

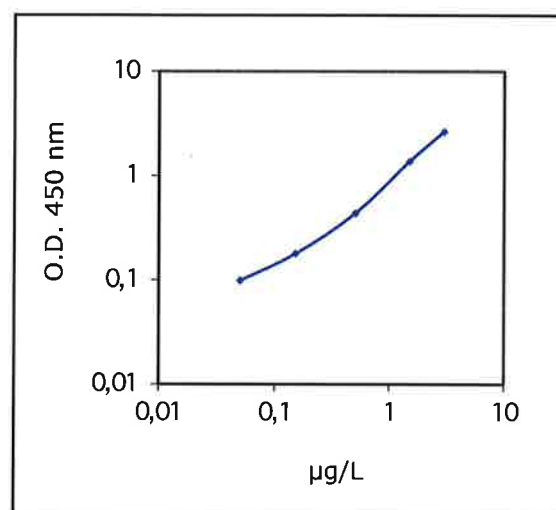
Certificate of Analysis

1. Manufacturer

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

2. Description

Catalog no: 10-1202-01
 Product: Mercodia Ovine Insulin ELISA
 Lot no: 35125
 Expiry date: 2025-08-31



<i>Component</i>	<i>Art no</i>	<i>Lot no</i>	<i>O.D. 450 nm</i>	<i>Exp. date</i>
Calibrator 0	20-6608	34172	0,068	2025-10-19
Calibrator 0,05 µg/L	20-5289	34116	0,099	2025-10-11
Calibrator 0,15 µg/L	20-5290	34117	0,179	2025-10-11
Calibrator 0,5 µg/L	20-5291	34118	0,436	2025-10-11
Calibrator 1,5 µg/L	20-5292	34119	1,375	2025-10-11
Calibrator 3,0 µg/L	20-5293	34120	2,639	2025-10-11
Coated Plate	20-6612	34100		2025-09-26
Enzyme Conjugate 11X	20-5312	35011		2025-10-06
Enzyme Conjugate Buffer	20-6610	34126		2025-10-07
Wash Buffer 21X	20-6746	30852		2027-02-25
Substrate TMB	20-2629	33423		2026-06-30
Stop Solution	20-2693	29028		2025-11-01

3. Quality control

Quality control has been performed for lot no 35125 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:

2023-01-31

Performed by:

DALAN ARABACI

Signature:

Date of approval:

2023-02-01

Approved by:

Thomas Kuf

Signature: