

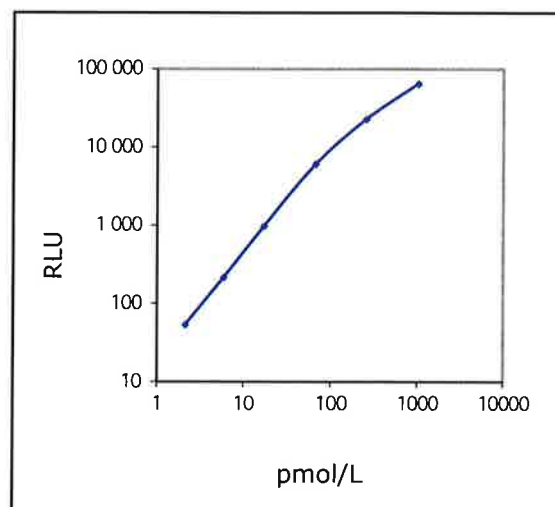
Certificate of Analysis

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: 35500
 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	33846	2029-08-12
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 35500 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>Mattias H.</u>	<u>[Signature]</u>
Date of approval:	Approved by:	Signature:
<u>2023-06-26</u>	<u>Elin Westberg</u>	<u>[Signature]</u>