# H. pylori Ag Rapid Test
# Package Insert

| REF VIHP-602 | English |
|---|---|

## INTENDED USE

The VivaDiag™ H. pylori Ag Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of H. Pylori in feces samples. It is intended to be used by professionals as a preliminary test result to aid in diagnosis of infection with H. Pylori. For *in vitro* diagnostic use only.

## SUMMARY

Helicobacter Pylori (also known as Campylobacter Pylori) is a spiral-shaped with a typical flagellum, Gram negative bacteria, infecting gastric mucosa. It causes several gastro-enteric diseases such as non-ulcerous dyspepsia, gastric and duodenal ulcer, active gastritis and can even increase the risk of stomach adenocarcinoma, so as to be classified as carcinogen agent type I. Many H. Pylori strains have been isolated: among them, the strain expressing CagA antigen is strongly immunogenic and, according to this, it is of utmost clinical importance because it is associated to the cytotoxic factor. It is widely reported in many literature articles that, in infected patients showing antibodies against CagA gene product, the risk of gastric cancer is up to five times higher than the reference group infected with a CagA negative bacterial strain. The presence of the gene itself determines the persistence of the infection, the ulceration and the protein associated, VacA toxin is frequently the main cause of infiltrations in the gastric mucosa. This antigen associated to others, such as CagII, CagC, seems to act as starting agent of a sudden inflammatory response which can provoke ulceration (peptic ulcer), allergic episodes, and a decrease of the therapy efficacy. At present several invasive and non-invasive approaches are available to detect this infection state. Invasive methodologies require endoscopy of the gastric mucosa with a histologic, cultural and urease investigation, which are cost-effective and requiring long times to come to a correct final diagnosis. Alternatively, non-invasive methods are available such as Breath Test, which is extremely complicated and not highly selective, or classical ELISA and immunoblotting assays.

## PRINCIPLE

The VivaDiag™ H. pylori Ag Rapid Test is a lateral flow chromatographic immunoassay. The test utilizes antibodies including a HP monoclonal antibody and Goat anti-mouse IgG antibody (polyclonal antibody) on the nitrocellulose membrane with colloidal gold marked HP antibody as a mark tracer. The reagent is used to detect the HP antigen in sample according to the principle of double antibody sandwich method and gold immunochromatography assay.
When an adequate volume of test specimen is dispensed into the sample well, respectively, the specimen migrates by capillary action across the test strip. If H. Pylori is present in the specimen, it will bind to the conjugates. The immunocomplex is then captured on the membrane by the pre-coated HP monoclonal antibody forming a burgundy colored T line, indicating a positive test result.
Absence of any test line suggests a negative result. The test contains an internal control (C line) which should exhibit a burgundy colored line of the immunocomplex of control line antibodies. Regardless of any color development on the test line, if the C line does not develop, the test result is invalid and the specimen must be retested with another device.

## WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- For professional use only.
- Use the Test Device only once.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use test if pouch is damaged.
- Do not use test kit after expiration date.
- Do not open the foil pouch until you are ready to perform the test.
- Do not spill solution into the reaction zone.
- Do not touch the reaction zone of the device to avoid contamination.
- Avoid cross-contamination of samples by using a new specimen collection container and specimen collection tube for each sample.
- All patient samples should be treated as if capable of transmitting disease. Observe established precautions against microbiological hazards throughout testing and follow standard procedures for proper disposal of specimens.
- Do not use more than the required amount of liquid.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.

## COMPOSITION

Materials provided and available for purchase:
1. Test device in foil pouch
2. Specimen collection tube with buffer
3. Package insert

Materials required but not provided:
1. Timer
2. Personal protective equipment, such as protective gloves, medical masks, lab coats, etc.
3. Appropriate biohazardous waste containers and disinfectants.
4. Dropper

## STORAGE AND HANDLING

- Store the test kit in a cool, dry place between 2-30°C. Keep away from light. Exposure to temperature and/or humidity outside the specified conditions may cause inaccurate results.
- Do not freeze. Use the test kit at temperatures between 15-30°C.
- Use the test kit between 10-90% humidity.
- Do not use the test kit beyond the expiration date (printed on the foil pouch and box).

