Mercodia

Mall-0514 v3.0

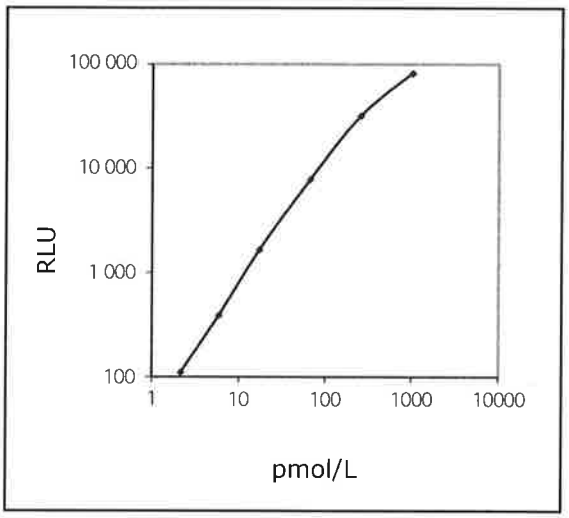
Certificate of Analysis

1. **Manufacturer**

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

2. **Description**

Catalog no:	10-1258-01
Product:	Mercodia Total GIP NL-ELISA
Lot no:	35492
Expiry date:	2025-05-31



Component	*Art no*	*Lot no*	*Exp. date*
Calibrator 0	20-7432	33710	2025-06-01
Calibrator 1, 2,14 pmol/L	20-7439	33909	2025-06-27
Calibrator 2, 5,88 pmol/L	20-7440	33718	2025-06-01
Calibrator 3, 17,1 pmol/L	20-7441	33719	2025-06-01
Calibrator 4, 66,2 pmol/L	20-7442	33720	2025-06-01
Calibrator 5, 254 pmol/L	20-7443	33721	2025-06-01
Calibrator 6, 1020 pmol/L	20-7444	33722	2025-06-01
Coated Plate	20-7454	34092	2025-09-12
Enzyme Conjugate 11X	20-7457	33726	2025-06-08
Enzyme Conjugate Buffer	20-7452	33773	2025-06-14
Wash Buffer 21X	20-6746	35178	2030-02-03
Substrate Reagent A	20-7300	35463	2026-05-26
Substrate Reagent B	20-7301	35464	2026-05-26

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E-mail info@mercodia.com | **Website** www.mercodia.com

3. **Quality control**

Quality control has been performed for lot no 35492 according to standard operating procedures at Mercodia AB, and the product is released based on fulfillment of established acceptance criteria.

4. **Calibration**

Mercodia Total GIP NL-ELISA is calibrated against a highly purified, commercial GIP(3-42) preparation, validated with amino acid analysis and HPLC-UV LC-MS/MS.

5. **Assay method**

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

6. **Intended use**

Mercodia Total GIP NL-ELISA provides a method for the quantitative determination of total GIP in human samples.

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 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:	Performed by:	Signature:
2023-07-12		

Date of approval:	Approved by:	Signature:
2023-07-12		

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