HELICHECK®

RAPID TEST TO INVESTIGATE THE PRESENCE OF *HELICOBACTER PYLORI*
BY UREASE ACTIVITY IN GASTRIC BIOPSY SPECIMENS

Cat. #: HP010 **Instructions for Use** **For In Vitro Diagnostic Use**

Product's name:
HELICHECK®

Product's intended use:
HELICHECK® is a rapid qualitative test that identifies urease activity in gastric biopsy specimens. The presence of urease activity strongly suggests the presence of *Helicobacter pylori* (*H. pylori*).

General information:
Many studies have revealed that *H. pylori* is an important agent causing ulcers in the gastrointestinal system. Drug regimens can successfully eradicate this microorganism. *H. pylori* produces a very active urease enzyme, which probably protects the bacteria in a strong acid environment, by splitting urea and producing ammonia, a very alkaline molecule. This type of very high urease activity is not common to other bacteria. Thus, identifying urease activity in biopsy specimens identifies the presence of *H. pylori* to a very high probability[1].
Culture is a specific method for detecting *H. pylori* in gastric biopsy specimens but the sensitivity is low and it requires 5 to 7 days to obtain the result. *H. pylori* detection using polymerase chain reaction (PCR) is accepted as being both sensitive and specific. However, it is both labor and time consuming. Microscopic examination is a rapid method but it requires experienced staff for evaluation of the preparations. For these reasons, the rapid urease test, **HELICHECK®** is very useful for detecting *H. pylori* infection at the site of endoscopy.[1-4]

Limitations of the method:
The time required to obtain positive results depends on the number of *H. pylori* present in the sample. Samples with low concentrations of *H. pylori* or samples containing high concentrations of non-living organisms may not be detected within two hours.

HELICHECK® requires a biopsy specimen. **HELICHECK®** can not detect urease activity with breath test.

Principles of the procedure:
Urease splits urea that is present in the test medium. This process creates a color change in the medium. The color change may take place in a period of time varying from a few minutes to several hours, depending on the amount of *H. pylori* in the specimen. **HELICHECK®** may be used in clinical diagnostic laboratory systems after the laboratory has validated their complete system as required by CLIA '88 regulations in the U.S. or equivalent regulations in other countries.

Ingredients:
The rapid urease test reagent contains:
- Water
- Urea
- Dye indicator
- Salts
- Agar

Cautions and warnings:
FOR *IN VITRO* DIAGNOSTIC USE.
- Use fresh samples for testing. Do not fix the samples with formaldehyde or other fixative agents.
- Always wear gloves when working with potential biohazard material.
- If spills of the contaminated material occur, disinfect with 2.5% hypochlorite solution.
- All contaminated material should be discarded according to biosafety rules.

General safety precautions:
- Always wear masks and gloves when working with potential biohazard material.
- Pathogenic microorganisms including Hepatitis B virus and Human Immunodeficiency Virus (HIV) may be present in specimens. Universal precautions should be followed in handling all items contaminated with blood or other body fluids.
- Tubes should be discarded in an appropriate manner.

Storage instructions:
Store at 2-8°C. Transportation that will take less than three days may be done at room temperature. Tubes should be placed into refrigerator immediately after receipt.

Indications of instability or deterioration:
Do not use **HELICHECK®** if the yellow color of the reagent (which is normal) has turned to purple.

List of materials provided:
20 **HELICHECK®** in cardboard box; package insert.

Instructions for use[2]:

Specimen collection:
The biopsy specimen (of a few mm size) obtained by endoscopy should be used directly by dipping it into the test reagent. Urease will be most active in fresh samples. If bedside application is not possible, for transportation, the biopsy specimen should be put into a small plastic or glass tube and the cap should be closed tightly in order to prevent drying. Specimens fixed by formaldehyde or other fixative agents for pathological examination are not suitable for evaluation with **HELICHECK®**.

Application:
1- Open the cap and submerge the sample into the test medium.
2- Replace the cap.
3- Place **HELICHECK®** to a warm place or into a 37°C incubator (if available).
4- Check frequently to observe the color change, from yellow to purple. This may occur in a few minutes if the amount of *H. pylori* is high. If there is no color change, keep the test for two hours at 37°C before evaluating the result as negative. Change of color from yellow to purple will indicate the presence of *H. pylori*.

HELICHECK®

Evaluation of the results:

Yellow: **Negative (-)** (No *H. pylori*)

Purple: **Positive (+)** (Presence of *H. pylori*)

The activity of urease can be observed much faster if HELICHECK® is incubated at 37°C (if a 37°C incubator is not available, incubation done at room temperature but putting HELICHECK® in a warm place will accelerate the result). The result should be accepted as negative if no color change is observed within 2 hours at 37°C.

Quality control:

The quality control of HELICHECK® is done by inoculating an urease-producing organism, *Proteus vulgaris* ATCC 13315 as positive control and an urease negative organism *Proteus mirabilis* ATCC 14153 as negative control. For this purpose a few colonies of bacteria from fresh culture plates are transferred into HELICHECK® reagent by the help of a wire-loop. The test tubes are incubated at 37°C. Positive control should turn purple within maximum 2 hours. Negative control should stay yellow.

Description of the amounts of reagents necessary, and the parameters of time and temperature:

The only reagents required are those included in the kit. The whole application procedure takes less than 1 minute after the biopsy specimen is obtained. The application is performed at room temperature. Although the test will work at room temperature, keeping the test tube at 37°C will speed up the result.

Time restrictions:

In order to conclude the result as negative, two hours of incubation is required after inoculation of the specimen.

Limitations of the procedure:

If the number of *H. pylori* is very low in the specimen tested, false negative results may be obtained if a 37°C incubator is not used.

Performance characteristics:

Compared to PCR, the sensitivity of HELICHECK® in identifying *Helicobacter pylori* in biopsy specimens was determined as 96% and the specificity 100%.[4]

Bibliography:

1- BE Dunn, H Cohen, and MJ Blaser. Helicobacter pylori. Clin. Microbiol. Rev. 1997 10: 720-741.

2- AP Lage, E Godfroid, A Fauconnier, A Burette, JP Butzler, A Bollen, and Y Glupczynski Diagnosis of Helicobacter pylori infection by PCR: comparison with other invasive techniques and detection of cagA gene in gastric biopsy specimens. J. Clin. Microbiol. 1995 33: 2752-2756.

3- P Lage, A Fauconnier, A Burette, Y Glupczynski, A Bollen, and E Godfroid. Rapid colorimetric hybridization assay for detecting amplified Helicobacter pylori DNA in gastric biopsy specimens. J. Clin. Microbiol. 1996 34: 530-533.

4- Y Akyön, T Kocagöz and I Unsal. Efficiency of a new urease test, in the detection of *Helicobacter pylori* in biopsy specimens. American Society for Microbiology, 98th General Meeting, Atlanta. 17-21 May 1998.

Manufacturer:

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