EnCore Biomedicals

EnSure Rapid Test H. Pylori

Rapid Diagnostics Test for H.Pylori

Store at 2°c to 30°c

INTENDED USE

The H. Pylori Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of antibodies (IgG, IgM) anti- Helicobacter pylori (H. Pylori) in human serum, plasma. It is intended to be used as a screening test and as an aid in the diagnosis of infection with H. Pylori. Any reactive specimen with the H. Pylori Ab Rapid Test Kit must be confirmed with alternative testing method(s) and clinical findings.

SUMMARY

Helicobacter pylori is associated with a variety of gastrointestinal diseases included non-ulcer dyspepsia, duodenal and gastric ulcer and active, chronic gastritis. The prevalence of H. pylori infection could exceed 90% in patients with signs and symptoms of gastrointestinal diseases. Recent studies indicate an association of H. Pylori infection with stomach cancer. H. Pylori colonizing in the gastrointestinal system elicits specific antibody responses which aids in the diagnosis of H. Pylori infection and in monitoring the prognosis of the treatment of H. Pylori related diseases. Antibiotics in combination with bismuth compounds have been shown to be effective in treating active H. Pylori infection. Successful eradication of H. pylori is associated with clinical improvement in patients with gastrointestinal diseases providing a further evidence. The H. Pylori Ab Rapid Test is a latest generation of chromatographic immunoassay which utilizes recombinant antigens to detect the antibodies to H. Pylori in human serum or plasma. The test is user friendly, highly sensitive and specific.

PRINCIPLE OF THE ASSAY

The H. Pylori Ab Rapid Test is a lateral flow chromatographic immunoassay based on the principle of the double antigen–sandwich technique. The test cassette consists of: a burgundy colored conjugate pad containing H. Pylori antigens including Cag-A conjugated with colloid gold (H. Pylori conjugates) and rabbit IgG-gold conjugates, a nitrocellulose membrane strip containing a test line (T line) and a control line. The T line is pre-coated with non-conjugated H. Pylori antigens, and the C line is pre-coated with goat anti-rabbit IgG.

When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the cassette. The antibodies: either the IgG, the IgM, to H. Pylori if present in the specimen will bind to the H. Pylori conjugates. The immunocomplex is then captured on the membrane by the pre-coated H. Pylori antigens, forming a burgundy colored T line, indicating a H. Pylori Ab positive test result. Absence of the T line suggests a negative result. The test contains an internal control (C line) which should exhibit a burgundy colored line of the immunocomplex of goat anti-rabbit IgG/rabbit IgG-gold conjugate regardless the presence of any antibodies to H. Pylori. Otherwise, the test result is invalid and the specimen must be retested with another device.

PACKAGE CONTAINS

1. Each Pouch contents: Test Cassette, Desiccant.
2. 1 Assay buffer bottle
3. 30-35 μL dropper
4. 1 instruction for use

MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock or Timer
2. Calibrated Mioropipette
3. Disposable Gloves

WARNINGS AND PRECAUTIONS

1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2. Do not open the sealed pouch, unless ready to conduct the assay.
3. Do not use expired devices.
4. Bring all reagents to room temperature (15°c-30°c) before use.
5. Do not use the components in any other type of test kit as a substitute for the components in this kit.
6. Do not use hemolized blood specimen for testing.
7. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
8. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
9. Dispose of all specimens and materials used to perform the test as biohazardous waste.
10. Handle the Negative and Positive Control in the same manner as patient specimens.
11. The testing results should be read within 20 minutes after a specimen is applied to the sample well or sample pad of the device. Read result after 20 minutes may give erroneous results.
12. Do not perform the test in a room with strong air flow, ie. electric fan or strong air-conditioning.

SPECIMEN COLLECTION

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

Plasma

1. Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer) by veinpuncture.
2. Separate the plasma by centrifugation.
3. Carefully withdraw the plasma into new pre-labeled tube.

Serum

1. Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer) by veinpuncture.
2. Allow the blood to clot.
3. Separate the serum by centrifugation.
4. Carefully withdraw the serum into a new pre-labeled tube.
5. Test specimens as soon as possible after collecting. Store specimens at 2°c to 8°c if not tested immediately.
6. Store specimens at 2°c to 8°c up to 5 days. The specimens should be frozen at -20°c for longer storage

TEST PROCEDURE

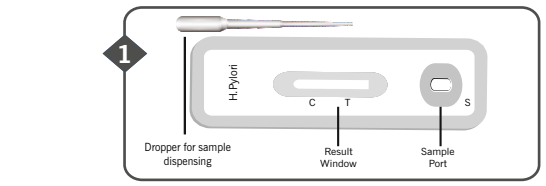
1. Bring the kit components to room temperature before testing.
2. Open the pouch and remove the test, dropper and silica gel pouch. Check the color of the silica gel. It should be blue, if it has turned colorless or pink, discard the test and use another test. Once opened, the test must be used immediately.

