One Step Stomach Ulcer (H.pylori) Test (Whole Blood/Serum/Plasma)

FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY

Intended Use
The One Step H.pylori Test is a rapid chromatographic immunoassay for the qualitative detection of antibodies to H.pylori (HP) in Whole Blood /Serum / Plasma to aid in the diagnosis of H.pylori.

Summary
H.pylori is associated with a variety of gastrointestinal diseases included non-ulcer dyspepsia, duodenal and gastric ulcer and active, chronic gastritis. The prevalence of H.pylori infection could exceed 90% in patients with signs and symptoms of gastrointestinal diseases. Recent studies indicate an association of H.pylori infection with stomach cancer. H.pylori colonizing in the gastrointestinal system elicits specific antibody responses which aids in the diagnosis of H.pylori infection and in monitoring the prognosis of the treatment of H.pylori related diseases. Antibiotics in combination with bismuth compounds have been shown to be effective in treating active H.pylori infection. Successful eradication of H.pylori is associated with clinical improvement in patients with gastrointestinal diseases providing a further evidence. One step H.pylori Test is a simple, visual qualitative test that detects antibodies in human Whole Blood/serum/plasma. The test is based on immunochromatography and can give a result within 15 minutes.

Principle
The One Step H.pylori Test is a qualitative membrane strip based immunoassay for the detection of H.pylori antibodies in Whole Blood /Serum / Plasma. In this test procedure, recombinant H.pylori antigen is immobilized in the test line region of the device. After a Whole Blood /Serum / Plasma specimen is placed in the specimen well, it reacts with H.pylori antigen coated particles that have been applied to the specimen pad. This mixture migrates chromatographically along the length of the test strip and interacts with the immobilized H.pylori antigen. 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 at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

Storage and Stability
- Store as packaged in the sealed pouch at room temperature or refrigerated (4-30℃ or 40-86℉). The test device is stable through the expiration date printed on the sealed pouch.
- The test must remain in the sealed pouch until used.

Additional Special Equipment

Materials Provided
- Test device
- Buffer (for whole blood only)
- 2 x Single Use Lancets
- Alcohol Wipe
- Pipette
- Package insert
- Capillary Tube

Please note that the blood sampling equipment (lancets, capillary tube & alcohol wipe) are only included in the 1 test pack

Materials that may be required but are not provided
- Timer
- Specimen collection containers
- Centrifuge

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 and kits are handled.
- Handle all specimens as if they contain infectious agents.
- Observe established precautions against microbiological hazards throughout all procedures 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 assayed.
- Follow standard biosafety guidelines for handling and disposal of potential infective material.
- Humidity and temperature can adversely affect results.

Specimen Collection and Preparation
1. The One Step H.pylori Test can be performed using Whole Blood /Serum / Plasma.
2. To collect whole blood, serum or plasma specimens following regular clinical laboratory procedures.
3. For immediate near patient testing, please follow the finger prick testing procedure overleaf.
4. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.
5. 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℃ for up to 3 days. For long term storage, specimens should be kept below -20℃. Whole blood should be stored at 2-8℃ if the test is to be run within 2 days of collection. Do not freeze whole blood specimens.
6. 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.

Test Procedure
Allow the test, specimen, buffer and/or controls to reach room temperature 15-30℃ (59-86℉) prior to testing.

1. Wash hands with soap and rinse with warm water.

2. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.

3. Place the test device on a clean and level surface.

4. **For serum or plasma specimen:** Hold the pipette vertically and transfer 3 drops of serum or plasma (approximately 100µl) to the specimen well (S) of the test device, then start the timer. See illustration under point 10 overleaf.

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5. **For whole blood specimens:** Medical professionals should obtain a 35µl blood sample following their own clinical methods and proceed to point 10. Alternatively, take the safety lancet holding the body and twist off the protective cap until you feel it has been separated from the device. Don't pull, just twist.

6. Clean the end of the forefinger or middle finger with an alcohol wipe. Massage the finger to enhance the blood flow.

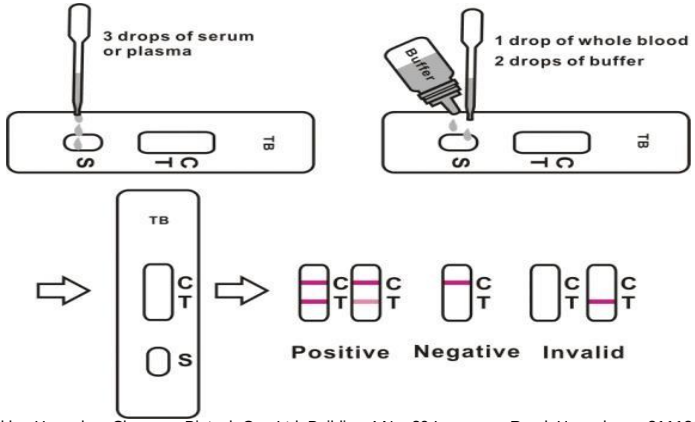
7. Press the safety lancet platform firmly against the chosen site.

8. Keeping the hand down, massage the finger to obtain a blood drop.

9. Without pressing the bulb, put the capillary tube in contact with the blood drop. The blood will migrate into the tube by capillary action. Fill to the black line indicated on the capillary tube trying to avoid getting any air bubbles in the tube.

If necessary you may massage your finger again or use the second provided lancet to obtain more blood in order to fill the capillary tube.

10. Transfer 1 drop of the collected blood (approximately 35µl) to the specimen well (S) of the test device, then add 2 drops of buffer (approximately 70µl) and start the timer. See illustration below.



11. Wait for the coloured line(s) to appear. Read results at 15 minutes. Do not interpret the result after 20 minutes.

12. Replace the protective cap and then dispose of lancet in a suitable container.

Notes

Applying sufficient amount of specimen is essential for a valid test result. If migration (the wetting of membrane) is not observed in the test window after one minute, add one more drop of buffer (for whole blood) or specimen (for serum or plasma) to the specimen well.

Interpretation of Results

Positive: Two lines appear. One line should always appear in the control line region (C), and another one apparent coloured line should appear in the test line region.

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

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 device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

Limitations

1. The One Step H.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 / Plasma specimens only. Neither the quantitative value nor the rate of increase in H.pylori antibodies can be determined by this qualitative test.
2. The One Step H.pylori 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.
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.

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