

# BIOHIT *Helicobacter pylori* UFT300 quick test



5 min  
FROM BIOPSY

## Ultra-fast *H. pylori* detection from a biopsy

The Biohit *H. pylori* UFT300 is a true quick test for the detection of *H. pylori* from a biopsy specimen. The biopsy taken during gastroscopy can be tested immediately to diagnose *H. pylori* infection or to determine the success of eradication therapy. The test results are ready in only 5 minutes enabling diagnosis and reporting at the same time. This saves the patient from an unnecessary visit to the doctor for hearing the test results. The Biohit *H. pylori* UFT300 quick test has excellent sensitivity and specificity which makes it a highly reliable and accurate tool for diagnostics.

## One-step test procedure

The Biohit *H. pylori* UFT300 quick test is easy and effortless to use. The biopsy specimen is placed into the test tube and mixed with the test reagent. Clear colour change indicates the presence of *H. pylori* in the specimen within 5 minutes. The closed test system of the UFT300 quick test makes the test procedure safe and hygienic for the user, and the interpretation of the results doesn't require specialist training.

## ***Helicobacter pylori* UFT300 quick test**

- Ready-to-use test kit
- Results ready in 5 min (both positive and negative)
- Storage in room temperature
- Sensitivity 94,5%, Specificity 100%
- Testing and reporting during one appointment



### *Helicobacter pylori* Quick test

Cat. No.	Product	Qty
602019	UFT300 quick test kit	50 tests
602021	UFT300 quick test kit	100 tests
602017	Positive control	1

*In the United States and Japan for research use only.*



## EC Declaration of Conformity

I, the undersigned, hereby declare that the Product(s)

***Helicobacter pylori* IgG Elisa, Cat. No. 601 040.02**  
**Gastrin-17 Elisa, Cat. No. 601 035**  
**Pepsinogen I Elisa, Cat. No. 601 010.01**  
**Pepsinogen II Elisa, Cat. No. 601 020.02**  
**Lactose Intolerance, quick test, Cat. No.s 602 010 (25 tests) and 602 012 (10 tests)**  
**Lactase CONTROL+, Cat. No. 602 018**  
***Helicobacter pylori*, quick test, Cat. No. 602 015**  
**BIOHIT *Helicobacter pylori* UFT300, quick test**  
**Cat. No.s 602 005, 602 005PLA (5 tests), 602 019, 602 019PLA (50 tests)**  
**and 602 021 (100 tests)**  
***Helicobacter pylori* CONTROL+, Cat. No. 602 017**  
**BIOHIT Celiac quick test, Cat. No. 602 070**  
**BIOHIT ColonView, Cat. No. 602 250.02**  
**BIOHIT Calprotectin ELISA, Cat. No. 602 260**  
**BIOHIT Extraction Tubes, Cat. No. 602 270**  
**BIOHIT Active B12 (Holo-transcobalamin), Cat. No. 602 290**  
**Gastrin-17 Stabilizer, Cat. No.s 601 050 (1 x 5,5 ml) and 601 051 (5 x 5,5 ml)**  
**GastroPanel: Pepsinogen I, Pepsinogen II, *H. pylori*, Gastrin-17 Elisa, Cat No. 601 300**

Conform to the applicable provisions of EC Directive 98/79/EC concerning *in vitro* diagnostic medical devices. Category: Other/General devices.

The conformity was established by the manufacturer in a conformity assessment procedure according to Annex III (excluding point 6) of the Directive.

Standards applied:

ISO 9001:2008, ISO 13485:2003

Certificate No. 111839-2012-AQ-FIN-FINAS issued by DNV on 09 February 2015

ISO 14001 Certificate No. 111840-2012-AE-FIN-FINAS issued by DNV on 09 February 2015

ISO 13485:2003 Certificate No. CERT-0075001 issued by QMI SAI Global on 08 March 2015

Signed:

Date: 24<sup>th</sup> June, 2015

Name: **Semi Korpela**

Title: **President & CEO**

Company: **Biohit Oyj, Laippatie 1, 00880 Helsinki, Finland**