

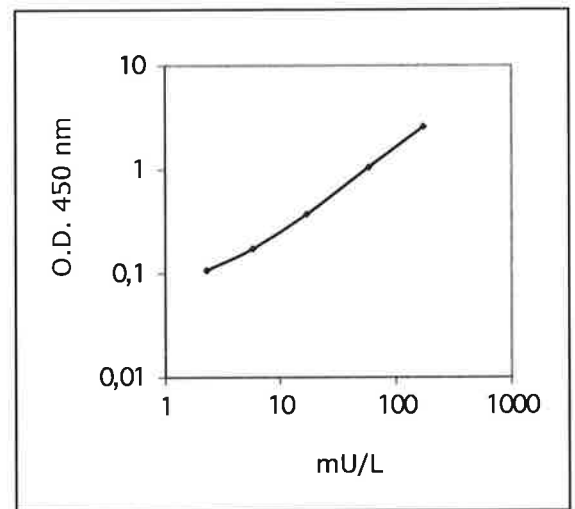
Certificate of Analysis

1. Manufacturer

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

2. Description

Catalog no: 10-1200-01
 Product: MercoDia Porcine Insulin ELISA
 Lot no: 37219
 Expiry date: 2029-01-31



<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	37109	0,065	2029-03-05
Calibrator 2,3 mU/L	20-5279	37110	0,107	2029-02-24
Calibrator 5,8 mU/L	20-5280	37111	0,173	2029-02-24
Calibrator 17 mU/L	20-5281	37112	0,372	2029-02-24
Calibrator 58 mU/L	20-5282	37113	1,050	2029-02-24
Calibrator 173 mU/L	20-5283	37114	2,573	2029-02-24
Coated Plate	20-5272	37103		2029-03-02
Enzyme Conjugate 11X	20-5308	37105		2029-03-03
Enzyme Conjugate Buffer	20-5305	37108		2029-02-20
Wash Buffer 21X	20-6746	36958		2032-12-03
Substrate TMB	20-2629	36313		2029-02-28
Stop Solution	20-2693	37095		2033-02-16

3. Quality control

Quality control has been performed for lot no 37219 according to standard operating procedures at Mercodia AB, and the product is released based on fulfillment of established acceptance criteria.

4. Calibration

The Mercodia Porcine 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 Porcine Insulin ELISA provides a method for the quantitative determination of porcine 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

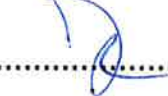
Date of analysis:

2026-04-13

Performed by:

Jonas Krick

Signature:



Date of approval:

2026-04-14

Approved by:

Elin Westberg

Signature:

