REF	Σ
PD242001	1
PD242002	20

Intended Use

ProDetect™ H. Pylori Antigen Rapid Test is a rapid, lateral flow chromatographic immunoassay for the qualitative detection of H. Pylori antigen in human fecal specimens. It is intended to be used by healthcare professionals as a screening test to aid diagnosis of infection with H. Pylori. The test only provides preliminary analysis results but not critical diagnosis criteria. Any use or interpretation of the test must be analyzed and confirmed with alternative testing method(s) and clinical findings based on professional judgment of healthcare providers.

Summary

Helicobacter pylori (H. Pylori) is a small, spiral-shaped bacterium that lives in the surface of the stomach and duodenum. It is implicated in the etiology of a variety of gastrointestinal diseases, including duodenal and gastric ulcer, non-ulcer dyspepsia and active and chronic gastritis. Both invasive and non-invasive methods are used to diagnose H. Pylori infection in patients with symptoms of gastrointestinal disease. Specimen dependent and costly invasive diagnostic methods include gastric or duodenal biopsy followed by urease testing (presumptive), culture, and/or histologic staining. A very common approach to the diagnosis of H. Pylori infection is the serological identification of specific antibodies in infection patients. The main limitation of serology test is the inability to distinguish current and past infections. Antibody may be present in the patient's serum long after eradication of the organisms. HpSA (H. Pylori stool antigen) testing is gaining popularity for diagnosis of H. Pylori infection and also for monitoring the efficacy of the treatment of H. Pylori infection. Studies have found that more than 90% of patients with duodenal ulcer and 80% of patients with gastric ulcer are infected with H. pylori. ProDetect™ H. Pylori Antigen Rapid Test utilizes specific antibodies to qualitatively detect H. Pylori antigens in human fecal specimens. The test can be performed without cumbersome laboratory equipment, and the results are available within 20 minutes.

Principle

ProDetect™ H. Pylori Antigen Rapid Test is a qualitative membrane-based immunoassay for the detection of H. Pylori antigens in human fecal specimens. The membrane is pre-coated with specific anti-H. Pylori antibodies in the test line region. During testing, the specimen reacts with the particle coated with anti-H. Pylori antibodies to form an antigen-antibody-gold complex. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-H. Pylori antibodies immobilized in the membrane and produce a colored line. The presence of this colored line in the test line region (T), indicates a positive result, while its absence indicates a negative result.

An internal quality control is included in the test, in the form of a colored line appearing in the control line region (C), indicating that the test is functional, and proper and sufficient volume of specimen has been applied to enable migration through the test and control line, regardless of whether there is a test line or not. If the control line (C) does not appear within the testing time, test result is invalid, and the test should be repeated with a new test device.

Materials Provided

- Test device(s) individually foil pouched with a desiccant
- Specimen collection tube(s) with extraction buffer
- Package inserts

Materials Required but Not Provided

- Timer
- Specimen collection containers

Warnings & Precautions

- For in vitro diagnostic use only. Do not reuse the test.
- Do not freeze the test kit or its components.
- These instructions must be carefully read and strictly followed by a trained healthcare professional to achieve accurate results. All users should read the instructions before performing test.
- The test is only for the detection of H. Pylori antigens, not for any other viruses or pathogens.
- Inadequate or inappropriate specimen collection, storage, and transportation are likely to result in false negative test results.
- Do not scoop fecal specimen as this may lead to excess fecal specimen which may block the specimen well and yield an invalid test result.
- Do not eat, drink or smoke in the area where handling specimens or performing the test.
- Do not use the test kit beyond its expiration date.
- Do not mix components from different kit lots.
- Leave test device sealed in its foil pouch until just before use. Do not use the test device if the pouch is damaged or the seal is broken.
- To avoid contamination or inaccurate test result, do not touch the reaction area of test device when performing the test.
- Wear appropriate personal protection equipment and gloves when performing the test, collecting and handling patient specimens.
- Dispose of all used test devices and potentially contaminated materials in a biohazard container as if they were infectious waste and dispose according to applicable local laws and regulations.

