ACCUCARE™

H.Pylori Ab RAPID TEST

For detection of Helicobacter Pylori antibodies in Human Serum, Plasma ..
Only for *In Vitro* diagnostic use.

ORDER INFORMATION

REF	Cont.
HPBC 1	1 Test
HPBC 10	10 Test
HPBC 25	25 Test

CLINICAL SIGNIFICANCE

Gastritis and peptic ulcers are one of the most common human diseases. Since the discovery of H. pylori, many reports have suggested that this organism is one of the main causes of ulcer diseases and stomach cancer. The eradication of H. pylori has been associated with elimination of ulcer diseases. The detection of the specific antibodies to H. pyiori has been shown to be an accurate method for detection of H. pylori infection in symptomatic patients.

PRINCIPLE

H.Pylori Ab test device has 2 precoated lines on the surface of the membrane. The “Control Line” is used for procedural control. Control line should always appear if the test procedure is performed properly and the test reagents of control line are working. Anti antibodies coated on the test line 2 . If sample contains antibody, reacts with gold conjugated nanoparticle and flow on the membrane. It will be captured by membrane coated antibodies depend on Ab type by developing purple color on test line.

KIT COMPONENTS

Test Cassette Device, assay buffer, Sample Dropper and Instructions for Use

PRECAUTIONS

1. For professional *in vitro* diagnostic use only. Do not use after the expiration date.
2. Wear protective gloves while handling specimens wash thoroughly afterwards.
3. The device is sensitive to humidity as well as heat. Therefore take out the device from seal pouch before test.
4. Do not mix reagents from different lot.
5. Dispose all the samples and kits properly as per the instruction after test in accordance in GLP.
6. Follow the testing procedure exactly as mention in the insert.

STORAGE AND STABILITY

1. The kit can be stored at room temperature or refrigerated (2-30°C). The test device must remain in the sealed pouch until use. DO NOT FREEZE.
2. Do not use beyond the expiration date.
3. Do not use the test kit, if the pouch is damaged or seal is broken.

SPECIMEN COLLECTION & PREPARATION

1. Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
2. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C.
3. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
4. If specimens are to be shipped, they should be packed in compliance with federal regulations for the transportation of etiologic agents.

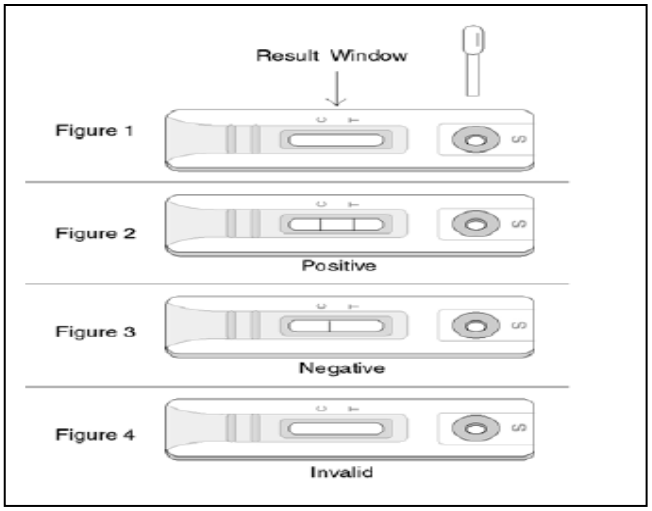
DIRECTIONS FOR USE

Allow the test device, specimen and/or buffer to equilibrate at room temperature (15-30°C) before testing.

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. With a micropipette (not provided) or a disposable dropper, add about 10 µL of serum/plasma/./ specimen into the sample well marked “S**”.**
3. Add 2 drop of diluents buffer to the sample well.
4. As the test begins to work, you will see red color move across the result window in the center of the test device.
5. Interpret test results at 15-20 minutes. Caution: Do not read test results after 30 minutes. Reading too late can give false results.

Note: Do not interpret the result after 30 minutes.

INTERPRETATION OF RESULTS



1) Positive
The control line (C) and test line (T) lines are visible on the test device. This is positive for antibodies. This is indicative of late primary or early secondary infection of H.Pylori Bacteria.

2) Negative
The control line is the only visible line on the test device. No Ab antibodies were detected. Retest in 3-5 days if H.Pylori Bacteria is suspected.

3) Invalid
The control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the likeliest reasons for control line failure. Repeat the test using a new test device.

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Limitations of the Test

1) The Assay Procedure and the Test Result Interpretation must be followed closely when testing the presence of antibodies to H.Pylori Bacteria in serum or 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 antibodies to H.Pylori Bacteria in human serum or plasma. The intensity of the test band does not correlate with antibody titer of the specimen.
3) A negative result for an individual subject indicates absence of detectable H.Pylori Bacteria antibodies. However, a negative test result does not preclude the possibility of exposure to or infection with H.Pylori Bacteria.

Internal Quality Control

The "Control Line" is used for procedural control. Control line should always appear if the test procedure is performed properly and the test reagents of control line are working. It confirms sufficient specimen volume and correct procedural technique. A clear background is also required

BIBLIOGRAPHY

1. Anderson, L.P., Nielsen, H. (1993) Peptic ulcer: an infectious disease? Ann. Med. 25, 563 - 568.
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