

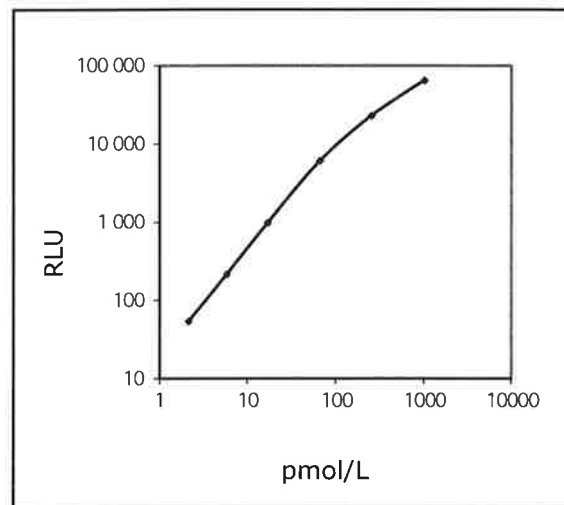
# Certificate of Analysis

## 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: 34166  
 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	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	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 34166 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:
<u>2022-09-29</u>	<u>[Signature]</u>	
Date of approval:	Approved by:	Signature:
<u>2022-10-03</u>	<u>[Signature]</u>	