

Biohit Oyj

*H. pylori*  
**CONTROL+**

Control Solution  
for *H. pylori* Quick Test

**INSTRUCTIONS FOR USE**

**REF** 602 017

**IVD**

CE

Biohit Oyj  
Laippatie 1  
FIN-00880 Helsinki, Finland  
Tel: +358-9-773 861  
Fax: +358-9-773 2867  
E-mail: info@biohit.fi  
www.biohithealthcare.com

## INTENDED USE

The use of the Biohit *H. pylori* Control+ solution is intended as positive *Helicobacter pylori* quality control test together with the Biohit *H. pylori* Quick Test (Cat. No. 602 015) or with the Biohit *H. pylori* UFT300 Quick Test (Cat. Nos. 602 005, 602 019 and 602 021).

## 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 *H. pylori* Control+ will remain stable until the labeled expiration date.

## USE OF THE *H. PYLORI* CONTROL+

Use with Biohit *H. pylori* Quick Test (Cat. No. 602 015):

Add one drop (10 µl) of the Control+ solution on the test plate of yellow agarose gel of the Biohit *H. 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 *H. pylori* UFT300 Quick Test (Cat. Nos. 602 005, 602 019 and 602 021):

Add one drop (10 µl) of the Control+ solution and two drops of the Reagent Solution of the Biohit *H. pylori* UFT300 Quick Test to the test tube. The solution should turn magenta in 5 minutes to indicate a positive reaction.

If the *H. 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.

## DATE OF ISSUE

Biohit *H. pylori* Control+ kit insert  
Version 05, 18.09.2015.





## 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.

## EXPLANATION OF THE SYMBOLS USED IN LABELS

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

## ORDERING INFORMATION

BIOHIT Oyj  
Laippatie 1  
00880 Helsinki, Finland  
Tel: +358-9-773 861  
Fax: +358-9-773 2687  
E-mail: [info@biohit.fi](mailto:info@biohit.fi)  
[www.biohithealthcare.com](http://www.biohithealthcare.com)