

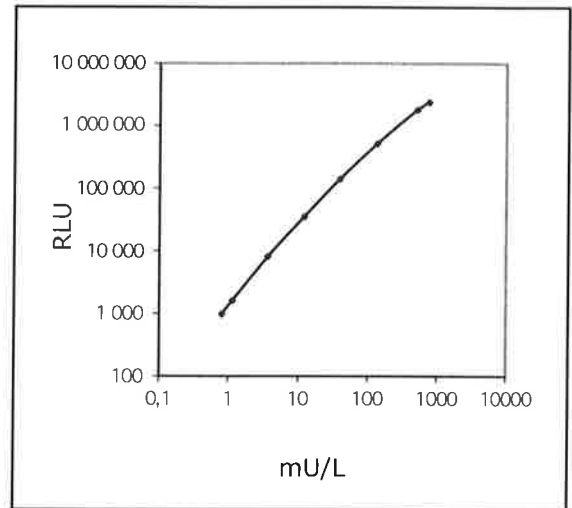
Certificate of Analysis

1. Manufacturer

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

2. Description

Catalog no: 10-1291-01
 Product: Mercodia Lispro NL-ELISA
 Lot no: 36645
 Expiry date: 2026-12-31



<i>Component</i>	<i>Art no</i>	<i>Lot no</i>	<i>RLU</i>	<i>Exp. date</i>
Calibrator 0	20-7473	36619	216	2027-01-25
Anchor Point Low, 0,793 mU/L	20-7474	36620	992	2027-01-25
Calibrator 1, 1,13 mU/L	20-7475	36621	1619	2027-01-25
Calibrator 2, 3,60 mU/L	20-7476	36622	8156	2027-01-25
Calibrator 3, 12,0 mU/L	20-7477	36623	35324	2027-01-25
Calibrator 4, 39,3 mU/L	20-7478	36624	142339	2027-01-25
Calibrator 5, 135 mU/L	20-7479	36625	523272	2027-01-25
Calibrator 6, 511 mU/L	20-7480	36626	1828089	2027-01-25
Anchor Point High, 749 mU/L	20-7481	36627	2418946	2027-01-25
Coated Plate	20-7463	31854	-	2027-02-22
Assay Buffer	20-7489	36633	-	2027-01-05
Enzyme Conjugate 11X	20-7494	36631	-	2027-01-12
Enzyme Conjugate Buffer	20-7491	36632	-	2027-01-05
Wash Buffer 21X	20-6746	36361	-	2031-12-18
Substrate NL Ultra A	20-7495	36634	-	2028-05-16
Substrate NL Ultra B	20-7496	36635	-	2028-05-16

<i>Quality Control Serum</i>	<i>Art no</i>	<i>Lot no</i>	<i>Exp. date</i>	<i>Assigned range (mU/L)</i>	<i>Results (mU/L)</i>
Control Low	20-7485	36628	2027-01-21	1,80 – 2,70	2,14
Control Medium	20-7486	36629	2027-01-21	21,0 – 31,4	27,5
Control High	20-7487	36630	2027-01-21	362 - 542	437

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

Phone +46 18 57 00 70 | **Fax** +46 18 57 00 80 | **Vat No** SE-556157510001

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

3. Quality control

Quality control has been performed for lot no 36645 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:

2025-04-24

Performed by:

Mattias JA

Signature:

Mattias JA

Date of approval:

2025-04-25

Approved by:

Elin Westberg

Signature:

Elin Westberg