

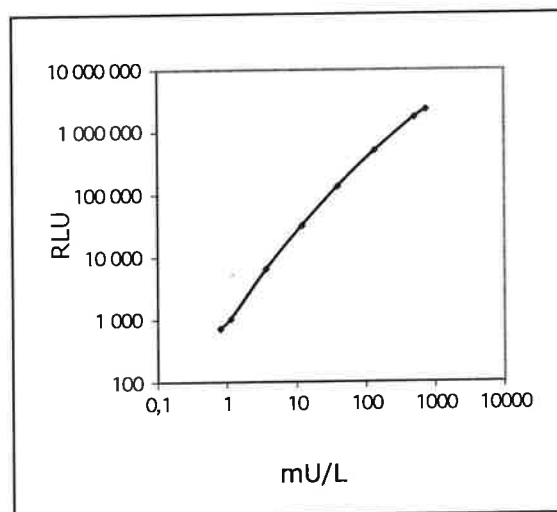
# Certificate of Analysis

## 1. Manufacturer

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

## 2. Description

Catalog no: 10-1291-01  
 Product: Mercodia Lispro NL-ELISA  
 Lot no: 37235  
 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	123	2027-01-25
Anchor Point Low, 0,793 mU/L	20-7474	36620	730	2027-01-25
Calibrator 1, 1,13 mU/L	20-7475	36621	1037	2027-01-25
Calibrator 2, 3,60 mU/L	20-7476	36622	6511	2027-01-25
Calibrator 3, 12,0 mU/L	20-7477	36623	32350	2027-01-25
Calibrator 4, 39,3 mU/L	20-7478	36624	136344	2027-01-25
Calibrator 5, 135 mU/L	20-7479	36625	511081	2027-01-25
Calibrator 6, 511 mU/L	20-7480	36626	1748365	2027-01-25
Anchor Point High, 749 mU/L	20-7481	36627	2322489	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	37164	-	2031-03-06
Substrate NL Ultra B	20-7496	37165	-	2031-03-06

<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	2,44
Control Medium	20-7486	36629	2027-01-21	21,0 – 31,4	26,2
Control High	20-7487	36630	2027-01-21	362 - 542	423

**3. Quality control**

Quality control has been performed for lot no 37235 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:

2026-04-10

Performed by:

Jonas Kvick

Signature:



Date of approval:

2026-04-10

Approved by:

Elin Westberg

Signature:

