Helicobacter Pylori

RAPU08V400

DIAsource ImmunoAssays S.A. - Rue du Bosquet, 2 - B-1348 Louvain-la-Neuve – Belgium

History

Resume of change :

Previous Version : **190717-1**	**Current Version :** **230714**
Old DiaSource logo	New DiaSource logo on the front page

H.Pylori Cassette Test

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A rapid test for the qualitative detection of antibodies to Helicobacter Pylori in whole blood, serum or plasma

For professional in vitro diagnostic use only

RAPU08V400

IN VITRO DIAGNOSTIC

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INTENDED USE

The **DIAsource Helicobacter pylori Test** is a rapid chromatographic immunoassay for the qualitative detection of antibodies to H. pylori in whole blood, serum, or plasma to aid in the diagnosis of H. pylori infection.

SUMMARY

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 histological staining.[3] Non-invasive techniques include the urea breath test, which requires expensive laboratory equipment and moderate radiation exposure, and serological methods.[4,5] Individuals infected with H. pylori develop antibodies which correlate strongly with histologically confirmed H. pylori infection.[6,7,8]

The **DIAsource Helicobacter pylori Test** 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.

TEST PRINCIPLE

The **DIAsource Helicobacter pylori Test** is a qualitative membrane based immunoassay for the detection of H. pylori antibodies in whole blood, serum, or plasma. In this test procedure, anti-human IgG is immobilized in the test line region of the test. After specimen is added to the specimen well of the device, it reacts with H. pylori antigen coated particles in the test. This mixture migrates chromatographically along the length of the test and interacts with the immobilized anti-human IgG. If the specimen contains H. pylori antibodies, a colored line will appear in the test line region indicating a positive result. If the specimen does not contain H. pylori antibodies, a colored line will not appear in this region indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test contains H. pylori antigen coated particles and anti-human IgG coated on the membrane.

PRECAUTIONS

- For professional in vitro diagnostic use only.
- The test device should remain in the sealed pouch until use.
- Do not use the test if the foil pouch is damaged
- Read the entire procedure carefully prior testing.
- 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.
- Humidity and temperature can adversely affect results.
- Do not use after the expiration date.
- Do not reuse tests
- Do not eat, drink or smoke in the area where the specimens and kits are handled.
- The used test device should be discarded according to federal state and local regulations.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.

STORAGE AND STABILITY

Store as packaged at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. Tests should be kept out of direct sunlight.

- Do not freeze
- Do not use beyond the expiration date.

MATERIALS PROVIDED

- CARD — 20 H. Pylori test cassette
- PIPETTE — 20 Sample droppers
- BUF — 1 Buffer (Tris-buffer), 3 ml
- Package insert

MATERIAL REQUIRED BUT NOT PROVIDED

- Specimen collection containers
- Centrifuge
- Timer
- Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)
- Lancets (for fingerstick whole blood only)

SPECIMEN COLLECTION AND PREPARATION

The **DIAsource Helicobacter pylori Test** can be performed using whole blood (from venipuncture or fingerstick) serum or plasma

To collect Fingerstick whole blood specimens:

- Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
- Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
- Puncture the skin with a sterile lancet. Wipe away the first sign of blood
- Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- Add the Fingerstick whole blood specimen to the test by using **a capillary tube:**
  - Touch the end of the capillary tube to the blood until filled to approximately 75 μL. Avoid air bubbles.
  - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen area of the test cassette.
- Add the Fingerstick whole blood specimen to the test by using **hanging drops:**
  - Position the patient's finger so that the drop of blood is just above the specimen area of the test cassette.
  - Allow 3 hanging drops of fingerstick whole blood to fall into the center of the specimen area on the test cassette, or move the patient's finger so that the hanging drop touches the center of the specimen area. Avoid touching the finger directly to the specimen area.

Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.

Testing should be performed immediately after the specimens have been collected.
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. Do not freeze whole bloodspecimens.
Whole blood collected by fingerstick should be tested immediately.

Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing.
specimens should not be frozen and thawed repeatedly.

If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

DIRECTIONS FOR USE

1. **Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.**
2. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible.
3. Place the cassette on a clean and level surface.

4.a For serum or plasma specimen:
Hold the dropper vertically and transfer 3 drops of serum or plasma (approximately 75 μL) to the specimen well of test cassette and start the timer.

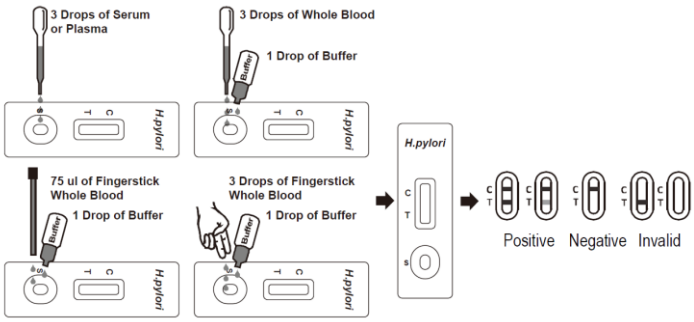
4.b For venipuncture whole blood specimen:
Hold the dropper vertically and transfer 3 drops of whole blood (approximately 75 μL) to the specimen well, then add 1 drop of buffer (approximately 40 μL), and start the timer.

4.c For fingerstick whole blood specimen:

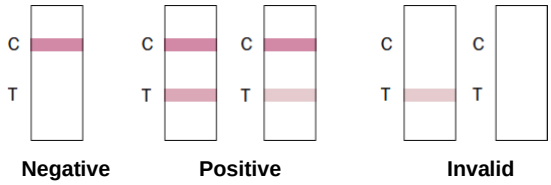
- To use a **capillary tube**: Fill the capillary tube and transfer approximately 75 μL of fingerstick whole blood specimen to the specimen area of test cassette, then add 1 drop of buffer (approximately 40 μL) and start the timer.

- To use **hanging drops**: Allow 3 hanging drops of fingerstick whole blood specimen (approximately 75 μL) to fall into the specimen area of test cassette, then add 1 drop of buffer (approximately 40 μL) and start the timer.

5. Wait for the colored line(s) to appear. Read results at 10 minutes. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS



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

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

Invalid: **Control lines 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 cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

Note: The intensity of the color in the test line region (T) will vary depending on the concentration of the **DIAsource Helicobacter pylori Test** in the specimen. Therefore, any shade of color in the test region (T) should be considered positive.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume 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 **DIAsource Helicobacter pylori Test** is for in vitro diagnostic use only. The test should be used for the detection of H. pylori antibodies in whole blood, serum or plasma specimens only. Neither the quantitative value nor the rate of increase in H. pylori antibody concentration can be determined by this qualitative test.
- The H. pylori Antibody Test will only indicate the presence of H. pylori antibodies 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.

EXPECTED VALUES

The **DIAsource Helicobacter pylori Test** has been compared with Culture/Histology, demonstrating an overall accuracy of 94.6%.

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy
The **DIAsource Helicobacter pylori Test** has been evaluated with specimens obtained from a population of symptomatic and asymptomatic individuals who presented for endoscopic examination. Biopsy (Culture) served as the reference method for the **DIAsource Helicobacter pylori Test** . Histology and a Rapid Urease Test (RUT) were performed on all negative culture specimens. The specimen was considered positive if Culture was positive. The specimen was also considered positive if the Culture was negative, but both Histology and RUT were positive. The result shows that the sensitivity of the H. pylori Antibody Test is 96.8% and the specificity is 93.0% relative to Biopsy/Histology/RUT.

DIAsource Helicobacter pylori Test vs. Biopsy/Histology/RUT

Method		Biopsy/Histology/RUT		Total Results
H.pylori Test Cassette	Results	Positive	Negative	
	Positive	150	15	165
	Negative	5	200	205
Total Results		155	215	370

Relative Sensitivity: 96.8% (95%CI*: 92.6%-98.9%)
Relatively Specificity: 93.0% (95%CI*: 88.8%-96.0%)
Accuracy: 94.6% (95%CI*: 91.8%-96.7%)
*Confidence Interval

Precision
Intra-Assay
Within-run precision has been determined by using 10 replicates of four specimens: a negative, a low positive, a medium positive and a high positive. The negative, low positive, medium positive and high positive values were correctly identified >99% of the time.

Inter-Assay
Between-run precision has been determined by 10 independent assays on the same four specimens: a negative, a low positive, a medium positive and a high positive. Three different lots of the H. pylori Antibody have been tested using negative, low positive, medium positive and high positive specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity
Sera containing known amounts of antibodies to H. pylori have been tested with Hepatitis A, B, C, E, HIV and Syphilis. No cross-reactivity was observed, indicating that the H. pylori Antibody Test has a high degree of specificity for antibodies to H. pylori.

Interfering Substances

The **DIAsource Helicobacter pylori Test** has been tested for possible interference from visibly hemolyzed and lipemic specimens, as well as serum specimens containing high bilirubin levels. In addition, no interference was observed in specimens containing up to 1,000 mg/dL hemoglobin; up to 1,000 mg/dL bilirubin; and up to 2,000 mg/dL human serum albumin.

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SYMBOLS

Consult instructions for use	Manufacturer
Storage temperature	Contains sufficient for n tests
Use by	IVD In vitro diagnostic medical device
LOT Batch code	CARD Card Test
REF Catalogue number	CONTENT Content
For single use only	Expiry date
PIPETTE Dropper	BUF Buffer
Capillary Tubes	Keep Dry
Keep away from direct sunlight	

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