

EpiTuub™ Fecal H. pylori Antigen Test Kit

Rapid Monoclonal Immunochromatographic Test Device for the detection of H. Pylori Antigen in Feces



30 Tests



2 – 8°C



EPI-KT 929

EU:



INTENDED USE

This H. pylori antigen test kit is intended for the direct qualitative detection of the presence of H. pylori antigen in patient fecal samples. The test might be used as an aid for detecting patients with acute and chronic gastroenteritis infected with H. pylori.

SUMMARY OF PHYSIOLOGY

Helicobacter pylori (H. pylori) is a helical shaped gram-negative, about 3 micrometres long with a diameter of about 0.5 micrometre, microaerophilic bacterium that infects various areas of the stomach and duodenum. Many cases of peptic ulcers, gastritis, duodenitis, and cancers are caused by H. pylori infections. However, many who are infected do not show any symptoms of disease.

H. pylori is a contagious bacterium. Many researchers think that H. pylori is transmitted orally by means of fecal matter through the ingestion of waste tainted food or water.

Diagnosis of gastroenteritis with H. pylori infection can be established based on the detection of the bacteria specific antigen by a specific immunoassay methods. The fecal H. pylori antigen test may also have significant clinical tracking value in monitoring the effectiveness of treatment and the recurrence of the infection in comparison to serum H. pylori antibody test.

ASSAY PRINCIPLE

The H. pylori Rapid Test Strip employs dye-conjugated monoclonal antibody against H. pylori antigen, and solid-phase/membrane coated specific anti-H. pylori monoclonal antibody. In this test the specimen is first treated with an extraction solution to extract H. pylori antigens from the feces. Following extraction, the only step required is to screw the H. pylori test strip tube into the sample collection tube. As the sample extraction upward flows through chamber and reach the test strip, the colored particles migrate. In the case of a positive result the specific antibody present on the membrane will capture the colored particles. Different colored lines will be visible, depending upon the bacteria content of the sample. These lines, after 10 minutes of incubation at room temperature, are used to interpret the result.

REAGENTS: Preparation and Storage

This test kit must be stored at 2 – 8°C upon receipt. For the expiration date of the kit refer to the label on the kit box. All components are stable until this expiration date.

Prior to use allow all reagents to come to room temperature if the kit is stored at refrigerated condition.

1. H. pylori Test Strip Tube	30
2. Fecal Sample Collection Tube	30
3. Patient label for sample collection tube	30
4. Paper for stool sample collection	30
5. Instruction for use	1

SAFETY PRECAUTIONS

The reagents are for professional use only. Source material from which reagents of bovine serum was derived in the contiguous 48 United States. It was obtained only from donor health animals maintained under veterinary supervision and found free of contagious diseases. Wear gloves while performing this test and handle these reagents and patient samples as if they are infectious. Do not get in eyes, on skin, or on clothing. Do not ingest. On contact, flush with copious amounts of water for at least 15 minutes. When the assay procedure is completed, dispose of specimens (biohazard materials) 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. Use Good Laboratory Practices.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Disposable pipette for watery sample collection
2. Positive Control

Both are for internal quality control use only. They are available from Epitope Diagnostics. Please contact your distributor or sales representative.

SPECIMEN COLLECTION

Stool samples must be collected in clean container or directly into the Fecal Sample Collection Tube. The assay should be done right after collection. The collected specimen can be stored in the refrigerator (2-8°C) for 1-2 days prior to testing. For longer storage, the specimen can be kept frozen at -20°C for maximum 1 year. In this case, the sample should be totally thawed, and brought to room temperature and homogenized before testing.

For each solid specimen: Unscrew the sampling lid and keep the sampling tube in a vertical position to prevent the loss of any extraction solution. Insert and twist the tip of the sampling lid into the stool specimen at two or more different sites. Collect fecal sample that is stuck to the surface of the sampling lid. Do not intentionally collect any separate and large pieces of fecal sample into the tube. Replace the sampling lid into the tube and secure tightly.

ASSAY PROCEDURE

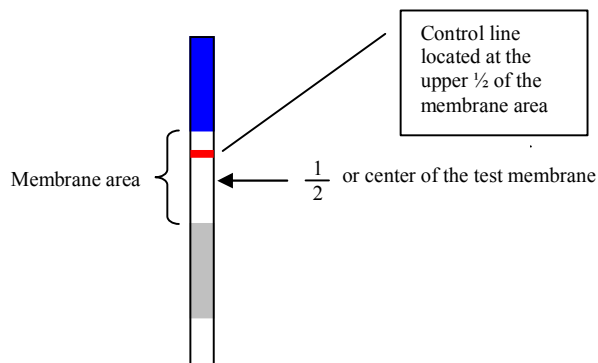
1. Bring foil pouch sealed test strips and collected specimens to room temperature (8 - 30°C).
2. Mix the sampling tube vigorously to ensure a good liquid suspension.
3. Position the sampling tube upper side down in vertical and let it sediment for about 1 minute.
4. Remove the test strip from the sealed foil pouch.