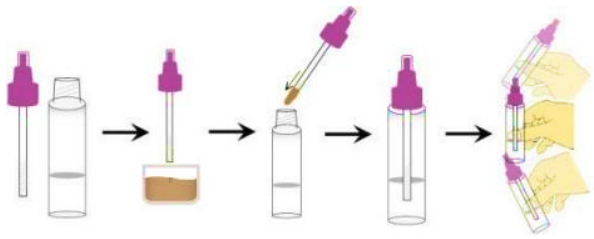
Storage & Stability

- The test kit should be stored either at room temperature or refrigerated (2-30°C), away from

direct sunlight. Do not freeze the kit or expose the kit to temperatures over 30°C.
- The shelf life of the kit is as indicated on the outer package (24 months from date of manufacture).
- This test kit is stable until the expiration date marked on the outer package and foil pouch. Ensure all test components are at room temperature (15-30°C) before use.
- Perform the test immediately after taking out the test device from the foil pouch.

Sample Collection & Preparation

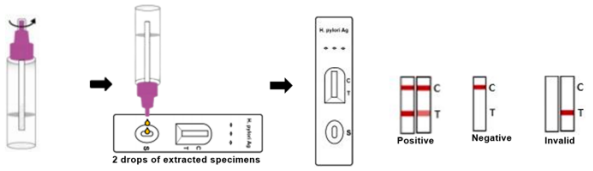
Consider any materials of human origin as infectious and handle them using standard biosafety procedures. Follow standard laboratory procedures to collect specimens.
- Collect a random sample of feces in a clean, dry specimen collection container.
- Label the specimen collection tube with the specimen's ID number. Unscrew the top of the specimen collection tube and then randomly stab the specimen collection stick into the fecal specimen in at least five different sites. Do not scoop the fecal specimen. Ensure that stool specimen is only in the grooves of the collection stick. Excess stool specimen may result in an invalid test result.
- Screw on the collection stick in the tube and tighten securely to close the specimen collection tube.
- Shake the specimen collection tube vigorously so as to extract the H. Pylori antigens in the specimen.



After above steps, the specimen is ready for testing, transportation or storage.
Note: It is recommended to test the specimen immediately after extraction. If test is not performed immediately, the extracted specimen may be stored at 2-8°C for up to 3 days. For longer storage, the extracted specimen may be frozen at ≤-20°C. Avoid multiple freeze- thaw cycles (maximum 3 times).

Test Procedures

1- Before testing, open the package and equilibrate the test device, specimens and/or controls to room temperature(15-30°C). Once the specimen is thawed, mix well prior to performing the test.
2- Take out the test device from sealed foil pouch and place on a dry, clean and level surface. Be sure to label the device with specimen's ID number.
3- Shake the specimen collection tube vigorously to ensure a homogenous liquid suspension.
4- Hold the specimen collection tube vertically. Unscrew the cap. Add 2 drops (approximately 70-90 µL) of the extracted specimen into the specimen well(S) of the test device. Do not overload samples. See illustrations below.
5- Start the timer immediately.
6- Wait for the colored line to appear. Read test results at 15-20 minutes. Positive results may be visible in as short as 1 minute. Negative results must be confirmed at the end of the 20 minutes only. Do not interpret the result after 20 minutes.



Interpretation of Test Results

(Please refer to the illustrations above)
- Positive: Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T).

NOTE: The intensity of the color in the test line region (T) will vary depending on the concentration of H. Pylori antigens present in the specimen. Therefore, the presence of any test line (T), no matter how faint, within the designated observation time, indicates a positive result.
- Negative: One colored line appears in the control line region (C). No line appears in the test line region (T).
- Invalid: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, stop using the test kit immediately and contact your local distributor.

