

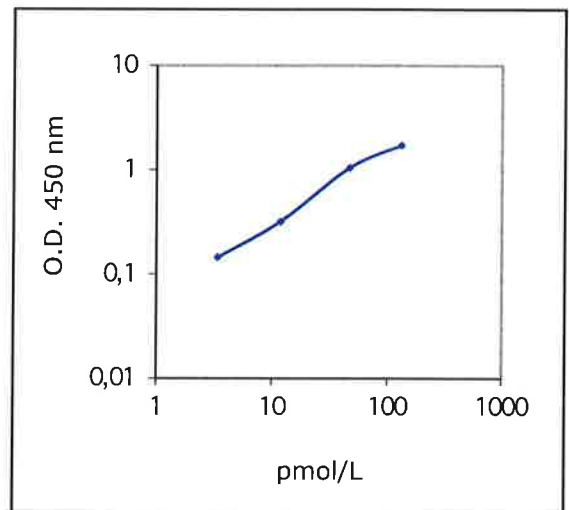
Certificate of Analysis

1. Manufacturer

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

2. Description

Catalog no: 10-1118-01
 Product: MercoDia Proinsulin ELISA
 Lot no: 36359
 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	36246		2031-10-10
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 36359 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:	Performed by:	Signature:
<u>2024-12-11</u>	<u>Elin Westberg</u>	<u>EW</u>

Date of approval:	Approved by:	Signature:
<u>2024-12-11</u>	<u>Mattias Bl</u>	<u>[Signature]</u>