

BIOHIT HealthCare

Innovating for Health

GastroPanel® Stabilizer

INSTRUCTION FOR USE



606050 (1 x 5.5 ml)

606051 (5 x 5.5 ml)

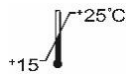


Store at +15 - +25°C upon receipt

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1. EXPLANATION OF THE SYMBOLS USED IN LABELS

	English
	For <i>in vitro</i> diagnostic use
	Catalogue Number
	CE Mark
	Batch code
	Use by
	Storage limitation Store at +15...+25 °C
	Manufacturer

2. INTENDED USE

GastroPanel Stabilizer is an *in vitro* diagnostic medical device intended to be used in conjunction with GastroPanel Gastrin-17 (REF 606035), GastroPanel Pepsinogen I (REF 606010), GastroPanel Pepsinogen II (REF 606020), GastroPanel Helicobacter pylori (REF 606040), Gastrin-17 Advanced (REF 601035), GastroPanel Four-in-One (REF 606080), GastroPanel quick test (REF 602320) and GastroPanel quick test NT (REF 602410) with the corresponding sample type, either EDTA plasma or serum to stabilize measured biomarkers. The product is used manually and is intended to be used by healthcare professionals, either in a laboratory-based or point of care (POC) setting.

3. WARNINGS AND PRECAUTIONS

CAUTION: Handle blood samples as potentially biohazardous material!

All human blood and control samples are to be treated as potentially infectious and handled according to standard precautions (e.g., GLP, GMMP, CLSI M29). Please refer to internationally or nationally recognized manuals concerning biosafety issues, such as Laboratory Biosafety Manual by World Health Organization or Biosafety in Microbiological and Biomedical Laboratories by Centers for Disease Control and Prevention/National Institutes of Health.

All recommended precautions for the handling of bio-derivatives should be followed.

Always use protective gloves and clothing when handling patient samples. Use a safety pipetting device for all liquid transfers. Read all instructions prior to performing this assay.

Dispose of solutions according to local waste management legislation.

4. PRODUCT CONTENTS, STABILITY AND STORAGE

4.1. GastroPanel Stabilizer

Contents: 5.5 ml of the stabilizer in a drop bottle.

Preparation: Ready for use.

Stability: Stable until expiration date when stored at 15-25 °C. The product may arrive as a solid.

The solidified product can be reliquefied by warming to room temperature (20-25 °C)

4.2. Instructions for use

Inserted into each kit.

5. USE OF THE STABILIZER

After separation of the plasma or serum, add GastroPanel Stabilizer to the sample as a 5% solution:

1. Allow stabilizer to reach room temperature (20-25 °C).
2. Add two drops (50 µl) of the solution into 1 ml of EDTA plasma or serum.
3. Mix by inverting the tube.
4. Treated samples can be stored for 7 days at +4 °C or 3 days at 20-25 °C. For longer storage the samples should be frozen (preferably at -70 °C, alternatively at -20 °C).

Use GastroPanel stabilizer for plasma and serum samples.

DO NOT USE GastroPanel stabilizer in whole blood samples, as it may cause hemolysis of the red blood cells.

6. PERFORMANCE CHARACTERISTICS

The stabilizer will keep GastroPanel samples stable for 7 days at +4 °C or 3 days at room temperature (20-25 °C).

7. DATE OF ISSUE

GastroPanel Stabilizer

Version 02, 05-2022

8. WARRANTY

The Manufacturer shall remedy all defects discovered in any Product (the “Defective Product”) that result from unsuitable materials or negligent workmanship and which prevent the mechanical functioning or intended use of the Products including, but not limited to, the functions specified in the Manufacturer’s specifications for the Products. ANY WARRANTY WILL, HOWEVER, BE DEEMED AS VOID IF FAULT IS FOUND TO HAVE BEEN CAUSED BY MALTREATMENT, MISUSE, ACCIDENTAL DAMAGE, INCORRECT STORAGE OR USE OF THE PRODUCTS FOR OPERATIONS OUTSIDE THEIR SPECIFIED LIMITATIONS OR OUTSIDE THEIR SPECIFICATIONS, CONTRARY TO THE INSTRUCTIONS GIVEN IN THE INSTRUCTION MANUAL.

The period of this warranty for the Distributor is defined in the instruction manual of the Products and will commence from the date the relevant Product is shipped by the Manufacturer. In case of interpretation disputes the English text applies. In case of any serious incident in relation to the product, contact the manufacturer

This Biohit diagnostic kit has been manufactured according to our ISO 9001 / ISO 13485 quality management protocols and has passed all relevant Quality Assurance procedures related to this product.

9. ORDERING INFORMATION

GastroPanel Stabilizer

Cat. No. 606050, 1 x 5.5 ml

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