H. pylori Stool Rapid Test (Cassette)

Cat. No.:DTS590
Pkg.Size:

Intended use

The H. pylori Stool Cassette is an immunochromatographic screening assay for the qualitative detectionof Helicobacter pylori antigen in stool samples.

General Description

Helicobacter pylori (also formerly known as Campylobacter pylori) is a spiral-shaped, Gram-negative bacterium with typical flagella. It is capable of infecting the gastric mucosa. It causes several gastro-enteric diseases such as non-ulcerous dyspepsia, gastric and duodenal ulcer, active gastritis and might even increase the risk of stomach adenocarcinoma, so that it has been classified as carcinogenic agent type I. Various H. pylori strains have been isolated that differ in their virulence. Strains exhibiting a high virulence are generally characterized by the possession of the vacuolating cytotoxin (Vac A) and the so called cytotoxin associated genes cag pathogenicity island. These factors seem to be necessary for an effective infiltration of the gastric mucosa and seem to be associated with the persistence of the infection. They also contribute to sudden inflammatory responses, ulceration (gastric and duodenal ulcer), allergic episodes, and decrease of therapy efficacy. Especially the CagA protein that is strongly immunogenic and is secreted into the gastric cells by a special mechanism is of special clinical importance. It has been widely reported in many literature articles that infected patients showing antibodies against the CagA gene product have a five times increased risk of developing gastric cancer if compared to a reference group infected with a CagA negative bacterial strain. At present several invasive and non-invasive approaches are available to detect the infection state. Invasive methodologies require endoscopy of the gastric mucosa with a histological, cultural and urease investigation, which are expensive and require a long time to come to a correct final diagnosis. Alternatively, non-invasive methods are available such as Breath Tests with isotope labelled urea, which are complicated and cost-intensive, or classical ELISA or immunoblotting assays. The H. pylori Stool Cassette is an immunological rapid assay that takes advantage of a highly specific antibody/antigen reaction to detect H. pylori antigen in stool samples.

Reagents And Materials Provided

individually wrapped test cassettes
sample collection tubes with 1 mL buffer
Instructions for use

Materials Required But Not Supplied

Absorbent tissue paper to prevent solution from splashing.
stool specimen collection units
Timer

When to Start Testing

The plastic case of the test cassette encloses the test strip. At the right site of the picture you can see the round sample well into which the specimen is dropped. The test result window is in the middle of the cassette. You can see the white membrane where the line(s) will appear after the addition of the sample that show if the analyte is present in the sample or not. In the picture the

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test result line region T and the control line region C are marked with ellipses.

Storage

The test kit (test cassettes and collection tubes with buffer) should be stored refrigerated (4-8°C) or at room temperature (up to 30°C). The test cassette must remain in the sealed pouch until used because they are susceptible to humidity. Under these storage conditions the test is stable for the duration of the shelf-life.

Specimen Collection And Preparation

Please ensure that patients will pay attention to the following instructions for the collection of the stool samples.
1) Collect a random sample of feces by using a stool specimen collection unit.
2) Unscrew and remove the collection tube applicator stick. Be careful not to spill or spatter solution from container.
3) Collect random sample by using the applicator stick (5-6 mm in diameter, approx. 100-200 mg). Take sample from various surfaces of the feces
specimen.
4) Re-insert the applicator stick into the tube and screw the cap tightly. Be careful not to break the tip of the Sample Collection Tube.
5) The specimen is now ready to be tested, stored, or transported. The specimen should be tested as soon possible, but may be held up to 3 days at 2-8°C prior to testing if necessary. The sample should be kept in an airtight container e.g. a plastic bag. It is recommended to store it at 2- 8°C (refrigerator) until tested. Short time exposure to temperatures up to 30°C e.g. during transportation do normally not affect the specimen. However, exposure times to high temperatures should be kept as short as possible. For long-term storage of specimens, -20°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.
Please note: If a patient is feeling unsure with the dilution of the stool sample into the collection tube it is also possible that the patient gives an untreated stool sample to the doctor’s office. The transfer of the sample to the buffer of the tube can also be done as described above by the personal of the doctor’s office or the laboratory. Watery or diarhea specimens are inappropriate for testing. 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 test.

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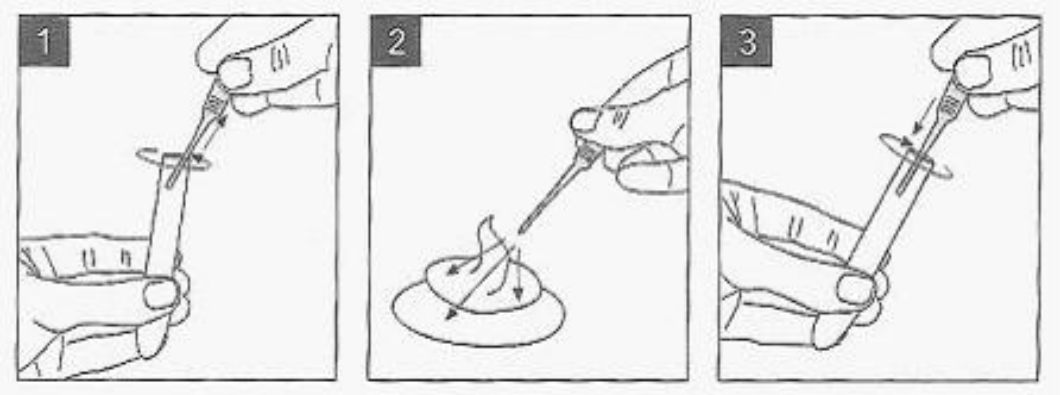

Assay Procedure

1) The sealed test cassette and the patient's sample dissolved in the buffer should be brought to room temperature (15-30°C) prior to testing. Do not open refrigerated test cassettes to prevent the condensation of moisture on the test membrane.
2) Remove the test device from its pouch when ready to perform the test. Label the device with patient or control identification.
3) Shake the collection tube thoroughly to ensure proper mixing of the fecal sample with the extraction solution.
4) Using a piece of tissue paper, break the tip of the collection tube using a twisting motion. Hold the collection tube vertically and dispense 3 drops (app. 120 µL) of solution into the sample well of the test device. Start the timer.
5) Read the result after 10 minutes. Strong positive results may be read sooner. The test result should not be read later than 15 minutes after the addition of the sample.

Quality Control

An internal procedural control is included in the test. A reddish control line appearing in the Control region (C-region) of the membrane indicates proper performance of the test and reactivity of the reagents. Good Laboratory Practice recommends the daily use of control materials to validate the reliability of the device. Control materials which is not provided with this test kit may be commercially available.
Note: When testing control material dissolved in buffer the background of the assay is usually clear within 5 minutes. However, when fecal samples are tested, the background may appear slightly yellowish due to the original color of the fecal samples. This is acceptable as long as it does not interfere with the interpretation of test result. The test is invalid if the background fails to clear and obscures the reading of the result.

Interpretation of Results

For the interpretation of the test result the line(s) that has(ve) appeared in the test result window are visually interpreted.
Positive Test Result
Two red colored lines appear in the test result window. In addition to the the red control line in the C-region a distinct red test result line appears at the T-region. The color intensities of the lines might vary. This result shows that H. pylori antigen is present in the stool sample.
Negative test Result
A single red control line appears in the C-region of the test result window. No line is visible in the T-region. This indicates that no H. pylori antigen has been detected in the sample.
Invalid Test Result
If no control line appears in the C-region the test is not conclusive and must be interpreted as invalid. The absence of the control line might indicate an error in the test procedure or that the ingredients of the assay have deteriorated. Please repeat the test

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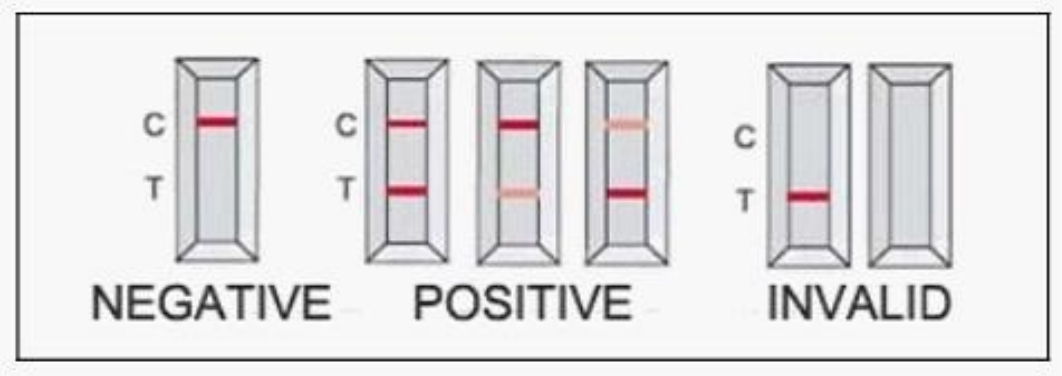
with a new test cassette paying special attention to the instructions. If the problem persists contact your manufacturer.



