

Biohit Oyj

H. pylori
CONTROL+

Control Solution
for *H. pylori* Quick Test

INSTRUCTIONS FOR USE

REF 602 017

IVD

CE

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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).

PRODUCT CONTENTS AND STABILITY

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

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+

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. 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

Control+ kit insert

Version 03, 3.1.2013.

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 PROD-

UCTS 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

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

ORDERING INFORMATION

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