HELICHECK

RAPID UREASE TEST FOR DETECTION OF *HELICOBACTER PYLORI* BY LOOKING AT UREASE ACTIVITY IN BIOPSY SAMPLES

Catalog No:HP010 | Instruction for Use | For In Vitro Use Only

Product name:
HELICHECK

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.
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:
No microorganism causing urease positivity other than *H. pylori* has been found in stomach biopsies, but there is a possibility, although low.

Principles of the procedure:
Urease splits urea that is present in the test medium. This process creates a color change in the medium. The change of color 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. Since the color change varies proportionally depending on the amount of *H. pylori*, information about the density of microorganisms in the tissue is obtained.

Ingredients:
One tube 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. These agents will denature the urease enzyme and eliminate urease activity. Reliable results cannot be obtained from samples fixed in this way for pathological examination.

General safety precautions:
- Always wear masks and gloves when working with potential biohazard material.
- If spills of the contaminated material occur, disinfect with 2.5% hypochlorite solution.
- Tubes should be discarded in an appropriate manner according to biosafety principles.

Storage instructions:
Store at 2-8°C.

Indications of instability or deterioration:
Do not use ***HELICHECK*** if the normal yellow color of the reagent has turned purple.

Materials provided:
20 plastic tubes in cardboard box.

Necessary materials that are not provided:
- Endoscopy supplies

Time and temperature Parameters:
H. pylori urease works fastest at body temperature at 37ºC. Therefore, keeping ***HELICHECK*** with a biopsy sample in a warm environment, as with all other rapid urease tests, can speed up the results. If this is not possible, incubation can be done at room temperature, but placing the test tube in a warm area of the room can speed up the results. In cases where the amount of *H. pylori* is high, results can be obtained in a few minutes. In general, no change occurs in tubes that do not change color within the first 30 minutes. To detect very small amounts of urease activity, it can be waited up to one hour before giving the result as negative. If there is no opportunity for evaluation during this period, the test result can remain intact for at least 4 hours.

Application:
1. Open the top cover by turning it slightly and pulling it upwards.
2. Submerge the biopsy sample into the test medium and close the cap again.
3. Check frequently to observe the color change. Yellow to purple color change indicates the presence of *H. Pylori.* This may occur in a few minutes if the amount of *H. pylori* is high. In cases where the number of bacteria is very low, it may be necessary to wait up to an hour for the color change to occur. If no color change occurs, the result should be given as negative.

Evaluation of the results:
YELLOW: Negative (-) (No *H. pylori*)
PURPLE: Positive (+) (Presence of *H. pylori*)
The purple color just around the biopsy sample is enough to indicate the presence of *H. pylori*. There is no need to wait for the entire reagent to turn purple. The color change occurs proportionally depending on the amount of *H. pylori* and time. In this way, it is possible to comment on the density of *H. pylori* in the sample.

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 *Escherichia coli* ATCC 25922 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 a maximum of 2 hours. Negative control should stay yellow.

Limitations of the procedure:
With ***HELICHECK***, *H. pylori* can only be diagnosed with tissue samples taken by biopsy. Samples such as stool, serum or other body secretions are not suitable for this test. ***HELICHECK*** cannot be used for methods such as urea breath test.

Performance characteristics:
Compared to PCR, the sensitivity of ***HELICHECK*** in identifying *H. pylori* in biopsy specimens was determined as 96% and the specificity 100%.

Shelf life:
8 months.

Bibliography:

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Manufacturer:

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