

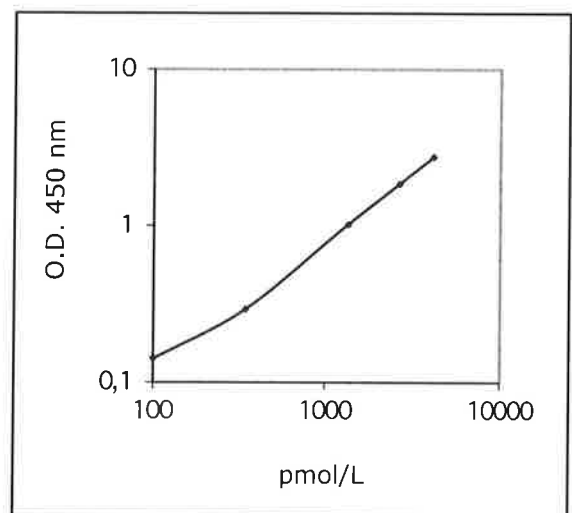
Certificate of Analysis

1. Manufacturer

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

2. Description

Catalog no: 10-1136-01
 Product: MercoDia C-peptide ELISA
 Lot no: 36271
 Expiry date: 2027-01-31



<i>Component</i>	<i>Art no</i>	<i>Lot no</i>	<i>O.D. 450 nm</i>	<i>Exp. date</i>
Calibrator 0	20-3415	35883	0,068	2027-02-22
Calibrator 100 pmol/L	20-3416	35914	0,142	2027-03-14
Calibrator 342 pmol/L	20-3417	35915	0,293	2027-03-14
Calibrator 1350 pmol/L	20-3418	35916	1,021	2027-03-14
Calibrator 2650 pmol/L	20-3419	35917	1,854	2027-03-14
Calibrator 4130 pmol/L	20-3420	35918	2,755	2027-03-14
Coated Plate	20-3422	35885		2027-04-08
Assay Buffer	20-2933	35884		2027-02-21
Enzyme Conjugate 11X	20-3425	35921		2027-04-04
Enzyme Conjugate Buffer	20-3427	35860		2027-02-20
Wash Buffer 21X	20-6746	33454		2029-03-14
Substrate TMB	20-2629	35551		2027-07-31
Stop Solution	20-2693	35136		2030-01-23

3. Quality control

Quality control has been performed for lot no 36271 according to standard operating procedures at Mercodia AB, and the product is released based on fulfillment of established acceptance criteria.

4. Calibration

The Mercodia 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 C-peptide ELISA provides a method for the quantitative determination of human c-peptide in serum, plasma or urine.

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:
<u>2024-06-26</u>	<u>Sonia Redondo</u>	<u>SR</u>

Date of approval:	Approved by:	Signature:
<u>2024-10-14</u>	<u>M. H. S. J.</u>	<u>MHS</u>