***Note:*** *All expiration dates are printed in Year-Month-Day format. 2022-06-18 indicates June 18, 2022.*

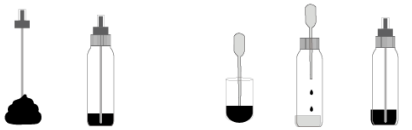
## SPECIMEN COLLECTION AND HANDLING

**1) Specimen collection**
Specimen collection and pre-treatment:
1. Use the specimen collection tube for specimen collection. Best results will be obtained if the assay is performed within 6 hours after collection.

**For solid specimens:**
Unscrew and remove the applicator stick attached on the cap. Be careful not to spill or spatter solution from the tube. Collect specimen by inserting the applicator stick into at least 6 different sites of the feces to collect approximately 50 mg of feces (equivalent to 1/4 of a pea).

**For liquid specimens:**
Hold the dropper vertically, aspirate feces specimens, and then transfer 2 drops (approx. 50 µL) into the specimen collection tube containing the extraction buffer.
2. Place the applicator back into the tube and screw the cap tightly.
3. Shake the specimen collection tube vigorously to mix the specimen and the extraction buffer.

Specimens prepared in the specimen collection tube may be stored for 6 months at -20° C if not tested within 1 hour after preparation.



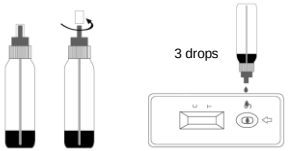
Solid Specimen  Liquid Specimen

**2) Specimen handling**
Perform the testing immediately after the specimen collection. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 48 hours.

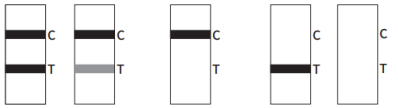
***Note:***
- *Patients should not collect samples during their menstrual period, if they have bleeding hemorrhoids, blood in the urine, or if they have strained during bowel movement.*
- *A sample must be collected in a clean and dry container.*

## TEST PROCEDURE

Allow the test, buffer, specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.
1. Take out a test device from sealed foil pouch and put it on a clean and level surface.
2. Open the tip of the buffer tube. Apply 3 drops of the specimen into the specimen well (S). Please avoid bubbles during applying.
3. Wait for the red line(s) to appear. Read the test result at **10 minutes**. Don't read the result after 20 minutes.




## INTERPRETATION OF TEST RESULTS




**Positive**  **Negative**  **Invalid**

**Positive*: Two distinct colored lines appear.** One line should be in the control line region (C) and another line should be in the test line region (T).

****Note:*** *The intensity of the color in the test line region (T) may vary depending on the concentration of H. Pylori antigens present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.*

**Negative:** One colored line appears in the control line region (C). No apparent colored line appears in the test line region (T).

**Invalid: Control line fails to appear.** Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

## QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

## LIMITATIONS

- The H. Pylori Ag Rapid Test is for *in vitro* diagnostic use only. The test should be used for the detection of H. Pylori antigens in feces only. Neither the quantitative value nor the rate of increase in H. Pylori antigen concentration can be determined by this qualitative test.
- The H. Pylori Ag Rapid Test will only indicate the presence of H. Pylori antigens in the specimen and should not be used as the sole criteria for the diagnosis of H. Pylori infection.
- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
- If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of H. Pylori infection.
- Reagent blocking by sample may occur according to too much or too sticky sample. Diluted samples should be centrifuged, filtered, or allowed to settle to obtain a clear sample for testing.

## PERFORMANCE

**1. Accuracy**

| VivaDiag™ H. pylori Ag Rapid Test | Biopsy/Histology/ RUT | | |
|---|---|---|---|
| | Positive | Negative | Total |
| Positive | 131 | 10 | 141 |
| Negative | 7 | 225 | 232 |
| Total | 138 | 235 | 373 |
| Sensitivity | 95.0% (131/138, 95%CI, 90.0%~97.9%) | | |
| Specificity | 95.7% (225/235, 95%CI, 92.3%~97.9%) | | |
| Accuracy | 95.4% (356/373, 95%CI, 92.8%~97.3%) | | |

## REFERENCES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## INDEX OF SYMBOLS

| | | | | | |
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| | Consult instructions for use | | Use by | Σ | Contains sufficient for <n> tests |
| IVD | For *in vitro* diagnostic use only | LOT | Lot number | REF | Catalog number |
| 2°C 30°C | Storage temperature limitations | | Manufacturer | | Do not reuse |
| EC REP | Authorized Representative | | | | |


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CE IVD


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