Helicobacter Pylori

RAPU08V400

DIAsource ImmunoAssays S.A. - Rue de l'Industrie, 8 - B-1400 Nivelles - Belgium

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Test Cassette for the detection of antibodies to Helicobacter Pylori in whole blood, serum or plasma specimens

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IN VITRO DIAGNOSTIC

DIAsource ImmunoAssays SA - Rue de l'Industrie 8, B-1400 Nivelles, Belgium - Tel: +32 67 88 99 99 - Fax : +32 67 88 99 96

INTENDED USE

The **DIAsource Helicobacter pylori Test** is a rapid chromatographic immunoassay for the qualitative detection antibodies to H. Pylori in whole blood, serum, or plasma to aid in the diagnosis of H. Pylori infection. It is a rapid assay for determination of H. Pylori IgG and IgM antibodies. For professional use only.

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. 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. Non-invasive techniques include the urea breath test, which requires expensive laboratory equipment and moderate radiation exposure, and serological methods. Individuals infected with H. Pylori develop serum antibodies which correlate strongly with histologically confirmed H. Pylori infection.

PRINCIPLE

The ulti med H: Pylori Test is a sandwich immunoassay test. The test cassette contains a strip with immobilized H. Pylori antigen in the test reaction zone (T). And an antibody, a goat–anti-rabbit antibody is immobilized in the control reaction zone (C).

If the sample contains antibodies against H. Pylori, they react with the H. Pylori antigen marked with red particles and this color antigen antibody complex is moving along the membrane. The complex reacts with the immobilized H. Pylori antigen and forms an antigen- antibody (analyte)- antigen color complex visible as a red line in the test zone, the test is positive. If there is not a red line the test is negative. In the area of the control region the H. Pylori antigen marked with red particles react with the goat-anti rabbit antibody and forms a red line. This indicates that the test performed correct.

PRECAUTIONS

The ulti med H. Pylori Test devices should be stored at 4-30^{o}C. The test device is sensitive to humidity as well as to heat. Perform the test immediately after removing the test device from the foil pouch. Do not use it beyond the expiration.

REAGENTS AND MATERIALS SUPPLIED

- CARD — 20 H. Pylori test cassette
- PIPETTE — Sample droppers / transferpipettes in plastic bag
- BUF — Buffer (Tris-buffer), 8 ml
- Instructions

MATERIAL REQUIRED BUT NOT PROVIDED

- Timer

SPECIMEN COLLECTION AND HANDLING

The H-pylori test can be performed by using whole blood (from venipuncture or fingerstick), serum or plasma.

Whole Blood specimen collection: Collect an anti-coagulated blood sample (sodium heparin or lithium heparin). Whole blood samples must be tested within 24 hours of drawing.

Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens. There are no limitations concerning the usage of any anticoagulants. 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.

WARNINGS

- For in vitro diagnostic use only.
- Do not eat or smoke while handling specimens.
- Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
- Avoid splashing or aerosol formation.
- Clean up spills thoroughly using an appropriate disinfectant.
- Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
- Do not use the test kit if the pouch is damaged or the seal is broken.

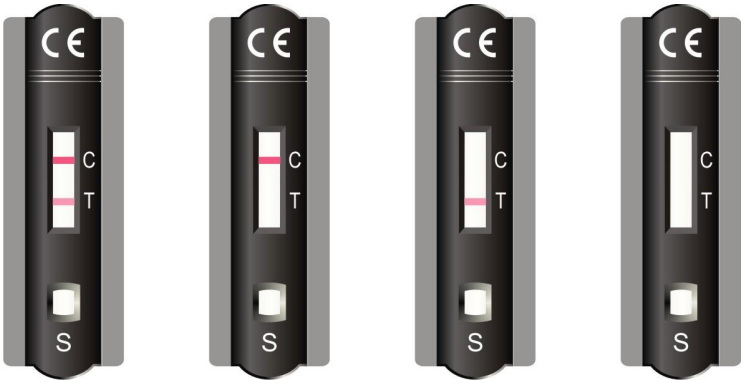
PROCEDURE

1. Remove the test cassette from the foil pouch, and place it on a flat, dry and clean surface.

   <u>To collect fingerstick whole blood specimens:</u>
   - 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 device by using a sample dropper:
   - Slightly squeeze the bulb and fill the sample dropper. Avoid air bubbles.

2. Hold the sample dropper above the test cassette and add 2 hanging drop into the Sample Well (S). After the drops are absorbed into the Sample Well, add 2 drops of buffer into the Sample Well. If the test does not start instantly, add one more drop of buffer.
3. As the test begins to work, you will see purple coloured front move across the Result Window in the centre of the test cassette.
4. Interpret test results after 10 minutes. Do not read it after more than 15 minutes.

Caution: The above waiting time is based on reading the test results at room temperature of 15 to 30°C. If your room temperature is significantly lower than 15°C, then the waiting time should be properly increased.



positive **negative** **invalid** **invalid**

INTERPRETATION OF RESULTS

I A coloured line will appear in the section of the result window marked with "C" to show that the test is working properly. This line is the Control Line.

I The section of the result window marked with "T" indicates the test results. If another coloured line appears here, this line is the Test Line.

Positive Result: The presence of two coloured lines ("T" line and "C" line) in the result window regardless of which line appears first indicates a positive result. **Note:** Generally, the higher the analyte level in the specimen, the stronger the "T" line colour will be. When the specimen analyte level is close to but still within the sensitivity limit of the test, the colour of the "T" line will be very faint.

Negative Result: The presence of only one purple colour line in the result window indicates a negative result.

Invalid: If after performing the test no purple coloured line is visible in the Result Window, or only one at "T", the result is considered invalid.
Some causes of invalid results: not following the directions correctly or the test is beyond the expiration date. It is recommended that the specimen be re-tested using a new cassette.
Note: A positive result will not change once it has been established at 10 minutes. However, in order to prevent any incorrect results, the test should not be interpreted after more than 15 minutes.

QUALITY CONTROL

Internal Quality Control
Internal procedural controls are included in the test. A red line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.
External quality control
Controls are not included in this kit. However, in compliance with Good Laboratory Practice (GLP) positive/negative controls are recommended.

LIMITATIONS OF THE TEST

Content of this kit is for the use in the qualitative detection of H. Pylori-specific IgG and IgM antibodies and does not indicate the titre of the antibody in the sample. The test should be used only to evaluate patients with clinical signs and symptoms suggestive of gastrointestinal disease. The performance characteristics of this test have not been established in a pediatric population.

Although the test is very accurate in detecting antibodies to H. Pylori, a low incidence of false results can occur. Other clinically available tests are required if questionable results are obtained. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity
Compared with the golden standard Biopsy n=300

ulti med H. Pylori Sensitivity: 93 % (140/150). ulti med H. Pylori Specificity: 93 % (150/160).

Specificity- and Interference study

1. Specificity study: The ability of the H. Pylori Test to specifically detect H. Pylori was challenged through cross reaction studies on serum samples containing known other closely related microorganisms such as Camplyobacter fetus, Campylobacter jejunii and E. coli. Serum samples that are negative to the H. Pylori Test were spiked with various concentration levels of the above microorganisms. These samples were tested on the H. Pylori Test kit. Each microorganism had 10 runs of the H. Pylori test. A total 30 test results indicated H. Pylori Test does not cross-react with the above microorganisms.
2. Interference Study: Potentially interfering chemicals such as pain medication, lipids, haemoglobin, bilirubin and glucose were supplemented to negative normal serum specimens. Above baseline specimens as well as H. Pylori positive specimens were then analyzed. All interference studies indicated none of the above substances interfered with the H. Pylori test procedure. Baseline serum samples with supplementation and potentially interfering substances gave consistently negative test results. The serum sample positive to H. Pylori scored consistently positive.

REFERENCES

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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

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