

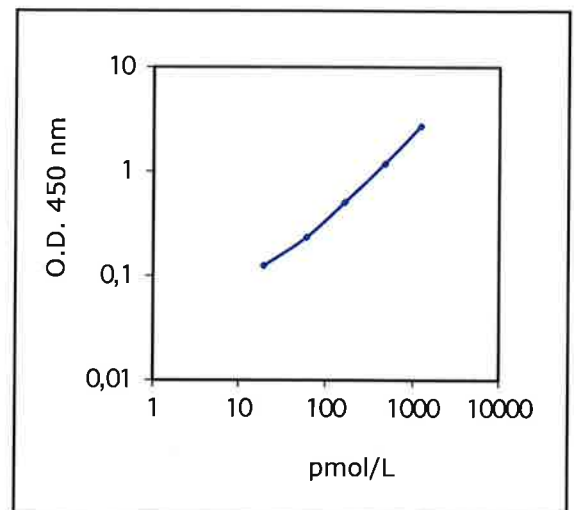
Certificate of Analysis

1. Manufacturer

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

2. Description

Catalog no: 10-1256-01
 Product: Merckodia Porcine C-peptide
 ELISA
 Lot no: 35651
 Expiry date: 2026-03-31



<i>Component</i>	<i>Art no</i>	<i>Lot no</i>	<i>O.D. 450 nm</i>	<i>Exp. date</i>
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	35568		2030-09-05
Substrate TMB	20-2629	33423		2026-06-30
Stop Solution	20-2693	35523		2030-08-10

3. Quality control

Quality control has been performed for lot no 35651 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:

2023-06-27

Performed by:

Elin Wenberg

Signature:

EW

Date of approval:

2023-10-11

Approved by:

Anders J. L.

Signature:

AL