ASAN Helicobacter Test®

Diagnostic Kit for Detection of *Helicobacter pylori*

Urease Test

1. EXPLANATION OF THE TEST

Helicobacter pylori has been shown to cause active chronic gastritis and implicated as a primary etiologic factor in duodenal ulcer disease. H. pylori produce large amounts of urease enzymes, and utilizes urea as a nitrogen source. If the urease of H. pylori is present in an inserted biopsy sample, the urease converts the urea to ammonia which raises the pH and changes the color of Test Kit. The ASAN Helicobacter Test Kit contains a pH indicator (chlorophenol red), an urea substrate for urease and buffers.

$$(NH_2)_2CO + 2H_2O + H^+ \xrightarrow{\text{Urease}} \underset{\text{Ammonium ion}}{2NH_4^+} + \underset{\text{Bicarbonate ion}}{HCO_3^-}$$

2. DESCRIPTION AND STORAGE

The ASAN Helicobacter Test should be stored at 2~8℃. Do not freeze. The kit is stable for 24 months at this storage temperature. After first opening the sealed label from the plastic slide, the kit should be used within 1 week.

"DO NOT USE BEYOND THE EXPIRATION DATE"

3. COMPOSITION

1) Test device containing acid agar and pH indicator
2) Instruction for use

4. PRECAUTIONS

1) For professional in vitro diagnostic use only.
2) **Do not use the test if the color is not a yellow, the test is past the expiration date.**
3) Read the instruction for use carefully prior to testing.
4) Used testing materials should be discarded according to local regulation

5. SPECIMEN COLLECTION AND PREPARATION

1) Patients should not take antibiotics or bismuth salts for at least 3weeks prior to endoscope. Suppression of H. pylori by these agents makes the organism difficult to detect by any means, and re-growth of H. pylori may be patchy, leading to false negative results in the first few weeks after treatment.
2) Wear protective gloves while handling specimens. Wash hands throughly afterwards.
3) Do not use test kit beyond expiration date, and mix sample collection tubes from different lots.
4) If the biopsy specimen appears to be very small, it may be worthwhile taking a second biopsy.
5) Carefully handle the biopsy sample, to prevent contamination. It may be effect to the test.
6) Biopsy an area of normal looking tissue rather than an area affected by erosions or ulceration.
7) The usual area of biopsy in the sump of the antrum, along the greater curve.

6. TEST PROCEDURE

1) Peel the label away from the plastic slide so that you can see the yellow gel. Do not remove the label.
2) With a sterile needle, take the biopsy sample from the biopsy forceps and push it into the yellow agar gel.
3) Reseal the test label by pressing the label back in the plastic slide, so that the gel is covered. The patient name, date and time should be named on the label.
4) After keeping the test warm for two hours (in place of 37℃), the slide is then kept at room temperature for a final reading.

7. INTERPRETATION OF THE TEST

The results can be read 10 minutes after the start of the test. After 2hour incubation, when the color of gel changes to red or violet, it is positive result, when the color of gel is kept in yellow, leave it at room temperature and read the final result at 24hours.

When biopsy sample is placed in the gel, if the color becomes red or violet within 24hours, it is positive, if the color kept in yellow after 24hours, it is negative.

A. POSITIVE RESULTS

The color of gel become red or violet it is positive within 24hours

B. NEGATIVE RESULTS

There is no color change of total gel from yellow within 24hours

※ CAUTION : Do not read the results after 24 hours, from the time that the sample was put in the gel.

ASAN PHARM. CO., LTD.

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C. FAIL SAFE TESTING for CLIA WAVER REQUIREMENTS

If the ASAN Helicobacter Test is still NEGATIVE at 24 hours, do the following test.

a) Put "Positive control"(Urease) into the gel.
b) Re-seal the label.
c) Wait 30 minutes.
d) Look at gel for positive color change(red or violet).
e) If the test does not turn to red or violet, contact ASAN Pharmaceutical company (+82-31-376-5990)

8. LIMITATION OF THE TEST

1) This test kit is to be used for the qualitative detection of H. pylori in biopsy samples.
2) False negative may occur when very low numbers of H. pylori are present, or has patchy distribution. As H. pylori do not colonize intestinal mucosa, a false negative test can result. There may be a case therefore for performing two tests, one from the antrum and the other from the body mucosa.
3) The ASAN Helicobater Test will be less sensitive if the patient has recently taken antibiotics of bismuth.
4) False positive could be occurred in patients who have achlorydria. For example, patients with pernicious anema, previous gastric surgery, or who have recently taken antiacid, or large dose of H2 receptor antagonista. When acid is absent, commensal organisma such as proteous spp, may grow in the stomach and produce urease.
   False positive reaction due to bacteria other than H. pylori will usually not react before two hours because these bacteria does not produce much more H. pylori.

9. PERFORMANCE CHARACTERISTICS

In a study of 232 patients with possible peptic ulcer disease, 155 demonstrated positive histological criteria (presence of H. pylori like organisms upon staining)for H. pylori gastritis and 77 patients did not demonstrate the criteria. ASAN Helicobacter Test agreed with the positive histological diagnosis in 137 cases and agreed with the negative diagnosis in 73 of the cases. This data provides a relative sensitivity of 88.39 % and a relative specificity of 94.80 %

	True +	False -
ASAN Helicobacter Test		
Positive	137	4
Negative	18	73

Histology Positive	155
Histology Negative	77
Sensitivity	88.39 %
Specificity	94.80 %

10. REFERENCES

1) Marshall BJ, McGechie DB, Rogers PAR, Glascy RG. Pyloric Campylobacter infection and gastroduodenal sisease. Med J Aust 1985; 149:439-444.
2) Marshall BJ, Warren JR, Francis GJ. Langton SR, Goodwin CS, Blincow E. Rapid urese test in the management If Campylobacter pyloridis-associated gastritis. Am J Gastroenterol 1987; 82(3): 200-210.
3) Genta RM, Graham DY, Comparison of biopsy sites for the histopathological diagnosis of Helicobacter pylori: a topographic study of H.pylori density and distribution. Gastrointestinal Endosc. 1994; 40(3): 342-345.

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Manufactured & Sold by
ASAN PHARM. CO., LTD.
163 Yeongcheon-ro, Hwaseong-si, Gyeonggi-do, 18462 Korea.

TEL : 82-31-376-5990
Fax : 82-31-376-5993
www.asanpharm.com