

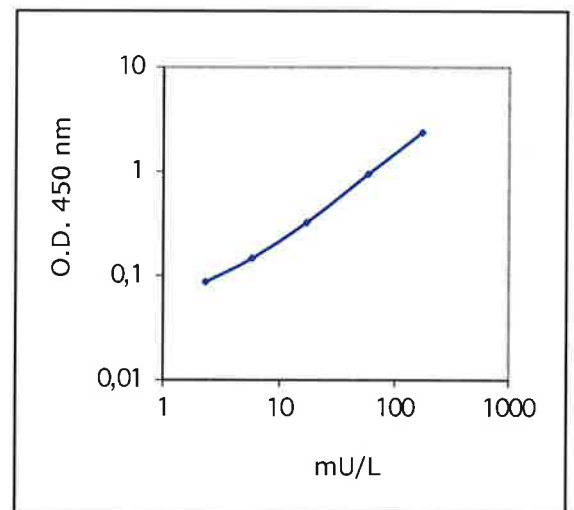
Certificate of Analysis

1. Manufacturer

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

2. Description

Catalog no: 10-1205-01
 Product: MercoDia Equine Insulin ELISA
 Lot no: 35179
 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	0,051	2024-03-11
Calibrator 2,3 mU/L	20-5320	35137	0,087	2024-03-09
Calibrator 5,8 mU/L	20-5321	35138	0,147	2024-03-09
Calibrator 17 mU/L	20-5322	35139	0,324	2024-03-09
Calibrator 58 mU/L	20-5323	35140	0,940	2024-03-09
Calibrator 173 mU/L	20-5324	35141	2,367	2024-03-09
Coated Plate	20-5272	32091		2024-03-15
Enzyme Conjugate 11X	20-5314	35177		2024-03-11
Enzyme Conjugate Buffer	20-5305	32096		2024-03-10
Wash Buffer 21X	20-6746	28599		2025-06-25
Substrate TMB	20-2629	34163		2026-11-30
Stop Solution	20-2693	32068		2028-02-25

3. Quality control

Quality control has been performed for lot no 35179 according to standard operating procedures at MercoDIA AB, and the product is released based on fulfillment of established acceptance criteria.

4. Calibration

The MercoDIA Equine 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 Equine Insulin ELISA provides a method for the quantitative determination of equine 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:

2023-02-03

Performed by:

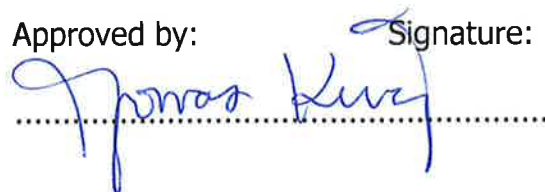


Signature:

Date of approval:

2023-02-03

Approved by:



Signature: