

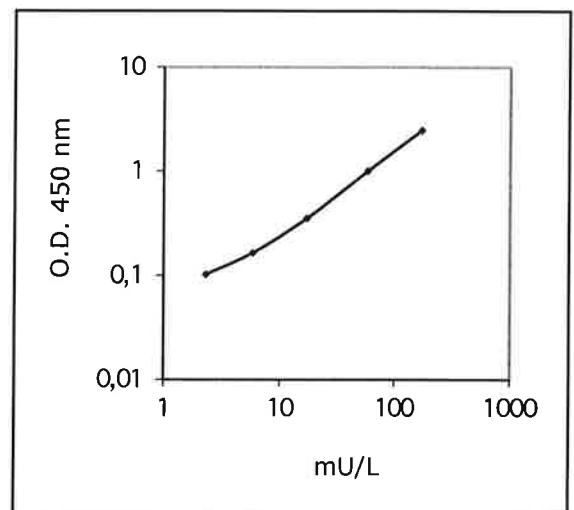
Certificate of Analysis

1. Manufacturer

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

2. Description

Catalog no: 10-1203-01
 Product: Mercodia Canine Insulin ELISA
 Lot no: 35701
 Expiry date: 2026-07-31



<i>Component</i>	<i>Art no</i>	<i>Lot no</i>	<i>O.D. 450 nm</i>	<i>Exp. date</i>
Calibrator 0	20-5325	35468	0,063	2026-08-23
Calibrator 2,3 mU/L	20-5315	35477	0,102	2026-08-23
Calibrator 5,8 mU/L	20-5316	35478	0,164	2026-08-23
Calibrator 17 mU/L	20-5317	35479	0,351	2026-08-23
Calibrator 58 mU/L	20-5318	35480	0,996	2026-08-23
Calibrator 173 mU/L	20-5319	35481	2,450	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	35603		2030-10-09
Substrate TMB	20-2629	34163		2026-11-30
Stop Solution	20-2693	35523		2030-08-10

3. Quality control

Quality control has been performed for lot no 35701 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:

2023-11-01

Performed by:

Elin Westberg EW

Signature:

Date of approval:

2023-11-15

Approved by:

Jonas Krick

Signature: