Mercodia

Mall-0590 v2.0

Certificate of Analysis

1. **Manufacturer**

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

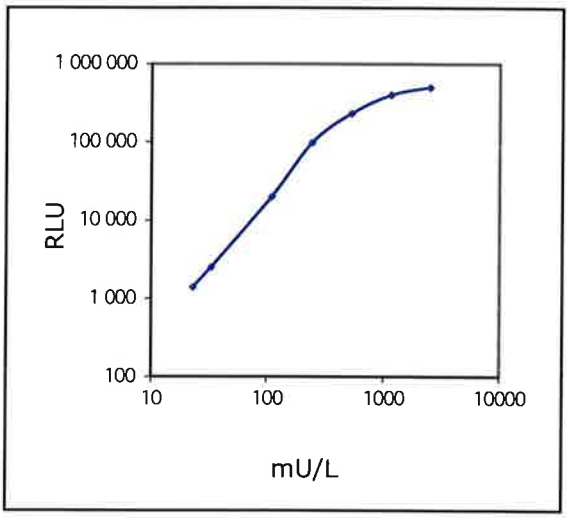
2. **Description**

Catalog no: 10-1353-01

Product: Total Insulin Northern Lights MBeads Assay

Lot no: 33797

Expiry date: 2025-04-30



Component	*Art no*	*Lot no*	*RLU*	*Exp. date*
Calibrator 0	20-7619	33591	254	2025-05-02
Calibrator 1, 24,5 mU/L	20-7620	33611	2332	2025-05-17
Calibrator 2, 36,3 mU/L	20-7621	33612	3689	2025-05-17
Calibrator 3, 98,4 mU/L	20-7622	33613	34047	2025-05-17
Calibrator 4, 226 mU/L	20-7623	33614	125064	2025-05-17
Calibrator 5, 525 mU/L	20-7624	33615	394701	2025-05-17
Calibrator 6, 1226 mU/L	20-7625	33616	639181	2025-05-17
Calibrator 7, 2208 mU/L	20-7626	33617	856127	2025-05-17
MBeads Antibody	20-7635	33620	-	2025-05-09
Assay Buffer	20-7630	33593	-	2025-05-03
Enzyme Conjugate 44X	20-7633	33623	-	2025-05-24
Wash Buffer 21X	20-6746	33635	-	2029-05-20
Substrate Reagent A	20-7300	33583	-	2025-05-11
Substrate Reagent B	20-7301	33584	-	2025-05-11

Quality Control	*Art no*	*Lot no*	*Exp. date*	*Assigned range (mU/L)*	*Results (mU/L)*
Control	20-7628	33618	2025-05-17	148 – 200	164

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3. **Quality control**

Quality control has been performed for lot no 33797 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:
2022-06-17	Emma Helmersson	Emma Helm

Date of approval:	Approved by:	Signature:
2022-11-08	Silan Tas	

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