3,46 pmol/L	20-6727	37036	0,149	2029-01-13
Calibrator 9,20 pmol/L	20-6728	37037	0,241	2029-01-13
Calibrator 29,0 pmol/L	20-6729	37038	0,535	2029-01-13
Calibrator 94,2 pmol/L	20-6730	37039	1,568	2029-01-13
Calibrator 205 pmol/L	20-6731	37040	3,087	2029-01-13
Coated Plate	20-6738	37041		2029-02-02
Enzyme Conjugate 11X	20-6734	37044		2028-03-11
Enzyme Conjugate Buffer	20-6736	37042		2029-01-14
Wash Buffer 21X	20-6746	36958		2032-12-03
Substrate TMB	20-2629	36313		2029-02-28
Stop Solution	20-2693	37095		2033-02-16

3. Quality control

Quality control has been performed for lot no 37167 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:

2026-03-31

Performed by:

Eli Westberg

Signature:

EW

Date of approval:

2026-04-07

Approved by:

Jonas Kuick

Signature:

JK