DRG

DRG® H. Pylori Rapid Test (RAP-2597)

Revised 4 Jan. 2007 **RUO in the USA**

For the rapid detection of antibodies to H. pylori in serum. For in vitro use.

Summary
The infection of Helicobacter Pylori (H. pylori) is associated with a variety of gastro-intestinal diseases, such as stomach ulcer, chronic active gastritis and gastric, duodenal, and gastric adenocarcinoma. Antibodies to H. pylori are developed in individuals infected with H. pylori as a serological response. Detecting these specific antibodies to H. pylori can be use as a qualitative assay in the diagnosis of H. pylori infection. It may be used either as an adjunct to endoscopy or as an alternative measure in symptomatic patients.

The H. pylori Rapid Test is a chromatographic immunoassay (CIA) for the rapid determination of antibodies to H. pylori in serum specimens. The test is to be used as an aid in the diagnosis of infection due to H. pylori.

Test Principle
The H. pylori Rapid Test is a lateral flow, immunochromatographic screening test. H. pylori specific antigens are pre-coated onto membrane as capture reagents on the test band region. During the assay, the specimen serum is allowed to react with H. pylori specific antigens-gold conjugate. The mixture then moves laterally on the membrane chromatographically to the test region with immobilized antibodies of H. pylori on the membrane. If H. pylori antibodies are present in the specimen, a colored band is formed on the test (T) region. Absence of the colored band in the test region indicates a negative result. To serve as a procedural control, a colored band in the control (C) region will always appear regardless the presence of H. pylori antibodies in serum specimen.

Reagent
A test device is sealed in a protection pouch. Dilution buffer is ready for use.

Storage and Stability
The H. pylori Rapid Test is to be stored refrigerated at room temperature (2-28ºC) in the sealed pouch for the duration of the shelf life.

Precaution
1. Do not use after expiration date. Test device should remain sealed until being ready for use.
2. There should be no smoking or eating where antigen contained material is handled.
3. Decontaminate area by disposing samples and all potentially contaminated materials as if they contained infectious agents.
4. Wear disposable gloves while handling samples. Wash hands thoroughly afterwards.
5. As with all screening tests, a definitive clinical diagnosis should not be based on the results of a single test but should rather be made by a physician after all clinical findings have been evaluated.

Specimen Collection and Storage
The H. Pylori Serum Rapid Test is intended use serum as a specimen.

Serum Specimens Collection:

1. Collect blood and centrifuge blood specimen following standard clinical procedure.
2. Remove serum as soon as possible to avoid hemolysis. Lipernic, icteric, or hemolyzed specimens may give inconsistent test results. Specimens containing a precipitate should be clarified prior to testing.
3. If specimens cannot be tested immediately, they should be stored refrigerated at 2-8ºC, but no longer than 3 days. Avoid repeated freezing and thawing of specimens.

Assay Procedure

1. Remove the device by tearing open the pouch and label the device with specimen identification.
2. Add one drop (25 µl) of serum into the sample well (for card) or sample pad (for dipstick). Then add three drops (150 µl) of test running buffer into the sample well or sample pad.
3. Observe the colored band developed over the control region (C), indicating the assay is complete.
4. Read the result within 10 minutes. Do not interpret the result after 15 minutes.

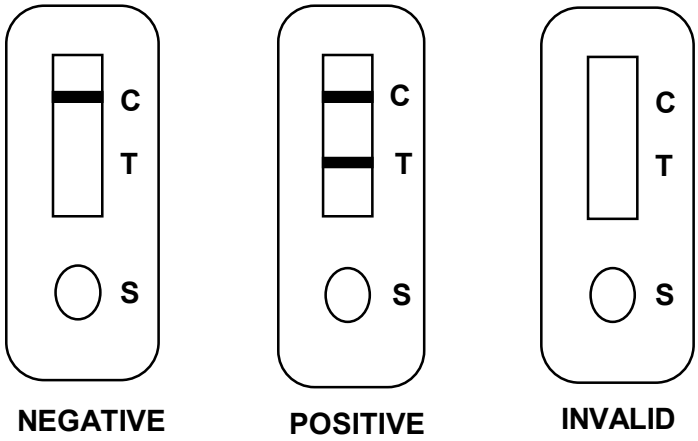
Interpretation of Result

Positive: Presence of two colored bands within the test window, one in the control region C and another in the test region (T), indivcates presence of antibodies to H. pylori in specimen.

Negative: Presence of a single colored band in the control region (C) indicates absence of antibodies to H. pylori in the specimen.

Invalid: If after 10 minutes no band is visible within the test window, the result is invalid. The protocol may not perform correctly or the test may have deteriorated. The assay should be repeated with a new kit.

Note: Do not interpret the result after 15 minutes.



Limitation

1. The H. pylori Rapid Test is not reusable. The test works only if the instructions are followed precisely. Do not use the test after the expiration date shown on the package or if the moisture absorbent pack is wet.
2. The result should be used as an aid in diagnosis and should not be interpreted as a final diagnosis. To confirm diagnosis of gastritis and/or peptic ulcers, clinical findings need to be considered.
3. Serum from patients infected with C. jejuni may have a low cross-reactivity with this test.

Reference

1. Warren J. R., et al. Unidentified curved bacillus on gastric epithelium in active chronic gastritis. Lancet 1: 1273-1275, 1983.

2. Evans D. J., et al. A sensitive and specific serologic test for detection of Campylobacter pylori infection. Gastroenterology 96: 1004-1008, 1989.
3. Vaira D. et al. Serum immunoglobulin G antibody levels for Campylobacter pylori diagnosis. Gastroenterology 97: 1069-1071, 1989.