Mercodia
Developing diagnostics

Mall-0213 v 1.0

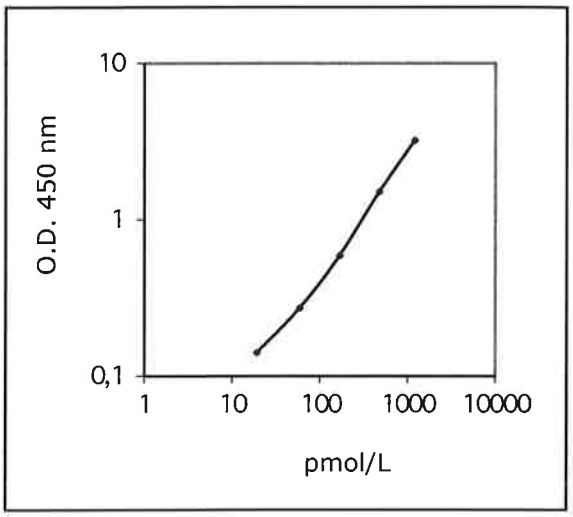
Certificate of Analysis

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: 31419
Expiry date: 2023-08-31



Component		*Art no*	*Lot no*	*O.D. 450 nm*	*Exp. date*
Calibrator 0		20-6977	31403	0,077	2023-09-14
Calibrator 19,1	pmol/L	20-6983	31409	0,141	2023-09-16
Calibrator 58,5	pmol/L	20-6984	31410	0,272	2023-09-16
Calibrator 167	pmol/L	20-6985	31411	0,590	2023-09-16
Calibrator 475	pmol/L	20-6986	31412	1,512	2023-09-16
Calibrator 1210	pmol/L	20-6987	31413	3,221	2023-09-16
Coated Plate		20-7001	31399		2023-09-14
Assay Buffer		20-6999	31401		2023-09-25
Enzyme Conjugate 11X		20-6995	31418		2023-10-09
Enzyme Conjugate Buffer		20-6997	31415		2023-09-15
Wash Buffer 21X		20-6746	31262		2027-08-10
Substrate TMB		20-2629	30305		2023-09-30
Stop Solution		20-2693	29481		2026-02-15

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

3. Quality control

Quality control has been performed for lot no 31419 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:
2020-11-11		

Date of approval:	Approved by:	Signature:
2020-12-02	Ingmarie Thorell	

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