

# H. pylori Ag Rapid Test Cassette (Feces)

## INTENDED USE

H. pylori Ag Rapid Test Cassette (Feces) is a sandwich lateral flow chromatographic immunoassay for the qualitative detection of H. Pylori antigen in feces. It is for professional in vitro diagnostic use only.

## INTRODUCTION

H. Pylori is associated with a variety of gastrointestinal diseases including non-ulcer dyspepsia, duodenal and gastric ulcer and active, chronic gastritis.<sup>1,2</sup> 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.<sup>3</sup> H. Pylori colonizing in the gastrointestinal system elicits specific antibody responses<sup>4,5,6</sup> which aids in the diagnosis of H. Pylori infection and in monitoring the prognosis of the treatment of H. Pylori related diseases. Antibiotics in combination with bismuth compounds have been shown to be effective in treating active H. Pylori infection. Successful eradication of H. pylori is associated with clinical improvement in patients with gastrointestinal diseases providing a further evidence.<sup>7</sup>

## PRINCIPLE

H. pylori Ag Rapid Test Cassette (Feces) is a lateral flow chromatographic immunoassay based on the principle of the double antibody-sandwich technique. The test cassette consists of: 1) a burgundy colored conjugate pad containing H. Pylori antibodies conjugated with color particles (H. Pylori conjugates. 2) a nitrocellulose membrane strip containing a test band (T band) and a control band (C band). The T band is pre-coated with non-conjugated H. Pylori antibodies.

When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the cassette. The antigen of H. Pylori if present in the specimen will bind to the H. Pylori antibodies conjugates. The immunocomplex is then captured on the membrane by the pre-coated H. Pylori antibodies, forming a burgundy colored T band, indicating a H. Pylori antigen positive test result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred. Otherwise, the test result is invalid and the specimen must be retested with another device.

## PRODUCT CONTENTS

H. pylori Ag Rapid Test Cassette (Feces) containing anti- H.pylori antibodies particles and anti-H.pylori antibodies coated on the membrane.

## MATERIALS SUPPLIED

20 Sealed pouches each containing a test cassette and a desiccant  
20 Specimen collection tubes with extraction buffer, 2.0 mL  
1 Package Insert

## MATERIAL REQUIRED BUT NOT PROVIDED

1. Clock or Timer
2. Specimen collection containers.

## STORAGE AND STABILITY

All reagents are ready to use as supplied. Store unused test device unopened at 2°C-30°C. If stored at 2°C-8°C, ensure that the test device is brought to room temperature before opening. The test is not stable out off the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

## WARNINGS AND PRECAUTIONS

1. For professional In Vitro diagnostic use only.
2. Do not use it if the tube/pouch is damaged or broken.
3. Test is for single use only. Do not re- use under any circumstances.
4. Handle all specimens as if they contain infectious agents. Observe established standard procedure for proper disposal of specimens
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assay.
6. Humidity and temperature can adversely affect results

## SPECIMEN COLLECTION

Collect sufficient quantity of feces (1-2 ml or 1-2 g) in a clean, dry specimen collection container to obtain maximum antigens (if present). Best results will be obtained if the assay is performed within 6 hours after collection. Specimen collected may be stored for 3 days at 2-8°C if not tested within 6 hours. For long term storage, specimens should be kept below -20°C.

To process fecal specimens:

•For Solid Specimens:

Unscrew the cap of the specimen collection tube, then randomly stab the specimen collection applicator into the fecal specimen in at least 3 different sites to collect approximately 50 mg of feces (equivalent to 1/4 of a pea). Do not scoop the fecal specimen.

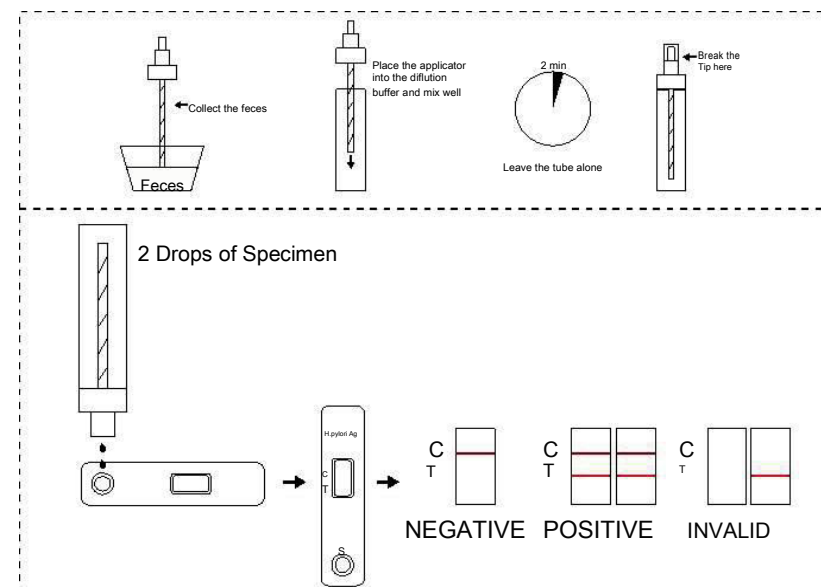
•For Liquid Specimens:

