**One Step *H.pylori* Antigen Rapid Test in Human fecal specimen**

# SD BIO LINE H.pylori Ag

## Explanation of the test

**[Introduction]** *Helicobacter pylori* is a spiral shaped bacterium that lives in the stomach and duodenum. *H. pylori* is a newly discovered stomach infection, which was first reported by Barry Marshall and Robin Warren of Perth, Western Australia, in 1983. The new bacterium lives in the stomach of about half the people in the world. Many are apparently well, but all have an inflammation of the stomach lining, a condition which is called "gastritis". Gastritis is the underlying condition which causes ulcers, and other digestive complaints, possibly including cancer of the stomach. In fact, it is now clear that *H. pylori* is the principle etiologic agent in type B gastritis (chronic active antral gastritis) pathology for which it appears to be the triggering and perhaps aggravating factor. Increasing data are being accumulated regarding the fundamental role of *H. pylori* in active chronic gastritis, in gastric ulcer and in duodenal ulcer and its close correlation with gastric lesions. *H. pylori* is isolated in culture medium and examined by microscopy after staining or is detected by urease test. Both these techniques are lengthy to implement and their sensitivity and specificity have yet to be demonstrated. The immunochromatographic techniques (rapid) for the detection of *H. pylori* antigen has substantially resolved these problems, ensuring a serological monitoring in a very short space of time using simple, highly specific technology without recourse to invasive techniques. The fecal test for *H. pylori* antigen can be utilized as a rapid screening process for large populations of patients and highly indicated in the early diagnosis of *H. pylori* infection as the immune response can often precede clinical manifestations of disease. From a diagnostic point of view, a high level of *H. pylori* antigen must be interpreted as an indication of type B asymptomatic gastritis.

**[Principle]** The SD BIOLINE H.pylori Ag Rapid test kit result window has 2 pre-coated lines, "T" (H.pylori Ag Test Line) and "C" (Control Line). Both the Test Line and the Control Line in result window are not visible before applying any samples. The Control Line is used for procedural control and should always appear if the test procedure is performed correctly. The SD BIOLINE H.pylori Ag Rapid test kit can identify Helicobacter pylori antigen in human fecal specimen with a high degree of sensitivity and specificity.

**[Intended Use]** The SD BIOLINE H.pylori Ag Rapid test it is a rapid test for the qualitative detection of *Helicobacter pylori* antigen in human fecal specimen. This test kit is intended as an aid in the diagnosis of *H. pylori* infection in patients with gastrointestinal symptoms.

## Materials provided

1. SD BIOLINE H.pylori Ag kit contains the following items to perform the assay.
   - Test devices individually foil pouched with a desiccant
   - Assay diluent (25 ml/ vial)
   - Sample collection tube
   - Sample collection swab
   - Disposable dropper
   - Disposable dropping cap
   - Instruction for use
2. Active ingredients of main components
   - 1 test device included; Gold conjugates (as main component) : Mouse monoclonal anti-*Helicobacter pylori* -gold conjugate (0.12±0.024㎍), Test Line (as main component) : Mouse monoclonal anti-*Helicobacter pylori* (0.64±0.128㎍), Control Line (as main component) : Goat anti-mouse IgG (0.64±0.128㎍)
   - Assay buffer included ; Phosphate buffer (20mM), Bovine serum albumin (1%), Sodium azide (0.01%), Sodium chloride (0.1M), Tween 20 (0.1%)

## Kit storage and stability

1. The SD BIOLINE H.pylori Ag test kit should be stored at 1~30℃.
2. The test device is sensitive to humidity as well as to heat.
3. Perform the test immediately after removing the test device from the foil pouch.
4. Do not use it beyond the expiration.
5. Do not store at refrigerator. Do not freeze.
6. The shelf-life of the kit is as indicated on the outer package.