Quality Control

- Internal Control: An internal quality control is included in the test, in the form of a colored line appearing in the control line region (C), indicating that the test is functional, and proper and sufficient volume of specimen has been applied to enable migration through the test and control line, regardless of whether there is a test line or not. If the control line (C) does not appear within the testing time, test result is invalid and the test should be repeated with a new test device.
- External Control: Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

Limits

- ProDetect™ H. Pylori Antigen Rapid Test is only used for the qualitative detection of H. Pylori antigens in

human fecal specimens. The intensity of the test line does not have a linear correlation with H. Pylori antigen concentration in the specimen.

- The test does not indicate the quantity of the H. Pylori antigens or the rate of increase of H. Pylori antigen concentration in the specimen and should not be used as the sole criteria for the diagnosis of infection with H. Pylori.
- A negative or non-reactive result may occur if the quantity of the H. Pylori antigens present in a specimen is below the detection limits of the test, or the antigens that are detected are not present in the fecal specimen collected.
- A negative or non-reactive result indicates the H. Pylori antigen is not present in the specimen. However, a negative or non- reactive result does not preclude the possibility of infection with H. Pylori.
- Study found that the seroprevalence of H. Pylori in specimens with positive fecal occult blood (FOB) test results is approximately 39.3%. Accordingly, ProDetect™ H. Pylori Antigen Rapid Test may give positive result when testing a specimen which has been detected positive with a FOB assay.
- If symptoms are suspicious or persist while test result from ProDetect™ H. Pylori Antigen Rapid Test is negative or non- reactive, additional testing using alternative clinical methods is recommended.
- Test results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

Performance Characteristics

- Clinical Performance

  ProDetect™ H. Pylori Antigen Rapid Test has been evaluated using a total of 309 fecal specimens collected from symptomatic patients and healthy individuals. A commercial urea breath test (UBT) is used as the reference test. Test results compared to the UBT assay are presented in the table below.

ProDetect™ H.Pylori Antigen Rapid Test	UBT Reference		
	Positive	Negative	Total
Positive	105	4	109
Negative	3	197	200
Total	108	201	309

Sensitivity (Positive Percent Agreement): 97.22% = 105 ÷ 108 (95% CI: 92.15% ~ 99.05%)
Specificity (Negative Percent Agreement): 98.00% = 197 ÷ 201 (95% CI: 95.00% ~ 99.22%)
Accuracy (Overall Percent Agreement): 97.73% = (105 + 197) ÷ 309 (95% CI: 95.40% ~ 98.90%)

- Analytical Sensitivity (Limit of Detection, LoD)

  The analytical sensitivity of ProDetect™ H. Pylori Antigen Rapid Test was evaluated and detection limit of the assay was determined as 1.0 ng/mL of H. Pylori lysate antigen.

- Cross-Reactivity

  Cross reactivity with following organisms has been studied at ≥ 1 × 10^8 organisms/mL. The following organisms were found negative when tested with ProDetect™ H. Pylori Antigen Rapid Test:

Acinetobacter calcoaceticus	α-hemolytic streptococcus	Proteus vulgaris Hauser
Adenovirus	B-hemolytic streptococcus	Pseudomonas aeruginosa
Enterococcus faecalis	Klebsiella pneumonia	Rotavirus
Escherichia coli	Moraxella catarrhalis	Salmonella Paratyphi A
Gardnerella vaginalis	Neisseria gonorrhea	Salmonella Paratyphi B
Geotrichum candidum	Neisseria meningitides	Salmonella Paratyphi C
Hemophilus influenza	Proteus mirabilis	Salmonella typhi

References

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5. Anand BS, Raed AK, Malaty HM, et al. Loe point prevalence of peptic ulcer in normal individual with Helicobacter pylori infection. Am. J. Gastroenterology (1996), 91: 1112-1115.
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Symbols

	Do not reuse	IVD	For in vitro diagnostic use only
	Temperature limit		Consult instruction for use
	Caution	LOT	Lot Number
	Keep away from sunlight	REF	Catalogue Number
	Use by	Σ	Contains sufficient for <n> tests

	Do not use if package is damaged		Keep dry
CE	CE Marking		Manufacturer
EC REP	EU Representative		Date of manufacture

Contact Information

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CE
IVD

Release Date: ... ... Date of Manufacture: ... ...