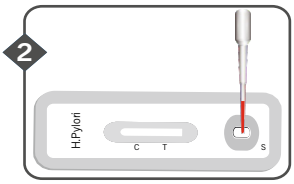
For serum or plasma

- Add 1 drop (approx 30-35 μL) of specimen into the sample well making sure that there are no air bubbles.
- Then add 2 drops (approx 60-70 μL) of Assay buffer immediately.

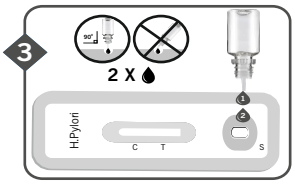
5. Set up timer.
6. Results can be read in 20 minutes. Positive results can be visible in as short as 1 minute.

   Don't read results after 30 minutes. To avoid confusion, discard the test device after interpreting the result.





Add 1 drop (approx 30-35 μL) of serum/plasma into small round port (S) touching the pad



Add 2 drops (approx 60-70 μL) of assay buffer into small round port (S) touching the pad

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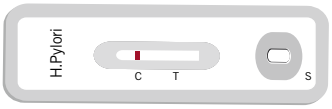
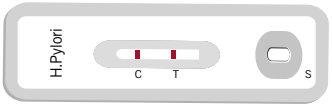
INTERPRETATION OF ASSAY RESULT

NEGATIVE : A colored line appears at control region 'C' only.



POSITIVE: A distinct colored lines appears at control region 'C' and at test region 'T'

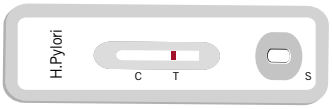


The appearance of any burgundy color in the T line, regardless of intensity, must be considered as presence of the H.Pylori Antibodies

INVALID: The test should be considered invalid if,

A) No line appears at 'C', 'T' region

B) No line appears at 'C' region and line appear at 'T' region.



LIMITATIONS

1. The Assay Procedure and the Assay Result Interpretation must be followed closely when testing the presence of antibodies to H. Pylori in serum, plasma from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The H. Pylori Ab Rapid Test is limited to the qualitative detection of IgG, IgM, and IgA anti- H. Pylori in human serum, plasma or whole blood. The intensity of the test line does not have linear correlation with the antibody titer in the specimen.
3. A negative result for an individual subject indicates absence of detectable antibodies to H. Pylori. However, a negative test result does not preclude the possibility of exposure to or infection with H. Pylori.
4. A negative result can occur if the quantity of the antibodies to H. Pylori present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
5. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
6. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

DISCLAIMER

All precaution shall be taken to ensure the diagnostic ability and accuracy of this product. This product is utilized outside the control of manufacturer and distributors. The various factors including storage temperature, environmental conditions and procedure error may affect the results. This test provides presumptive diagnosis of H.Pylori infection. A confirmed infection diagnosis should only be made by a physician after all clinical and laboratory Findings have been evaluated.

REFERENCES

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2. Soll, A.H. Pathogenesis of peptic ulcer and implication for therapy. New England J.Med.1990.322:909-916.
3. Parsonnet, J., Friedman, G.D., Vandersteen, D.P., et.al. Helicobacter pylori infectionand risk of gastric carcinoma. New England J. Med. 1991.325:1127-31.
4. Ansorg, R., Von Recklinghausen, G., Pomarius, R., et.al. Evaluation of techniques forisolation, subcultivation and preservation of Helicobecter pylori. J. Clin. Micro.1991.29:51-53.
5. Pronovost, A.P., Rose, S.L., Pawlak, J., et.al. Evaluation of new immunodiagnosticassay for Helicobacter pylori antibody detection: Correlation with histopathological andmicrobiological results. J. Clin. Microbiol.1994.32:46-50.

PERFORMANCE CHARACTERISTICS

Internal Evaluation:

In an in-house study, total 210 samples were evaluated for sensitivity and specificity. We found the relative sensitivity was 98.36 % (i. e. 60/61) and the relative specificity was 99.33% (i. e. 150/151). The results are summarized in the following table:

Sample	Total Number of samples tested	Rapid H.Pylori Test		Sensitivity (%)	Specificity (%)
		Positive	Negative		
H.Pylori Positive Serum Samples	30	29	1	98.36%	
H.Pylori Positive Plasma Samples	30	30	-		
Negative Human Serum	75	1	74		99.33%
Negative Human Plasma	75	-	75		

SYMBOL KEY

IVD	In Vitro Diagnostic Use	30°C / 2°C	Temperature limitation
	Manufacturer	2	Single Use
	Manufacturing Date	Σ	Number of tests in the pack
	Expiry Date		Do not use if pouch or kit damaged
LOT	Lot Number	i	Read package insert before use

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