

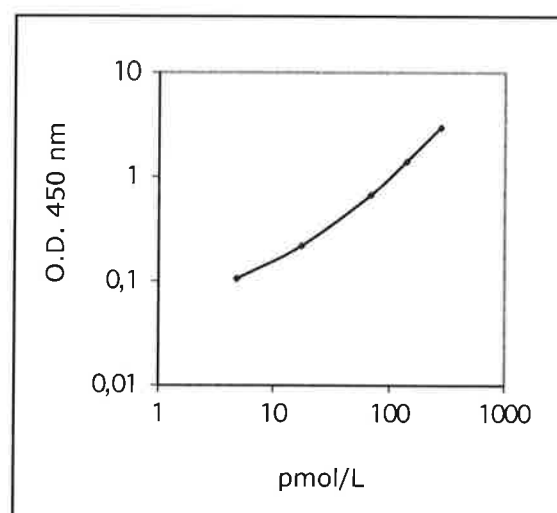
Certificate of Analysis

1. Manufacturer

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

2. Description

Catalog no: 10-1141-01
 Product: Mercodia Ultrasensitive
 C-peptide ELISA
 Lot no: 35793
 Expiry date: 2025-08-31



Component	Art no	Lot no	O.D. 450 nm	Exp. date
Calibrator 0	20-6636	35555	0,063	2025-09-18
Calibrator 4,80 pmol/L	20-3514	35558	0,105	2025-08-31
Calibrator 17,3 pmol/L	20-3515	35559	0,217	2025-08-31
Calibrator 67,7 pmol/L	20-3516	35560	0,665	2025-08-31
Calibrator 138 pmol/L	20-3517	35561	1,394	2025-08-31
Calibrator 273 pmol/L	20-3518	35562	2,958	2025-08-31
Coated Plate	20-3422	35649		2026-11-13
Assay Buffer	20-6640	35563		2025-09-08
Enzyme Conjugate 21X	20-7100	35566		2025-11-28
Enzyme Conjugate Buffer	20-7098	35565		2025-09-05
Wash Buffer 21X	20-6746	35603		2030-10-09
Substrate TMB	20-2629	35551		2027-07-31
Stop Solution	20-2693	35772		2030-11-16

3. Quality control

Quality control has been performed for lot no 35793 according to standard operating procedures at Mercodia AB, and the product is released based on fulfillment of established acceptance criteria.

4. Calibration

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

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:

2023-12-19

Performed by:

Yonas Krick

Signature:

[Signature]

Date of approval:

2023-12-20

Approved by:

Elin Wenberg

Signature:

[Signature]