5. Screw the test strip in a vertical position into the sampling tube by breaking into the bottom seal of the sampling tube. Tighten securely!
6. Allow the solution flow into the bottom space of the test strip and keep the device in a vertical position.
7. Read test result at **10 minutes** and do not interpret test result after 20 minutes.

INTERPRETATION OF RESULTS

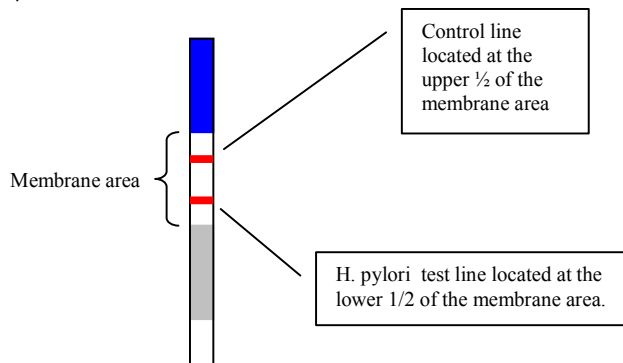
• Valid Test:

The appearance of control line on the test reading membrane area indicates the test is valid. The control line located at the upper half of the test membrane area.



• Positive:

If two red/pink colored bands are visible within 10 minutes, the test result is positive and valid.



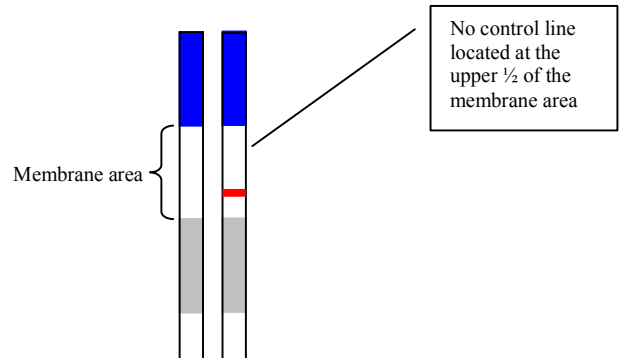
• Negative:

If test area has no colored band and the control area displays a red/pink colored band, the test result is negative (see figure as Valid Test).

• Invalid:

If a colored band does not form in the control area regardless there is any band in the test area, the test result is invalid.

Note: The control line located at the upper half of the test membrane area and the test line located at the lower half of it.



QUALITY CONTROL

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

1. **Internal procedural control:** Each *EpiTuub*TM fecal H. pylori antigen test consists a build in procedural control. It will appear if the test has been performed correctly and the reagents are reactive. It does not ensure that the test line antibody is accurately detecting the presence or absence of viral antigen 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.

You should always follow local, state, federal guidelines for running quality control.

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. Two hundred samples were evaluated to assure the correct performance of the test. The correlation of the results with other techniques (ELISA) was satisfactory. However, interferences in the performance of the tests should not be excluded.
4. No cross-reactions with other viruses or substances were observed during the evaluation of the test. A negative result does not totally exclude a possible H. pylori infection. The significance of the results must be evaluated in relation to the patient's clinical symptoms.
5. 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. *EpiTuub*TM fecal H. pylori antigen test is designed for the aid of clinical diagnosis and should not replace other diagnostic procedures.

PERFORMANCE

Sensitivity

Detection limit: A culture of *H. pylori* bacteria was sonicated, centrifuged and its protein concentration was determined. This reference antigen preparation of *H. pylori* was diluted in 0.01M PBS-BSA buffer and tested with this kit according to the above described test procedures. The detection limit of *H. pylori* is about 4 – 8 ng/ml.

Specificity

The evaluation was performed by comparison this rapid test with an 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 recognise epitopes present in the antigen found in stool of patients, as well as in preparations from the bacteria cultures in vitro. Sonicated *H. pylori* extract from different commercial samples reacts with this *H. pylori* antigen rapid test.

The possibility for interference of human anti-mouse antibodies (HAMA) or high levels of RF in the stool sample have not been evaluated.

LITERATURES

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.
4. Domínguez J, Forné M, Blanco S, Prat C, Galí N, Latorre I, Viver JM, Ausina V. Comparison of a monoclonal with a polyclonal antibody-based enzyme immunoassay stool test in diagnosing Helicobacter pylori infection before and after eradication therapy. Aliment Pharmacol Ther. 2006 Jun 15;23(12):1735-40.
5. Veijola L, Myllyluoma E, Korpela R, Rautelin H. Stool antigen tests in the diagnosis of Helicobacter pylori infection before and after eradication therapy. World J Gastroenterol. 2005 Dec 14;11(46):7340-4.

TECHNICAL ASSISTANCE AND CUSTOMER SERVICE

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Epitope Diagnostics, Inc.



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