IVD

Asan Easy Test® H.pylori Ag

ASAN

Diagnostic kit for Helicobacter pylori Antigen

Immunochromatography

INTENDED USE

The Asan Easy Test® H. pylori Ag is a qualitative test for visual detection of H. pylori (Helicobacter pylori) Ag in human stool. It is intended for health care professional use as an aid on the diagnosis of H. pylori.

EXPLANATION OF THE TEST

The Asan Easy Test® H. pylori Ag employs a solid phase chromatographic immunoassay technology to qualitatively detect H. pylori Ag in human stool. For diagnosis H. pylori Ag in human stool, specific monoclonal antibodies against H. pylori antigen was used as a capture materials. The test contains the membrane pre-coated with specific monoclonal antibodies against H. pylori antigen on the test line region. During test, the sample is allowed to react with specific monoclonal antibodies against H. pylori antigen conjugated with colloid gold, which has been pre-dried on the conjugate pad between membrane and sample pad. The mixture then moves upward on the membrane by capillary action. For positive result, a visible line with high sensitivity and specificity as forming Ag-Ab-Gold complex appears in the test band region(T) of the membrane. Regardless of the presence of H. pylori Ag, the mixture continuously moves across the membrane to predried control line. The control band region(C) will always appear and verify proper performance of the test.

MATERIALS PROVIDED

Asan Easy Test® H. pylori Ag contains following items to perform the assay.

1. Test device in aluminium pouch with a desiccant.
2. Sample collection tubes with assay buffer.
3. Instructions manual for use.

PRECAUTIONS

1. For *in-vitro* diagnostic use only
2. The test kit should remain in the sealed pouch until ready for use.
3. The test kit is sensitive to humidity and to heat.
4. Do not smoke, eat or drink in areas where specimens or kit component are handled.
5. All specimens and reagents should be considered potentially hazardous and handled in the same manner as an infection agent.
6. Wear protective gloves while handling samples and wash hands thoroughly after the assay is complete.
7. Avoid any contact with the eyes, broken skin or mucous membranes.
8. The test device and all materials should be discarded in a proper biohazard container after testing.

SPECIMEN COLLECTION AND STORAGE

1. Specimens should be obtained and handled by specialist in accordance with standard feces collection method.
2. The test should be performed using fresh human feces.
3. Specimens must be tested as soon as they are collected. If necessary, they may be stored at 2~8℃ for up to 48hours or at -20 for longer periods.
4. Fecal specimen in the assay buffer are stable for up to 3 days at room temperature or at 2~8℃ for longer periods.

TEST PROCEDURE

1. All materials should be equilibrated to room temperature before performing the test.
2. Remove the test device from its protective pouch.
4. Take a portion of stool from inside and surface of specimens at 5~6 different sites thoroughtly.
5. Unscrew a cap.
6. Insert the swab with specimen into the sample collection tube and swirl the swab at least 10times.
7. Discard the swab squeezing against the wall of the tube.
8. Shake the sample collection tube thoroughly to mix with specimen and assay buffer.
9. Unscrew another cap on the top of sample collection tube and discard 1~2 drops of buffer.
10. Hold the collection tube vertically and dispense 2drops (about 100㎕) of buffer into sample well(S) of the test device.
11. Interpret test results at 10~15 minutes. Do not interpret after 15 minutes.

(**NOTE**: The above interpretation time is based on reading test results at room temperature (15~30℃). If your room temperature is significantly lower than 15 ℃ , the interpretation time may be increased. A low H. pylori antigen concentration might result in a weak line appearing in the test region (T) after an extended period of time; therefore, do not interpret the result after 15 minutes)

INTERPRETATION OF THE TEST

A. NEGATIVE RESULTS:

The presence of only one purple color band ("C" band) within the window indicates a negative result.

B. POSITIVE RESULTS:

The presence of two color bands ("T" band and "C" band) within the result window regardless of which band appears first indicates a positive result.

C. INVALID RESULTS:

If No band is visible within the window after performing the test, the result is considered invalid. Some causes of invalid results are: not following the directions correctly or the test may have deteriorated beyond the expiration date. It is recommended that the specimen be re-tested using a new test kit.

LIMITATIONS OF THE TEST

1. Other clinically available tests are required if questionable results are obtained. As all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but be made by the physician after all clinical and laboratory findings have been evaluated.
2. Antibiotics, PPI (proton pump inhibitors) and bismuth preparations inhibit H. pylori. Negative test results obtained during or shortly after a therapy might be false negative.
3. For accurate diagnosis of follow-up, It is recommend to perform at least 4weeks after eradication therapy.

