

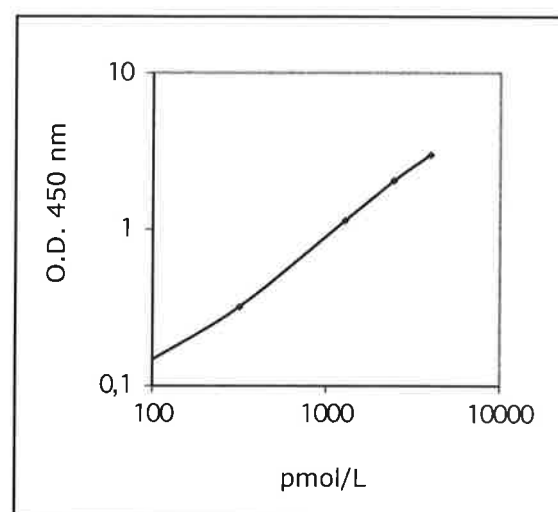
Certificate of Analysis

1. Manufacturer

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

2. Description

Catalog no: 10-1136-01
Product: Mercodia C-peptide ELISA
Lot no: 36946
Expiry date: 2028-07-31



Component	Art no	Lot no	O.D. 450 nm	Exp. date
Calibrator 0	20-3415	36814	0,062	2028-09-04
Calibrator 97,8 pmol/L	20-3416	36815	0,145	2028-08-26
Calibrator 315 pmol/L	20-3417	36816	0,319	2028-08-26
Calibrator 1280 pmol/L	20-3418	36817	1,137	2028-08-26
Calibrator 2450 pmol/L	20-3419	36818	2,044	2028-08-26
Calibrator 3980 pmol/L	20-3420	36819	2,983	2028-08-26
Coated Plate	20-3422	36810		2028-09-08
Assay Buffer	20-2933	36813		2028-08-28
Enzyme Conjugate 11X	20-3425	36820		2028-09-18
Enzyme Conjugate Buffer	20-3427	36812		2028-08-27
Wash Buffer 21X	20-6746	36804		2032-08-21
Substrate TMB	20-2629	36313		2029-02-28
Stop Solution	20-2693	36746		2032-07-01

3. Quality control

Quality control has been performed for lot no 36946 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:

2025-11-03

Performed by:

Mathias St

Signature:

M

Date of approval:

2025-11-03

Approved by:

Cecilia Westberg

Signature:

CW