Mercodia

Mall-0213 v 2.0

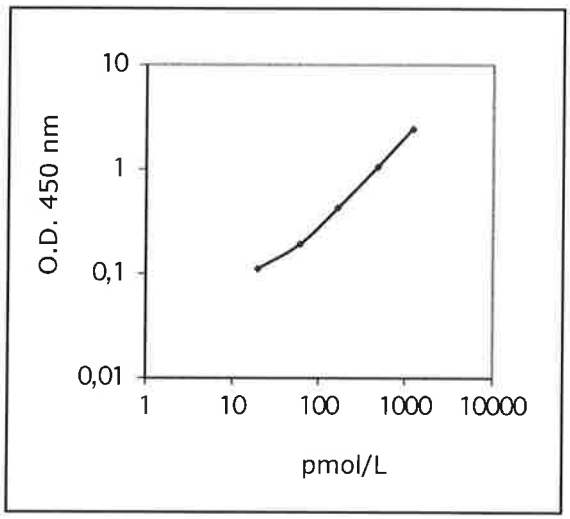
Certificate of Analysis

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:	36731
Expiry date:	2028-03-31



Component		*Art no*	*Lot no*	*O.D. 450 nm*	*Exp. date*
Calibrator 0		20-6977	36690	0,063	2028-04-06
Calibrator 19,4	pmol/L	20-6983	36694	0,111	2028-04-04
Calibrator 60,1	pmol/L	20-6984	36695	0,191	2028-04-04
Calibrator 164	pmol/L	20-6985	36696	0,426	2028-04-04
Calibrator 470	pmol/L	20-6986	36697	1,047	2028-04-04
Calibrator 1210	pmol/L	20-6987	36698	2,428	2028-04-04
Coated Plate		20-7001	35225		2028-04-11
Assay Buffer		20-6999	36693		2028-04-06
Enzyme Conjugate 11X		20-6995	36691		2028-04-12
Enzyme Conjugate Buffer		20-6997	36692		2028-04-06
Wash Buffer 21X		20-6746	36608		2032-04-07
Substrate TMB		20-2629	36313		2029-02-28
Stop Solution		20-2693	36554		2032-03-07

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3. Quality control

Quality control has been performed for lot no 36731 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:
2025-06-17	Mattias	

Date of approval:	Approved by:	Signature:
2025-06-17	Jonas Kvick	

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