PATHKITS

SIMPLE H. pylori ANTIBODY

Product Code: **PKRK022**
Kit Contents (**25 Kits**)
Shelf Life: **24 Months**

Kit Components	Quantity (Units)
Test Strips	25
Assay Buffer	1 Bottle
Sample Dropper	25
IFU	1

Introduction

H. pylori is a small, spiral-shaped bacterium that lives in the surface of the stomach and duodenum. It is implicated in the etiology of a variety of gastrointestinal diseases, including duodenal and gastric ulcer, non-ulcer dyspepsia and active and chronic gastritis (1,2). Both invasive and non-invasive methods are used to diagnose *H. pylori* infection in patients with symptoms of gastrointestinal disease. Specimen dependent and costly invasive diagnostic methods include gastric or duodenal biopsy followed by urease testing (presumptive), culture, and/or histologic staining (3). Non-invasive techniques include the urea breath test, which requires expensive laboratory equipment and moderate radiation exposure, and serological methods (4). Individuals infected with *H. pylori* develop antibodies which correlate strongly with histologically confirmed *H. pylor*i infection (5). The *H. pylori* Rapid Test Device (Whole Blood/Serum/Plasma) is a simple test that utilizes a combination of *H. pylori* antigen coated particles and anti-human IgG to qualitatively and selectively detect *H. pylori* antibodies in whole blood, serum, or plasma in just minutes.

Intended Use

Simple *H.pylori* antibody is lateral flow chromatographic immunoassay for the qualitative detection of antibodies (IgG/IgM) 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.*

Test Principle

The Simple *H. pylori* Antibody Rapid Test is a lateral flow chromatographic immunoassay based on the principle of the double-antigen sandwich technique. A pink purple 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 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) 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 pink purple colored T line, indicating a *H. pylori* Ab positive test result. Absence of the T line suggests a negative result. To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

Warnings and Precautions

1. Read these Instructions for Use completely before performing the test. Failure to follow the instructions could 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 (15-30°C) before use.
5. Do not use the components in any other type of test kit as a substitute for the components in this kit.
6. Do not smoke, drink or eat in areas where specimens or kit reagents are being handled.
7. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
8. Handle the negative and positive controls in the same manner as the patient specimens

Reagent Preparation and Storage Instructions

All reagents are ready to use as supplied. Store unused test devices unopened at 2-40°C. If stored at 2-8°C, ensure that the test device is brought to room temperature (15-30°C) before opening. The test device is stable through the expiration date printed on the pouch. Do not freeze or expose the kit to temperatures above 40°C.

Specimen Collection and Handling

Specimen to be tested should be obtained and handled by standard methods for their collections.

1. **Serum:** Allow the blood to clot, then centrifuge to separate the serum.
2. **Plasma:** Collect the whole blood into the tube containing anticoagulants such as heparin, citrate, or EDTA. Centrifuge the blood and separate the plasma

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3. **Whole blood:** Fresh blood from finger prick/puncture may be used as a test specimen for collection of whole blood as a test specimen.
4. Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection.
5. Do not freeze whole blood specimens.
6. Whole blood collected by fingerstick should be tested immediately.
7. Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.
8. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

Materials Required but not provided

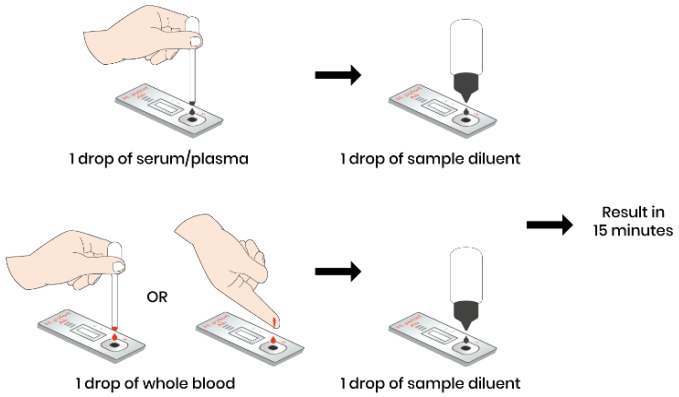
1. Timer or Stopwatch
2. PPE and other consumables for collection and disposal of samples.

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 Simple *H. pylori* Antibody Rapid Test is limited to the qualitative detection of IgG, IgM 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. Infection may progress rapidly. If the symptom persists, while the result from Simple *H. pylori* antibody 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.
4. 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*.
5. 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.

Procedure

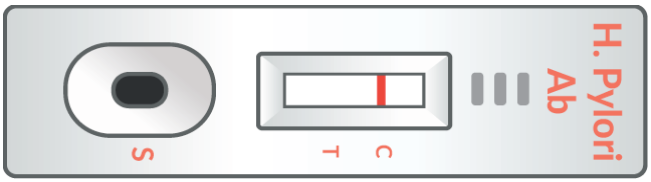
1. Allow the test cassette to reach room temperature (appropriately 30 minutes).
2. When ready to test, open the pouch at the notch and remove the device. Place the test device on a clean, flat surface.
3. Fill the dropper with the specimen. Holding the dropper vertically, dispense 1 drop of serum/plasma (approximately 25µl) or 1 drop of whole blood (approximately 25µl) into the sample well, making sure there are no air bubbles. Immediately add 1 drop (approximately 40µl) of sample diluent with the bottle positioned vertically.



4. Results read in 15 minutes. Negative results must be confirmed at the end of the 20 minutes only.

Interpretation of results

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.