Hold the dropper vertically, aspirate fecal specimens, and then transfer 2 drops (approximately 80 µL) into the specimen collection tube containing the dilution buffer. Screw on and tighten the cap onto the specimen collection tube, then shake the specimen collection tube vigorously to mix the specimen and the dilution buffer. Leave the tube alone for 2 minutes.

## TEST PROCEDURE

1. Remove the test device from its foil pouch by tearing along the notch and use it as soon as possible.
2. Specimen collection. See also specimen collection.
3. Holding the sample collection device upright, carefully break off the tip of collection device.
4. Squeeze 2 drops (~80µL) of the sample solution in the sample well of the cassette, as in the illustration.
5. Read the test results in 10 minutes. It is important that the background is clear before the result is read. Do not read results after 10 minutes. To avoid confusion, discard the test device after interpreting the result.

## INTERPRETATION OF RESULTS



# H. pylori Ag Rapid Test Cassette (Feces)

Positive: Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T).

Negative: One colored line appears in the control line region(C). No line appears in the test line region (T).

Invalid: Control line fails to appear.

## QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Control standards are not supplied with this kit; however, 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

1. The Assay Procedure and the Assay Result Interpretation must be followed closely when testing the presence of H. Pylori antigen in feces from individual subjects. Failure to follow the procedure may give inaccurate results.

2. H. pylori Ag Rapid Test Cassette (Feces) is limited to the qualitative detection of H. Pylori antigen in feces. The intensity of the test band does not have linear correlation with the antigen titer in the specimen.

3. A negative result for an individual subject indicates absence of detectable H. Pylori antigen. However, a negative test result does not preclude the possibility of exposure to or 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 the antigen that are detected are not present during the stage of disease in which a sample is collected.

5. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

## PERFORMANCE CHARACTERISTICS

A study was performed with 165 patient feces samples including both symptomatic gastrointestinal disorders and samples from non-symptomatic patients and 100 normal feces samples. Comparison for all subjects with H. pylori Ag Rapid Test Cassette (Feces) and reference ELISA kit is showed in the following table:

Method		EIA		Total Results
H.P Test Cassette	Results	Positive	Negative	
	Positive	163	0	163
	Negative	2	100	102
Total Results		165	100	265

Relative sensitivity: 98.8%

Relative specificity: 100%

Accuracy:98.9%

## REFERENCE

1. Marshall,B.J.et.al. Pyloric Campylobacter infection and gastroduodenal disease. Med. J. Australia.149:439-44, 1985.

2. Marshall,B.J.et.al. Prospective double-blind trial of duodenal ulcer relapse after eradication of Campylobacter pylori. Lancet. Dec.1437-42,1988.

3. Megraud,F.et.al. Seroepidemiology of Campylobacter pylori infection in virious populations J.Clin.Microbiology. 27:1870-3,1989.










4. Soll,A.H. Pathogenesis of peptic ulcer and implications for therapy. New England J. Med.322:909-916,1990.

5. Parsonnet,J.et.al. Helicobacter pylori infection and the risk of gastric carcinoma. New England J.Med. 325:1127-31,1991.

6. Ansong,R. et.al. Evaluation of techniques for isolation, subcultivation and preservation of Helicobacter pylori. J.Clin.Micro. 29:51-53,1991.

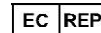
7. Pronovost,A.P.et.al. Evaluation of a new immunodiagnostic assay for Helicobacter pylori antibody detection: Correlation with histopathological and microbiological results. J.Clin.Microbiol.32:46-50,1994.

## INDEX OF SYMBOLS

	Consult instructions for use		Tests per kit		Authorized Representative
	For <i>in vitro</i> diagnostic use only		Use by		Do not reuse
	Store between 2-30°C		Lot Number		Catalog#



Healgen Scientific Limited Liability Company  
Address: 3818 Fuqua Street, Houston, TX 77047, USA.  
TEL: +1 713-733-8088 FAX: +1 713-733-8848  
Website: www.healgen.com



QARAD b.v.b.a.  
Cipalstraat 3, B-2440 Geel, Belgium



GCHP-602a

Revision Date: 2017-08-26  
Version: 1.0  
B21412-01