Mercodia

Mall-0137 v 4.0

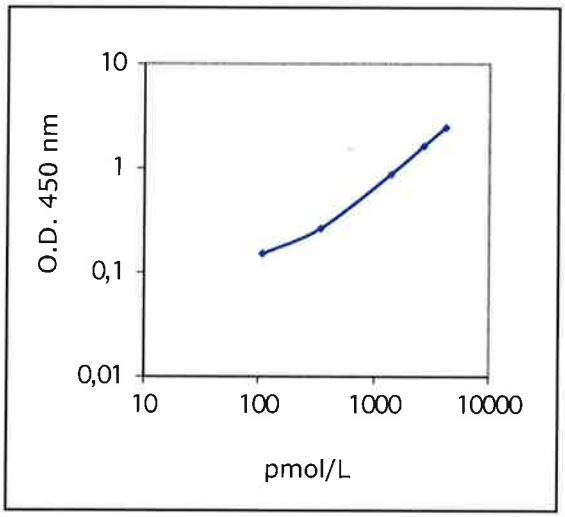
Certificate of Analysis

1. **Manufacturer**

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

2. **Description**

Catalog no: 10-1172-01
Product: Mercodia Rat C-peptide ELISA
Lot no: 35316
Expiry date: 2024-01-31



Component		*Art no*	*Lot no*	*O.D. 450 nm*	*Exp. date*
Calibrator 0		20-6373	33245	0,106	2025-01-17
Calibrator 107	pmol/L	20-6374	33232	0,151	2025-01-28
Calibrator 337	pmol/L	20-6375	33233	0,264	2025-01-28
Calibrator 1370	pmol/L	20-6376	33234	0,874	2025-01-28
Calibrator 2640	pmol/L	20-6377	33235	1,629	2025-01-28
Calibrator 4120	pmol/L	20-6378	33236	2,458	2025-01-28
Coated Plate		20-6407	33238		2025-01-17
Assay Buffer		20-6400	33241		2025-01-18
Enzyme Conjugate 11X		20-6403	33247		2024-02-03
Enzyme Conjugate Buffer		20-6405	33243		2025-01-18
Wash Buffer 21X		20-6746	35178		2030-02-03
Substrate TMB		20-2629	31053		2024-07-31
Stop Solution		20-2693	32965		2028-10-29

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3. Quality control

Quality control has been performed for lot no 35316 according to standard operating procedures at Mercodia AB, and the product is released based on fulfillment of established acceptance criteria.

4. Calibration

The Mercodia Rat C-peptide ELISA is calibrated against an in-house reference preparation of rat c-peptide.

5. Assay method

Test procedure used is according to current Direction for Use for the product and lot.

6. Intended use

Mercodia Rat C-peptide ELISA provides a method for the quantitative determination of rat c-peptide in serum, plasma or cell cultures.

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:
2023-03-30	Elin Wernberg	EW
Date of approval:	**Approved by:**	**Signature:**
2023-03-30	Jonas Ku	

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