



REF R0191C **IVD** In vitro Diagnostic

INTENDED USE

The 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 by professionals as a screening test and provides a preliminary test result to aid in the diagnosis of infection with *H. pylori*.

Any use or interpretation of this preliminary test result must also rely on other clinical findings and the professional judgment of health care providers. Alternative test method(s) should be considered to confirm the test result obtained by this device.

SUMMARY AND EXPLANATION OF THE TEST

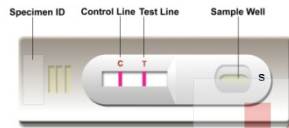
Helicobacter pylori is associated with a variety of gastrointestinal diseases including non-ulcer dyspepsia, duodenal and gastric ulcers and active, chronic gastritis^{1,2}. The prevalence of *H. pylori* infection could exceed 90% in patients with signs and symptoms of gastrointestinal diseases. Recent 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 Combo Ab Rapid Test is the latest generation of chromatographic immunoassays which utilizes recombinant antibodies 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
- Plastic droppers
- Sample diluent (REF SB-R0191, 5 mL/bottle)
- 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 (15-30°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 results should be read 15-20 minutes after a specimen is applied to the sample

well or sample pad of the device. Any results interpreted outside of the 15-20 minutes window should be considered invalid and must be repeated.

- 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 2-30°C. If stored at 2-8°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 temperature above 30°C.

SPECIMEN COLLECTION AND HANDLING

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

Plasma/Serum

- Collect blood specimen into collection tube containing EDTA, citrate or heparin for plasma or collection tube containing no anticoagulants for serum by venipuncture.
- To make plasma specimen, centrifuge collected specimens and carefully withdraw the plasma into a new pre-labeled tube.
- To make serum specimen, allow blood to clot, then centrifuge collected specimens and carefully withdraw the serum into a new pre-labeled tube.

Test specimens as soon as possible after collecting. Store specimens at 2-8°C, if not tested immediately. The specimens can be stored at 2-8°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 with result interpretation.

Whole Blood

- Drops of whole blood can be obtained by either fingertip puncture or venipuncture. Collect blood specimen into a collection tube containing EDTA, citrate or heparin. Do not use hemolyzed blood for testing.

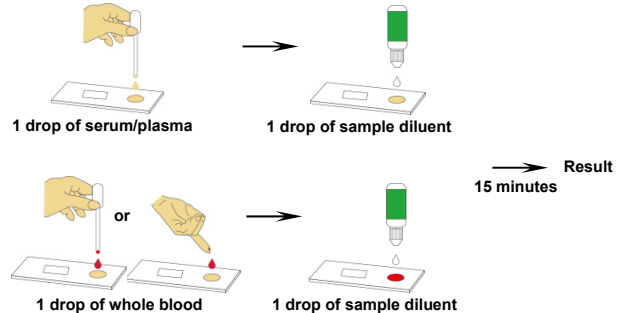
Whole blood specimens should be stored in refrigeration (2-8°C), if not tested immediately. The specimens must be tested within 24 hours of collection.

ASSAY PROCEDURE

- Bring the specimen and test components to room temperature if refrigerated or frozen. Once thawed, mix the specimen well prior to performing the assay.
- When ready to test, open the pouch at the notch and remove the device. Place the test device on a clean, flat surface.
- Be sure to label the device with the specimen ID number.

- 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.



- Set up timer.
- Results should be read at 15 minutes. Positive results may be visible in as short as 1 minute. Negative results must be confirmed at the end of the 20 minutes only. **Any results interpreted outside of the 15-20 minutes window should be considered invalid and must be repeated. Discard used devices after interpreting the result following local requirements governing the disposal of devices.**

QUALITY CONTROL

- 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.
- 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 2-30°C.
 - The temperature of the test area falls outside of 15-30°C.
 - To verify a higher than expected frequency of positive or negative results.
 - To investigate the cause of repeated invalid results.

INTERPRETATION OF ASSAY RESULT

- NEGATIVE RESULT:** If only the C line develops, the test indicates that no detectable antibodies to *H. pylori* are present in the specimen. The result is non-reactive or negative.



- POSITIVE RESULT:** If both the C and the T lines develop, 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.

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




Mfd. By: M/s. CTK Biotech, Inc.
13855 Stowe Drive, Poway, California 92064,
USA (United States) having factory premises at
M/s Beijing Genesee Biotech Inc., #36, Yanqi
Donger Road, Huairou Yanqi Industrial
Development Zone, Beijing, China

For Export Only, Not For Re-sale In the USA

EC	REP
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MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

PI-R0191C-ATH Rev. FP
Date released: 2019-01-28
English version

PERFORMANCE CHARACTERISTICS

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

H. pylori Patients	H. pylori Ab Combo Rapid Test		Total
	Positive	Negative	
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 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.
- A negative or non-reactive result for an individual subject indicates absence of detectable antibodies to *H. pylori*. However, a negative or non-reactive test result does not preclude the possibility of exposure to or infection with *H. pylori*.
- A negative or non-reactive 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.
- Infection may progress rapidly. If the symptom persists, while the result from 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.
- 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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- 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.

Index of CE Symbols

	Consult instructions for use		For <i>in vitro</i> 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		