Expected Values

Helicobacter pylori infects more than half the people in the world. The prevalence of the infection varies among countries and among different groups within the same country. The prevalence rate in the United State suggests an incidence of infection of 2%. The lifetime prevalence of peptic ulcer disease is about 12% in men and 9% in women. Studies have found that more than 90% of patients with duodenal ulcer and 80% of patients with gastric ulcer are infected with H. pylori. The H.pylori Stool Cassette detects the presence of H. pylori antigens in stool specimens. Expected values for any given population should be determined for each laboratory.The positivity rate of any given laboratory may vary depending on geographic location, ethnic group, and living environment.

Sensitivity

The H.pylori Stool Cassette 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 positive samples and one hundred and twenty negative samples, the H.pylori Stool Cassette showed 94.0% clinical sensitivity and 96.7% specificity. The accuracy is 97.5%.
Sensitivity = 94.0% (47/50)
Positive Predictive Value = 92.2% (47/51)
Negative Predictive Value = 97.5% (116/119)

Specificity

Following bacterial and viral strains were used to test the specificity of the H.pylori Stool Cassette. Positive and negative stools were spiked with >1x108 organism/ml and tested by the H.pylori Stool Cassette. H. pylori positive stool remained positive with the spiked organisms. Negative stool remained negative with the spiked organisms.
Specificity = 96.7% (116/120)

Accuracy

Accuracy = 95.9% (163/170)

Precautions

For in-vitro diagnostic use only

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For professional use only
Use each test device only once.
Do not eat, drink or smoke in the area where the specimens or kits arehandled.
Do not use test if pouch is damaged.
Do not use test kit after expiration date.
Do not mix Sample Collection Tubes from different lots.
Do not open the protective pouch until ready to perform the assay.
Do not spill solution into the reaction zone
Do not touch the result window of the cassette to avoid contaminations.
Avoid cross-contamination of samples by using a new specimen collection containers/stool specimen collection units and sample collection tubes for each sample.
All patient samples and positive controls should be treated as if capable of transmitting disease. Observe established precautions against microbiological hazards throughout testing and follow standard procedures for proper disposal of specimens.
Do not use more than the required amount of liquid.
Bring all reagents to room temperature (15-30°C) before use.
Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
Store and transport the test device always at 4-30°C.
Humidity and high temperature can adversely affect results.
Patients should closely follow the specimen collection procedures.
Dispose all used materials in appropriate containers. Treat as potential biohazard.

Limitations

The test is for qualitative detection of H. pylori antigen in stool sample and does not indicate the quantity of the antigens. 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. Antibiotics, proton pump inhibitors and bismuth preparations inhibit H. pylori. Negative test results obtained during or shortly after a therapy might be false negative. In this case it is useful to repeat the H. pylori test 2 weeks after the end of the therapy.

REFERENCES

1. Graham, David Y. (Editor), (2007) Journal compilation© 2007 Blackwell Publishing Ltd., Helicobacter 12 (Suppl.1): 1-56.
2. Kist, M.; Glocker, E.; Suerbaum S. (2005): Pathogenese, Diagnostik und Therapie der Helicobacter pylori-Infektion, Bundesgesundheitsbl – Gesundheitsforsch – Gesundheitssschutz 2005, 48: 669-678, Springer Verlag 2005.
3. Meurer, Linda N.; Meurer, M.D., M.P.H., Bower, Douglas J.,M.D. (2002): Management of Helicobacter pylori infection, American Family Physician
Vol.65, No.7, 1. April 2002.
4. Weiss, Judith; Mecca, James; da Silva, Elvira; Gassner, Dieter (1994): Comparison of PCR and other Diagnostic Techniques for Detection of Helicobacter Pylori Infection in Dyspeptic Patients, Journal of Clinical Microbiology Vol.32, No.7, p.1663-1668, (1994).
5. Marshall BJ. JAMA. 1995;274:1064-1066
6. Breuer T, Malaty HM, Graham DY. The epidermiology of H. pylori-associated gastroduodenal diseases. In: Ernst PB, Michetti P, Smith PD, eds. The Immunobiology of H. pylori: From Pathogenesis to Prevention. Philadephia. Lippincott-Raven, 1997:1-14.
7. Graham DY, Malaty HM, Evans DG, Evans, Jr. DJ, Klein PD, and Adam E. Epidermiology of Helicobacter pylori in a asymptomatic population in the United States. Effect of age, race, and socioeconomic status. Gastroenterology, 1991;100:1495-1501.
8. Anand BS, Raed AK, Malaty HM, et al. Low point prevalence of peptic ulcer in normal individual with Helicobacter pylori infection. Am J Gastroenterol. 1996,91:1112-1115.
9. Tytgat GNJ, Noach LA, Rauws EAJ. Helicobacter pylori infection and duodenal ulcer disease. Gastroenterol Clin North Am. 1993;22:2

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