

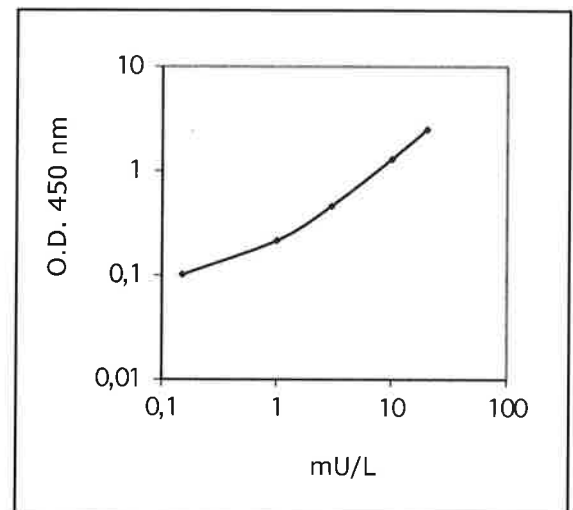
Certificate of Analysis

1. Manufacturer

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

2. Description

Catalog no: 10-1132-01
Product: Mercodia Ultrasensitive
Insulin ELISA
Lot no: 35104
Expiry date: 2024-09-30



Component	Art no	Lot no	O.D. 450 nm	Exp. date
Calibrator 0	20-6600	32994	0,081	2024-11-22
Calibrator 0,15 mU/L	20-3317	32985	0,101	2024-11-30
Calibrator 1 mU/L	20-3319	32986	0,214	2024-11-30
Calibrator 3 mU/L	20-3320	32987	0,458	2024-11-30
Calibrator 10 mU/L	20-3321	32988	1,297	2024-11-30
Calibrator 20 mU/L	20-3322	32989	2,482	2024-11-30
Coated Plate	20-6604	35090		2024-10-04
Enzyme Conjugate 11X	20-3325	32998		2025-01-04
Enzyme Conjugate Buffer	20-6602	32996		2024-11-24
Wash Buffer 21X	20-6746	32934		2028-10-18
Substrate TMB	20-2629	32367		2025-07-31
Stop Solution	20-2693	32965		2028-10-29

3. Quality control

Quality control has been performed for lot no 35104 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:

2023-01-04

Performed by:

Malin St

Signature:

Malin St

Date of approval:

2023-01-04

Approved by:

Göran K

Signature:

Göran K