

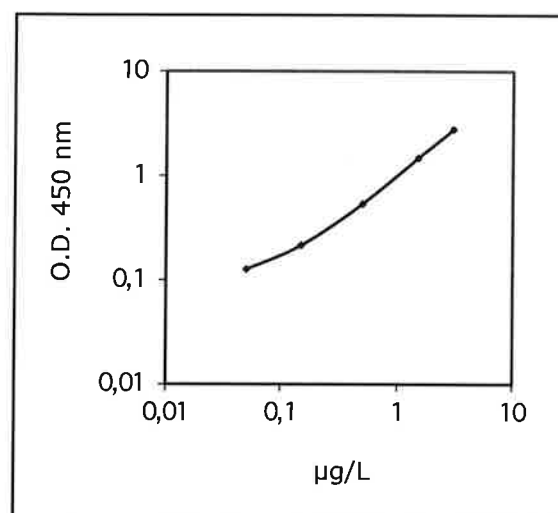
Certificate of Analysis

1. Manufacturer

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

2. Description

Catalog no: 10-1201-01
 Product: Mercodia Bovine Insulin ELISA
 Lot no: 36076
 Expiry date: 2026-10-31



<i>Component</i>	<i>Art no</i>	<i>Lot no</i>	<i>O.D. 450 nm</i>	<i>Exp. date</i>
Calibrator 0	20-6608	35694	0,081	2026-11-20
Calibrator 0,05 µg/L	20-5299	35711	0,126	2026-11-22
Calibrator 0,15 µg/L	20-5300	35712	0,214	2026-11-22
Calibrator 0,5 µg/L	20-5301	35713	0,534	2026-11-22
Calibrator 1,5 µg/L	20-5302	35714	1,476	2026-11-22
Calibrator 3,0 µg/L	20-5303	35715	2,767	2026-11-22
Coated Plate	20-6612	35693		2026-12-04
Enzyme Conjugate 11X	20-5310	35717		2026-11-30
Enzyme Conjugate Buffer	20-6610	35696		2026-11-28
Wash Buffer 21X	20-6746	33193		2029-01-03
Substrate TMB	20-2629	35551		2027-07-31
Stop Solution	20-2693	32372		2028-04-22

3. Quality control

Quality control has been performed for lot no 36076 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:

2024-01-30

Performed by:

Mattias H

Signature:

Date of approval:

2024-05-22

Approved by:

Jonas Knick

Signature: