

Biohit Oyj

BIOHIT
Helicobacter
pylori
Control

Control solution for
Helicobacter pylori quick test
and
BIOHIT *Helicobacter pylori* UFT300

INSTRUCTIONS FOR USE



602017



1. INTENDED USE

BIOHIT *Helicobacter pylori* Control is an *in vitro* diagnostic medical device and is intended to be a positive quality control for *Helicobacter pylori* quick test (REF 602015) and BIOHIT *Helicobacter pylori* UFT300 (REF 602019, 602021, 602005PLA, 602019PLA). The product is used manually and is intended to be used by healthcare professionals only.

2. PRODUCT CONTENTS AND STABILITY

Contents: 1.0 ml of the urease solution in a drop bottle.

WARNING: UREASE MAY CAUSE ALLERGY OR ASTMA SYMPTOMS OR BREATHING DIFFICULTIES IF INHALED.

Preparation: Ready for use.

Stability: When stored as directed (at 2-8 °C), BIOHIT *Helicobacter pylori* Control will remain stable until the labeled expiration date.

3. USE OF THE BIOHIT *Helicobacter pylori* Control

Use with *Helicobacter pylori* quick test (REF 602015):

Add one drop (10 µl) of the Control solution on the test plate of yellow agarose gel of *Helicobacter pylori* quick test. To avoid the contamination of the solution, do not touch the gel with the dropper tip! The gel should turn red after 2-30 minutes to indicate a positive reaction.

Use with BIOHIT *Helicobacter pylori* UFT300 (REF 602019, 602021 and 602005PLA, 602019PLA):

Add one drop (10 µl) of the Control solution and two drops of the Reagent Solution of BIOHIT *Helicobacter pylori* UFT300 to the test tube or plate. The solution should turn magenta in 5 minutes to indicate a positive reaction.

If BIOHIT *Helicobacter pylori* Control does not perform as expected, repeat the test or contact Biohit for technical assistance before testing patient samples. DO NOT use reagents beyond

their labeled expiration dates.

Dispose of waste and residues in accordance with local authority requirements.

4. DATE OF ISSUE

BIOHIT *Helicobacter pylori* Control kit insert

Version 06, 05-2022

5. 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.

The product has been manufactured according to our ISO 9001 / ISO 13485 quality management protocols and have passed all relevant Quality Assurance procedures related to these products.

In case of any serious incident in relation to the product, contact the manufacturer.

6. EXPLANATION OF THE SYMBOLS USED IN LABELS

	Catalogue number
	Lot number
	Use by
	Temperature limitation. Store at 2-8 °C

7. ORDERING INFORMATION

BIOHIT *Helicobacter pylori* Control
REF 602017



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