CE CTK BIOTECH SIMPLIFYING DIAGNOSTICS

REF

Catalog Number R0191C

IVD

In vitro Diagnostic

INTENDED USE

The *OnSite* H. pylori Ab Combo 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 by professional and as an aid in the diagnosis of infection with *H. pylori*. Any reactive specimen with the *OnSite* H. pylori Ab Combo Rapid Test must be confirmed with alternative testing method(s) and clinical findings.

SUMMARY AND EXPLANATION OF THE TEST

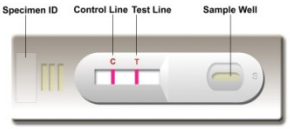
Helicobacter pylori is associated with a variety of gastrointestinal diseases including non-ulcer dyspepsia, duodenal and gastric ulcers and active, chronic gastritis[1,2]. The prevalence of *H. pylori* infection could exceed 90% in patients with signs and symptoms of gastrointestinal diseases. Recent studies indicate an association of *H. pylori* infection with stomach cancer[3].

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 evidence[7].

The *OnSite* H. pylori Combo Ab 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 *OnSite* 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

1. Individually sealed foil pouches containing:
   a. One cassette device
   b. One desiccant
2. Plastic droppers
3. Sample Diluent (REF SB-R0191, 5 mL/bottle)
4. One package insert (instruction for use)

MATERIALS MAY BE REQUIRED AND NOT PROVIDED

1. Positive Control
2. Negative Control

MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock or Timer
2. Lancing device for whole blood test

WARNINGS AND PRECAUTIONS

For *in Vitro* Diagnostic Use

1. This package insert must be read completely before performing the test. Failure to follow the insert may lead to 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 components from any other type of test kit as a substitute for the components in this kit.
6. Do not use hemolyzed blood specimens 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. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
9. Do not smoke, drink or eat in areas where specimens or kit reagents are being handled.
10. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
11. Handle the negative and positive controls in the same manner as patient specimens.
12. 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.
13. 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 devices 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 to temperatures 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 finger tip 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

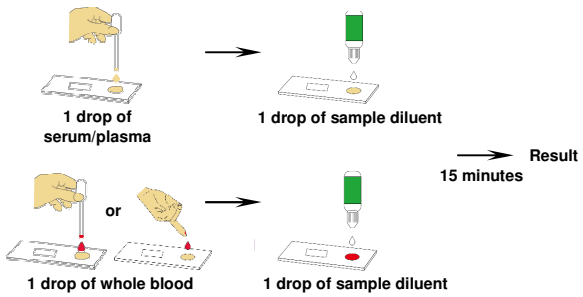
Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen. Once thawed, mix the specimen well prior to performing the assay.

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 30-45 µL) or 1 drop of whole blood (about 40-50 µL) into the sample well, making sure there are no air bubbles.

Immediately add 1 drop (about 35-50 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.

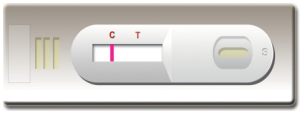
Do not read the result after 20 minutes. To avoid confusion, discard the test device after interpreting the result.

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

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.

Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a diagnostic decision is made.

3. **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.

PERFORMANCE CHARACTERISTICS

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 *OnSite* H. pylori Ab Combo Rapid Test. Comparison for all subjects is shown in the following table.

	OnSite H. pylori Ab Combo Rapid Test		
***H. pylori* Patients**	**Positive**	**Negative**	**Total**
Positive	65	10	75
Negative	18	182	200
Total	83	180	275

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

LIMITATIONS OF TEST

1. 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.
2. The *OnSite* H. pylori Ab Combo 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.
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 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.
5. Infection may progress rapidly. If the symptom persists, while the result from *OnSite* H. pylori Ab Combo Rapid Test is negative or non-reactive, it is recommended to re-test the patient a few days later or test with an alternative test method.
6. Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factor may affect expected results.
7. Results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

REFERENCES

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6. 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.
7. 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.

Index of CE Symbols

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

CTK Biotech, Inc.
10110 Mesa Rim Road
San Diego, CA 92121, USA
Tel: 858-457-8698
Fax: 858-535-1739
E-mail: info@ctkbiotech.com

EC REP **MDSS GmbH**
Schiffgraben 41, 30175 Hannover, Germany

PI-R0191C Rev. F
Effective date: 2014-04-21
English version