Mercodia

Mall-0130 v 5.0

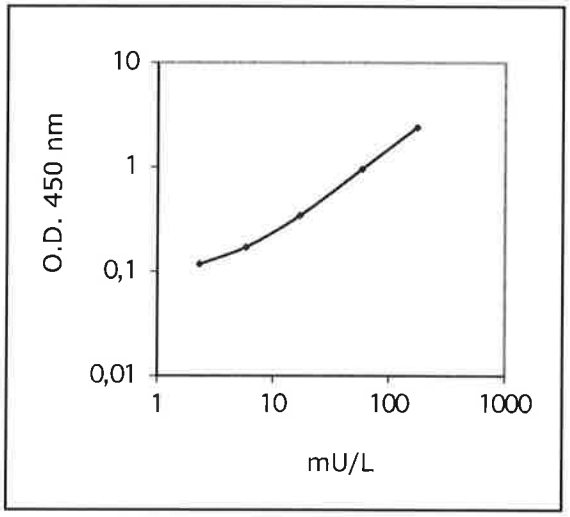
Certificate of Analysis

1. **Manufacturer**

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

2. **Description**

Catalog no: 10-1203-01
Product: Mercodia Canine Insulin ELISA
Lot no: 36745
Expiry date: 2026-07-31



Component	*Art no*	*Lot no*	*O.D. 450 nm*	*Exp. date*
Calibrator 0	20-5325	35468	0,081	2026-08-23
Calibrator 2,3 mU/L	20-5315	35477	0,117	2026-08-23
Calibrator 5,8 mU/L	20-5316	35478	0,170	2026-08-23
Calibrator 17 mU/L	20-5317	35479	0,342	2026-08-23
Calibrator 58 mU/L	20-5318	35480	0,950	2026-08-23
Calibrator 173 mU/L	20-5319	35481	2,391	2026-08-23
Coated Plate	20-5272	35471		2026-08-21
Enzyme Conjugate 11X	20-5313	35488		2026-09-07
Enzyme Conjugate Buffer	20-5305	35469		2026-08-23
Wash Buffer 21X	20-6746	36608		2032-04-07
Substrate TMB	20-2629	36313		2029-02-28
Stop Solution	20-2693	36554		2032-03-07

Address Mercodia AB, Sylveniusgatan 8A, SE-754 50 Uppsala, Sweden
Phone +46 18 57 00 70 | **Fax** +46 18 57 00 80 | **Vat No** SE-556157510001
E-mail info@mercodia.com | **Website** www.mercodia.com

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3. Quality control

Quality control has been performed for lot no 36745 according to standard operating procedures at Mercodia AB, and the product is released based on fulfillment of established acceptance criteria.

4. Calibration

The Mercodia Canine Insulin ELISA is calibrated against an in-house reference preparation of porcine insulin.

5. Assay method

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

6. Intended use

Mercodia Canine Insulin ELISA provides a method for the quantitative determination of canine insulin 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:	Performed by:	Signature:
2025-07-02	Jonas Kvick	

Date of approval:	Approved by:	Signature:
2025-07-03	Elin Wertberg	EW

Address Mercodia AB, Sylveniusgatan 8A, SE-754 50 Uppsala, Sweden
Phone +46 18 57 00 70 | **Fax** +46 18 57 00 80 | **Vat No** SE-556157510001
E-mail info@mercodia.com | **Website** www.mercodia.com