

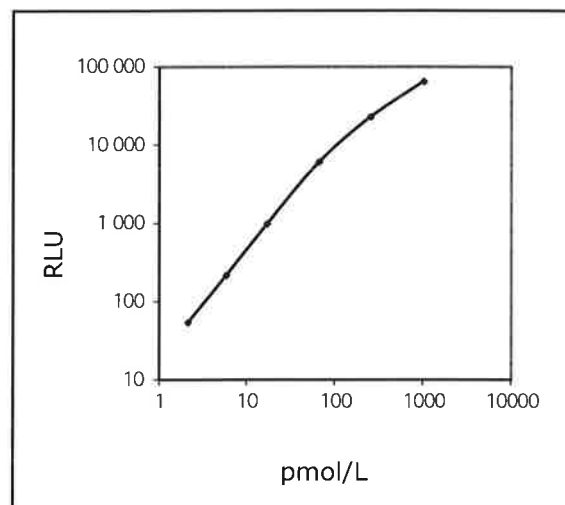
# Certificate of Analysis

## 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: 34167  
 Expiry date: 2025-04-30



| <i>Component</i>          | <i>Art no</i> | <i>Lot no</i> | <i>Exp. date</i> |
|---------------------------|---------------|---------------|------------------|
| 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       | 34094         | 2025-09-13       |
| Enzyme Conjugate 11X      | 20-7457       | 33726         | 2025-06-08       |
| Enzyme Conjugate Buffer   | 20-7452       | 33773         | 2025-06-14       |
| Wash Buffer 21X           | 20-6746       | 33635         | 2029-05-20       |
| Substrate Reagent A       | 20-7300       | 33583         | 2025-05-11       |
| Substrate Reagent B       | 20-7301       | 33584         | 2025-05-11       |

**3. Quality control**

Quality control has been performed for lot no 34167 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:

2022-09-29

Performed by:

Multis Ltd

Signature:

Date of approval:

2022-10-10

Approved by:

Göran K

Signature: