



H. pylori Ag Test Cassette Procedure How to Perform a Test – Cassette Test

Allow the test, specimen, buffer, and/or controls to reach room temperature (15-30°C) prior to testing.

1. To collect fecal specimens:

- a) Collect 1-2 ml or 1-2 g of feces in a clean, dry specimen collection container to obtain maximum antigens (if present).
- b) Best results will be obtained if the assay is performed within 6 hours after collection. Specimen collected may be stored for 3 days at 2-8°C if not tested within 6 hours. For long term storage, specimens should be kept below -20°C

2. To process fecal specimens:

For Solid Specimens:

1. Unscrew the cap of the specimen collection tube.
2. Stick the specimen collection applicator into the fecal specimen in order to collect feces from the specimen.
3. With the applicator, collect feces from at least 3 random locations on the fecal specimen. Collect a total of approximately 50 mg of feces (about ¼ of a pea). Do not scoop the fecal specimen.

For Liquid Specimens:

1. Use the included dropper. Hold the dropper vertically over the fecal specimen and aspirate the sample.
2. Transfer 2 drops (approximately 80 µL) into the specimen collection tube containing the extraction buffer.
3. Tighten the cap onto the specimen collection tube. Then shake the specimen collection tube vigorously to mix the specimen and the extraction buffer. Leave the tube alone for 2 minutes.

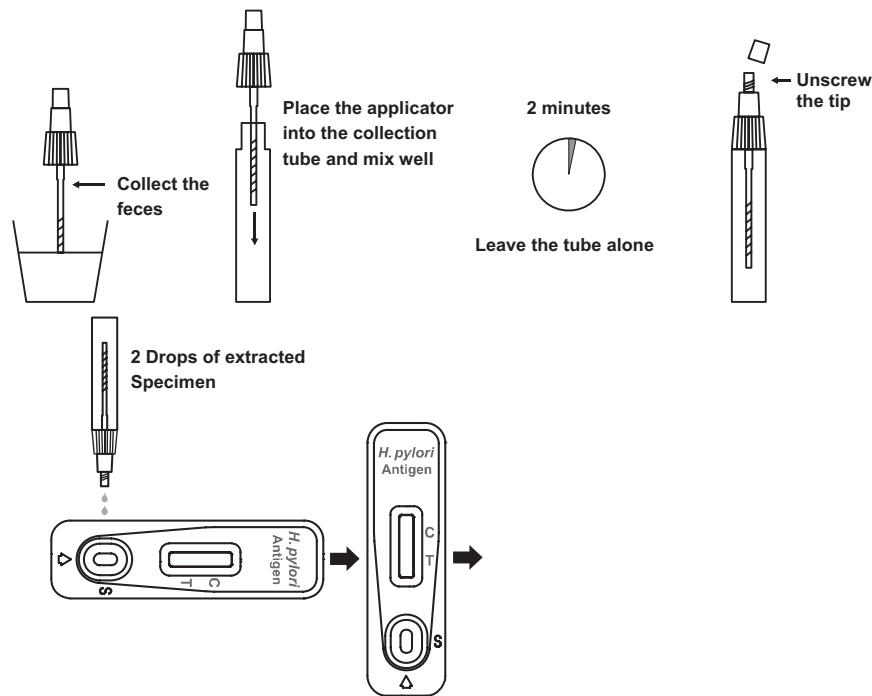
3. Testing the Sample

1. Bring the pouch to room temperature before opening it.
2. Remove the test Cassette from the foil pouch and use it as soon as possible.
 - a. Best results will be obtained if the test is performed immediately after opening the foil pouch.
3. Hold the specimen collection tube upright and unscrew the tip of the specimen collection tube.
4. Invert the specimen collection tube and transfer 2 full drops of the extracted specimen (approximately 90 µL) to the specimen well (S) of the test cassette, then start a timer for 10 minutes. Avoid air bubbles. See illustration below.

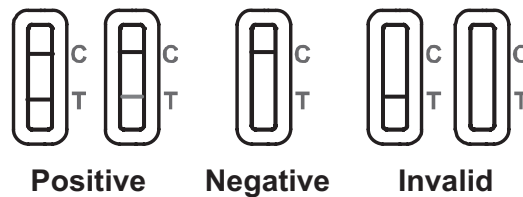
4. Reading the Results

1. At 10 minutes, the test is complete. Interpret the results. Do not interpret results after 20 minutes.

Note: If the specimen does not migrate (presence of particles), centrifuge the extracted specimens in the specimen collection tube. Collect 80 µL of supernatant, dispense into the specimen well (S) of a new test cassette and repeat the testing procedure.



Interpretation of Results



- **POSITIVE:** Two distinct colored lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T).
 - The intensity of the color in the test line region (T) will vary depending on the concentration H. pylori antigens present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.
- **NEGATIVE:** One colored line appears in the control line region (C). No line appears in the test line region (T).
- **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 cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.