Mercodia

Mall-0673 v 1.0

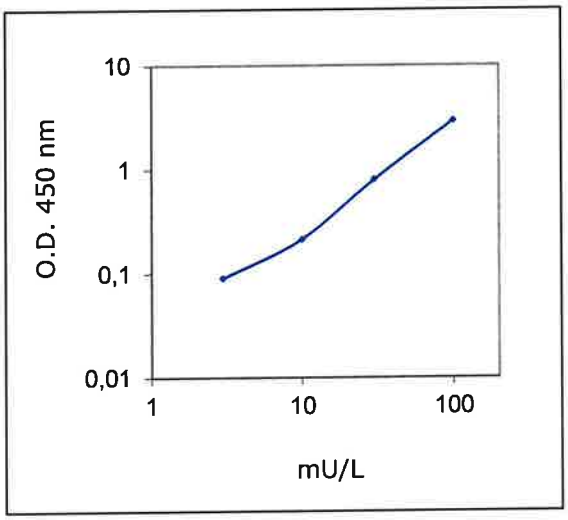
# *Certificate of Analysis*

## 1. **Manufacturer**

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

## 2. **Description**

Catalog no: 10-1128-03
Product: Mercodia Iso Insulin ELISA
Lot no: 37693
Expiry date: 2027-04-30




| *Component* | | *Art no* | *Lot no* | *O.D. 450 nm* | *Exp. date* |
|---|---|---|---|---|---|
| Calibrator 0 | | 20-2702 | 35994 | 0,069 | 2027-05-29 |
| Calibrator 3 | mU/L | 20-2703 | 35996 | 0,091 | 2027-06-19 |
| Calibrator 10 | mU/L | 20-2704 | 35997 | 0,215 | 2027-06-19 |
| Calibrator 30 | mU/L | 20-2705 | 35998 | 0,805 | 2027-06-19 |
| Calibrator 100 | mU/L | 20-2706 | 35999 | 2,960 | 2027-06-19 |
| Coated Plate | | 20-2701 | 36362 | | 2028-03-03 |
| Enzyme Conjugate 11X | | 20-2707 | 36000 | | 2027-06-18 |
| Enzyme Conjugate Buffer | | 20-2708 | 35995 | | 2027-06-13 |
| Wash Buffer 21X | | 20-6746 | 37311 | | 2033-06-18 |
| Substrate TMB | | 20-2629 | 36313 | | 2029-02-28 |
| Stop Solution | | 20-2693 | 37095 | | 2033-02-16 |

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**E-mail** info@mercodia.com | **Website** www.mercodia.com

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## 3. Quality control

Quality control has been performed for lot no 37693 according to standard operating procedures at Mercodia AB, and the product is released based on fulfillment of established acceptance criteria.

## 4. Calibration

The Mercodia Insulin ELISA is calibrated against 1st International Reference Preparation 66/304.

## 5. Assay method

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

## 6. Intended use

Mercodia Insulin ELISA provides a method for the quantitative determination of 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

Mercodia is ISO 13485 certified, demonstrating compliance with the international quality management system standard for medical devices. This product is supplied for research use only and is not intended for use as an in vitro diagnostic (IVD) medical device.

## 10. Names and signatures of certifying officers

| Date of analysis: | Performed by: | Signature: |
|---|---|---|
| 2025-04-14 | Dalan Arabaci DA | |

| Date of approval: | Approved by: | Signature: |
|---|---|---|
| 2026-10-27 | Mattias Tatarn | |

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