

BIOHIT HealthCare

Innovating for Health

GastroPanel® Stabilizer

INSTRUCTIONS FOR USE

REF 606 050 (1 x 5.5 ml)
606 051 (5 x 5.5 ml)



Store at +15 - +25°C upon receipt

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INSTRUCTIONS FOR USE







English

Note! Other languages available at www.biohithealthcare.com

GastroPanel® Stabilizer

Cat. nos. 606 050, 606 051

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

1. INTENDED USE

GastroPanel® Stabilizer is an additive for the stabilization of EDTA plasma samples to be analyzed with the GastroPanel kits. GastroPanel Stabilizer is used with GastroPanel Gastrin-17 (cat.no. 606 035), GastroPanel Pepsinogen I (cat.no. 606 010), GastroPanel Pepsinogen II (cat.no. 606 020) and GastroPanel Helicobacter pylori (cat.no. 606 040).

2. WARNINGS AND PRECAUTIONS

CAUTION: Handle the plasma samples as potentially biohazardous material.

All samples should be regarded as potentially contaminated and treated as if they were infectious. Please refer to the U.S. Department of Health and Human Services (Bethesda, MD., USA) publication Biosafety in Microbiological and Biomedical Laboratories, 1999, 4th

ed. (CDC/NIH) and No. (CDC) 88-8395 on reports of laboratory safety procedures on different diseases or any other local or national regulation.

Always use protective gloves when handling patient samples. Use a safety pipetting device for all pipetting. Never pipette by mouth. Read all instructions prior to performing this assay.

3. PRODUCT CONTENTS, STABILITY, AND STORAGE

3.1. 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 reliquified by warming to room temperature (20-25 °C)

3.2. Instructions for use

Inserted into each kit.

4. USE OF THE STABILIZER

After separation of the plasma, 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 to 1 ml of EDTA plasma.
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 temporary storage, the plasma samples can be stored frozen at -20 °C, but in long-term storage of over two weeks, the storage should be at -70 °C.

5. PERFORMANCE CHARACTERISTICS

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

6. DATE OF ISSUE

GastroPanel® Stabilizer

Version 01, January 2016

7. WARRANTY

The Manufacturer shall remedy all defects discovered in any Product (“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 VOID IF FAULT IS FOUND TO HAVE BEEN CAUSED BY MALTREATMENT, MISUSE, ACCIDENTIAL 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.

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.

8. ORDERING INFORMATION

GastroPanel Stabilizer

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