Mercodia

Mall-0060 v 6.0

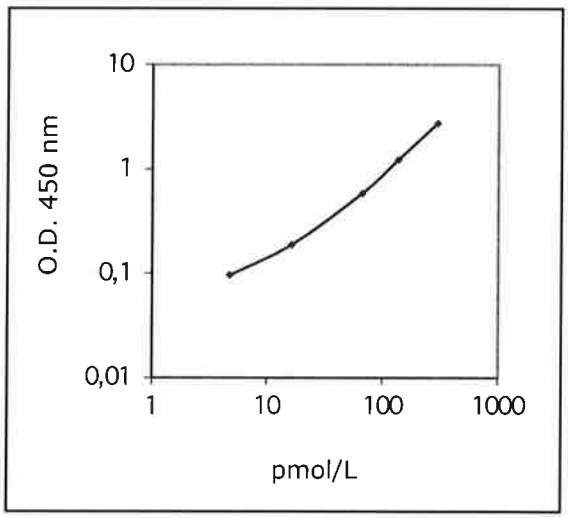
Certificate of Analysis

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: 35557
Expiry date: 2024-12-31



Component		*Art no*	*Lot no*	*O.D. 450 nm*	*Exp. date*
Calibrator 0		20-6636	35131	0,062	2025-01-30
Calibrator 4,73	pmol/L	20-3514	35126	0,096	2025-02-01
Calibrator 16,3	pmol/L	20-3515	35127	0,187	2025-02-01
Calibrator 66,0	pmol/L	20-3516	35128	0,581	2025-02-01
Calibrator 136	pmol/L	20-3517	35129	1,227	2025-02-01
Calibrator 295	pmol/L	20-3518	35130	2,740	2025-02-01
Coated Plate		20-3422	35135		2026-02-06
Assay Buffer		20-6640	35133		2025-01-31
Enzyme Conjugate 21X		20-7100	35147		2025-03-01
Enzyme Conjugate Buffer		20-7098	35132		2025-01-31
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

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3. Quality control

Quality control has been performed for lot no 35557 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:
2023-03-22	Jonas Kvick	

Date of approval:	Approved by:	Signature:
2023-09-01	Elin Westberg	EW

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