

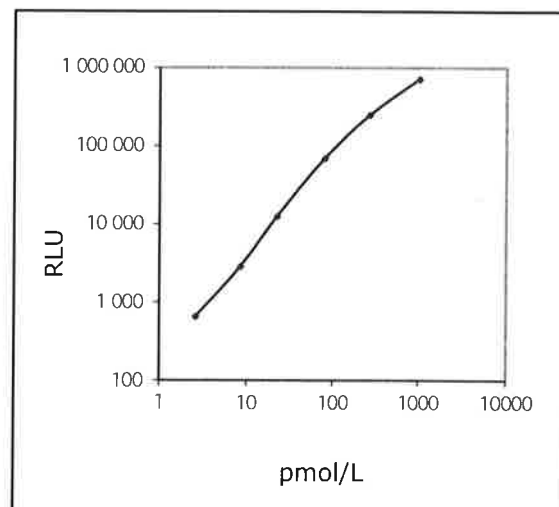
Certificate of Analysis

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: 35949
 Expiry date: 2026-12-31



<i>Component</i>	<i>Art no</i>	<i>Lot no</i>	<i>Exp. date</i>
Calibrator 0	20-7432	35825	2027-01-19
Calibrator 1, 2,60 pmol/L	20-7439	35818	2027-01-18
Calibrator 2, 8,45 pmol/L	20-7440	35819	2027-01-18
Calibrator 3, 22,4 pmol/L	20-7441	35820	2027-01-18
Calibrator 4, 79,8 pmol/L	20-7442	35821	2027-01-18
Calibrator 5, 270 pmol/L	20-7443	35822	2027-01-18
Calibrator 6, 1030 pmol/L	20-7444	35823	2027-01-18
Coated Plate	20-7454	35826	2027-01-16
Enzyme Conjugate 11X	20-7457	35827	2027-01-31
Enzyme Conjugate Buffer	20-7452	35824	2027-01-24
Wash Buffer 21X	20-6746	31676	2027-11-03
Substrate Reagent A	20-7300	35950	2027-02-19
Substrate Reagent B	20-7301	35951	2027-02-19

3. Quality control

Quality control has been performed for lot no 35949 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:

2024-03-21

Performed by:

Jane Rindlund

Signature:

SR

Date of approval:

2024-03-27

Approved by:

Elin Westberg

Signature:

EW