

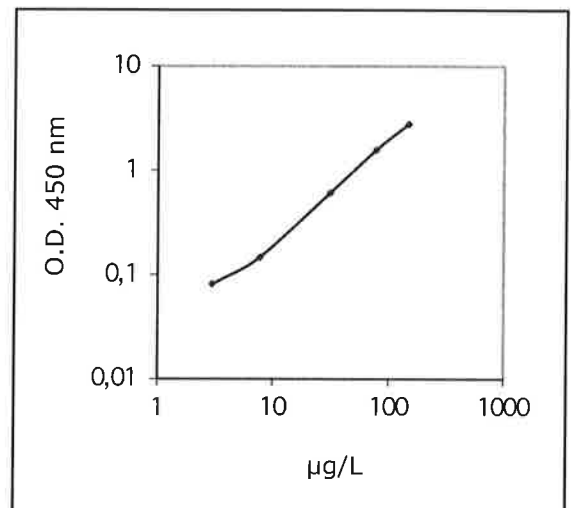
Certificate of Analysis

1. Manufacturer

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

2. Description

Catalog no: 10-1145-01
 Product: Merckodia High Range Rat
 Insulin ELISA
 Lot no: 35773
 Expiry date: 2025-07-31



<i>Component</i>	<i>Art no</i>	<i>Lot no</i>	<i>O.D. 450 nm</i>	<i>Exp. date</i>
Calibrator 0	20-3621	33380	0,059	2027-02-24
Calibrator 2,99 µg/L	20-3611	33386	0,081	2027-03-10
Calibrator 7,64 µg/L	20-3612	33387	0,146	2027-03-10
Calibrator 30,9 µg/L	20-3613	33388	0,608	2027-03-10
Calibrator 76,5 µg/L	20-3614	33389	1,567	2027-03-10
Calibrator 148 µg/L	20-3615	33390	2,780	2027-03-10
Coated Plate	20-3193	33378		2027-02-21
Enzyme Conjugate 11X	20-3619	33396		2027-02-24
Enzyme Conjugate Buffer	20-3625	33393		2027-02-25
Wash Buffer 21X	20-6746	35603		2030-10-09
Substrate TMB	20-2629	32367		2025-07-31
Stop Solution	20-2693	35523		2030-08-10

3. Quality control

Quality control has been performed for lot no 35773 according to standard operating procedures at Mercodia AB, and the product is released based on fulfillment of established acceptance criteria.

4. Calibration

The Mercodia High Range Rat Insulin ELISA is calibrated against an in-house reference preparation of rat insulin.

5. Assay method

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

6. Intended use

Mercodia High Range Rat Insulin ELISA provides a method for the quantitative determination of rat 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

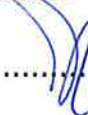
Date of analysis:

2022-05-03

Performed by:

FJonas Kirsch

Signature:



Date of approval:

2023-11-15

Approved by:

Elin Westberg EW

Signature:

