

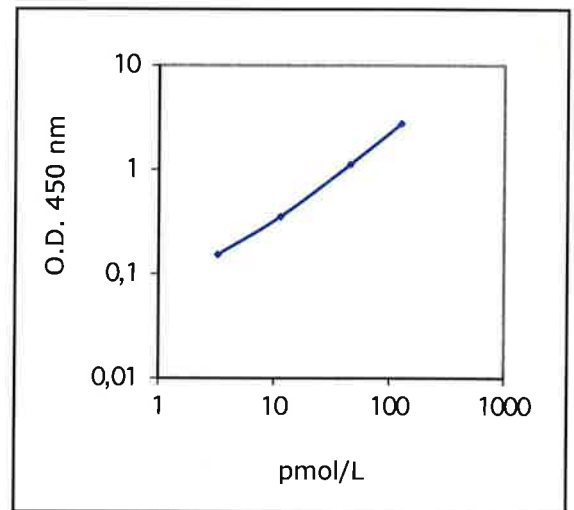
Certificate of Analysis

1. Manufacturer

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

2. Description

Catalog no: 10-1118-01
 Product: Merckodia Proinsulin ELISA
 Lot no: 35902
 Expiry date: 2025-10-31



<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	35684	0,071	2025-11-28
Calibrator 3,24 pmol/L	20-3014	35687	0,154	2025-11-29
Calibrator 11,2 pmol/L	20-3015	35688	0,354	2025-11-29
Calibrator 44,8 pmol/L	20-3016	35689	1,124	2025-11-29
Calibrator 125 pmol/L	20-3017	35690	2,765	2025-11-29
Coated Plate	20-3019	35683		2025-12-11
Assay Buffer	20-3024	35686		2025-11-30
Enzyme Conjugate 21X	20-3022	35692		2026-01-10
Enzyme Conjugate Buffer	20-3028	35685		2025-11-28
Wash Buffer 21X	20-6746	35704		2030-11-14
Substrate TMB	20-2629	35551		2027-07-31
Stop Solution	20-2693	35772		2030-11-16

3. Quality control

Quality control has been performed for lot no 35902 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:

2024-02-13

Performed by:

Eli Westberg EW

Signature:

Date of approval:

2024-02-16

Approved by:

Jonas Krick

Signature: