

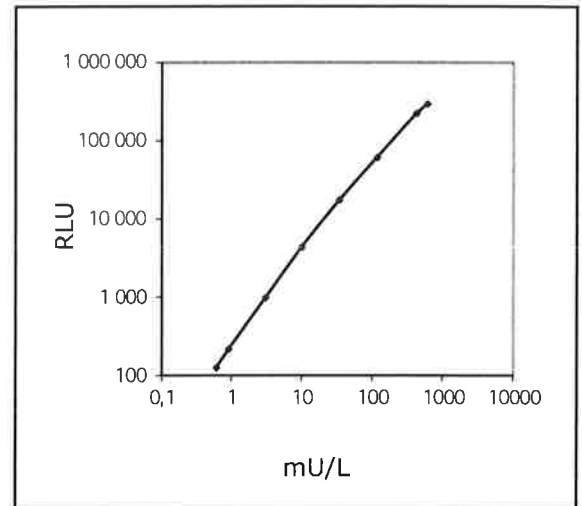
Certificate of Analysis

1. Manufacturer

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

2. Description

Catalog no: 10-1291-01
Product: Mercodia Lispro NL-ELISA
Lot no: 32438
Expiry date: 2023-12-31



Component	Art no	Lot no	RLU	Exp. date
Calibrator 0	20-7473	31869	8	2024-01-25
Anchor Point Low, 0,602 mU/L	20-7474	31870	127	2024-01-25
Calibrator 1, 0,904 mU/L	20-7475	31871	218	2024-01-25
Calibrator 2, 3,02 mU/L	20-7476	31872	989	2024-01-25
Calibrator 3, 10,0 mU/L	20-7477	31873	4382	2024-01-25
Calibrator 4, 34,2 mU/L	20-7478	31874	17530	2024-01-25
Calibrator 5, 117 mU/L	20-7479	31875	61209	2024-01-25
Calibrator 6, 423 mU/L	20-7480	31876	225010	2024-01-25
Anchor Point High, 600 mU/L	20-7481	31877	295882	2024-01-25
Coated Plate	20-7463	31854	-	2024-02-22
Assay Buffer	20-7489	31859	-	2024-01-05
Enzyme Conjugate 11X	20-7494	31885	-	2024-01-12
Enzyme Conjugate Buffer	20-7491	31857	-	2024-01-05
Wash Buffer 21X	20-6746	32170	-	2028-03-12
Substrate NL Ultra A	20-7495	32010	-	2024-01-14
Substrate NL Ultra B	20-7496	32011	-	2024-01-14

Quality Control Serum	Art no	Lot no	Exp. date	Assigned range (mU/L)	Results (mU/L)
Control Low	20-7485	31881	2024-01-21	1,67 – 2,51	2,06
Control Medium	20-7486	31882	2024-01-21	20,6 – 30,8	24,6
Control High	20-7487	31883	2024-01-21	349 - 523	427

Address Mercodia AB, Sylveniusgatan 8A, SE-754 50 Uppsala, Sweden

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3. Quality control

Quality control has been performed for lot no 32438 according to standard operating procedures at Mercodia AB, and the product is released based on fulfillment of established acceptance criteria.

4. Calibration

Mercodia Lispro NL-ELISA is calibrated against a highly purified, fully validated, commercial European Pharmacopoeia Reference Standards: Insulin Lispro CRS. Accuracy of reference standard was evaluated by measuring known concentration of insulin lispro from Humalog® (Eli Lilly and Company).

5. Assay method

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

6. Intended use

Mercodia Lispro NL-ELISA provides a method for the quantitative determination of Lispro in plasma or serum 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.

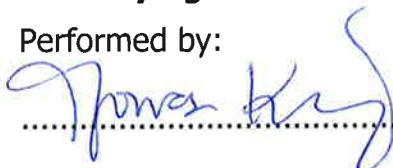
8. Hazardous information

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:
2021-05-26	
Date of approval:	Approved by:	Signature:
2021-06-14	