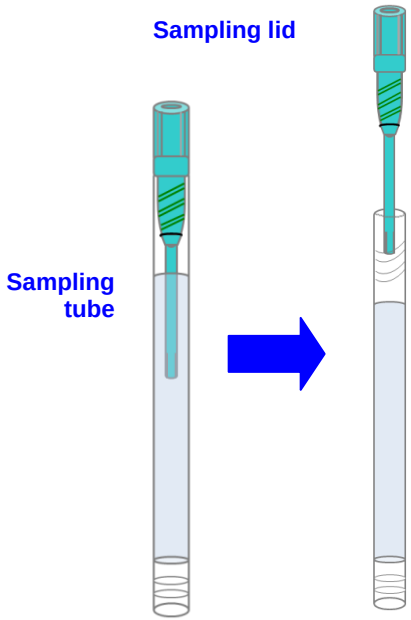
# *EpiTuub*® Fecal H. Pylori Antigen Rapid Test Kit - Instructions for Fecal Sample Collection

*Qualitative detection of H. Pylori antigen in human feces.*

Version 6

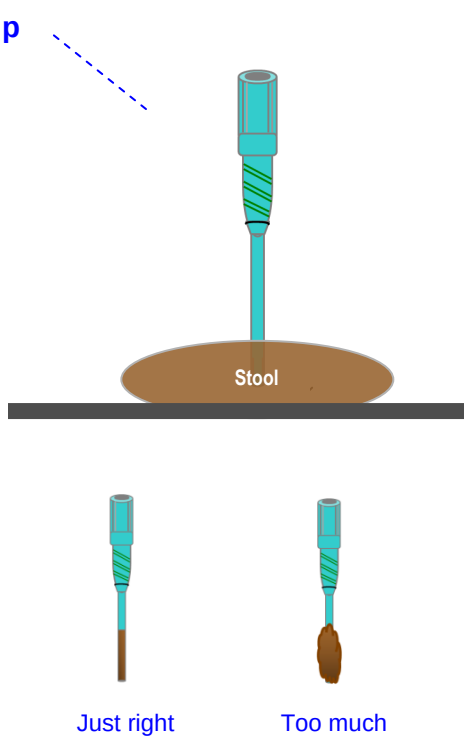
## 1

1. Collect a stool sample using the enclosed stool sampling paper:
   a. Clean the bowl and flush the toilet two times. Unfold and lay the Sample Collection Paper directly on top of the water in the toilet bowl (the paper should float above the water).
   b. After bowel movement, take the sampling tube and unscrew the sampling lid, keeping the sampling tube in a **vertical position** to prevent loss of solution.



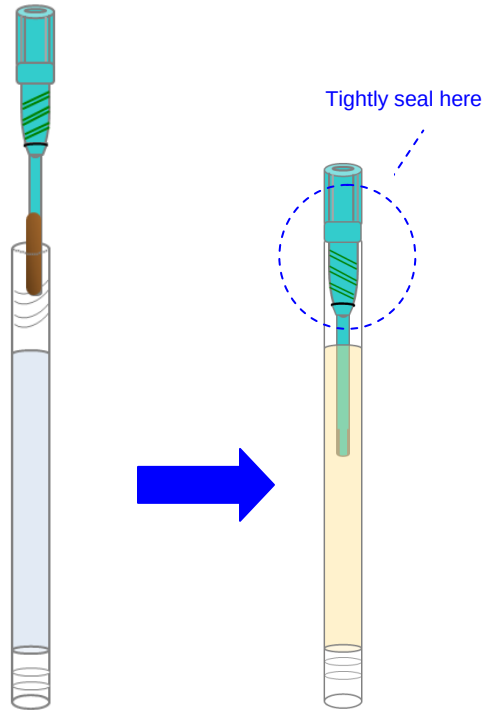

## 2

1. Hold the sampling lid by the **Thumb Grip**.
2. Use the tip of the sampling lid to collect a small amount of fecal sample at two or more sites. Only take the fecal sample that sticks to the sampling lid tip (never intentionally place any separate piece of fecal sample into the tube). The total amount of stool collected should be less than one grain of cooked rice. For liquid stool, collect 0.1mL into the sampling tube.




## 3

1. Insert and screw the sampling lid back into the sampling tube **in a vertical position**. Do not spill any solution from the tube.
2. Tightly seal the lid with the tube.
3. Flush toilet.




**READ ALL THE INFORMATION IN THIS LEAFLET BEFORE SAMPLING**

Store at 2-8°C. Do not freeze. Keep out of reach of children. For in-vitro diagnostic use. Not to be taken internally. Not to be sampled directly from anus.

If you have any questions, please contact your physician or laboratory staff or call Epitope Diagnostics at 858-693-7877 from 8:00 a.m. to 5:00 p.m. PST

EU: IVD CE +2 +8 °C

EC REP MDSS GmbH Schiffgraben 41 30175 Hannover Germany

Manufactured by Epitope Diagnostics, Inc. San Diego CA 92121, USA (V6/2019-08)



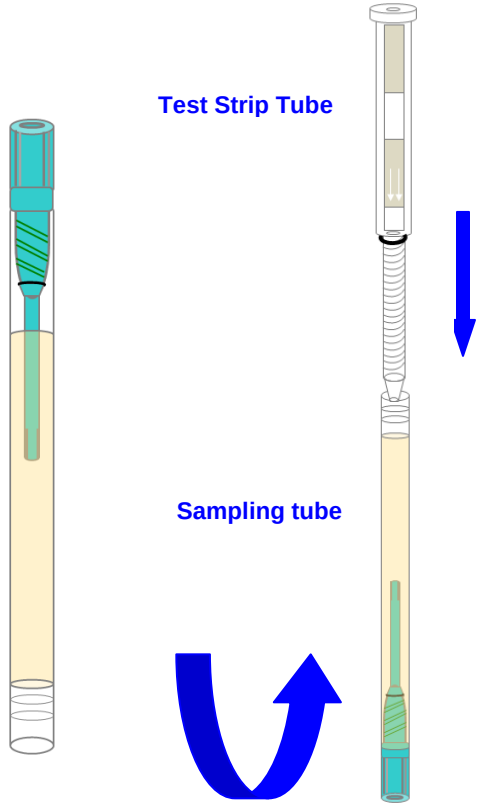
US Patent: 7,780,915

# *EpiTuub® Fecal H. pylori Antigen Rapid Test Kit* - Instructions for Test Procedures

*Qualitative detection of H. Pylori antigen in human feces.*

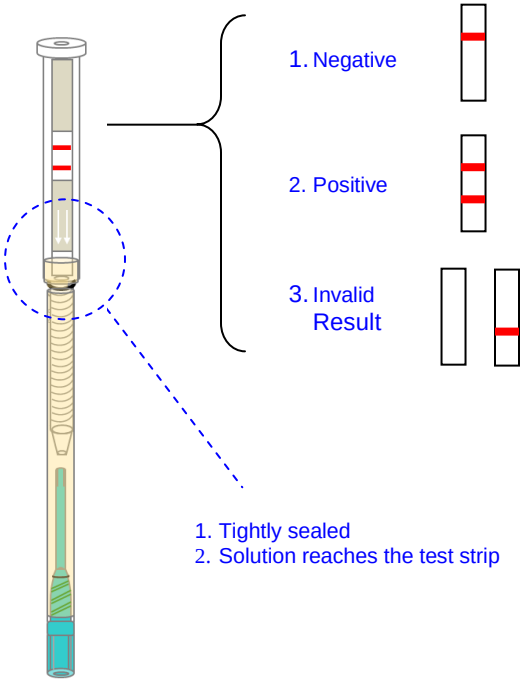
**A**

1. Shake sampling tube to dissolve the stool into the solution.
2. Turn the sampling tube **upside down vertically.**
3. Remove the test strip from foil pouch.




**B**

1. Insert and screw the test strip **in a vertical position** into the sampling tube by breaking the bottom seal of the sampling tube.
2. Allow the solution to flow into the bottom space of test strip, keeping the device **in a vertical position**.
3. You may soon see a red fluid moving across the white area of the test strip. Read test result after 5 minutes.




**For In-Vitro Diagnostic Use**

Catalog Number: KT929 (30T/Kit)
KT929.10 (10T/Kit)

**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 the 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 EpiTuub® H. pylori Rapid Test 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 stool. Following extraction, the only step required is to screw the H. pylori test strip tube into the sample collection tube. As the sample extraction flows upward through chamber and reaches 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 5 minutes of incubation at room temperature, are used to interpret the result.

**REAGENTS: Preparation and Storage**

1. Fecal specimen collection device (30205): containing sampling tube, sampling lid and pre-added extraction solution in the sampling tube. This device should be stored at 2 to 8°C. Do not freeze.

**READ ALL THE INFORMATION IN THIS INSERT BEFORE TESTING**

Store at 2-8°C. Do not freeze. Keep out of reach of children. For in-vitro diagnostic use. Not to be taken internally. Not to be sampled directly from anus. If you have any questions, call customer information staff of Epitope Diagnostics at 1-858-693-7877, 8:00 a.m. to 5:00 p.m. PST.

EC REP
MDSS GmbH
Schiffgraben 41
30175 Hannover
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## *Qualitative detection of H. pylori antigen in human feces.*

2. Test strip tube (30197): one dipstick for the H. pylori test is assembled in a transparent housing and sealed in a foil pouch with desiccant. It should remain in its original sealed pouch until ready for use. The test strip should be stored at 2 to 8ºC. Do not freeze.
3. Instruction for use.

**MATERIALS REQUIRED BUT NOT SUPPLIED**

1. Timer or clock

**PRECAUTIONS**

1. For in-vitro diagnostic use only. Not to be taken internally.
2. Do not use product beyond the expiration date.
3. Handle all specimens as potentially infectious.
4. Do not reuse the test.

**PATIENT PREPARATION**

1. Dietary restrictions are not necessary.

**SPECIMEN COLLECTION**

1. Stool specimens can be collected at any time of the day.
2. Collect a random sample of feces in a clean, dry cup or toilet paper or as indicated in the Figure 1.
3. Unscrew the sampling lid and keep the sampling tube in a vertical position to prevent the loss of any extraction solution.
4. Insert and twist the tip of the sampling lid into the stool specimen at two or more different sites (Figure 2).
5. Collect fecal sample that is stuck to the surface of the sampling lid. The total amount of stool sample should be less than one grain of cooked rice. Do not intentionally collect any separate and large pieces of fecal sample into the tube.
6. Replace the sampling lid into the tube and secure tightly (Figure 3).
7. The specimen is ready for testing, transportation or storage. It can be stored at 2-8ºC for up to 21 days and at room temperature for up to 14 days.

**TEST PROCEDURE**

1. Bring the sealed foil pouch test strips and collected specimens to room temperature.
2. Shake the sampling tube vigorously to ensure a good liquid suspension.
3. Position the sampling tube upside down vertically and let it settle for about 1 minute.
4. Remove the test strip from the sealed foil pouch.
5. Screw the test strip tube into the sampling tube by **breaking** the bottom seal of the sampling tube. Secure tightly! (Figure A)
6. Allow the solution to flow into the bottom space of the test strip and keeping the device **in a vertical position**.
7. Read test result at 5 minutes. Do not interpret test result after 10 minutes.

**PROCEDURAL NOTES**

1. After the test strip tube is screwed completely into the sampling tube, you should see a minimum 5 mm extraction buffer liquid in the bottom of the strip tube.
2. You should see liquid migrating across the membrane area right after the screw in process. If not, take the tube and tap against the table several times, and the migration of the liquid should be observed.

**INTERPRETATION OF RESULTS**

- **Positive:**
  If two red/pink colored bands are visible within 5 minutes, the test result is positive and valid (Figure B).
- **Negative:**
  If test area has no red/pink colored band and the control area displays a red/pink colored band, the test result is negative (Figure B).
- **Invalid:**
  If a colored band does not form in the control area regardless of there being any band in the test area, the test result is invalid (Figure B) and needs to be retested.

**QUALITY CONTROL**

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

1. **Internal procedural control:** Each EpiTuub® 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.

**Follow local, state, and 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. 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*™ Fecal H. pylori antigen test is designed for the aid of clinical diagnosis and should not replace other diagnostic procedures.

**PERFORMANCE CHARACTERISTICS**

**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 regognises 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.

**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.

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| | 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 | | |



US Patent: 7,780,915