Mercodia

Mall-0213 v 2.0

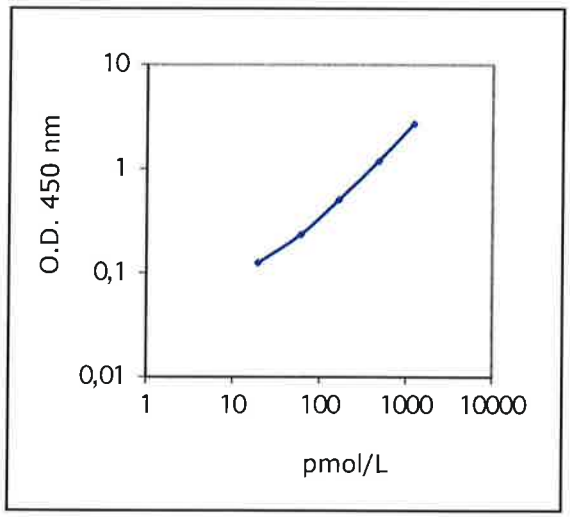
Certificate of Analysis

1. **Manufacturer**

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

2. **Description**

Catalog no:	10-1256-01
Product:	Mercodia Porcine C-peptide ELISA
Lot no:	36649
Expiry date:	2026-03-31



Component		*Art no*	*Lot no*	*O.D. 450 nm*	*Exp. date*
Calibrator 0		20-6977	35229	0,067	2026-04-06
Calibrator 19,4	pmol/L	20-6983	35230	0,125	2026-04-04
Calibrator 60,1	pmol/L	20-6984	35231	0,234	2026-04-04
Calibrator 164	pmol/L	20-6985	35232	0,506	2026-04-04
Calibrator 470	pmol/L	20-6986	35233	1,184	2026-04-04
Calibrator 1210	pmol/L	20-6987	35234	2,721	2026-04-04
Coated Plate		20-7001	35225		2026-04-11
Assay Buffer		20-6999	35227		2026-04-06
Enzyme Conjugate 11X		20-6995	35235		2026-04-12
Enzyme Conjugate Buffer		20-6997	35228		2026-04-06
Wash Buffer 21X		20-6746	35603		2030-10-09
Substrate TMB		20-2629	33423		2026-06-30
Stop Solution		20-2693	33839		2029-06-27

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E-mail info@mercodia.com | **Website** www.mercodia.com

3. Quality control

Quality control has been performed for lot no 36649 according to standard operating procedures at Mercodia AB, and the product is released based on fulfillment of established acceptance criteria.

4. Calibration

The Mercodia Porcine C-peptide ELISA is calibrated against an in-house reference preparation of porcine c-peptide.

5. Assay method

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

6. Intended use

Mercodia Porcine C-peptide ELISA provides a method for the quantitative determination of porcine c-peptide in serum, plasma and cell culture medium.

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:
2023-06-27	Elin Wetterberg	EW

Date of approval:	Approved by:	Signature:
2025-04-23	Matthias Ost	MO

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