mö-screen H. Pylori Antigen Test Disk
For Stool/Fecal Specimen
(Revised 2016-09-27)

INTENDED USE
The mö-screen H. Pylori Ag Test is a simple one step immunochromatographic assay for the rapid, qualitative detection of Helicobacter Pylori antigen in human stool. The mö-screen H. Pylori Ag Test is intended for professional use as an aid in the diagnosis of H. Pylori infections and for verification of successful eradication therapy at least 4 to 5 weeks after the completion of the therapy.

EXPLANATION OF THE TEST
H. Pylori infections are implicated in a variety of gastrointestinal diseases, including duodenal and gastric ulcer, non-ulcer dyspepsia and active and chronic gastritis. Recent studies also suggest an association of H. Pylori infection with stomach cancer; the role of H. pylori and the factors involved in the development of these diseases are still under investigation.

The mö-screen H. Pylori test cassette has a letter "T" and "C" as "Test Line" and "Control Line" on the surface of the case. Both the "Test Line" and "Control Line" in the result window are not visible before applying any samples. The "Control Line" is used for procedural control. The "Control Line" should always appear if the test procedure is performed properly and the test reagents of the control line are working properly. A purple "Test Line" will be visible in the Result Window if there are sufficient H. Pylori Antigen in the sample. If no H. Pylori antigen are not detected in the sample, no color appears in the "Test Line".

MATERIALS PROVIDED
The mö-screen H. Pylori Ag test kit contains the following items to perform the assay;
1. H. Pylori Ag test cassette.
2. Disposable sample collection dropper.
3. Collection Device
4. Instructions for use.

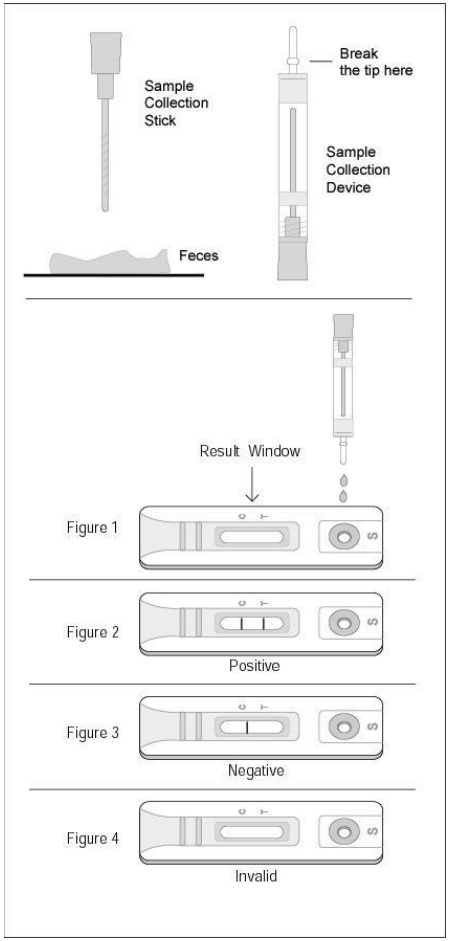
PRECAUTIONS
The mö-screen H. Pylori Ag test devices should be stored at room temperature 4-30ºC (40-86ºF). The test device is sensitive to humidity as well as to heat. Perform the test immediately after removing the test device from the foil pouch. Do not use it beyond the expiration.

WARNINGS
1. For in vitro diagnostic use only.
2. Do not eat or smoke while handling specimens.
3. Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
4. Avoid splashing or aerosol formation.
5. Clean up spills thoroughly using an appropriate disinfectant.
6. Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
7. Do not use the test kit if the pouch is damaged or the seal is broken.

SPECIMEN COLLECTION AND STORAGE

A) Formed/Solid Stool:
1) Uncap the collection device as shown in Figure 1A.
2) Use the collection stick attached to the cap of the collection device to collect stool, at least 3 different sites of stool should be stabbed with the collection stick. (Figure 2A)
3) Replace the cap with stick in the collection device (Figure 3A)
4) Thoroughly mix the stool with the buffer inside the collection device (Figure 4A)
5) Either use a Vortex for 15 seconds or vigorously shake the collection device for at least 30 seconds just prior to testing (Figure 4A)

