

H. pylori Ab Cassette Rapid Test - (Serum / Plasma / Whole Blood)



IVD

In Vitro Diagnostic

INTENDED USE

The H. pylori Ab Cassette Rapid Test is a sandwich lateral flow chromatographic immunoassay for the qualitative detection of antibodies (IgG, IgM and IgA) against Helicobacter pylori (H. pylori) in human serum, plasma or whole blood. 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 Cassette Rapid Test must be confirmed with alternative testing method(s) and clinical findings.

SUMMARY AND EXPLANATION OF THE TEST

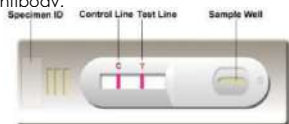
Helicobacter pylori is associated with a variety of gastrointestinal diseases including non-ulcer dyspepsia, duodenal and gastric ulcers and active, chronic gastritis^{1,2}. The prevalence of H. pylori infection could exceed 90% in patients with signs and symptoms of gastrointestinal diseases. Recent studies indicate an association of H. pylori infection with stomach cancer³.

H. pylori colonizing in the gastrointestinal system elicits specific antibody responses^{4,5,6} which aid in the diagnosis of H. pylori infections and in monitoring the effectiveness of treatment for 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 further evidence⁷.

The H. pylori Ab Cassette Rapid Test is the latest generation of chromatographic immunoassays which utilizes recombinant antigens to detect antibodies to H. pylori in human serum, plasma or whole blood. The test is user friendly, highly sensitive and specific.

TEST PRINCIPLE

The H. pylori Ab Combo Rapid Test is a lateral flow chromatographic immunoassay based on the principle of the double-antigen sandwich technique. The test cassette consists of: 1) a burgundy colored conjugate pad containing H. pylori antigens including Cag-A conjugated with colloidal gold (H. pylori conjugates) and a control antibody conjugated with colloidal gold, and 2) a nitrocellulose membrane strip containing a test line (T line) and a control line (C line). The T line is pre-coated with non-conjugated H. pylori antigens, and the C line is pre-coated with a control line antibody.



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. Antibodies (IgG, IgM or IgA) 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 the control antibodies regardless of color development on the T line. If the C line does not develop, the test result is invalid, and the specimen must be retested with another device.

REAGENTS AND MATERIALS PROVIDED

- Individually sealed foil pouches containing:
 - One cassette device
 - One desiccant
 - Dropper
 - Sample diluent (1 bottle, 5 ml)
- One package insert (instruction for use)

MATERIALS MAY BE REQUIRED AND NOT PROVIDED

- Positive Control
- Negative Control

MATERIALS REQUIRED BUT NOT PROVIDED

- Clock or Timer
- Lancing device for whole blood test

WARNINGS AND PRECAUTIONS

For In Vitro Diagnostic Use

- This package insert must be read completely before performing the test. Failure to follow the insert may lead to inaccurate test results.
- Do not open the sealed pouch unless ready to conduct the assay.
- Do not use expired devices.
- Bring all reagents to room temperature (15°C-30°C) before use.
- Do not use components from any other type of test kit as a substitute for the components in this kit.
- Do not use hemolyzed blood specimens for testing.
- Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
- Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.

- Do not smoke, drink or eat in areas where specimens or kit reagents are being handled.
- Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
- Handle the negative and positive controls in the same manner as patient specimens.
- The test result should be read 15 minutes after a specimen is applied to the sample well. Reading the result after 20 minutes may give erroneous results.
- Do not perform the test in a room with strong air flow, i.e. electric fan or strong air-conditioning.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test device unopened at 2°C -30°C. If stored at 2°C -8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.

Plasma

Step 1: Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively, in Vacutainer®) by venipuncture.

Step 2: Separate the plasma by centrifugation.

Step 3: Carefully withdraw the plasma into a new pre-labeled tube.

Serum

Step 1: Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer®) by venipuncture.

Step 2: Allow the blood to clot.

Step 3: Separate the serum by centrifugation.

Step 4: Carefully withdraw the serum into a new pre-labeled tube.

Test specimens as soon as possible after collecting. Store specimens at 2°C-8°C if not tested immediately. Specimens can be stored at 2°C -8°C for up to 5 days. The specimens should be frozen at -20°C for longer storage.

Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing.

Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on result interpretation.

Blood

Drops of whole blood can be obtained by either fingertip puncture or venipuncture.

Whole blood specimens should be stored in refrigeration (2°C-8°C), if not tested immediately. The specimens must be tested within 24 hours of collection.

ASSAY PROCEDURE

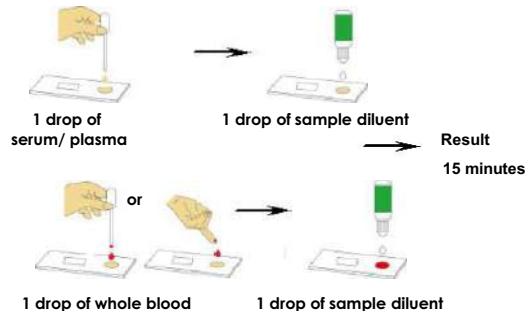
Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen. Once thawed, mix the specimen well prior to performing the assay.

