

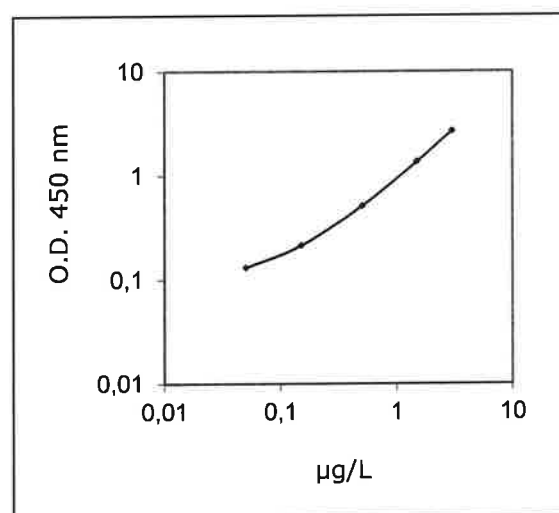
Certificate of Analysis

1. Manufacturer

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

2. Description

Catalog no: 10-1201-01
 Product: Mercodia Bovine Insulin ELISA
 Lot no: 37623
 Expiry date: 2027-11-30



Component	Art no	Lot no	O.D. 450 nm	Exp. date
Calibrator 0	20-6608	36515	0,092	2028-02-27
Calibrator 0,05 µg/L	20-5299	36399	0,131	2028-02-20
Calibrator 0,15 µg/L	20-5300	36400	0,215	2028-02-20
Calibrator 0,5 µg/L	20-5301	36401	0,514	2028-02-20
Calibrator 1,5 µg/L	20-5302	36402	1,371	2028-02-20
Calibrator 3,0 µg/L	20-5303	36403	2,698	2028-02-20
Coated Plate	20-6612	36407		2027-12-16
Enzyme Conjugate 11X	20-5310	36398		2028-03-06
Enzyme Conjugate Buffer	20-6610	36555		2028-03-18
Wash Buffer 21X	20-6746	37528		2033-08-28
Substrate TMB	20-2629	36313		2029-02-28
Stop Solution	20-2693	37299		2033-05-29

3. Quality control

Quality control has been performed for lot no 37623 according to standard operating procedures at Mercodia AB, and the product is released based on fulfillment of established acceptance criteria.

4. Calibration

The Mercodia Bovine Insulin ELISA is calibrated against an in-house reference preparation of bovine insulin.

5. Assay method

Test procedure used is according to current Direction for Use for the product and lot.

6. Intended use

Mercodia Bovine Insulin ELISA provides a method for the quantitative determination of bovine 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:

2025-06-03

Performed by:

Jonas Kvick

Signature:



Date of approval:

2026-10-01

Approved by:

Eli Westberg

Signature:

