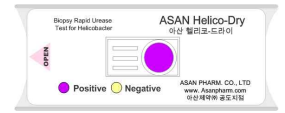
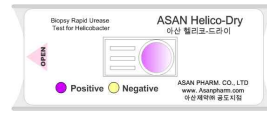


ASAN Helico-Dry Test

Low risk infectious disease immunity test



1. PACKAGE UNIT AND EXPIRY DATE

Refer to the external(packaging box), indications(EXP, LOT)

2. PACKAGE UNIT

In-house packing unit: Refer to external(packaging box) indication

Ingredients \ Packing	25 Test/Kit	50 Test/Kit
Test Device	1 Device × 25	1 Device × 50

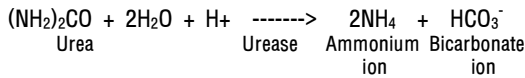
3. INTENDED USE

It is a medical device using the urease activation of Helicobacter pylori(hereinafter H.pylori) in biopsy tissue.

4. TEST PROCEDURE

(1) TEST PRINCIPLE

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

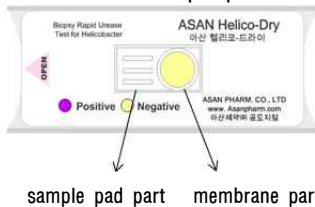


(2) SPECIMEN COLLECTION AND HANDLING

- 1) Collection of specimens takes about 2-3mm of tissue that appears to be normal on the antrum pylori.
- 2) When collecting specimens, try to avoid getting blood on the biopsy tissue as much as possible.

(3) TEST PROCEDURE

- 1) Peel off the sticker so that the sample pad area is visible.
- 2) Using a sterile needle, remove the biopsy tissue from the forcep and place it on the sample pad



- 3) Re-seal the sticker on the reagent back and rub or press on the sticker to ensure that the biopsy tissue is in contact with the sample pad.
- 4) Record the patient name, date, and time on the label.
- 5) Leave it at room temperature(25-40°C) for 1hour and interpret test result..

(4) INTERPRETATION OF RESULTS

The result can be read 10minutes after the start of the test and inspected the color of gel change yellow to purple at 1hour intervals, the result is positive or negative.

*Reading a result up to 1hour, more than 90% is positive result.

- 1) **NEGATIVE RESULTS** : After the start of the test, there is no color change of total gel from the yellow within 2hours. It is negative result.



- 2) **POSITIVE RESULTS** : After test start of the test, the color of gel become red or violet within 2hours. It is positive result.

※ CAUTION FOR READING

- 1) If blood is present on the biopsy tissue, the reaction may be slightly positive due to the pH of the blood itself. In this case, it cannot be determined as positive, and care should be taken to avoid getting blood when collecting biopsy tissue.
- 2) If there is a large amount of H.Pylori in the biopsy tissue, the positive result may be faster, but the reaction time may be delayed if the biopsy tissue is small or there are not many bacteria.
If the color change immediately after the reaction starts, it is highly likely to be positive and interpret positive result. However, if the color does not change after 1 hour, the result is read by 2 hours and decide final interpretation.
- 3) If the result of this test is positive, it is likely to be positive because the symptoms of digestive diseases are first identified through endoscopy. However, an accurate diagnosis should be combined with other results, such as histological examination, culture, histology, and patient symptoms.

5. STORAGE & EXPIRATION

Store at 1~30°C in airtight container, 24month from the date of manufacture.

6. PRECAUTION AND DISPOSAL

- (1) This product is medical device, For in-vitro diagnostic use only
- (2) Patients should not take bismuth or antibiotics for at least three weeks before the test. These reagents can inhibit H.Pylori's urease secretion, which can result in false negatives for weeks after taking.
- (3) If the biopsy tissue is too small, it may affect the reaction time, so retake it for testing and take care that the collected biopsy tissue is not contaminated with blood at the biopsy site.
- (4) Collect the biopsy from the antrum pylori, test should be performed using fresh biopsy tissue after collection.
- (5) If epithelial cells break down or get eroded, H.Pylori may be present in trace amounts. biopsy tissue should be taken from areas that appear to be normal.
- (6) Samples may be contaminated with unknown microorganisms and viruses, so be careful when handling them.
- (7) Wear protective gloves while handling samples and wash hands thoroughly after the assay is complete.
- (8) Solid waste used in the inspection must be sterilized by auto-clave at 121°C for at least 1 hour.
- (9) Do not use if the expiration date has passed or if the color of the reagent before use is not yellow.
- (10) Do not reuse this product as it is disposable.

7. COMPONENT

One of the test device

Urea -----	1 ± 0.2mg
chlorophenol red -----	0.12 ± 0.02mg
Tris -----	Suitable amount
potassium chloride -----	Suitable amount
sodium acetate -----	Suitable amount
ethyl alcohol -----	Suitable amount
Membrane(Nitrocellulose pad) -----	9.8 ± 2.0 X 9.7 ± 1.9 mm
Plastic card -----	13.0 ± 2.6 X 9.7 ± 1.9 mm
Sample pad -----	9.3 ± 1.9 X 9.7 ± 1.9 mm
Plastic cassette -----	1unit

8. FEATURE

- (1) H.Pylori rapid diagnostic test by urease activity.
- (2) It is a very simple test performing by putting the sample in the reaction pad.
- (3) The test can be performed immediately at the endoscope site.
- (4) It is economical because it is packaged individually and used one by one