

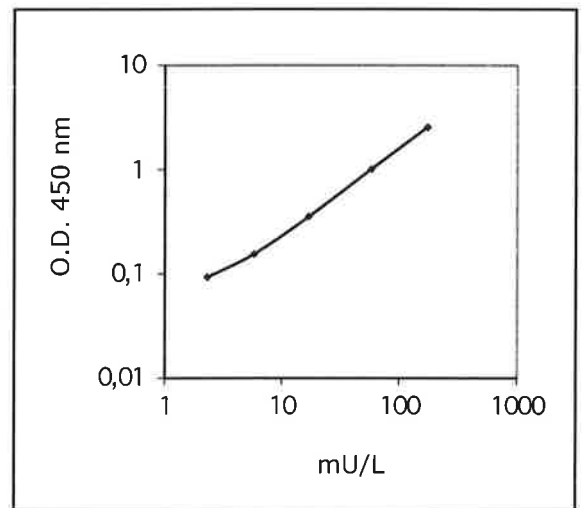
Certificate of Analysis

1. Manufacturer

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

2. Description

Catalog no: 10-1203-01
Product: Mercodia Canine Insulin ELISA
Lot no: 33757
Expiry date: 2024-02-29



<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	32094	0,054	2024-03-11
Calibrator 2,3 mU/L	20-5315	32080	0,093	2024-03-09
Calibrator 5,8 mU/L	20-5316	32081	0,155	2024-03-09
Calibrator 17 mU/L	20-5317	32082	0,354	2024-03-09
Calibrator 58 mU/L	20-5318	32083	1,008	2024-03-09
Calibrator 173 mU/L	20-5319	32084	2,547	2024-03-09
Coated Plate	20-5272	32091		2024-03-15
Enzyme Conjugate 11X	20-5313	32099		2024-03-11
Enzyme Conjugate Buffer	20-5305	32096		2024-03-10
Wash Buffer 21X	20-6746	33454		2029-03-14
Substrate TMB	20-2629	31053		2024-07-31
Stop Solution	20-2693	33452		2027-03-07

3. Quality control

Quality control has been performed for lot no 33757 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:

2021-04-27

Performed by:

Jonas Kjell

Signature:

Date of approval:

2022-05-31

Approved by:

Elin Westberg ew

Signature: