



## H. Pylori Ab Rapid Test Package Insert

REF VIHP-402

English

### INTENDED USE

The VivaDiag™ H. pylori Ab Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of antibodies (IgG, IgM and IgA) against *Helicobacter pylori* (H. pylori) in human whole blood, serum, or plasma. It is intended to be used by professionals as a preliminary test result to aid in the diagnosis of infection with H. pylori. For *in vitro* diagnostic use only.

### SUMMARY

*Helicobacter Pylori* (HP) grows in gastric mucus deep layer, surface of gastric mucosa, and mostly in gastric antrum, gastric pit, epithelial deep fold and gland cavity. There will be a short-term acute gastritis symptom with epigastric pain, nausea, emesis and flatulence after *Helicobacter pylori* enter the stomach. The most common infections is chronic gastric inflammation with no obvious symptoms, which will cause duodenal ulcer and gastric ulcer. HP is a pathogenic factor of stomach cancer, for causing induction of bacterial proliferation, changes of gastric mucosa, decrease of hydrochloric acid in gastric juice. Over 90% of duodenal ulcer is found with HP, over 70% of gastric ulcer is found with HP and over 60% of chronic gastritis is associated with HP.

### PRINCIPLE

The H. pylori Ab Rapid Test is a lateral flow chromatographic immunoassay based on the principle of the double-antigen sandwich technique. The test device consists of: 1) a 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 device, the specimen migrates by capillary action across the device. Antibodies (IgG, IgM or IgA) to H. pylori, if present in the specimen, will bind to the H. pylori conjugates. The compounds are then captured on the membrane by the pre-coated H. pylori antigens forming a colored line (T), 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 colored line of the compounds 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.

### WARNINGS AND PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Carefully read through the test procedure prior to testing.
- Do not use the test after the expiration date indicated on the package.
- Do not use the test if the foil pouch is damaged.
- Do not reuse tests.
- Do not add samples to the reaction area (result area).
- In order to avoid contamination, do not touch the reaction area (result area).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Do not substitute or mix components from different test kits.
- Do not eat, drink or smoke in the area where specimens and test kits are handled.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being assayed.

### COMPOSITION

Materials provided and available for purchase:

- Test device (dropper) in foil pouch
- Buffer
- Package insert

Materials required but not provided:

- Specimen collection container
- Centrifuge (for serum/plasma samples)
- Timer
- Personal protective equipment, such as protective gloves, medical masks, lab coats, etc.
- Appropriate biohazardous waste containers and disinfectants.

### STORAGE AND HANDLING

- Store the test kit in a cool, dry place between 36-86°F (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 59-86°F (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

The H. pylori Ab Rapid Test can be performed using whole blood, serum, or plasma.

#### Serum/Plasma

- Specimens should be collected by standard protocol.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for a long time.
- If not tested immediately, store specimens at 2-8°C for up to 7 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.

#### Whole Blood

- Drops of whole blood can be obtained by either fingertip puncture or vein-puncture. Do not use hemolysis for testing.
- Whole blood specimens should be stored in refrigeration at 2-8°C if not tested immediately. The specimens must be tested within 3 days of collection.

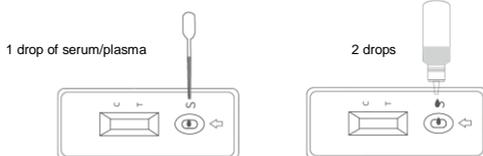
### TEST PROCEDURE

Allow the test, buffer, specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

- Take out a test device from sealed foil pouch and put it on a clean and level surface.
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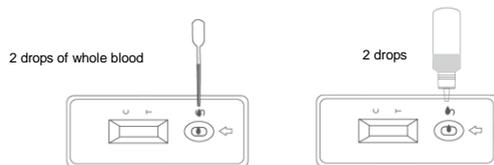
#### [For Serum/Plasma]

Transfer 1 drop of serum/plasma specimen (approx. 25 µL) into the specimen well (S), then add 2 drops (approx. 80 µL-100 µL) of buffer. Please avoid bubbles during applying.



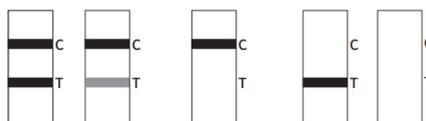
#### [For Whole blood]

Transfer 2 drops of whole blood specimen (approximately 50 µL) into the specimen well (S), then add 2 drops (80 µL-100 µL) of buffer. Please avoid bubbles during applying.



- Wait for the red line(s) to appear. Read results at **15 minutes**. Do not interpret results 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 Ab 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

- Handle all specimens as if they contain infectious agents. Observe established precautions for microbiological risks throughout all procedures and standard guidelines for the appropriate disposal of specimens.
- The test kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled in accordance with usual safety precautions (e.g., do not ingest or inhale).
- Humidity and temperature can adversely affect test results.
- Used testing materials should be discarded according to local regulations.

### PERFORMANCE

#### 1. Using internal quality control samples:

- Negative specificity: The results should all be negative when detecting 10 kits of HP negative quality control samples.
- Positive specificity: The results should all be positive when detecting 10 kits of HP positive quality control samples. (Including strong, medium and weak positive samples)
- Limit of detection: The results should all be positive when detecting diluted HP positive quality control samples with the diluent rate at 1:8.
- Repeatability: The results should be consistent and the coloration degree should be consistent when detecting the precision control samples by 10 kits of the same batch.

#### 2. Accuracy

A clinical evaluation was conducted on 1050 samples comparing the results obtained using the H. Pylori Ab Rapid Test and other commercially available HP tests.

VivaDiag™ H. Pylori Ab Rapid Test	Reference reagent		
	Positive	Negative	Total
Positive	322	2	324
Negative	6	720	726
Total	328	722	1050
Sensitivity	98.2%(322/328, 95%CI, 96.1%~99.3%)		
Specificity	99.7%(720/722, 95%CI, 99%~100%)		
Accuracy	99.2%(1042/1050, 95%CI, 98.5%~99.7%)		

#### 3. Interference

1000 mol/L bilirubin, 5.65 mmol/L triglyceride, 6.5 g/L hemoglobin has no effect on the detection result.

#### 4. Cross-Reactivity

The reagent is not affected by the rheumatoid factor. The addition of hepatitis B virus, hepatitis A virus, hepatitis C virus, syphilis, human immunodeficiency virus samples showed no cross-reactivity.

### REFERENCES

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- Warren, J.R. & Marshall, B. (1983). Unidentified curved bacillus on gastric epithelium in active chronic gastritis (letters), *Lancet* 1: 1273-1275.

**INDEX OF SYMBOLS**

	Consult instructions for use		Use by		Contains sufficient for <n> tests
	For <i>in vitro</i> diagnostic use only		Lot number		Catalog number
	Storage temperature limitations		Manufacturer		Do not reuse
	Authorized Representative				


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