Helicobacter Pylori Ag cassette CE

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For professional *in vitro* diagnostic use only			

Helicobacter Pylori Ag

A rapid test for the qualitative detection of Helicobacter pylori in faeces.

ONE STEP

PRINCIPLE

The Linear *Helicobacter pylori* Ag cassette is a lateral flow chromatographic immunoassay for the qualitative detection of H. Pylori antigen in human fecal specimen. It is intended to be used as a screening test and as an aid in the diagnosis of infection with H. Pylori. Any reactive specimen with the *Helicobacter pylori* Ag cassette must be confirmed with alternative testing method(s) and clinical findings.

The Linear *Helicobacter pylori* Ag cassette is a sandwich lateral flow chromatographic immunoassay. The test strip consists of: 1) a burgundy colored conjugate pad containing monoclonal anti-H.pylori antibody conjugated with colloid gold (anti-H.P conjugates) and 2) a nitrocellulose membrane strip containing a test band (T band) and a control band (C band). The T band is pre-coated with another monoclonal anti-H.P antibody, and the C band is pre-coated with goat anti-mouse IgG antibody.

When an adequate volume of extracted fecal specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the cassette. H.P antigen if present in the specimen will bind to the anti-H.P conjugates. The immunocomplex is then captured on the membrane by the pre-coated antibody, forming a burgundy colored T band, indicating a H.P positive test result. Absence of this band suggests that the concentration of H.P in the specimen is below the detectable level, indicating a H.P negative result.

Absence of the T band suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex of goat anti-mouse IgG/mouse IgG-gold conjugate regardless of the color development on the T band. Otherwise, the test result is invalid and the specimen must be retested with another device.

PACKAGING CONTENTS

REF	4245122	25 helicobacter pylori Ag cassette 25 Stool collection tubes with buffer 25 Plastic droppers for transferring watery stool

STORAGE AND STABILITY

Store at 2-30ºC. The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. **DO NOT FREEZE** or expose the kit over 30°C. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

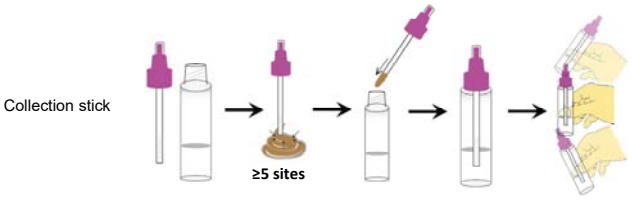
Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

1. Collect a random stool sample in a clean, dry receptacle.

Solid stool samples

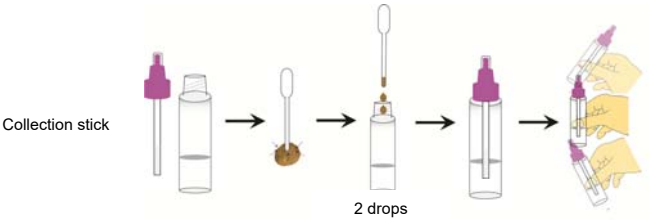
2. Open the stool collection device by unscrewing the top and use the collection stick to randomly pierce the stool sample in at least five different sites. Do not scoop stool sample as this may lead to an invalid test result.
3. Ensure stool sample is only in the grooves of the collection stick. Excess stool sample may lead to an invalid test result.
4. Replace the collection stick and tighten securely to close the stool collection device.
5. Shake the stool collection device vigorously.
6. The specimen is now ready for testing, transportation or storage.

Note: Specimens extracted may be stored at 2°C-8°C for up to 3 days. If longer storage is required, freezing at ≤-20°C is recommended.



Watery stool samples

5. Collect a random stool sample in a clean, dry receptacle.
6. Open the stool collection device by unscrewing the top.
7. Fill the plastic dropper with the sample; dispense 2 drops (70-85 µL) into the stool collection device.
8. Replace the collection stick and tighten securely to close the stool collection device.
9. Shake the stool collection device vigorously.



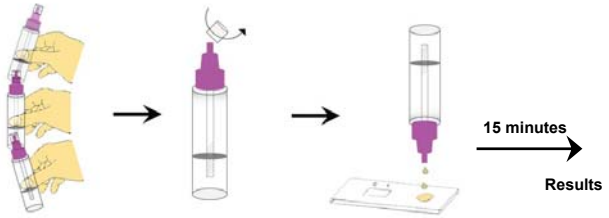
MATERIALS REQUIRED

- Specimen collection container
- Timer
- Positive Control and Negative Control

PROCEDURE

Allow the tests, stool samples and controls to reach to room temperature (15-30ºC) prior to testing. Do not open pouches until ready to pe

1. When ready to test, open the pouch at the notch and remove the test device. Place the test device on a clean, flat surface.
2. Shake the stool collection device vigorously to ensure a homogenous liquid suspension.
3. Position the stool collection device upright and twist off the dispenser cap. Holding the stool collection device vertically, dispense 2 drops of the solution into the sample well of the test device. Do not overload sample.



4. Set up the timer.

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5. Results can be read in 15 minutes after adding the specimen. Positive results can be visible in as short as 1 minute.

   Don't read results after 20 minutes. To avoid confusion, discard the test device after interpreting the result.

INTERPRETATION OF RESULTS

NEGATIVE RESULT: If only the C band is developed, the test indicates that no detectable *H. Pylori antigen* is present in the specimen. The result is negative.
POSITIVE RESULT: If both C and T bands are developed, the test indicates for the presence of *H. Pylori antigen* in the specimen. The result is positive.
Samples with positive results should be interpreted in conjunction with other testing procedure and clinical findings before a diagnostic decision is made.
INVALID: If no C line is developed, the assay is invalid regardless of any color development on the T line as indicated below. Repeat the assay with a new test device. **Excess fecal specimen can lead to invalid test results; if this is the cause, re-sample and re-test (see instructions for collection of specimen).**

QUALITY CONTROL

Internal procedural control is included in the test. A Control line appearing in the control region (C) is the internal procedural control.

