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DIAQUICK H. pylori Cassette
(*Helicobacter pylori*)

for serum, plasma and whole blood samples

REF **Content**

Z06229CE - 30 cassettes individually packed + disposable pipette (30x REF Z98229B)
- 1 vial buffer, sufficient for 30 tests
- 1 package insert

For professional in vitro diagnostic use only

INTENDED USE

The DIAQUICK H. pylori Cassette (whole blood/serum/plasma) 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 in adults 18 years of age and older.

SUMMARY

H. pylori is a small, spiral-shaped bacterium that lives in the surface of the stomach and duodenum. It is implicated in the aetiology 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.[4,5] Individuals infected with *H. pylori* develop antibodies which correlate strongly with histologically confirmed *H. pylori* infection.[6,7,8]
The DIAQUICK H. pylori Cassette (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.

TEST PRINCIPLE

The DIAQUICK H. pylori Cassette (whole blood/serum/plasma) 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 cassette, 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 coloured line will appear in the test line region indicating a positive result. If the specimen does not contain *H. pylori* antibodies, a coloured line will not appear in this region indicating a negative result. To serve as a procedural control, a coloured 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.

STORAGE AND STABILITY

Store as packaged in the sealed pouch 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. **DO NOT FREEZE.** Do not use beyond the expiration date.

PRECAUTIONS

- For professional in vitro diagnostic use only. Do not use after the expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use test if pouch is damaged
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

MATERIALS PROVIDED

- test cassettes
- package insert
- dropper
- buffer

MATERIAL REQUIRED BUT NOT PROVIDED

- specimen collection container
- timer
- centrifuge (for plasma only)

For fingerstick whole blood:
- heparinized capillary tubes and dispensing bulb
- lancets

SPECIMEN COLLECTION AND PREPERATION

- The DIAQUICK H. pylori Cassette (whole blood/serum/plasma) can be performed using whole blood (from venipuncture or fingerstick), serum, or plasma.
- To collect **Venipuncture Whole Blood specimens**:

  Collect anti-coagulated blood specimen (sodium or lithium heparin, potassium or sodium EDTA, sodium oxalate, sodium citrate) following standard laboratory procedures.
- 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 approx. 50 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 well (S) of the test cassette.
- Separate serum or plasma from blood as soon as possible to avoid haemolysis. Use only clear, non-haemolysed specimens.
- 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. Do not freeze whole blood specimens. 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.

ASSAY PROCEDURE

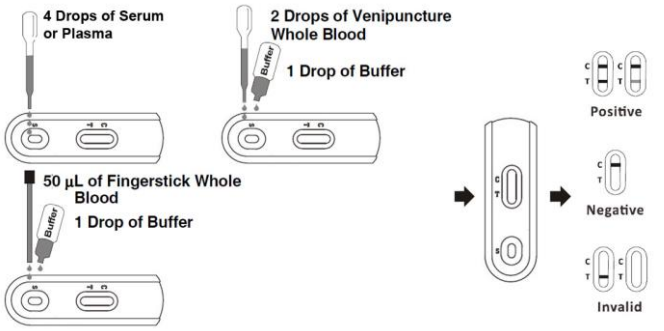
Allow the test, specimen, buffer, and/or controls to reach room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible.
2. Place the test cassette on a clean and level surface.

   For **Serum or Plasma specimens**: Hold the dropper vertically and **transfer 4 drops of serum or plasma** (approx. 100 µL) to the specimen well (S) of the test cassette and start the timer.

   For **Venipuncture Whole Blood specimens**: Hold the dropper vertically and **transfer 2 drops of whole blood** (approx. 50 µL) to the specimen well (S) of the test cassette, then **add 1 drop of buffer** (approx. 40 µL) and start the timer.

   For **Fingerstick Whole Blood specimens**:
   - Fill the capillary tube and **transfer approx. 50 µL of fingerstick whole blood** to the specimen well (S) of the test cassette, then **add 1 drop of buffer** (approx. 40 µL) and start the timer.
3. Wait for the coloured line(s) to appear. **Read results at 10 minutes.** Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

POSITIVE:* Two distinctly coloured lines appear. One line should be in the control line region (C) and another apparent line should be in the test line region (T).

***NOTE**: The intensity of the colour in the test line region (T) will vary depending on the concentration of *H. pylori* antibody present in the specimen. Therefore, any shade of colour in the test region (T) should be considered positive.

NEGATIVE: One coloured line appears in the control line region (C). No 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

An internal procedural control is included in the test. A coloured line appearing in the control line region (C) is an internal positive 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.

EXPECTED VALUES

The DIAQUICK H. pylori Cassette has been compared with Culture/Histology, demonstrating an overall accuracy of 91.4 %.

LIMITATIONS

1. The DIAQUICK H. pylori Cassette (whole blood/serum/plasma) should be used only to evaluate patients with clinical signs and symptoms suggestive of gastrointestinal disease and is not intended for use with asymptomatic patients.
2. The DIAQUICK H. pylori Cassette (whole blood/serum/plasma) 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 deter-

mined by this qualitative test.

3. The DIAQUICK H. pylori Cassette (whole blood/serum/plasma) 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.
4. Grossly haemolysed samples will yield invalid results. Strictly follow the Package Insert instructions to obtain accurate results.
5. A positive result does not allow one to distinguish between active infection and colonization by *H. pylori*.
6. A positive result only indicates the presence of IgG antibody to H. pylori and does not necessarily indicate that gastrointestinal disease is present.
7. A negative result indicates that IgG antibody to *H. pylori* is not present or is below the detection limit of the test.
8. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
9. Literature references have suggested cross reactivity of IgG antibody with a closely related organism, *Borrelia burgdorferi*. Performance of this assay has not been evaluated with this organism. Therefore, the specificity of this test device is not known if this organism is encountered.
10. 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.
11. This assay has not been established for patients under 18 years of age.

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy

The DIAQUICK H. pylori Cassette (whole blood/serum/plasma) 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 DIAQUICK H. pylori Cassette. 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 DIAQUICK H. pylori Cassette is 93.8 % and the specificity is 89.7 % relative to Biopsy/Histology/RUT.

DIAQUICK *H. pylori* Cassette vs. Biopsy/Histology/RUT

Method		Biopsy/Histology/RUT		Total Results
DIAQUICK H. pylori Cassette	**Results**	Positive	Negative	
	Positive	122	19	141
	Negative	8	166	174
Total Results		130	185	315

Relative Sensitivity: >93.8 % (88.2% – 97.3 %)
Relative Specificity: 89.7 % (84.4% – 93.7 %)
Accuracy: 91.4 % (87.8% – 94.3 %)
* 95 % Confidence Intervals

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 DIAQUICK H. pylori Cassette 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 DIAQUICK H. pylori Cassette has a high degree of specificity for antibodies to H.pylori.

Interference Studies

The DIAQUICK H. pylori Cassette has been tested for possible interference from visibly haemolysed and lipaemic specimens, as well as serum specimens containing high bilirubin levels. No interference was observed in specimens containing up to 1,000 mg/dL haemoglobin; up to 1,000 mg/dL bilirubin; and up to 2,000 mg/dL human serum albumin

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