## Specimen collection, Preparation, Storage and Precaution

1. Sample collection and Preparation
   - To take a portion of feces (about 50mg), insert the sterile swab into a stool sample that presents the most secretion under visual inspection.
   - Insert the swab into the sample collection tube containing assay diluent.
   - Swirl the swab at least 10 times until the sample has been dissolved into the assay diluent and discard the swab while squeezing the swab against the wall of tube, replace the cap.
   - Specimen extracted in assay diluent may be stored at 2 ~ 8℃ for up to 1 week prior to testing.
2. Specimen transport and storage
   - Specimen should be tested as soon as possible after collection. Do not use any kind of transport media to store or transport specimens
   - Faecal sample may be stored refrigerated (2 ~ 8℃) for 72 hours. If longer storage is required, freezing at -20℃ is recommended.
3. Precaution
   - Faecal specimens for direct test should be collected into containers that do not contain media, preservatives, as all of these additives may interfere with SD BIOLINE H.pylori Ag test.

## Warnings & Precautions

1. Precautions
   - SD BIOLINE H.pylori Ag test should be stored at room temperature.
   - The test device is sensitive to humidity as well as to heat.
   - Perform the test immediately after removing the test device from the foil pouch.
   - Do not use the test kit if the pouch is damaged or the seal is broken.
2. Warnings
   - For in vitro diagnostic use only. Do Not Re-use test device.
   - The instruction must be followed exactly to get accurate results. Anyone performing an assay with this product must be trained in its use and must be experienced in laboratory procedures.
   - Do not eat or smoke while handling specimens.
   - Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
   - Avoid splashing or aerosol formation.
   - Clean up spills thoroughly using an appropriate disinfectant.
   - Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
   - Do not mix and interchange different specimen.
   - Care should be taken to avoid contamination of the end of sample collection tube when dropping assay diluent into sample well.
   - SD BIOLINE H.pylori Ag assay diluent contains a proprietary anti-microbial agent which presents no hazard to the user if normal laboratory safety precautions are followed.

## Procedure of the Test (Refer to figure)

[Extraction Procedure : preparation of extracted sample]

1. Allow test device and extracted sample to room temperature prior to testing.
2. Take assay diluent up to the Fill Line as shown in Figure. And then, transfer into the sample collection tube.
3. Repeat 2)
4. Take a portion of feces(about 50mg) from a stool sample with the sample collection swab.
5. Insert the swab into the sample collection tube containing assay diluent.
6. Swirl the swab at least 10 times until the sample has been dissolved into the assay diluent and discard the swab while squeezing the swab against the wall of tube.
7. Leave to settle the tube for 5 minutes.
8. Assemble dropping cap on the sample collection tube.

[Test Procedure]

1. Remove the test device from the foil pouch, and place it on a flat, dry surface.
2. Add 3 drops (about 100㎕) into the sample well (s) of the test device.
3. As the test begins to work, you will see purple color move across the result window in the center of the test device.
4. Interpret test results at 10~15 minutes. Do not interpret test result after 15 minutes.

## Interpretation of the test

1. A color band will appear in the left section of the result window to show that the test is working properly. This band is the Control Band.
2. The right section of the result window indicates the test results. If another color band appears in the right section of the result window, this band is the Test Band.
   **Negative Result :** The presence of only control band (C) within the result window indicates a negative result.
   **Positive Result :** The presence of two color bands as test band (T) and control band (C) within the result window, no matter which band appears first, indicates a positive result.
   **Invalid Result :** If the control band (C) is not visible within the result window after performing the test, the result is considered invalid. Some causes of invalid results are because of 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.

## Limitation of the test

1. The test is for qualitative detection of *H. pylori* antigen in stool sample and dose not indicate the quantity of the antigens.
2. A negative result does not preclude the possibility of infection with *H. pylori*. Other clinically available tests are required if questionable results are obtained.
3. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
4. The test procedure, precautions and interpretation of results for this test must be followed when testing.

## Internal Quality Control

The SD BIOLINE H.pylori Ag test device has "Test Line" and "Control Line" on the surface of the cassette. Both the Test Line and Control Line in result window are not visible before applying any samples. The Control Line is used for procedural control. Control line should always appear if the test procedure is performed properly and the test reagents of control line are working.

