

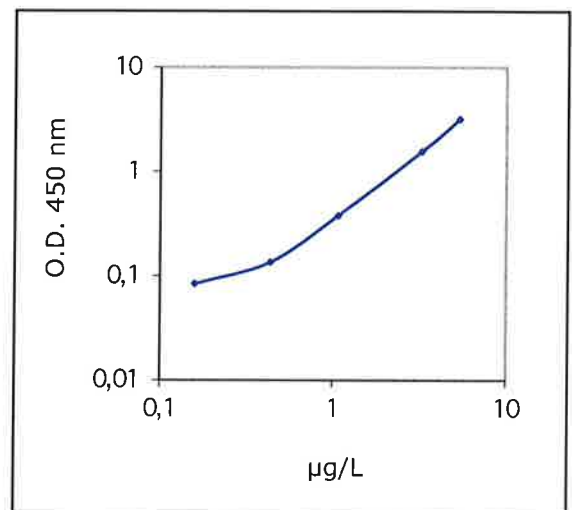
Certificate of Analysis

1. Manufacturer

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

2. Description

Catalog no: 10-1250-01
 Product: MercoDia Rat Insulin ELISA
 Lot no: 36540
 Expiry date: 2027-07-31



<i>Component</i>		<i>Art no</i>	<i>Lot no</i>	<i>O.D. 450 nm</i>	<i>Exp. date</i>
Calibrator 0		20-3082	36153	0,070	2027-08-23
Calibrator 0,159	µg/L	20-3116	36148	0,084	2027-08-28
Calibrator 0,437	µg/L	20-3117	36149	0,135	2027-08-28
Calibrator 1,07	µg/L	20-3118	36150	0,379	2027-08-28
Calibrator 3,24	µg/L	20-3119	36151	1,560	2027-08-28
Calibrator 5,31	µg/L	20-3120	36152	3,189	2027-08-28
Coated Plate		20-3193	36145		2029-08-26
Enzyme Conjugate 11X		20-3084	36156		2027-10-01
Enzyme Conjugate Buffer		20-3087	36154		2027-08-28
Wash Buffer 21X		20-6746	36422		2031-12-30
Substrate TMB		20-2629	35551		2027-07-31
Stop Solution		20-2693	34128		2029-09-19

3. Quality control

Quality control has been performed for lot no 36540 according to standard operating procedures at MercoDia AB, and the product is released based on fulfillment of established acceptance criteria.

4. Calibration

The MercoDia Rat Insulin ELISA is calibrated against an in-house reference preparation of rat insulin.

5. Assay method

Test procedure used is according to current Direction for Use for the product and lot.

6. Intended use

MercoDia Rat Insulin ELISA provides a method for the quantitative determination of rat 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>2024-11-14</u>	<u>Elin Westberg</u>	<u>EW</u>

Date of approval:	Approved by:	Signature:
<u>2025-02-24</u>	<u>[Signature]</u>	<u>[Signature]</u>