H. pylori Ab Rapid Test (WB,S,P)

Labgene biotech

INTENDED USE

The Labgene 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 healthcare professionals as an 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.

ORDER INFORMATION AND MATERIALS PROVIDED

Cat No.	Test Devices	Assay Buffer	Dropper & Sillica Gel	Lancets & Alcohol Swabs
LG019-10T	10	1 X 2 mL	01 in an individual pouch	-
LG019-25T	25	1 X 3 mL		
LG019-30T	30	1 X 3 mL		
LG019-40T	40	2 X 2 mL		
LG019-50T	50	2 X 3 mL		
LG019-100T	100	4 X 3 mL		
LG019LS-10T	10	1 X 2 mL		10
LG019LS-25T	25	1 X 3 mL		25
LG019LS-30T	30	1 X 3 mL		30
LG019LS-40T	40	2 X 2 mL		40
LG019LS-50T	50	2 X 3 mL		50
LG019LS-100T	100	4 X 3 mL		100
*IFU: O1 in an individual carton box				

INTRODUCTION

The Labgene Helicobacter pylori is associated with a variety of gastrointestinal diseases including non-ulcer dyspepsia, duodenal and gastric ulcers and active, chronic gastritis1,2. 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 responses4,5,6 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 antigens to detect antibodies to H. pylori in human serum, plasma or whole blood. The test is user friendly, highly sensitive and specific.

PRINCIPLE

The Labgene 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 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 © 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 colored T line, indicating a H. pylori Ab positive test result. Absence of the T line suggests a negative result.

MATERIALS NEEDED BUT NOT PROVIDED

- Specimen collection container
- Timer
- Centrifuge
- Micropipette

PRECAUTIONS

- For professional in vitro diagnostic use only. Do not use after expiration date.
- Do not use if pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves or eye protection when specimens are being tested.
- Humidity and temperature can adversely affect results.
- The used test should be discarded according to local regulations.
- Do not use expired lancet.
- Do not share used lancet.

STORAGE AND STABILITY

- Store as packaged in the sealed pouch either at room temperature or refrigerated (2°C-30°C).
- DO NOT FREEZE.
- The test device is stable through the expiration date printed on the sealed pouch.
- The test device must remain in the sealed pouch until use.

SPECIMEN COLLECTION AND PREPARATION

The H. Pylori Rapid Test can be performed using either serum, plasma or whole blood.

Plasma :

- Collect blood specimen into collection tube containing EDTA, Citrate or Heparin.
- Separate the plasma by centrifugation.
- Carefully withdraw the plasma into a new pre-labeled tube.

Serum :

- Collect blood specimen into a collection tube containing no anticoagulants.
- Allow the blood to clot.
- Separate the serum by centrifugation,
- Carefully withdraw the serum into a new Pre-Labeled Tube.

Test the specimens as soon as possible after collections. Store serum/ plasma at 2°C-8°C for up to three days if the tests cannot be performed immediately. 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 and mix gently. Do not use haemolysed sample.

Whole Blood :

Venipuncture:

- Collect the whole blood into the collection tube (containing EDTA, citrate or heparin) by Venipuncture.
- Transfer the sample to sample well of device using sample pipette.
- Whole blood specimens should be stored in refrigeration (2°C-8°C) if not tested immediately. The whole blood must be tested within 24 hours of collection.

Collection using a lancet:

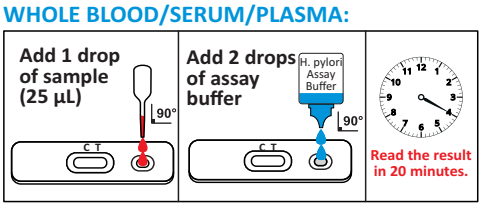
- Clean the area to be lanced with the alcohol swab.
- Squeeze the fingertip then prick the lateral side of the finger with a lancet provided .
- Wipe away the first blood drop. And immerse the open end of a micropipette and release the pressure to draw blood into it.

PROCEDURE

For Serum/ Plasma specimens: Hold the sample dropper vertically and transfer **01 Drops of Serum/ Plasma (25 µL)** to the specimen well of the test device, add **2 drops of buffer (80 µL)** solution into the well and start the timer.

For Whole Blood Specimens: Hold the sample dropper vertically and transfer **01 Drops of whole blood (25 µL)** to the specimen well of the test device, add **2 drops of buffer (80 µL) solution** into the well and start the timer. Read the results at the end of 20 minutes.

WHOLE BLOOD/SERUM/PLASMA:

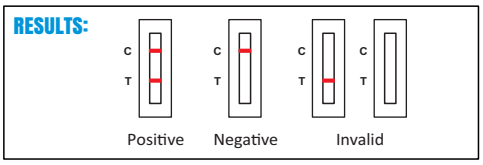


INTERPRETATION OF RESULTS

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.

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.

Invalid Result: 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.



LIMITATIONS

- 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 Labgene 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 labgene 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

PERFORMANCE CHARACTERISTICS

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.

H. pylori Samples	Positive	Negative	Total
Positive	65	10	75
Negative	18	182	200
Total	83	192	275

Relative Sensitivity: 86.7% (95% CI: 76.8-93.4%),
Relative Specificity: 91% (95% CI: 86.1-94.6%),
Overall Agreement: 89.8% (95% CI: 85.6-93.1%).

REFERENCES

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4. Ansorg, R., Von Recklinghausen, G., Pomarius, R., et.al. Evaluation of techniques for isolation, subcultivation and preservation of Helicobecter pylori. J. Clin. Micro. 1991.29:51-3.
5. Pronovost, A.P., Rose, S.L., Pawlak, J., et.al. Evaluation of new immunodiagnostic assay for Helicobacter pylori antibody detection: Correlation with histopathological and microbiological results. J. Clin. Microbiol.1994.32:46-50.
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 SYMBOLS

REF	Product Reference No.	ISO ISO 13485	International Organization or Standardization
	Manufacturer		Keep out of Sunlight
	Expiry date	IVD	For invitro diagnostic use only
LOT	Lot (batch) number		Read product insert before use.
2°C 30°C	Store between 2-30°c		Do not use if package is damaged
	Do not reuse		Keep Away From Moisture
	Contains sufficient for test	ART/IFU-019-01	

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