Mercodia

Mall-0060 v 6.0

Certificate of Analysis

1. **Manufacturer**

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

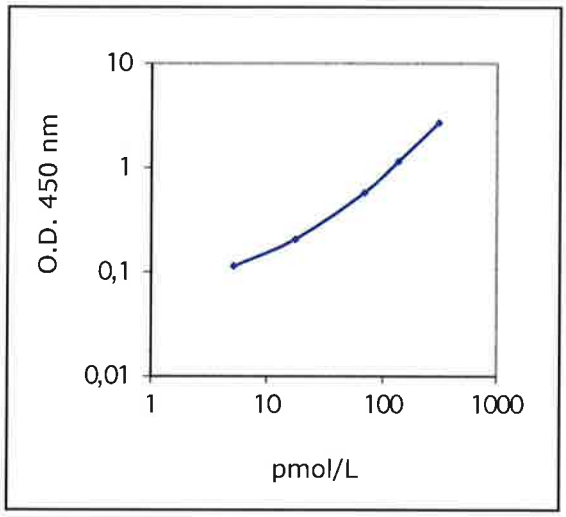
2. **Description**

Catalog no: 10-1141-01

Product: Mercodia Ultrasensitive C-peptide ELISA

Lot no: 36957

Expiry date: 2027-08-31



Component		*Art no*	*Lot no*	*O.D. 450 nm*	*Exp. date*
Calibrator 0		20-6636	36850	0,080	2027-09-02
Calibrator 5,20	pmol/L	20-3514	36851	0,114	2027-09-11
Calibrator 17,5	pmol/L	20-3515	36852	0,206	2027-09-11
Calibrator 68,3	pmol/L	20-3516	36853	0,576	2027-09-11
Calibrator 136	pmol/L	20-3517	36854	1,153	2027-09-11
Calibrator 307	pmol/L	20-3518	36855	2,702	2027-09-11
Coated Plate		20-3422	36857		2028-09-15
Assay Buffer		20-6640	36856		2027-09-04
Enzyme Conjugate 21X		20-7100	36859		2027-10-29
Enzyme Conjugate Buffer		20-7098	36849		2027-09-03
Wash Buffer 21X		20-6746	36422		2031-12-30
Substrate TMB		20-2629	36313		2029-02-28
Stop Solution		20-2693	36746		2032-07-01

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3. Quality control

Quality control has been performed for lot no 36957 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:
2025-11-25	Elin Westberg	EW

Date of approval:	Approved by:	Signature:
2025-11-25	Mattias St	MS

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