## Performance Characteristics

The performance of SD BIOLINE H.pylori Ag was confirmed by Respiratory test and CLO test. The results are summarized in the following table.

| Used methods for detection of H.pylori antigen and results | | | | |
|---|---|---|---|---|
| **Confirmed by Respiratory test & CLO test** | **Standard Diagnostics, INC. H.pylori Ag Rapid** | | **Commercial H.pylori Ag Rapid test kit** | |
| | **POS** | **NEG** | **POS** | **NEG** |
| POS. 61 specimens | 61 | 0 | 61 | 0 |
| Sensitivity | 61/61 x 100 = 100% | | 61/61 x 100 = 100% | |
| NEG. 90 specimens | 0 | 90 | 2 | 88 |
| Specificity | 90/90 x 100 = 100% | | 88/90 x 100 = 97.8% | |

## Bibliography of suggested reading


1. Marshall B.J. et al. Pyloric Campylobacter infection and gastroduodenal disease. Med. J. Aust. 142 : 439-444 (1985).
2. Lambert, J.r., Lin, S.K. and Aranda-Michel, J. *Helicobacter pylori*, Scand. J. *Gastroenterol*. 30 suppl 208 : 33-46 (1995).
3. Evans, D.J., Evans, D.G., Graham, D.Y. and Klein, P.D.A sensitive and specific serologic test for detection of *Campylobacter pylori* infection. *Gastroenterology*. 96 : 1004-1008 (1989).
4. Applicability of a monoclonal antibody-based stool antigen test to evaluate the results of Helicobacter pylori eradication therapy. Shimoyama T, Kato C, Kodama M, Kobayashi I, Fukuda Y. Jpn J Infect Dis. 2009 May;62 (3):225-7.
5. Analysis of Helicobacter pylori isolates from Chile: occurrence of selective type 1 Lewis b antigen expression in lipopolysaccharide. Altman E, Fernández H, Chandan V, Harrison BA, Schuster MW, Rademacher LO, Toledo C. J Med Microbiol. 2008 May;57(Pt 5):585-91.
6. Evaluation of a rapid new stool antigen test for diagnosis of Helicobacter pylori infection in adult patients. Krausse R, Müller G, Doniec M. J Clin Microbiol. 2008 Jun;46(6):2062-5. Epub 2008 Apr 2.



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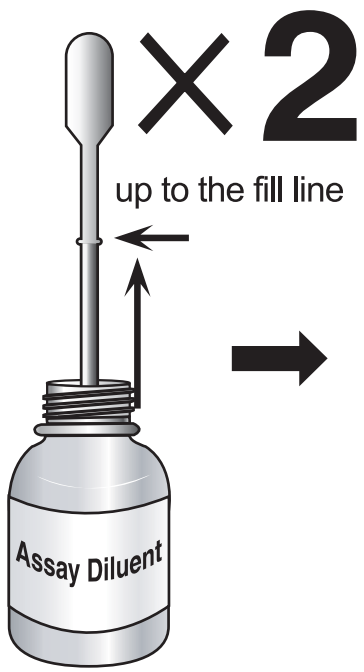
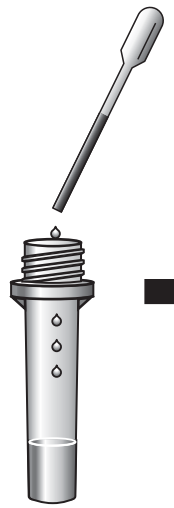
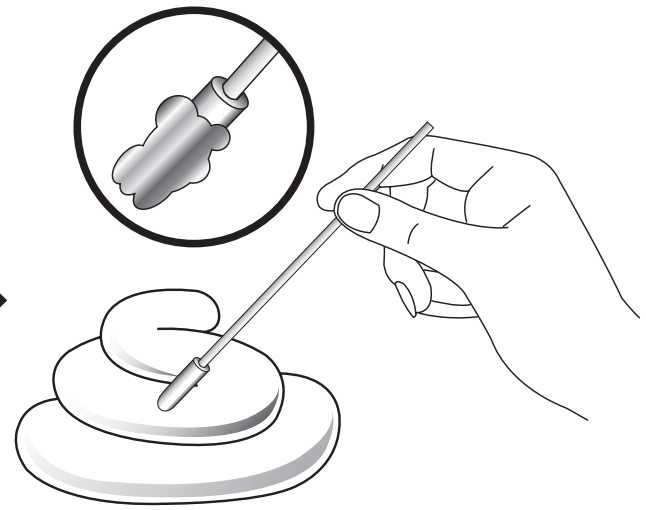
# SD BIOLINE H.pylori Ag Rapid Test Procedure

