

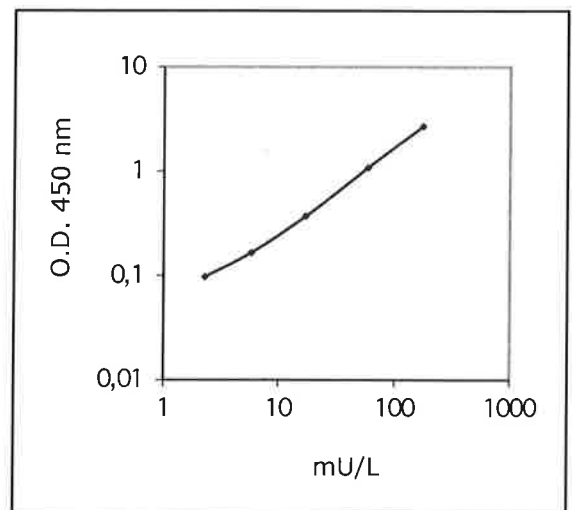
Certificate of Analysis

1. Manufacturer

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

2. Description

Catalog no: 10-1200-01
 Product: Mercodia Porcine Insulin ELISA
 Lot no: 36513
 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	0,053	2026-08-23
Calibrator 2,3 mU/L	20-5279	35472	0,097	2026-08-23
Calibrator 5,8 mU/L	20-5280	35473	0,165	2026-08-23
Calibrator 17 mU/L	20-5281	35474	0,369	2026-08-23
Calibrator 58 mU/L	20-5282	35475	1,079	2026-08-23
Calibrator 173 mU/L	20-5283	35476	2,684	2026-08-23
Coated Plate	20-5272	35471		2026-08-21
Enzyme Conjugate 11X	20-5308	35487		2026-09-07
Enzyme Conjugate Buffer	20-5305	35469		2026-08-23
Wash Buffer 21X	20-6746	36422		2031-12-30
Substrate TMB	20-2629	34163		2026-11-30
Stop Solution	20-2693	34128		2029-09-19

3. Quality control

Quality control has been performed for lot no 36513 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:	Performed by:	Signature:
<u>2023-11-01</u>	<u>Jonas Kvick</u>	<u></u>

Date of approval:	Approved by:	Signature:
<u>2025-02-24</u>	<u>Elin Wernberg</u>	<u></u>