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CE

"See Now" H.Pylori. Antigen in human stool -cassette test

For in vitro Diagnosis Use
Product Code: SN 2.2'

INTRODUCTION

The *"See Now"* H. pylori Antigen Test Card is an *in vitro* qualitative immunochromatographic assay for the rapid detection of *Helicobacter pylori* antigens in human stool specimen. The test results are intended to aid in the diagnosis of *H. pylori* infection, to monitor the effectiveness of therapeutic treatment and to confirm the eradication of *H. pylori* in peptic ulcer patients.

PRINCIPLE

The*"See Now"* H.Pylori Antigen Test is a sandwich solid phase immunochromatographic assay. To perform the test, an aliquot of diluted stool sample is added to the sample well of the test cassette. The sample flows through a label pad containing H. pylori antibody coupled to red-colored colloidal gold. If the sample contains H. pylori antigens, the antigen will bind to the antibody coated on the colloidal gold particles to form antigen-antibody-gold complexes. These complexes move on the nitrocellulose membrane by capillary action toward the test line region on which H. pylori specific antibodies are immobilized. As the complexes reach the test line, they will bind to the antibody on the membrane in the form of a line. A second red control line will always appear in the result window to indicate that the test has been correctly performed and the test device functions properly. If H. pylori antigen is not present or lower than the detection limit of the test, only the control line will be visible.

A color band will always appear in the control region (C). This control band serves as a procedural indicator that: 1) verification that sufficient volume has been added, 2) verification that proper flow is obtained and 3) reagent control.

Materials Provided

1.Test kit; 2. Sample bottle: each sample bottle contains 1 ml of stool specimen collection buffer. Store at 4-30^{0}C

SPECIMEN COLLECTION AND STORAGE

Stool specimens should be collected in containers that do not contain media, preservatives, animal serum or detergents as any of these additives may interfere with the Rapid H. pylori Antigen Test. Specimens may be stored at 2-8^{0}C for 3 days without interfering with the assay performance. For long-term storage of specimens, -20^{0}C or colder is recommended. Repeated freezing and thawing of specimens is not recommended and may cause erroneous results. Do not store specimens in self-defrosting freezers.

TEST PROCEDURE

1. When you are ready to begin testing, open the sealed pouch by tearing along the notch. Remove the test device from the pouch and use it as soon as possible.
2. Sample dispensing:
   Hold the sample bottle upright with the tip point toward the direction away from the test performer, snap off the tip.
   Hold the bottle in a vertical position over the sample well of the test card, deliver 3 drops (120 -150 µL) of diluted stool sample to the sample well.
3. Wait for 10 – 15 minutes and read results. It is important that the background is clear before the result is read. Do not read results after 15 minutes.

INTERPRETATION OF RESULTS

- Negative: Only one colored band appears on the control (C) region. No apparent band on the test (T) region.
- Positive: In addition to a pink colored control (C) band, a distinct pink colored band will appear in the test (T) region.
- Invalid: A total absence of color in both regions or no colored line appears in the control (C) region is an indication of procedure error and/or test reagent deterioration. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS

1. The test is for qualitative detection of H.pylori antigen in stool sample and dose not indicate the quantity of the antigens.
2. The test is for *in vitro* diagnostic use only.
3. The test result should be used only to evaluate with patient with signs and symptoms of gastrointestinal disease. A definitive clinical diagnosis should only be made by the physician after all clinical and laboratory finding have been evaluated

STORAGE AND STABILITY

The test kit can be stored at temperatures between 15 to 25ºC in the sealed pouch to the date of expiration. The test kit should be kept away from direct sunlight, moisture and heat.

PRECAUTION

1. For in vitro diagnostic use only.
2. Do not use test kit beyond expiry date.
3. The test device should not be reused.
4. The above interpreting time is based on reading the test results at room temperature of 15 to 25 ºC. If your room temperature is significantly lower than 15 ºC, then the interpreting time should be properly increased.
5. The instructions for use and reading of the test must be followed exactly in order for the test to perform properly.

Sensitivity and Specificity

Rapid Helicobacter pylori Antigen Test Card was evaluated on 170 adults. The test results were compared to diagnosis of *H. pylori* infection by reference tests, urease breath test and histology tests. Patients were considered positive if both rapid urease and histology tests were positive. Patients with both negative urease breath test and histology tests were considered negative. Among fifty (50) positive samples and one hundred and twenty (120) negative samples, Rapid H.pylori Antigen Test showed 94.0% clinical sensitivity and 96.7% specificity. The accuracy is 97.5%.

	Reference Test		
Rapid H.Pylori Antigen Test		Positive	Negative
	Positive	47	4
	Negative	3	116

Sensitivity = 94.0% (47/50)
Specificity = 96.7% (116/120)
Accuracy = 95.9% (163/170)

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