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**H. Pylori Test Cassette
(Whole Blood)**

A rapid test for the detection of antibodies to H. Pylori in serum, plasma and whole blood samples.

For professional in vitro diagnostic use only.

Intended Use

The SMI One-Step *H. Pylori* Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of *H. pylori* in serum, plasma or whole blood.

Summary

Helicobacter pylori (*H. pylori*) was initially isolated by Warren and Marshall from biopsy samples taken from patients suffering from active chronic gastritis. In fact, it is now clear that *H. pylori* is the principle etiologic agent in type B gastritis (chronic active antral gastritis) pathology for which it appears to be the triggering and perhaps aggravating factor. Increasing data are being accumulated regarding the fundamental role of *H. pylori* in active chronic gastritis, in gastric ulcer and in duodenal ulcer and its close correlation with gastric lesions. *H. pylori* is isolated in culture medium and examined by microscopy after staining or is detected by urease test. Both these techniques are lengthy to implement and their sensitivity and specificity have yet to be demonstrated. The immunochromatographic techniques (rapid) for the detection of antibodies specific to *H. pylori* has substantially resolved these problems, ensuring a serological monitoring in a very short space of time using simple, highly specific technology without recourse to invasive techniques. The serum, plasma, whole blood test for *H. pylori* can be utilized as a rapid screening process for large populations of patients and highly indicated in the early diagnosis of *H. pylori* infection as the immune response can often precede clinical manifestations of disease. From a diagnostic point of view, a high serum, plasma or whole blood level specific antibodies against *H. pylori* must be interpreted as an indication of type B asymptomatic gastritis.

Principle

The *H. pylori* test is a rapid test for the qualitative detection of antibodies of all isotypes (IgG, IgM, IgA, etc) specific to *Helicobacter pylori* in human serum, plasma or whole blood. This test kit is intended as an aid in the diagnosis of *H. pylori* infection in patients with gastrointestinal symptoms.

The *H. pylori* test contains a membrane strip, which is pre-coated with *H. pylori* capture antigen on test band region. The *H. pylori* antigen-colloid gold conjugate and serum, plasma or whole blood sample moves along the membrane chromatographically to the test region (T) and forms a visible line as the antigen-antibody-antigen gold particle complex forms with high degree of sensitivity and specificity. Both the Test Line and Control Line in result window are not visible before applying any samples. The Control Line is used for procedural control. Control line should always appear if the test procedure is performed properly and the test reagents of control line are working.

Storage & Stability

H. pylori test device(s) should be stored at room temperature. The test device is sensitive to humidity and 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

Precautions

- This test is for *in vitro* diagnostic use only. Not to be taken internally.
- Do not use after expiration date printed on the foil pouch.
- Store in a dry place. Do not Freeze. Foil pouch should be at room temperature before use.
- Keep out of reach of children.

Materials

Materials provided:

- Test cassette
- Instructions
- 20uL transfer pipette
- Buffer

Materials required but not supplied:

- Centrifuge (for serum or plasma samples)
- Timer

Directions for Use:

Allow test device, buffer, and serum, plasma, or whole blood specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test device from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test strip on a clean and level surface. Add 10ul of Serum, Plasma or 20ul Whole Blood to the sample well (S).
3. Add 1 drop of buffer to the sample well (S), then hen start the timer.
4. Wait for the red line(s) to appear. The test line should be read at 10 minutes, and not longer than 30 minutes.

Note: If solution does not flow up the test strip, add 1 more drop of buffer solution.

Interpretation of Results:

(See illustration on next page)

1. Positive Result

Two colored lines appear in the result area - one in the Control Line area (C) and one in the Test Line area (T). This indicates active infection.

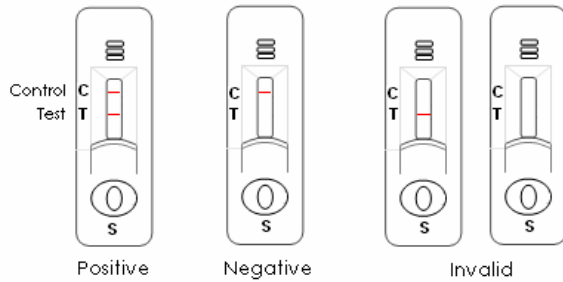
2. Negative Result

Only one colored line appears in the results area, in the Control Line area (C), with no distinctive colored line in the Test Line area (T). This indicates that no active infection was detected.

3. Invalid Result

A distinct colored line should always appear in the Control Line area (C). The test is invalid if no Control Line appears.

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 30 minutes.



Quality Control

A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is also required.

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

1. The SMI *H. pylori* Test Cassette is for *in vitro* diagnostic use only. The test should be used for the detection of *H. pylori* antibodies in Serum, Plasma or Whole Blood) specimen only. Neither the quantitative value nor the rate of increase in *H. pylori* antibody concentration can be determined by this qualitative test.
2. The SMI *H. pylori* Test Cassette 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.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. 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.

Bibliography

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