Mercodia

Mall-0052 v 6.0

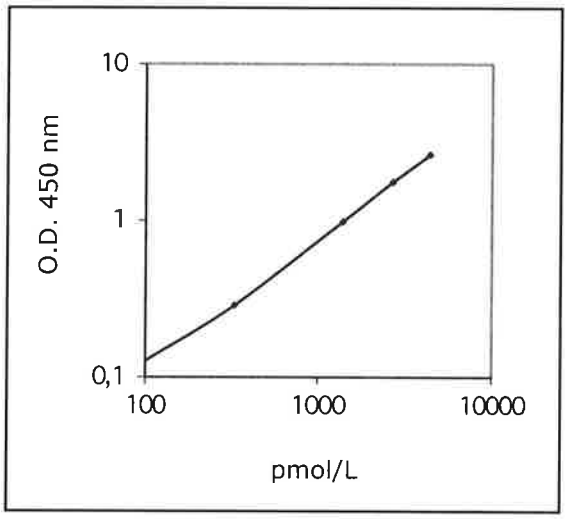
Certificate of Analysis

1. **Manufacturer**

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

2. **Description**

Catalog no: 10-1136-01
Product: Mercodia C-peptide ELISA
Lot no: 35515
Expiry date: 2026-03-31



Component	*Art no*	*Lot no*	*O.D. 450 nm*	*Exp. date*
Calibrator 0	20-3415	35325	0,062	2026-04-14
Calibrator 98,7 pmol/L	20-3416	35318	0,126	2026-04-19
Calibrator 332 pmol/L	20-3417	35319	0,287	2026-04-19
Calibrator 1380 pmol/L	20-3418	35320	0,983	2026-04-19
Calibrator 2660 pmol/L	20-3419	35321	1,762	2026-04-19
Calibrator 4340 pmol/L	20-3420	35322	2,633	2026-04-19
Coated Plate	20-3422	35329		2026-04-17
Assay Buffer	20-2933	35324		2026-05-26
Enzyme Conjugate 11X	20-3425	35326		2026-05-25
Enzyme Conjugate Buffer	20-3427	35317		2026-05-26
Wash Buffer 21X	20-6746	35429		2030-06-01
Substrate TMB	20-2629	34163		2026-11-30
Stop Solution	20-2693	35136		2030-01-23

Address Mercodia AB, Sylveniusgatan 8A, SE-754 50 Uppsala, Sweden
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E-mail info@mercodia.com | **Website** www.mercodia.com

3. Quality control

Quality control has been performed for lot no 35515 according to standard operating procedures at Mercodia AB, and the product is released based on fulfillment of established acceptance criteria.

4. Calibration

The Mercodia 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 C-peptide ELISA provides a method for the quantitative determination of human c-peptide in serum, plasma or urine.

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:
2023-07-12		

Date of approval:	Approved by:	Signature:
2023-07-12		

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