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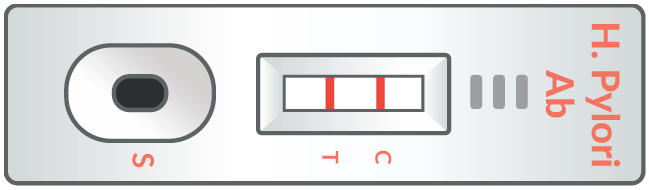
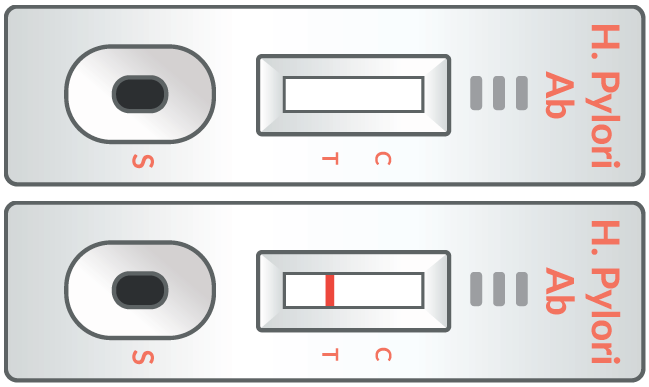


INVALID: If no C line develops, the assay is invalid regardless of color development on the T line. Repeat the assay with a new device.



Quality Control

Internal procedural controls are included in the test. A Colored line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume.

Reference

1. Marshall, B.J., McGechie, D.B., Rogers, P.A. and Clancy, R.J., 1985. *Pyloric Campylobacter* infection and gastroduodenal disease. *Medical Journal of Australia*, *142*(8), pp.439-444.
2. Soll, A.H., 1990. Pathogenesis of peptic ulcer and implications for therapy. *New England Journal of Medicine*, *322*(13), pp.909-916.
3. Hazell, S.L., Borody, T.J., Gal, A. and Lee, A., 1987. *Campylobacter* pyloridis gastritis I: Detection of urease as a marker of bacterial colonization and gastritis. *American Journal of Gastroenterology (Springer Nature)*, *82*(4).
4. Loffeld, R.J., Vriese, W.T. and Stobberingh, E.E., 1993. Usefulness of several commercial enzyme-linked immunoassays for detection of *Helicobacter pylori* infection in clinical medicine. *European journal of Gastroenterology & Hepatology*, *5*(5), pp.333-338.
5. Ansorg, R., Von Recklinghausen, G., Pomarius, R. and Schmid, E.N., 1991. Evaluation of techniques for isolation, subcultivation, and preservation of Helicobacter pylori. *Journal of Clinical Microbiology*, *29*(1), pp.51-53.

Technical Assistance

For customer support, please contact our Technical Support:
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Email: info@pathkits.com

Food and Drugs Administration Haryana
SCO-94, SEC-5, Panchkula

From

State Drugs Controller-cum-Licensing Authority
Food and Drugs Administration, Haryana,
SCO-94, Sector-5, Panchkula.

To

M/s Pathkits Healthcare Pvt.,
4th Floor, 28, 29 Electronic City, Sector -18,
Gurgaon, Haryana

Dated: 20-05-2022

Subject: **Regarding additional items.**

With reference to your application no. MFG/IVD/2022/58713 dated 22.05.2022 on the subject cited above.

Find enclosed herewith copy of Form MD-5, Lic No MFG/IVD/2021/000069 Endorsement No 06.

Manmohan Taneja
Digitally signed by Manmohan Taneja
Date: 2022.05.20 10:03:32 +05'30'

State Drugs Controller Haryana

सत्यमेव जयते

FORM MD-5

[See sub-rule (4) of rule 20 and sub-rule (6) of rule 20]

Licence to Manufacture for Sale or for Distribution of Class A or Class B medical device

Licence Number: MFG/IVD/2021/000069

Endorsement No. 6

1. M/s PATHKITS HEALTHCARE PRIVATE LIMITED, Plot No-28-29, Sector-18Gurgaon, Gurgaon, Haryana (India) - 122001 Telephone No.: 8802872273 FAX: 8802872273 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s PATHKITS HEALTHCARE PRIVATE LIMITED, 4th Floor, 28, 29 Electronic City, Sector -18, Gurgaon, Haryana (India) - 122001 Telephone No.: 8588869343 FAX: 8588869343

2. Details of medical device(s) [Annexed]

3. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

ANNEXURE

S.No.	Details Of Device(s)
1	Generic Name:Chikungunya Antibody (IgG/IgM) Test Kit Model No.:NIL Intended Use:It is a rapid immunochromatographic assay for the simultaneous detection of IgG and IgM antibodies to Chikungunya virus Class of medical device:Class B Material of construction:NA Dimension(if any):NA Shelflife:24 Months Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):SIMPLE Chikungunya Antibody (IgG/IgM) Test Kit
2	Generic Name:Filaria Antibody (IgG/IgM) Test Kit Model No.:NIL Intended Use:It is an immunoassay for the simultaneous detection and differentiation of anti-lymphatic filarial parasites (W.bancrofti and B.malayi) IgG and IgM in human serum, plasma, or whole blood. Class of medical device:Class B Material of construction:NA Dimension(if any):NA Shelflife:24 Months Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):SIMPLE Filaria Antibody (IgG/IgM) Test Kit

3	Generic Name:H.Pylori Antibody (IgG/IgM) Test Kit Model No.:NIL Intended Use:H. pylori Antibody Rapid Test is a sandwich lateral flow chromatographic immunoassay for the qualitative detection of antibodies (IgG, IgM) against Helicobacter pylori (H. pylori) in human serum, plasma or whole blood. Class of medical device:Class B Material of construction:NA Dimension(if any):NA Shelflife:24 Months Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):SIMPLE H.Pylori Antibody (IgG/IgM) Test Kit

Place:

Date20-May-22

Manmohan Taneja
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Date: 2022.05.20 10:04:33 +05'30'

State Licensing Authority