

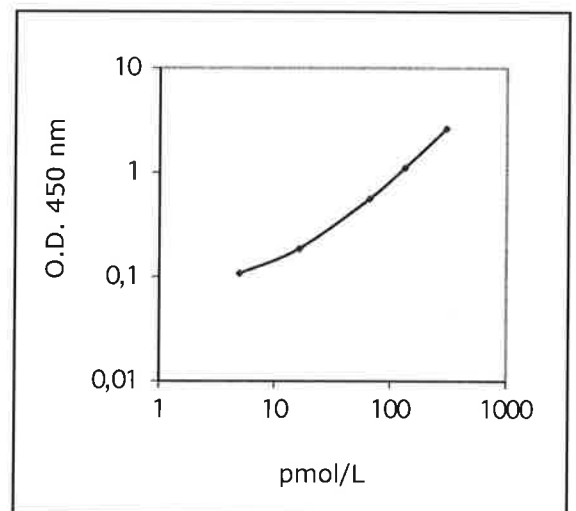
## *Certificate of Analysis*

### 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: 36225  
 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	20-6636	35987	0,069	2026-04-24
Calibrator 4,92 pmol/L	20-3514	35982	0,107	2026-04-09
Calibrator 16,3 pmol/L	20-3515	35983	0,185	2026-04-09
Calibrator 65,8 pmol/L	20-3516	35984	0,560	2026-04-09
Calibrator 132 pmol/L	20-3517	35985	1,102	2026-04-09
Calibrator 299 pmol/L	20-3518	35986	2,615	2026-04-09
Coated Plate	20-3422	36138		2027-07-15
Assay Buffer	20-6640	35988		2026-04-19
Enzyme Conjugate 21X	20-7100	35990		2026-05-29
Enzyme Conjugate Buffer	20-7098	35989		2026-04-19
Wash Buffer 21X	20-6746	35568		2030-09-05
Substrate TMB	20-2629	33423		2026-06-30
Stop Solution	20-2693	34128		2029-09-19

### 3. Quality control

Quality control has been performed for lot no 36225 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:

2024-09-20

Performed by:

Martin H

Signature:

Martin H

Date of approval:

2024-09-20

Approved by:

Elin Westberg

Signature:

Elin Westberg