Mercodia

Mall-0590 v3.0

Certificate of Analysis

1. **Manufacturer**

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

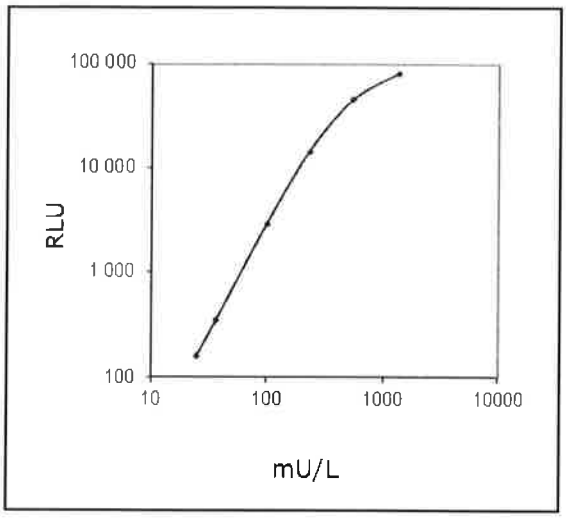
2. **Description**

Catalog no: 10-1353-01

Product: Total Insulin Northern Lights MBeads Assay

Lot no: 36406

Expiry date: 2027-04-30



Component	*Art no*	*Lot no*	*RLU*	*Exp. date*
Calibrator 0	20-7619	36383	49	2027-05-02
Calibrator 1, 24,9 mU/L	20-7620	36387	158	2027-05-17
Calibrator 2, 36,4 mU/L	20-7621	36388	349	2027-05-17
Calibrator 3, 100 mU/L	20-7622	36389	2918	2027-05-17
Calibrator 4, 228 mU/L	20-7623	36390	14347	2027-05-17
Calibrator 5, 545 mU/L	20-7624	36391	45393	2027-05-17
Calibrator 6, 1302 mU/L	20-7625	36392	80058	2027-05-17
MBeads Antibody	20-7635	36384	-	2027-05-09
Assay Buffer	20-7630	36385	-	2027-05-03
Enzyme Conjugate 44X	20-7633	36386	-	2027-05-24
Wash Buffer 21X	20-6746	33635	-	2029-05-20
Substrate Reagent A	20-7300	36394	-	2027-05-11
Substrate Reagent B	20-7301	36395	-	2027-05-11

Quality Control	*Art no*	*Lot no*	*Exp. date*	*Assigned range (mU/L)*	*Results (mU/L)*
Control	20-7628	36393	2027-05-17	124 – 230	179

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

3. Quality control

Quality control has been performed for lot no 36406 according to standard operating procedures at Mercodia AB, and the product is released based on fulfillment of established acceptance criteria.

4. Calibration

Total Insulin Northern Lights MBeads Assay 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

Total Insulin Northern Lights MBeads Assay provides a method for the quantitative determination of insulin in perifusion samples.

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 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:
2025-01-24	Eira Lindqvist	

Date of approval:	Approved by:	Signature:
2025-01-30	Elin Westberg	

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