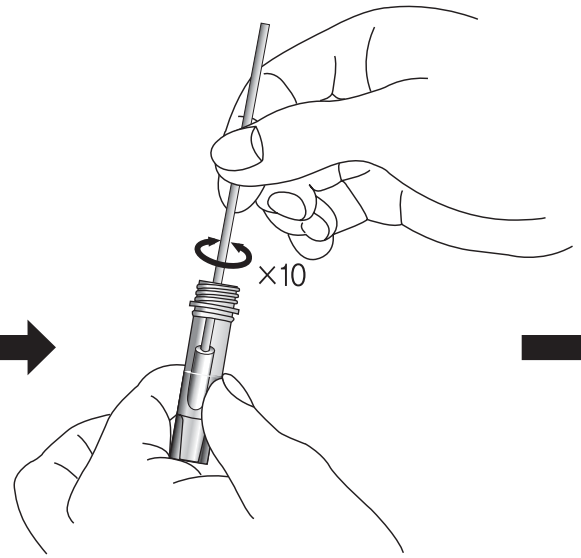



Transfer assay diluent twice.

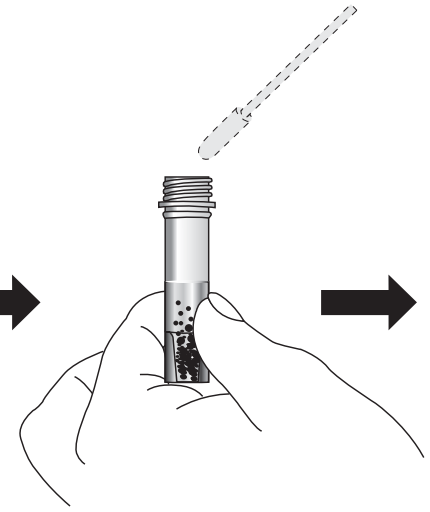




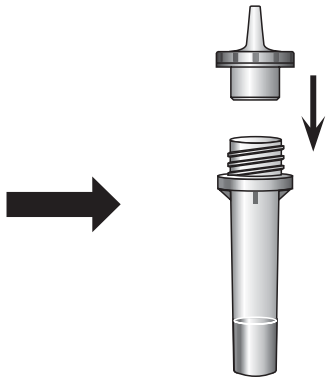
Take a portion of feces (about 50mg) from a stool sample.



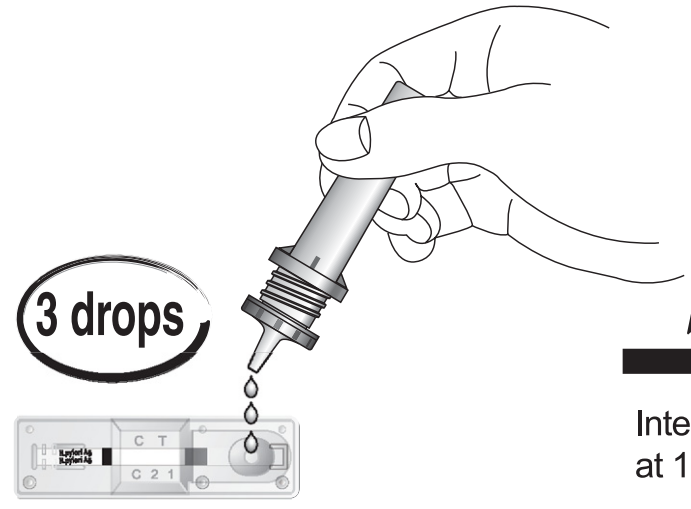

Insert the swab into the sample collection tube and swirl the swab at least 10 times.



Discard the swab while squeezing the swab against the wall of tube. And leave to settle the tube for 5 minutes.



Assemble dropping cap on the sample collection tube.

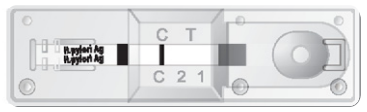



Add 3 drops (about 100㎕) into the sample well (S) of test device.

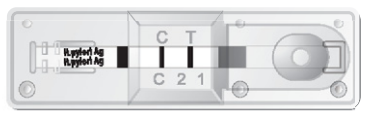

Interpret test results at 10~15 minutes.

## Interpretation of the test

Negative




Positive




Invalid