File No: (CBAHI.07210,08100.02) Title: SOP for H. Pylori Antibody Rapid Test	PROCEDURE
Version numbers, revision dates and approval processes will be issued directly from Media Lab. Please check the online portal for up-to-date information. All printed documents will be labelled as Uncontrolled documents.	

1. Purpose

To provide a standardized procedure for the detection of Helicobacter pylori (H. pylori) antigen in stool samples using a rapid diagnostic test kit.

2. Scope

This SOP applies to all laboratory personnel performing the H. pylori antigen test at Alfa Lab

3. Principle

The H. pylori antigen test is based on an immunological reaction where the H. pylori antigen in the stool sample binds to conjugate-red latex particles coated with anti-H. pylori monoclonal antibodies. This complex migrates through the membrane, forming a green band in the control zone to indicate the test's functionality. A red band in the result zone signifies a positive test.

4. Materials

4.1 Materials Provided

- Test Cassette
- Sample Diluent in Extraction Tubes
- H. pylori Positive Control
- Package Insert

4.2 Materials Needed but Not Provided

- Tubes or Vials
- Disposable Gloves
- Shaker/Vortex Mixer
- Timer

5. Storage and Stability

- Store all reagents at **2-8°C**.
- Do not freeze the reagents.
- Reagents are stable until the expiration date indicated on the label.

6. Specimen Collection and Preparation

- Collect stool samples in a clean container. Avoid using watery or diarrheal samples.
- Samples can be stored at **2-8°C** for up to 7 days or at **-20°C** for up to 3 months if testing is delayed.
- Allow the test device, controls, and samples to reach room temperature (15-30°C) before testing.

7. Procedure

7.1 Sample Preparation

1. Using the applicator stick from the sample diluent vial, transfer a small portion (approximately 5 mm in diameter) of the stool specimen into the sample diluent.
2. Shake gently to facilitate sample dispersion.
3. Hold the vial and break the tip off.
4. Add 4 drops of the prepared sample to the sample well in the test device.

7.2 Control Preparation

- For the positive control, add **75 µL** of the control serum to the sample well in the test device.

7.3 Testing

- Read the results after **5 minutes**.
-

8. Reading the Results

- **Negative Result**: Only one green band (Control Line) appears in the control zone.
- **Positive Result**: Two bands appear; a green control band and a red band in the result zone (T).
- **Invalid Result**: No colored bands appear, or only one band appears in the T zone. If an inconclusive result is obtained, re-assay the sample with a new strip 12.

9. Quality Control

- Internal procedural controls are included in the test. A green band in the control region confirms sufficient specimen volume and correct procedural technique.
- Run positive and negative controls with each batch of tests to ensure accuracy.

10. Limitations

- The test must be performed within **2 hours** of opening the sealed bag.
- Clinical diagnosis should not rely solely on test results; consider the patient's clinical background.
- High levels of human anti-mouse antibodies (HAMA) or rheumatoid factor (RF) may interfere with results 3.

11. Documentation

- Record all test results in the laboratory information system (LIS).
- Maintain records of quality control results and any deviations from the SOP.

12. Safety Precautions

- Wear appropriate personal protective equipment (PPE) when handling reagents and samples.
- Dispose of reagents properly to prevent contamination.

13. References

- Manufacturer’s instructions for the H. pylori antigen test kit.