# H. Pylori Ag Rapydtest®

APACOR

H. pylori Ag Rapydtest®


BACTERIOLOGY

SINGLE USE IN VITRO DIAGNOSTIC DEVICE

H. pylori Ag Rapydtest®

## Intended Use

The H. pylori Ag Rapydtest® is a lateral flow chromatographic immunoassay for the qualitative detection of H. pylori antigen in human faecal specimen. 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 interpretation or use of this preliminary test result must also rely on other clinical findings as well as on 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 (H. pylori) a gram-negative, helical, rod-shaped bacterium, colonizes the gastric mucosa of approximately one-half of the world population[1]. H. pylori infection is a risk factor for a variety of gastrointestinal diseases including non-ulcer dyspepsia, duodenal and gastric ulcers and active, chronic gastritis[2-6]. Therefore elimination of H. pylori may be the most promising strategy to reduce the incidence of gastric cancer[7].

H. pylori can be transmitted through the ingestion of food or water that is tainted with faecal matter. Antibiotics in combination with bismuth compounds have been shown to be effective in treating active H. pylori infection.

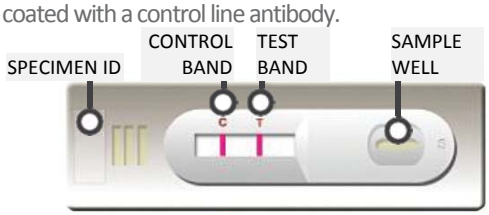
H. pylori infection is currently detected by invasive testing methods based on endoscopy and biopsy (i.e. histology, culture) or non-invasive testing methods such as Urea Breath Test (UBT), serologic antibody test and stool antigen test. UBT has a high accuracy but requires expensive lab equipment and use of a radioactive reagent[8]. Serologic antibody tests detect IgG specific to H. pylori, and cannot distinguish between current active infections and past infections. The stool antigen test detects antigen present in the faeces, which indicates an active H. pylori infection. It can also be used to monitor the effectiveness of treatment and the recurrence of an infection, and is not affected by the use of Proton Pump Inhibitors (PPI)[9].

The H. pylori Ag Rapydtest detects H. pylori antigen present in the faecal specimen by using specific antibodies. The test can be performed within 10 minutes by minimally skilled personnel without the use of laboratory equipment.

## Test Principle

The H. pylori Ag Rapydtest® is a lateral flow chromatographic immunoassay. The test strip in the cassette device consists of:

1. a burgundy coloured conjugate pad containing anti-H. pylori specific antibody conjugated with colloidal gold (anti-H. pylori conjugate); and
2. a nitrocellulose membrane strip containing a test band (T band) and a control band (C band). The T band is pre-coated with anti-H. pylori antibody, and the C band is pre-coated with a control line antibody.




When an adequate volume of extracted faecal specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the cassette. The H. pylori antigen, if present in the specimen, will bind to the anti-H. pylori conjugate. The immunocomplex is then captured on the membrane by the pre-coated antibody, forming a burgundy coloured T band, indicating an H. pylori positive test result. Absence of the T band suggests an H. pylori negative test result.

The test contains an internal control (C band) which should exhibit a burgundy coloured band of the immunocomplex of the control antibodies regardless of the colour development on the T band. If no control (C band) develops, 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 test device.
   b. One desiccant.
2. Sample collection tubes, each containing 1ml of extraction buffer.
3. Plastic droppers for transferring watery stool.
4. Patient ID stickers.
5. One package insert (instruction for use).

## Materials Required but not Provided

1. Clock or timer.
2. A container to hold faecal specimen.

## 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 can give inaccurate test results.
2. Do not open the sealed pouch, unless ready to conduct the assay.
3. Do not use any kit components beyond their stated expiration date.
4. Do not use the components from any other type of test kit as a substitute for the components in this kit.
5. Bring all reagents to room temperature (15°C - 30°C) before use.
6. Do not scoop stool sample as this may lead to excess faecal specimen that tends to clog the sample pad and interfere with sample migration.
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 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. Avoid extraction buffer contact with skin or eyes. Do not ingest.
11. Dispose of all specimens and materials used to perform the test as biohazardous waste.
12. The test results should be read 10-15 minutes after a specimen is applied to the sample well of the device. Any results interpreted outside of the 10-15 minute window should be considered invalid and must be repeated.
13. Do not perform the test in a room with strong air flow, ie electric fan or strong air-conditioning.

## Reagent Preparation and Storage Instructions

All reagents are ready to use as supplied. Store unopened test devices 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.

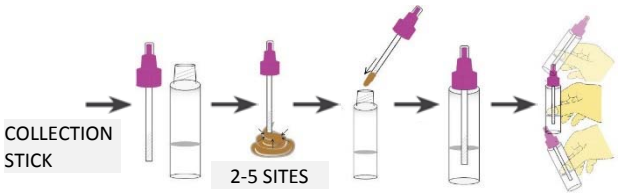
## Specimen Collection and Handling

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

To prepare specimens using solid stool samples follow Procedure A below. To prepare specimens using watery stool samples follow Procedure B below.

**Procedure A: Solid stool samples**

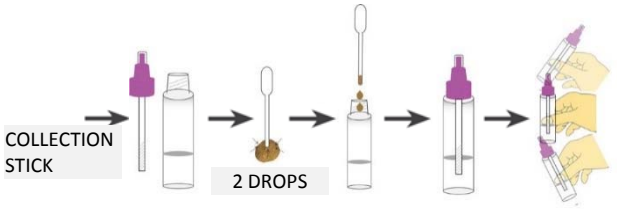
1. Collect a random stool sample in a clean, dry receptacle.
2. Label the sample collection tube with the specimen's ID number (patient ID sticker). Open the sample collection tube by unscrewing the top and use the collection stick to randomly pierce the stool sample in 2-5 different sites, twisting the collection stick into the stool specimen to help collection is necessary. Do not scoop stool sample as this may lead to an invalid test result.
3. Ensure that all inner grooves of the collection stick are filled with stool sample. Excess stool sample on the outside of the grooves should be scraped off. Incorrect sampling may lead to an erroneous test result.
4. Replace the collection stick and tighten securely to close the sample collection tube.
5. Shake the sample collection tube vigorously.




The specimen is now ready for testing, transportation or storage.

**Procedure B: Watery stool samples**

1. Collect a random stool sample in a clean, dry receptacle.
2. Label the sample collection tube with the specimen's ID number (patient ID sticker). Open the sample collection tube by unscrewing the top.
3. Fill the plastic dropper with the sample; dispense 2 drops (70-85µL) into the sample collection tube.
4. Replace the collection stick and tighten securely to close the sample collection tube.
5. Shake the sample collection tube vigorously.




The specimen is now ready for testing, transportation or storage.

Note: Specimens extracted may be stored at 2°C-8°C or at room temperature up to 37°C for 10 days. For longer storage, the extracted specimen may be frozen at -20°C. Avoid multiple free-thaw cycles.

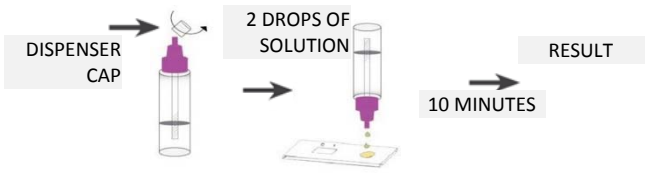
## Test Procedure

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

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

**Step 3** Shake the sample collection tube vigorously to ensure a homogenous liquid suspension.

**Step 4** Position the sample collection tube upright and twist off the dispenser cap. Dispense 2 drops (70-90µl) of the solution into the sample well of the cassette. Do not overload the solution.




**Step 5** Set up the timer.

**Step 6** Results can be read 10 minutes after adding the specimen. Positive results can be visible in a time period as short as 1 minute. Negative results must be confirmed at the end of the 15 minutes only. However, any results interpreted outside of the 10-15 minute window should be considered invalid and must be repeated. Discard used device after interpreting the result following local requirements governing the disposal of device.

## Quality Control

1. Internal Control: This test contains a built-in control feature, the C band. The C band develops after adding specimen extract. If the C band does not develop, review the entire procedure and repeat the test with a new device.
2. External Control: Good Laboratory Practice recommends using external positive and negative controls to assure the proper performance of the assay, particularly under the following circumstances:
   a. A new operator uses the kit, prior to performing testing of specimens.
   b. A new lot of test kits is used.
   c. A new shipment of kits is used.
   d. The temperature during storage of the kit falls outside of 2 - 30°C.
   e. The temperature of the test area falls outside of 15 - 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 band is developed, the test indicates that no detectable H. pylori antigen is present in the specimen. The result is negative or non-reactive.

2. **Positive Result:** If both C and T bands develop, the test indicates the presence of H. pylori antigen in the specimen. The result is positive or reactive.

3. **Invalid:** If no C band develops, the assay is invalid regardless of any colour development on the T band as indicated below. Repeat the assay with a new test device. Excess faecal specimen can lead to invalid test results; if this is the cause, re-sample and re-test (see instructions for collection of specimen).