It confirms sufficient specimen volume and correct procedural technique. A clear background is an internal negative background control. If the test is working properly, the background in the result area should be clear and not interfere with the ability to read the result.

It is recommended that a positive and a negative control be evaluated to verify proper test performance when:
1. A new operator uses the kit.
2. A new test kit is used.
3. A new shipment of kits is used.
4. The temperature during storage of the kit falls outside of 2-30°C.
5. The temperature of the test area falls outside of 15-30°C.

CLINICAL SIGNIFICANCE

Helicobacter pylori is associated with a variety of gastrointestinal diseases including non-ulcer dyspepsia, duodenal and gastric ulcer and active, chronic gastritis1,2. The prevalence of H. pylori infection could exceed 90% in patients with signs and symptoms of gastrointestinal diseases. Recent studies indicate an association of H. Pylori infection with stomach cancer[3].
H. pylori can be transmitted through the ingestion of food or water that is tainted with fecal matter. Antibiotics in combination with bismuth compounds showed to be effective in treating active H. Pylori infection.
H. pylori infection is currently detected by invasive testing methods (ie histology, culture) based on endoscopy and biopsy, or non-invasive testing method, such as urea breath test (UBT), serologic antibody test and stool antigen test. UBT test requires expensive lab equipment and radioactive reagent. Serologic antibody tests do not distinguish between currently active infection and past exposure or infection that has been cured. The stool antigen test detects antigen presence in the feces that indicates an active H. pylori infection. It can also be used to monitor the effectiveness of treatment and the recurrence of the infection.
The Linear *Helicobacter Pylori Ag cassette* uses a combination of the polyclonal anti H. pylori antibody and collid gold conjugated monoclonal anti-H. Pylori antibody to specifically detect H. pylori antigen present in the infected patient fecal specimen. The test is user friendly, accurate, and the result is available instantly.

ANALYTICAL PERFORMANCE

Clinical Performance
324 fecal samples collected from subjects with symptomatic gastrointestinal disorders and non-gastrointestinal symptoms were tested with Linear Helicobacter Pylori Ag and with the UBT as reference test. A comparison of the results for all subjects is shown in the following table:

	Linear Helicobacter Pylori Ag		
UBT	**Positive**	**Negative**	**Total**
Positive	118	7	125
Negative	0	199	199
Total	118	206	324

Relative Sensitivity: 94.4% , Relative Specificity: 100.0%, Overall Agreement: 97.8%

The detection limit for Linear Helicobacter pylori Ag is 5 ng/ml of *H. pylori* lysate. Fecal specimen extractions containing *H. pylori* lysate equal to or greater than 5 ng/ml routinely test positive. Specimens containing *H. pylori* lysate less than 5 ng/ml may also produce a very faint positive line, especially with an assay time extended beyond 15 minutes. The following experiments were done to validate the sensitivity of the Linear Helicobacter pylori Ag:
Normal fecal specimen extractions were spiked with *H. pylori* lysate to concentrations of 0, 1.25, 2.5, 5, 10, 20 ng/ml. The specimens were run on the Linear Helicobacter pylori Ag.
Results are shown in the table below.

***H. pylori* lysate ng/ml**	**0**	**1.25**	**2.5**	**5**	**10**	**20**
Number of positive	0	0	12	20	20	20
Number of negative	20	20	8	0	0	0

n=20 Relative Sensitivity at 5 ng/ml = 20/20 x 100% = 100%

PRECAUTIONS

- This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
- Do not open the sealed pouch, unless ready to conduct the assay.
- Do not use any kit components beyond their stated expiration dates.
- Do not use the components from any other type of test kit as a substitute for the components in this kit.
- Bring all reagents to room temperature (15°C-30°C) before use.
- **Do not scoop stool sample as this may lead to excess fecal specimen that tends to clot the sample pad and interfere with sample migration.**
- Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
- Users of this test should follow the US CDC Universal Precautions for biosafety.
- Do not smoke, drink or eat in areas where specimens or kit reagents are being handled.
- Extraction buffer contains 0.1% NaN3. Avoid contact with skin or eyes. Do not ingest.
- Dispose of all specimens and materials used to perform the test as biohazardous waste.
- The test results should be read within 15 minutes after a specimen is applied to the sample well of the device. Reading results after 20 minutes may give erroneous results.
- Do not perform the test in a room with strong air flow, i.e. electric fan or strong air-conditioning.

LIMITATIONS

1. The Assay Procedure and the Interpretation of Assay Result sections must be followed closely when testing for the presence of *H. pylori* antigen in feces. Failure to follow the procedure, particularly the Specimen Collection procedure, may cause inaccurate results.
2. The assay is limited to the qualitative detection of *H. pylori* antigen in human fecal specimen. The intensity of the test line does not have a linear correlation with the antigen titer in the specimen.
3. A negative result for an individual subject indicates the absence of detectable *H. pylori*–antigen. However, a negative test result does not preclude the possibility of infection with *H. pylori*.
4. A negative result can occur if the quantity of the *H. pylori* antigen present in the specimen is below the detection limits of the assay or if the antigens that are detected are not present in the fecal sample collected.
5. If symptoms persist and the result from the Linear Helicobacter pylori Ag is negative or non-reactive, it is recommended to re-sample the patient a few days later or test with alternative test methods.
6. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

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