Step 2: When ready to test, open the pouch at the notch and remove the device. Place the test device on a clean, flat surface.

Step 3: Be sure to label the device with the specimen ID number.

Step 4: Fill the plastic dropper with the specimen. Holding the dropper vertically, dispense 1 drop of serum/plasma (about 25-30 µL) or 1 drop of whole blood (about 20-25 µL) into the sample well, making sure there are no air bubbles.

Immediately add 1 drop (about 30-35 µL) of sample diluent with the bottle positioned vertically.



Step 5: Set up timer.

Step 6: Result can be read in 15 minutes. Positive results may be visible in as soon as 1 minute.

Don't read result after 15 minutes. To avoid confusion, discard the test device after interpreting the result.

QUALITY CONTROL

1. Internal Control: This test contains a built-in control feature, the C line. The C line develops after adding the specimen and the sample diluent. If the C line does not develop, review the whole procedure and repeat the test with a new device.

2. External Control: Good Laboratory Practice recommends using external controls, positive and negative, to ensure the proper performance of the assay, particularly under the following circumstances:

- A new operator uses the kit prior to performing the testing of specimens.
- A new lot of test kits is used.
- A new shipment of kits is used.
- The temperature used during storage of the kits fall outside of 2°C-8°C.
- The temperature of the test area falls outside of 15°C-30°C.
- To verify a higher than expected frequency of positive or negative results.
- To investigate the cause of repeated invalid results.

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INTERPRETATION OF ASSAY RESULT

1. NEGATIVE RESULT: If only the C line is developed, the test indicates that no detectable antibodies to H. pylori are present in the specimen. The result is nonreactive or negative.



2. POSITIVE RESULT: If both the C and the T lines are developed, the test indicates the presence of antibodies to H. pylori in the specimen. The result is reactive or positive.



3. INVALID RESULT: If no C line is developed, the assay is invalid regardless of color development on the T line as indicated below. Repeat the assay with a new device.

4. INVALID: If no C line is developed, the assay is invalid regardless of color development on the T line as indicated below. Repeat the assay with a new device.



Clinical Performance

A total of 200 specimens from non-H. pylori infected patients and 75 specimens from patients undergoing anti-H. pylori treatment were tested with the Cellex qH. pylori Ab Cassette Rapid Test. Comparison for all subjects is shown in the following table.

H. pylori Ab Cassette Rapid Test			
H. pylori Patients	Positive	Negative	Total
Positive	65	10	75
Negative	18	182	200
Total	83	192	275

Relative Sensitivity: 86.7%, Relative Specificity: 91%, Overall Agreement: 89.8%

LIMITATIONS OF TEST

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

REFERENCES

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- Soll, A.H. Pathogenesis of peptic ulcer and implication for therapy. New England J. Med.1990.322:909-916.
- Parsonnet, J., Friedman, G.D., Vandersteen, D.P., et.al. Helicobacter pylori infection and risk of gastric carcinoma. New England J. Med. 1991.325:1127-31.
- Ansorg, R., Von Recklinghausen, G., Pomarius, R., et.al. Evaluation of techniques for isolation, subcultivation and preservation of Helicobacter pylori. J. Clin. Micro. 1991.29:51-53.
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- Megraud, F., Bassens-Rabbe, M.P., Denis, F., et.al. Seroepidemiology of Campylobacter pylori infection in various populations. J. Clin. Microbiol. 1989. 27:1870-3.
- Marshall, B.J., Goodwin, C.S., Warren, J.R., et.al. Prospective double-blind trial of duodenal ulcer relapse after eradication of Campylobacter pylori. Lancet.1988. 2:1437-42.

WASTE MANAGEMENT OR DISPOSABLE:

The contents of RDTs can be divided into :

Infectious waste:












- sharps (lancets, needles, scalpel blades)
- blood collection devices (tubes, straws, and loops); gloves; swabs; and cotton
- used cassettes.

Non-infectious waste (Recyclable):

- packaging materials, desiccant, buffer, and unused or unusable RDTs.

****You must collect and dispose each type of waste in separate containers as per your waste management policies.**

Index of CE Symbols

 Consult instructions for use	 For in vitro diagnostic use only	 Use by
 Catalog #	 Lot Number	 Tests per kit
 Store between 2-30°C	 Authorized Representative	 Do not reuse
 Manufacturer	 Date of manufacture	

Mfg. By: BIOGENIX INC. PVT. LTD.

Factory: B - 19/A, S.I.L Ancillary Estate, Amausi Industrial Area,

Nadarganj, Kanpur Road, Lucknow - 226008 (U.P.), India

Email: biogenix2007@yahoo.com, info@biogenixinc.com

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