## Performance Characteristics

### Clinical Performance

A total of 157 faecal specimens were collected from symptomatic patients and healthy individuals. Specimens were tested with the H. pylori Ag Rapydtest®. The urea breath test (UBT) gold standard is used as the reference test method. Comparison for all subjects is shown in the following table:

| | H. pylori Ag Rapydtest® | | |
|---|---|---|---|
| UBT | Positive | Negative | Total |
| Positive | 58 | 2 | 60 |
| Negative | 6 | 91 | 97 |
| Total | 64 | 93 | 157 |

Relative Sensitivity: 96.7%, Relative Specificity: 93.8%, Overall Agreement: 94.9%

### Analytic Sensitivity

Six groups of faecal specimen extracts from 20 healthy individuals were spiked with H. pylori lysate antigen (Strain 43504) at concentrations of 0, 0.25, 0.5, 0.75, 1, and 2ng/mL, respectively, and tested with the H. pylori Ag Rapydtest®. The results are showed in the following table. The detection limit of the H. pylori Ag Rapydtest® as defined as the level of ≥95% positive detection is 1ng/mL of H. pylori lysate antigen.

| H. pylori lysate ng/ml | 0 | 0.25 | 0.5 | 0.75 | 1 | 2 |
|---|---|---|---|---|---|---|
| Positive | 0 | 0 | 0 | 9 | 20 | 20 |
| Negative | 20 | 20 | 20 | 11 | 0 | 0 |
| Detection Rate % | 0 | 0 | 0 | 45 | 100 | 100 |

n=20, relative sensitivity at 1ng/mL is 100%

### Cross-Reactivity

The organisms listed below were tested for cross-reactivity with the H. pylori Ag Rapydtest®. No cross-reactivity was observed on the organisms at ≥ 1 x 108 org/ml.

*Acinetobacter calcoaceticus*
*Adenovirus*
*Enterococcus faecalis*
*Escherichia coli*
*Gardnerella vaginalis*
*Geotrichum candidum*
*Haemophilus influenza*
*α-haemolytics streptococcus*
*B-haemolytic streptococcus*
*Klebsiella pneumonia*
*Moraxella catarrhalis*
*Neisseria gonorrheae*
*Neisseria meningitides*
*Proteus mirabilis*
*Proteus vulgaris Hauser*
*Pseudomonas aeruginosa*
*Rotavirus*
*Salmonella Paratyphi A*
*Salmonella Paratyphi B*
*Salmonella Paratyphi C*
*Salmonella typhi*

### Interference

The following common and potentially interfering substances may affect the performance of the H. pylori Ag Rapydtest®. This was studied by spiking these substances into negative and positive faecal specimens, respectively. The results demonstrate, at the concentrations tested, the substances studied do not affect the performance of the H. pylori Ag Rapydtest®.

List of potentially interfering substances and concentrations tested:

| | | | |
|---|---|---|---|
| Tums® Antacid | 5mg/ml | Pepto-Bismol® Antacid | 1:20 |
| Tagamet® Antacid | 5mg/ml | Barium sulfate | 5% |
| Prilosec® Antacid | 5mg/ml | Haemoglobin (tarry stool) | 12.5% |
| Mylanta® Antacid | 1:20 | | |

## Limitations

1. The Test Procedure and the Interpretation of Assay Result sections must be followed closely when testing for the presence of H. pylori antigen in faeces. **Failure to follow the procedure, particularly the Specimen Collection and Handling procedure, may lead to inaccurate results.**
2. The H. pylori Ag Rapydtest® is limited to the qualitative detection of H. pylori antigen in human faecal specimen. The intensity of the test band does not have linear correlation with antigen titer in the specimen.
3. A negative or non-reactive result indicates the absence of detectable H. pylori antigen. However, a negative test result does not preclude the possibility of infection with H. pylori.
4. A negative or non-reactive result can occur if the quantity of the H. pylori antigen present in the specimen is below the detection limits of the assay or if the antigens that are detected are not present in the faecal specimen collected.
5. It is reported that the seroprevalence of H. pylori in specimens with positive faecal occult blood (FOB) test results is approximately 39.3%[10]. Therefore a specimen that tests positive with an FOB test may also be tested positive with the H. pylori Ag Rapydtest®.
6. If symptoms persist and the result from the H. pylori Ag Rapydtest® is negative or non-reactive, it is recommended to test with alternative test methods.
7. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

## References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## Ordering Information

| PRODUCT | PACK SIZE | CODE |
|---|---|---|
| H. pylori Ag Rapydtest® | 25 | 1632 |

**Products can be ordered direct from Apacor or from an appointed distributor**

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