

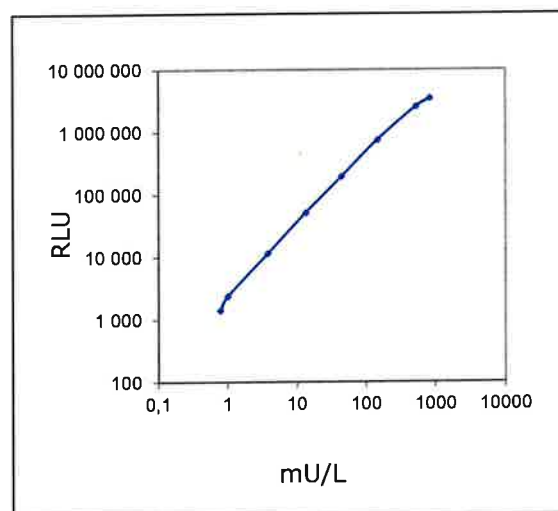
Certificate of Analysis

1. Manufacturer

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

2. Description

Catalog no: 10-1291-01
 Product: Mercodia Lispro NL-ELISA
 Lot no: 37615
 Expiry date: 2031-02-28



<i>Component</i>	<i>Art no</i>	<i>Lot no</i>	<i>RLU</i>	<i>Exp. date</i>
Calibrator 0	20-7473	37154	161	2032-03-09
Anchor Point Low, 0,791 mU/L	20-7474	37155	1422	2032-03-09
Calibrator 1, 1,02 mU/L	20-7475	37156	2428	2032-03-09
Calibrator 2, 3,83 mU/L	20-7476	37157	11660	2032-03-09
Calibrator 3, 13,5 mU/L	20-7477	37158	51919	2032-03-09
Calibrator 4, 45,0 mU/L	20-7478	37159	199409	2032-03-09
Calibrator 5, 148 mU/L	20-7479	37160	759191	2032-03-09
Calibrator 6, 538 mU/L	20-7480	37161	2592426	2032-03-09
Anchor Point High, 843 mU/L	20-7481	37162	3492415	2032-03-09
Coated Plate	20-7463	37153	-	2032-02-23
Assay Buffer	20-7489	37163	-	2032-03-11
Enzyme Conjugate 11X	20-7494	37149	-	2032-02-24
Enzyme Conjugate Buffer	20-7491	37147	-	2032-02-27
Wash Buffer 21X	20-6746	37311	-	2033-06-18
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	37150	2032-03-02	1,61 – 2,41	2,07
Control Medium	20-7486	37151	2032-03-02	20,7 – 31,1	25,4
Control High	20-7487	37152	2032-03-02	322 - 484	406

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3. Quality control

Quality control has been performed for lot no 37615 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:

2026-04-21

Performed by:

Mathias Jäder genom Elin Westberg EW

Signature:

Date of approval:

2026-09-25

Approved by:

Jonas Kvick

Signature: