SPESERA
Sağlık Ürünleri İç ve Dış Tic. Ltd. Şti.

Instructions for H. Pylori Antigen Feces Test Cassette (Colloidal Gold)

[Product Name]

H. Pylori Antigen Feces Test Cassette (Colloidal Gold)

[Intended Use]

This kit is intended for the qualitative measurement of H. Pylori Antigen in human feces, and is appropriate for a rapid, simple and accurate auxiliary diagnosis of HP Antigen infection.

[Principle]

The H. Pylori Antigen Feces Test Cassette is a qualitative membrane strip based immunoassay for the detection of H. Pylori Antigen in feces. In this test procedure, H. pylori antibody is immobilized in the test line region of the device. After an adequate volume of test specimen is placed in the specimen well, it reacts with H. Pylori antibody 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 antibody. If the specimen contains H. Pylori antigen, a colored line will appear in the test line region indicating a positive result. If the specimen does not contain H. Pylori antigen, a colored line will not appear in this region indicating a negative result. To serve as a procedural control, a colored 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 at 4 to 30℃ in a dry place and avoid direct sunlight. Do not freeze. It is valid for 24 months from date of manufacturing.

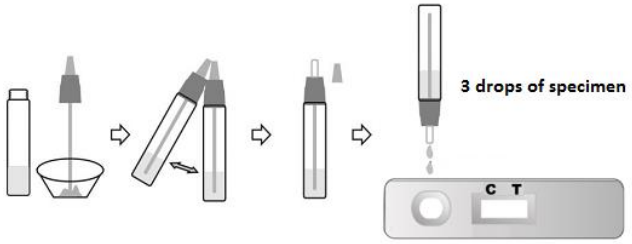
[Specimen Requirements]

1. The H. Pylori Antigen Feces Test Cassette can be performed used on feces.
2. Collect sufficient quantity of feces (1-2 ml or 1-2 g) in a clean, dry specimen collection container to obtain maximum antigens (if present). Best results will be obtained if the assays performed within 6 hours after collection.
3. Specimen collected may be stored for 3 days at 2-8℃ if not tested within 6 hours. For long term storage, specimens should be kept below -20℃.
4. Unscrew the cap of the specimen collection tube, then randomly stab the specimen collection applicator into the fecal specimen in at least 3 different sites to collect approximately 50 mg of feces (equivalent to 1/4 of a pea). Do not scoop the fecal specimen.
5. Screw on and tighten the cap onto the specimen collection tube, then shake the specimen collection tube vigorously to mix the specimen and the dilution buffer. Leave the tube alone for 2 minutes.
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.

[Assay Procedure]

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. Holding the sample collection tube upright, carefully take off the tip of collection tube, transfer 3 drops (approximately 100µl) to the sample well of the cassette, and then start the timer.
3. Wait for the colored line(s) to appear. Read results at 15 minutes. Do not interpret the result after 20 minutes.

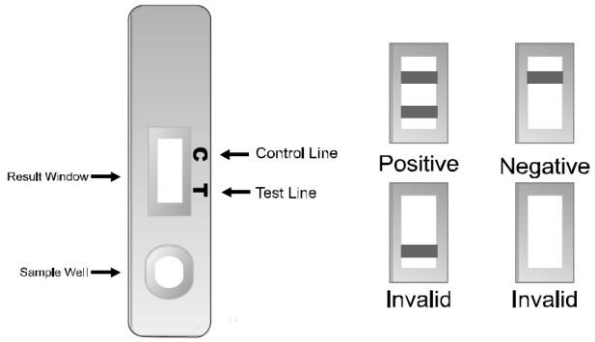
Notes: Applying sufficient amount of specimen is essential for a valid test result. If migration (the wetting of membrane) is not observed in the test window after one minute, add one more drop of specimen to the specimen well.



[Interpretation of Results]

1. **Negative**: The control line is the only visible line on the test device. This indicates a negative result.
2. **Positive**: The presence of two color lines (“T” line and “C” line) within the result window, no matter which line appears first, indicates a positive result.

3. **Invalid**: If the “C” line (control) is not visible within the result window after performing the test, the result is considered invalid. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be re-tested.



[Limitations]

The kit is used for auxiliary diagnosis of H. Pylori Antigen. Any positive sample must be confirmed with other available methods (such as EIA or RIBA). Negative samples generally does not require further confirmation.

[Manufacturer]

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