Epitope Diagnostics,Inc.

eCasset™ Helicobacter pylori Antigen Rapid Test Kit

REF **KT-113**

Lateral flow rapid test cassette for detection of H. pylori Antigen in stool samples

This kit is an immunochromatographic assay for rapid qualitative determination of Helicobacter pylori (H. pylori) Antigen in feces. It is for in vitro diagnostics use only.

TEST PRINCIPLE

This H. pylori Ag rapid test kit contains a fecal sampling tube and a test cassette. Fecal specimen is collected in the sampling tube containing sample extraction buffer and then added to the test device. When the sample is added to sample pad, it moves through the conjugate pad and mobilizes colloid gold conjugated anti-H. pylori antibody. The mixture moves along the membrane by capillary action and reacts with another anti-H. pylori antibody that is coated on the test region. If H. pylori is present of 8ng/mL stool or greater, the result is the formation of a colored band in the test region. If there is no H. pylori present in the sample, the test area will remain colorless. The sample continues to move to the control area where Goat anti-mouse IgG antibody will capture colloid gold antibody conjugate to form a pink to purple color, indicating the test is working and the result is valid.

REAGENTS AND MATERIALS

• H. pylori Cassette	REF	31082	20
• Sampling Tube	REF	31083	20
• Instruction for use	REF	31039	1
• Rapid Cassette Test Reader	(EPC – 100):		(optional-inquire)

PRECAUTION FOR USERS

1. For in-vitro diagnostic use only.
2. Handle all specimens as if they contain infectious agents. When the assay procedure is completed, dispose of specimens carefully after autoclaving for at least one hour. Alternatively, treat with a 0.5 or 1% solution of sodium hypochlorite for one hour before disposal.
3. Wear protective clothing (laboratory coats and disposable gloves) when assaying samples.
4. Do not eat, drink or smoke in areas where specimens and kit reagents are handled.
5. Avoid contact between hands and eyes or nose during specimen collection and testing.

SPECIMEN COLLECTION

1. Collect a random sample of feces in a clean, dry container.
2. While trying not to spill the buffer, unscrew and remove the white color cap with attached sampling stick from the sampling tube.
3. Insert the sampling stick into the feces about 15 mm 3 times, at 3 different sites.
4. If necessary, remove excess of feces from the stick by gently wiping it with an absorbent tissue.
5. Reinsert the stick into the tube and tighten the cap thoroughly.
6. For liquid sample, add 100 µl of stool using an appropriate pipette into the vial via the green cap site.

STORAGE OF TEST KIT

The H. pylori kit can be stored between 2-30°C. **Do not freeze**. Use the reagents as soon as possible after the kit is unpacked.

TEST PROCEDURE

Step 1. Mix and dissolve stool sample completely by shaking or votexing.

Step 2. Unscrew the natural colored cap on top of the green cap. Add **2 drops** to the sample well of the test cassette. Follow the illustration below:

Step 3. Incubate the test at room temperature and read the test result between **5- 10 minutes.**

INTERPRETATION OF RESULTS

Negative: Only one colored band appears on the control region. No apparent band on the test region.
Positive: In addition to a pink colored control band, a distinct pink colored band will also appear in the test region.
Invalid: A total absence of color in both regions is an indication of procedure error and/or that test reagent deterioration has occurred.

LIMITATION OF THE PROCEDURE

1. The test should be used only for the detection of H. Pylori antigen in fecal samples.

2. The test is qualitative, and no quantitative interpretation should be made with respect to the intensity of the positive line, when reporting the result.

3. The correlation of the results with other techniques (ELISA) was satisfactory. However, interferences in the performance of the tests should not be excluded.

4. As with all diagnostic tests, the definitive clinical diagnosis must not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated. *eCasset™* Fecal H Pylori antigen test is designed for the aid of clinical diagnosis and should not replace other diagnostic procedures.

QUALITY CONTROL

Good laboratory practices recommend the use of appropriate controls. There are two types of controls for the eCasset™ H. Pylori test, the internal procedural control and external controls.

1. **Internal procedural control:** Each eCasset™ H. Pylori test has a built-in procedural control. It will appear if the test has been performed correctly, sample wicking has occurred and the reagents are reactive. It does not ensure that the test line antibody is accurately detecting the presence or absence of H. Pylori in the test fecal sample.
2. **External controls:** It is recommended to use external positive controls. The external positive controls are not provided with this kit, but are commercially available from Epitope Diagnostics. External controls are used to assure that the test line antibody is reactive. However, external controls will not detect an error in performing the patient sample test procedure. It is recommended that the external control be tested once per kit.

PERFORMANCE CHARACTERISTICS

Sensitivity
Detection limit: A purified H.pylori Antigen was used to determine the detection limit. This reference antigen preparation of H. pylori was diluted in H. pylori Antigen buffer used to extract the fecal samples and tested with this kit according to the above described test procedures. The detection limit of H. pylori is about 10 ng/ml.

Specificity
The evaluation was performed by comparison this rapid test with a commercial H. pylori antigen ELISA kit. The detection of H. pylori showed 95% of concordance with the ELISA.
The monoclonal antibody used in this rapid test recognizes epitopes present in the antigen found in stool of patients, as well as in preparations from the bacteria cultures in vitro.
The possibility for interference of human anti-mouse antibodies (HAMA) in the stool sample have not been evaluated.

REFERENCES

1. Yang HR, Seo JK. Helicobacter pylori Stool Antigen (HpSA) Tests in Children Before and After Eradication Therapy: Comparison of Rapid Immunochromatographic Assay and HpSA ELISA. Dig Dis Sci. 2007 Dec 13;
2. Wu DC, Wu IC, Wang SW, Lu CY, Ke HL, Yuan SS, Wang YY, Chang WH, Wang TE, Bair MJ, Kuo FC. Comparison of stool enzyme immunoassay and immunochromatographic method for detecting Helicobacter pylori antigens before and after eradication. Diagn Microbiol Infect Dis. 2006 Dec;56(4):373-8.
3. Kato S, Ozawa K, Okuda M, Fujisawa T, Kagimoto S, Konno M, Maisawa S, Iinuma K. Accuracy of the stool antigen test for the diagnosis of childhood Helicobacter pylori infection: a multicenter Japanese study. Am J Gastroenterol. 2003 Feb;98(2):296-300.

	Manufacturer	IVD	For *in vitro* diagnostic use only
EC REP	Authorized representative		Consult instructions for use
Σ n	Contains sufficient for <n> tests		Keep dry
REF	Catalogue Code		Temperature limitation
LOT	Lot Number		Use by
DIL	Sample diluent		

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CE EC REP

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