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CE

"See Now" H.Pylori. Antibody Serum/Plasma/Whole Blood Cassette Test

For in vitro Diagnosis Use
Product Code: SN 2.2

INTRODUCTION

The *"See Now"* H.Pylori Antibody Test is a rapid test for the qualitative detection of IgG antibodies specific to Helicobacter pylori in human serum, plasma and whole blood specimens. This test kit is intended as an aid in the diagnosis of H.Pylori infection in patients with gastrointestinal symptoms.

PRINCIPLE

The*"See Now"* H.Pylori Antibody Test is a chromatographic immunoassay for the qualitative determination of anti-H.Pylori. IgG antibodies in human serum, plasma and whole blood. The test device contains a membrane strip which is pre-coated with H.Pylori antigens on the test band region and H.Pylori specific monoclonal antibody on the control band region. The H.Pylori antigens-colloid gold conjugate pad is placed at the end of the membrane. When the H.Pylori specific IgG antibodies are present in patient samples, the mixture of colloid gold conjugate, patient sample and developer buffer moves along the membrane chromatographically to the test region (T) and form a visible line as the antigen-antibody-antigen gold particle complex forms. Therefore, the formation of a visible line in the test region (T) indicates a positive result for the detection of H.Pylori specific IgG antibodies. When the H.Pylori specific IgG antibodies are absent in the sample, no visible color band will form in the test region (T). Therefore, the absence of a color band in the test region (T) indicates a negative result for the detection of H.Pylori specific IgG antibodies.

A color band will always appear in the control region (C). This control band serves as a procedural indicator that: 1) verification that sufficient volume has been added, 2) verification that proper flow is obtained and 3) reagent control.

Materials Provided

1. Test kit; 2. Specimen diluent in dropper bottle;3. Desiccant.

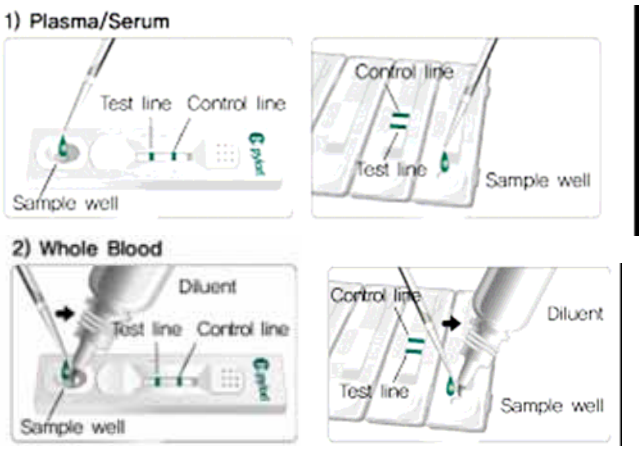
SPECIMEN COLLECTION AND STORAGE

- For serum samples collect blood in a tube without anticoagulant and allow it to clot.
- For whole blood or plasma samples collect blood in a tube containing anticoagulant (EDTA, citrate or heparin, respectively).
- Finger puncture whole blood

  Clean the finger with an alcohol pad and let dry
  Take a lancet and make a quick deep slab on the side of the finger.
  Avoid squeezing the fingertip to accelerate bleeding as this tends to dilute the blood with excess tissue fluid.

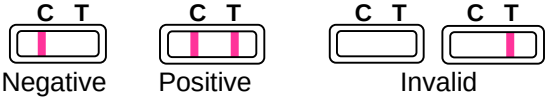
TEST PROCEDURE

1. When you are ready to begin testing, open the sealed pouch by tearing along the notch. Remove the test device from the pouch and use it as soon as possible.
2. Sample dispensing:
   2.1. Draw the sample into the pipette, then dispense 100µL of serum or plasma into the sample well of the cassette.
   2.2. Draw the sample into the pipette, than dispense 50 µL of whole blood and add 1 drop of diluent provided into the sample well. Use the dropper bottle provided, not the sample pipette.
3. Wait for 10 minutes and read results. It is important that the background is clear before the result is read. Do not read results after 20 minutes.



INTERPRETATION OF RESULTS

- Negative: Only one colored band appears on the control (C) region. No apparent band on the test (T) region.
- Positive: In addition to a pink colored control (C) band, a distinct pink colored band will appear in the test (T) region.
- Invalid: A total absence of color in both regions or no colored line appears in the control (C) region is an indication of procedure error and/or test reagent deterioration. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



LIMITATIONS

1. As with all diagnostic tests, all results must be considered with other clinical information available to the physician. A definite clinical diagnosis should only be made by the physician after all clinical and laboratory findings have been evaluated.
2. The test should be used for the detection of antibodies to H. Pylori in serum and whole blood specimen.

STORAGE AND STABILITY

The test kit can be stored at temperatures between 15 to 25ºC in the sealed pouch to the date of expiration. The test kit should be kept away from direct sunlight, moisture and heat.

PRECAUTION

1. For in vitro diagnostic use only.
2. Do not use test kit beyond expiry date.
3. The test device should not be reused.
4. The above interpreting time is based on reading the test results at room temperature of 15 to 25 ºC. If your room temperature is significantly lower than 15 ºC, then the interpreting time should be properly increased.
5. The instructions for use and reading of the test must be followed exactly in order for the test to perform properly.