Mercodia

Mall-0060 v 6.0

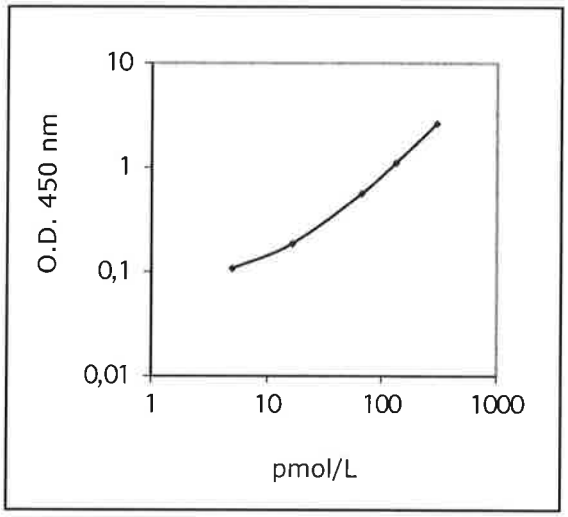
Certificate of Analysis

1. **Manufacturer**

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

2. **Description**

Catalog no:	10-1141-01
Product:	Mercodia Ultrasensitive C-peptide ELISA
Lot no:	36480
Expiry date:	2026-03-31



Component		*Art no*	*Lot no*	*O.D. 450 nm*	*Exp. Date*
Calibrator 0		20-6636	35987	0,069	2026-04-24
Calibrator 4,92	pmol/L	20-3514	35982	0,107	2026-04-09
Calibrator 16,3	pmol/L	20-3515	35983	0,185	2026-04-09
Calibrator 65,8	pmol/L	20-3516	35984	0,560	2026-04-09
Calibrator 132	pmol/L	20-3517	35985	1,102	2026-04-09
Calibrator 299	pmol/L	20-3518	35986	2,615	2026-04-09
Coated Plate		20-3422	36138		2027-07-15
Assay Buffer		20-6640	35988		2026-04-19
Enzyme Conjugate 21X		20-7100	35990		2026-05-29
Enzyme Conjugate Buffer		20-7098	35989		2026-04-19
Wash Buffer 21X		20-6746	36361		2031-12-18
Substrate TMB		20-2629	33423		2026-06-30
Stop Solution		20-2693	34128		2029-09-19

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3. Quality control

Quality control has been performed for lot no 36480 according to standard operating procedures at Mercodia AB, and the product is released based on fulfillment of established acceptance criteria.

4. Calibration

The Mercodia Ultrasensitive C-peptide ELISA is calibrated against the International Reference Reagent for C-peptide, IRR C-peptide 84/510.

5. Assay method

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

6. Intended use

Mercodia Ultrasensitive C-peptide ELISA provides a method for the quantitative determination of human c-peptide 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:
2024-09-20	Mattias H	MH

Date of approval:	Approved by:	Signature:
2025-01-30	Elin Westberg	EW

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