

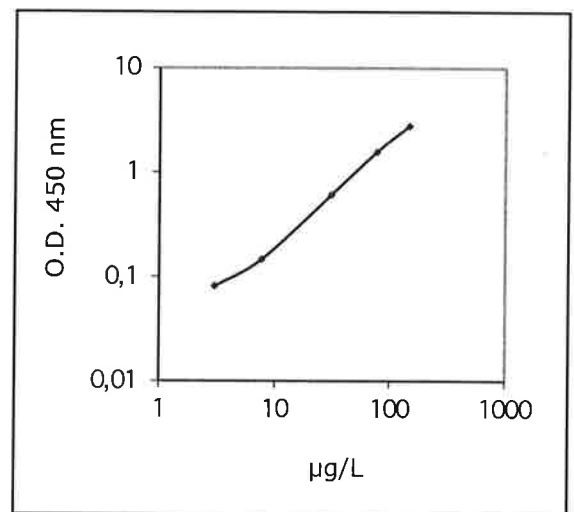
Certificate of Analysis

1. Manufacturer

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

2. Description

Catalog no: 10-1145-01
 Product: Merck High Range Rat
 Insulin ELISA
 Lot no: 35328
 Expiry date: 2025-07-31



| <i>Component</i> | <i>Art no</i> | <i>Lot no</i> | <i>O.D. 450 nm</i> | <i>Exp. date</i> |
|-------------------------|---------------|---------------|--------------------|------------------|
| Calibrator 0 | 20-3621 | 33380 | 0,059 | 2027-02-24 |
| Calibrator 2,99 µg/L | 20-3611 | 33386 | 0,081 | 2027-03-10 |
| Calibrator 7,64 µg/L | 20-3612 | 33387 | 0,146 | 2027-03-10 |
| Calibrator 30,9 µg/L | 20-3613 | 33388 | 0,608 | 2027-03-10 |
| Calibrator 76,5 µg/L | 20-3614 | 33389 | 1,567 | 2027-03-10 |
| Calibrator 148 µg/L | 20-3615 | 33390 | 2,780 | 2027-03-10 |
| Coated Plate | 20-3193 | 33378 | | 2027-02-21 |
| Enzyme Conjugate 11X | 20-3619 | 33396 | | 2027-02-24 |
| Enzyme Conjugate Buffer | 20-3625 | 33393 | | 2027-02-25 |
| Wash Buffer 21X | 20-6746 | 35178 | | 2030-02-03 |
| Substrate TMB | 20-2629 | 32367 | | 2025-07-31 |
| Stop Solution | 20-2693 | 35136 | | 2030-01-23 |

3. Quality control

Quality control has been performed for lot no 35328 according to standard operating procedures at Mercodia AB, and the product is released based on fulfillment of established acceptance criteria.

4. Calibration

The Mercodia High Range 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 High Range 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:

2022-05-03

Performed by:

Jonas Kuvaj

Signature:

[Signature]

Date of approval:

2023-03-29

Approved by:

Eli Westberg

Signature:

[Signature]