STORAGE & EXPIRATION

1. Asan Easy Test® H.pylori Ag should be stored at 2 to 30℃ (35.6-86 °F).
2. Expiration date of this kit is 24 months after its manufacture date.

PERFORMANCE CHARACTERISTICS

A. ACCURACY

A clinical evaluation was conducted comparing the results obtained using the Asan Easy Test® H. pylori Ag to another commercially available EIA test kit. The study included 272 fecal specimens. The result shows that the Asan Easy Test® H. pylori Ag test is very accurate to commercial EIA test kit.

n=272		Reference Method (EIA)		Total
		Positive	Negative	
Asan Easy Test® H.pylori Ag	Positive	111	0	111
	Negative	5	156	161
Total		116	156	272

※ Relative sensitivity : 96%, Relative specificity : 96.9%, Accuracy : 98.2%
※ Detection limit : 8ng/ml

B. CROSS-REACTIVITY

To determine the cross-reactivity of the Asan EasyTest® H. pylori Ag, 12 pathogenic microorganisms were tested. All of following microorganisms were negative when tested at concentrations to 1×10^8 CFU/ml.

Microorganisms	Concentration (CFU/ml)
Shigella sonnei	1.0×10^8
Salmonella typhi	
Salmonella paratyphi	
Salmonella typhimurium	
Salmonella enteritidis	
Salmonella schottmuelleri	
Escherichia coli	
Klebsiella pneumoniae	
Yersinia enterocolitica	
Clostridium difficile	
Clostridium perfringens	
Vibrio parahaemolyticus	

BIBLIOGRAPHY

1. Accuracy of the stool antigen test in the diagnosis of Helicobacter pylori infection before treatment and in patients on omeprazole therapy. G.Manes, A.Balzano, G.Iaquonto, et al. Aliment Pharmacol Ther 2001;15;73-79.
2. Evaluation of two enzyme immunoassays for detecting Helicobacter pylori in stool specimens of dyspeptic patients after eradication therapy. Y.Erzin, S.Altun, A.Dobrucali, M.Aslan, S.Erdamar, A.Dirican and B.Kocazeybek. Journal of Medical Microbiology 2005;54;863-866.
3. Review : Current Role of Helicobacter pylori Stool Tests. Frank Serge Lehmann, Christoph Beglinger. Digestion 2003;68:119-123.
4. Evaluation of a Monoclonal Antibody-based tests for Detection of Helicobacter pylori-Specific Antigen in Stool Samples from Mice. Julia Crone, Erin Symonds, Fiona Campbell, and Ross Butler. Clinical And Diagnostic Laboratory Immunology. 2004;11;799-800.

ASAN

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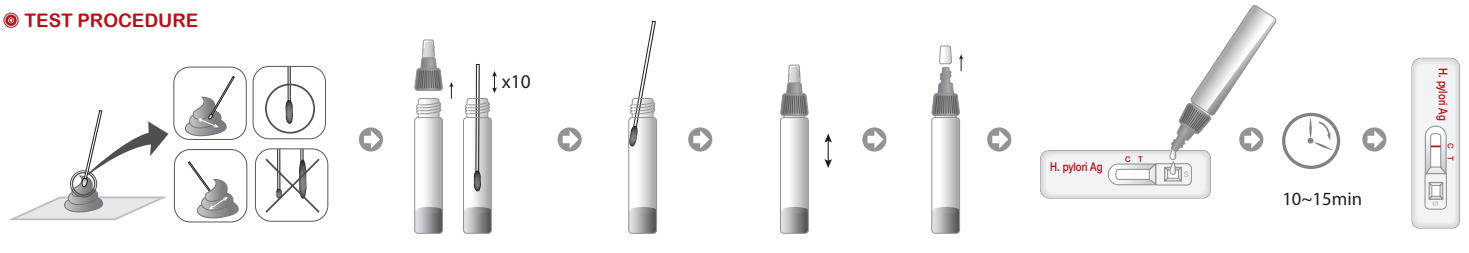
TEST PROCEDURE



Take a portion of stool

Insert the swab into the tube and swirl the swab at least 10times

Discard the swab squeezing against the wall of the tube

Shake well

Unscrew another cap and discard 1~2drops of buffer

Dispense 1~2drops

Reading