B) Liquid or Semi-Solid Stool:
1) Use the provided collection dropper to draw stool (Figure 1B).
2) Uncap the collection device, and expel the 5 to 6 drops of the collected stool in to the collection device (Figure 2B)
3) Either use a Vortex for 15 seconds or vigorously shake the collection device for at least 30 seconds just prior to testing (Figure 3B and 4B)



PROCEDURE OF THE TEST
1. Remove the test disk from the foil pouch, and place it on a flat, dry surface.
2. Break the top off the collection device (Figure 5)
3. Invert and holding the collection device above the test disk (Figure 6) and add 2 to 3 hanging drop to the sample well of the test. As the test begins to work, you will see purple color move across the Result Window in the center of the test disk.
4. Interpret test results at 10 minutes. Do not read result after 20 minutes.

Caution: The above interpretation time is based on reading the test results at room temperature of 15 to 30 ºC. If your room temperature is significantly lower than 15 ºC, then the interpretation time should be properly increased.

INTERPRETATION OF THE TEST
1. As the test kit begins to work, a color band will appear at the left section of the Result Window to show that the test is working properly. This band is the "Control Line."
2. The right section of the Result Window indicates the test results. If another color band appears at the right section of the result window, this band is the "Test Line."

POSITIVE RESULT: TWO COLOR BANDS
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 (Figure 7). Note: Generally, the higher the analyte level in the specimen, the stronger the "T" band color will be. When the specimen analyte level is close to but still within the sensitivity limit of the test, the color of the "T" band will be very faint.

NEGATIVE RESULT: ONE COLOR BAND
The presence of only one purple color band within the result window indicates a negative result (Figure8).

INVALID RESULT
If after performing the test no purple color band is visible within the Result Window, the result is considered invalid (Figure 9). Some causes of invalid results: not following the directions correctly or the test is beyond the expiration date. It is recommended that the specimen be re-tested using a new test kit.

Note: A positive result will not change once it has been established at 10 minutes. However, in order to prevent any incorrect results, the test should not be interpreted after 20 minutes.

LIMITATIONS OF THE TEST
The content of this kit is for the use in the qualitative detection of H. Pylori antigen.

1) The sensitivity of the test is dependent on the proper collection of the stool specimen; 2) Antimicrobials, proton pump inhibitors and bismuth preparations are known to suppress H.Pylori activities and may cause false-negative results, in such cases, new stool specimen should be obtained for testing 2 weeks after these compounds are last ingested.
3) Specimen consists of mostly watery stool with no or little solid matters may cause false negative.

Although the test is very accurate in detecting antibodies to H. Pylori antigen, a low incidence of false results can occur. Other clinically available tests are required if questionable results are obtained. 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.

SPECIFICITY AND INTERFERENCE STUDY

An in-house study is conducted with 3 separate lots of the mö-screen Step H. Pylori-Ag Test to determine the Specificity of mö-screen H. Pylori-Ag test. Compounds tested include: Specimen with triglyceride concentrations up to 500 mg/ml, Bilirubin concentrations up to 10 mg/100ml, Hemolyzed specimens with hemoglobin concentrations up to 10 mg/ml, Prostatic acid phosphatase with concentrations up to 1000 mIU/ml and Albumin with concentrations up to 20 mg/ml. All of the above were analyzed and did not show interference or cross reactivity with the test.

REFERENCES

1. Warren, J.R. and B. Marshall, Unidentified curved bacillus on gastric epithelium in active chronic gastritis Lancet 1983;1-137.
2. Peterson WL. Helicobacter pylori and peptic ulcer disease. N Engl J Med 1991; 324:1043-1047.
3. Mcguigan JE., Peptic ulcer and gastritis. In Harrison's Principles of Internal Medicine, 12th Edition, 1988, Chapter 238,1229-1248.
4. Podolsky I, Lee E, Cohen K, Paterson, WL. Prevalence of C. Pylori in healthy subjects and patients with peptic diseases. Gastroenterology 1989: Suppl:A394.abstract.
5. Graham DY, Klein PD, Evans DJ et al., Campylobacter pylori detected non-invasively by the 13 C-urea breath test. Lancet 1987;1:1174-7.

6. Talley NJ, Newell DG, Ormand JE, Carpenter HA, Wilson WR, Zinsmeister AR, Perez-Perez GI, Blaser MJ. Serodiagnosis of Helicobacter pylori: comparison of enzyme-linked immunosorbent assays. J.Clin Microbiol 1991;29:1635-1639.