LIMING BIO

H. pylori Antigen Rapid Test Device

REF 501040	Specimen: Feces
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For professional *in vitro* diagnostic use only.

INTENDED USE

The *StrongStep® H. pylori* Antigen Rapid Test Device (Feces) is a rapid visual immunoassay for the qualitative, presumptive detection of *Helicobacter pylori* antigen in human fecal specimens. This kit is intended for use as an aid in the diagnosis of *H. pylori* infection.

INTRODUCTION

Helicobacter pylori (also known as *Campylobacter pylori*) is a spiral-shaped gram negative bacteria which infects the gastric mucosa. *H. pylori* causes several gastro-enteric diseases such as non-ulcerous dyspepsia, gastric and duodenal ulcer, active gastritis and can even increase the risk of stomach adenocarcinoma.
Many *H. pylori* strains have been isolated. Among them, the strain expressing CagA antigen is strongly immunogenic and is of utmost clinical importance. Literature articles report that in infected patients producing antibodies against CagA, the risk of gastric cancer is up to five times higher than reference groups infected with CagA negative bacteria.
Other associated antigens such as CagII and CagC seems to act as starting agents of sudden inflammatory responses which can provoke ulceration (peptic ulcer), allergic episodes, and decrease of therapy efficacy.
At present several invasive and non-invasive approaches are available to detect this infection state. Invasive methodologies require endoscopy of the gastric mucosa with histologic, cultural and urease investigation, which are expensive and require some time for diagnosis. Alternatively, non-invasive methods are available such as breath tests, which are extremely complicated and not highly selective, and classical ELISA and immunoblot assays.

PRINCIPLE

The H. pylori Antigen Rapid Test Device (Feces) detects Helicobacter pylori through visual interpretation of color development on the internal strip. Anti-H. pylori antibodies are immobilized on the test region of the membrane. During testing, the specimen reacts with anti-H. pylori antibodies conjugated to colored particles and precoated onto the sample pad of the test. The mixture then migrates through the membrane by capillary action and interacts with reagents on the membrane. If there is sufficient H. pylori antigens in the specimen, a colored band will form at the test region of the membrane. The presence of this colored band indicates a positive result, while its absence indicates a negative result. The appearance of a colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

KIT COMPONENTS

Individually packed test devices	Each device contains a strip with coloredconjugates and reactive reagents precoated at the corresponding regions.
Specimens dilution tube with buffer	0.1 M Phosphate buffered saline (PBS) and 0.02% sodium azide
Package insert	For operating instructions

MATERIALS REQUIRED BUT NOT PROVIDED

Timer	For timing use
Centrifuge	For treatment of specimens in special

PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled by observing usual safety precautions (e.g., do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to testing.
- Do not eat, drink or smoke in any area where specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The specimen dilution buffer contains sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of the specimen dilution buffer or extracted samples, always flush with copious quantities of water to prevent azide build up.
- Do not interchange or mix reagents from different lots.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded according to local regulations.

STORAGE AND STABILITY

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- Do not freeze.
- Cares should be taken to protect components in this kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipments, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND STORAGE

- The H. pylori Antigen Rapid Test Device (Feces) is intended for use with human fecal specimens only.
- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 72 hours.
- Bring specimens to room temperature prior to testing.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.

PROCEDURE

Bring tests, specimens, buffer and/or controls to room temperature (15-30°C) before use.

1. Specimen collection and pre-treatment:
   1) Use clean, dry containers for specimen collection. Best results will be obtained if the assay is performed within 6 hours after collection.
   2) Unscrew and remove the dilution tube applicator. Be careful not to spill or spatter solution from the tube. Collect specimens by inserting the applicator stick into at least 3 different sites of the feces to collect approximately 50 mg of feces (equivalent to 1/4 of a pea).
   3) Replace the applicator back into the tube and screw the cap tightly. Be careful not to break the tip of the dilution tube.
   4) Shake the specimen collection tube vigorously to mix the specimen and the extraction buffer.
2. Testing
   1) Remove the test from its sealed pouch, and place it on a clean, level surface. Label the test with patient or control identification. To obtain a best result, the assay should be performed within one hour.
   2) Using a piece of tissue paper, break the tip of the dilution tube. Hold the tube vertically and dispense 3 drops of solution into the specimen well (S) of the test device.
      Avoid trapping air bubbles in the specimen well (S), and do not add any solution to the result area.
      As the test begins to work, color will migrate across the membrane.
   3) Wait for the colored band(s) to appear. The result should be read at 10minutes. Do not interpret the result after 20 minutes.

Note: If the specimen does not migrate due to the presence of particles, centrifuge the extracted specimens contained in the extraction buffer vial. Collect 100 µL of supernatant, dispense into the specimen well (S) of a new test device and start again, following the instructions described above.

INTERPRETATION OF RESULTS

POSITIVE RESULT: 	Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).
NEGATIVE RESULT: 	Only one colored band appears in the control region (C). No apparent colored band appears in the test region (T).

INVALID RESULT: 	Control band fails to appear. Results from any test which has not produced a control band at the specified reading time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

1. The intensity of the color in test region (T) may vary depending on the concentration of aimed substances present in the specimen. But the substances level can not be determined by this qualitative test.
2. Insufficient specimen volume, incorrect operation procedure, or performing expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

1. Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.
2. External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS OF THE TEST

1. The H. pylori Antigen Rapid Test Device (Feces) is for professional in vitro diagnostic use, and should only be used for the qualitative detection of Helicobacter pylori.
2. Following certain antibiotic treatments, the concentration of H. pylori antigen may decrease to concentrations below the minimum detection level of the test. Therefore, diagnosis should be made with caution during antibiotic treatment.
3. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERISTICS

Table: *H. pylori* Antigen Rapid Test vs. Endoscopy

Female Cervical Specimens

Relative Sensitivity:
98.5% (94.6%-99.8%)*
Relative Specificity:
98.1% (94.2%-99.6%)*
Overall Agreement:
98.3% (96.0%-99.4%)*
*95% Confidence Interval

		H. pylori Antigen Rapid Test		
		+	-	Total
Endoscopy	+	130	2	132
	-	3	151	154
		133	153	286

Specificity :

Cross reactivity with the following organisms has been studied at 1.0 x 10^9 organisms/mL. The following organisms produced negative results when tested with the One Step H. pylori Antigen Test Device (Feces)

Staphylococcus aureus	*Proteus mirabilis*	*Neisseria gonorrhea*
Pseudomonas aeruginosa	*Acinetobacter spp*	*Group B Streptococcus*
Enterococcus faecalis	*Salmonella choleraesius*	*Proteus vulgaris*
Group C Streptococcus	*Gardnerella vaginalis*	*Enterococcus faecium*
Klebsiella pneumoniae	*Acinetobacter calcoaceticus*	*Hemophilus influenzae*
Branhamella catarrhalis	*E.coli*	*Neisseria meningitidis*
Candida albicans	*Chlamydia trachomatis*	*Rotavirus*

LITERATURE REFERENCES

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GLOSSARY OF SYMBOLS

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	In vitro diagnostic medical device		Use by
	Manufacturer	Σ	Contains sufficient for <n> tests
	Do not reuse	EC REP	Authorized representative in the European Community
CE	CE marked according to IVD Medical Devices Directive 98/79/EC		

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