

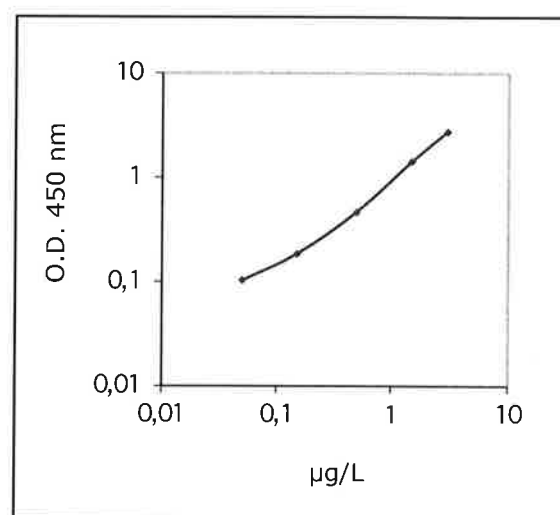
Certificate of Analysis

1. Manufacturer

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

2. Description

Catalog no: 10-1202-01
 Product: Mercodia Ovine Insulin ELISA
 Lot no: 35900
 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	0,064	2026-11-20
Calibrator 0,05 µg/L	20-5289	35706	0,103	2026-11-30
Calibrator 0,15 µg/L	20-5290	35707	0,185	2026-11-30
Calibrator 0,5 µg/L	20-5291	35708	0,465	2026-11-30
Calibrator 1,5 µg/L	20-5292	35709	1,420	2026-11-30
Calibrator 3,0 µg/L	20-5293	35710	2,736	2026-11-30
Coated Plate	20-6612	35693		2026-12-04
Enzyme Conjugate 11X	20-5312	35716		2026-12-21
Enzyme Conjugate Buffer	20-6610	35696		2026-11-28
Wash Buffer 21X	20-6746	32170		2028-03-12
Substrate TMB	20-2629	35551		2027-07-31
Stop Solution	20-2693	31476		2027-09-21

3. Quality control

Quality control has been performed for lot no 35900 according to standard operating procedures at Mercodia AB, and the product is released based on fulfillment of established acceptance criteria.

4. Calibration

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

5. Assay method

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

6. Intended use

Mercodia Ovine Insulin ELISA provides a method for the quantitative determination of ovine 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

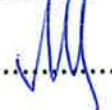
Date of analysis:

2024-02-20

Performed by:

Malin Johansson

Signature:



Date of approval:

2024-02-20

Approved by:

Jonas Knick

Signature:

