

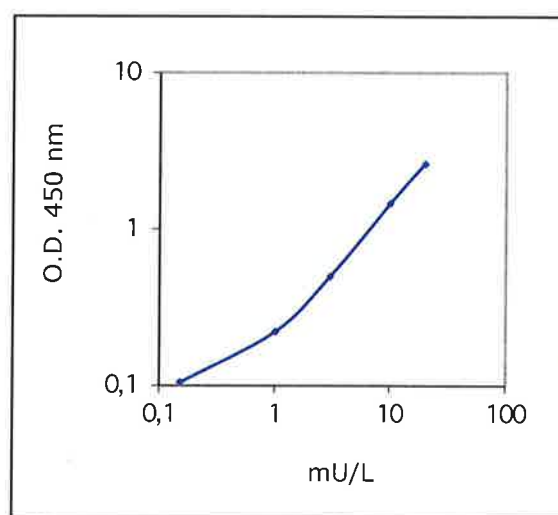
Certificate of Analysis

1. Manufacturer

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

2. Description

Catalog no: 10-1132-01
 Product: Mercodia Ultrasensitive
 Insulin ELISA
 Lot no: 36744
 Expiry date: 2026-08-31



<i>Component</i>	<i>Art no</i>	<i>Lot no</i>	<i>O.D. 450 nm</i>	<i>Exp. date</i>
Calibrator 0	20-6600	35571	0,085	2026-09-11
Calibrator 0,15 mU/L	20-3317	35572	0,104	2026-10-12
Calibrator 1 mU/L	20-3319	35573	0,220	2026-10-12
Calibrator 3 mU/L	20-3320	35574	0,494	2026-10-12
Calibrator 10 mU/L	20-3321	35575	1,451	2026-10-12
Calibrator 20 mU/L	20-3322	35576	2,593	2026-10-12
Coated Plate	20-6604	35569		2026-09-11
Enzyme Conjugate 11X	20-3325	35579		2026-11-16
Enzyme Conjugate Buffer	20-6602	35578		2026-09-14
Wash Buffer 21X	20-6746	36724		2032-06-12
Substrate TMB	20-2629	36313		2029-02-28
Stop Solution	20-2693	36554		2032-03-07

3. Quality control

Quality control has been performed for lot no 36744 according to standard operating procedures at Mercodia AB, and the product is released based on fulfillment of established acceptance criteria.

4. Calibration

The Mercodia Ultrasensitive Insulin ELISA 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

Mercodia Ultrasensitive Insulin ELISA provides a method for the quantitative determination of insulin in serum or plasma.

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 Material 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:

2025-07-01

Performed by:

Ellen Westberg

Signature:

EW

Date of approval:

2025-07-01

Approved by:

Jonas Kvick

Signature:

JK