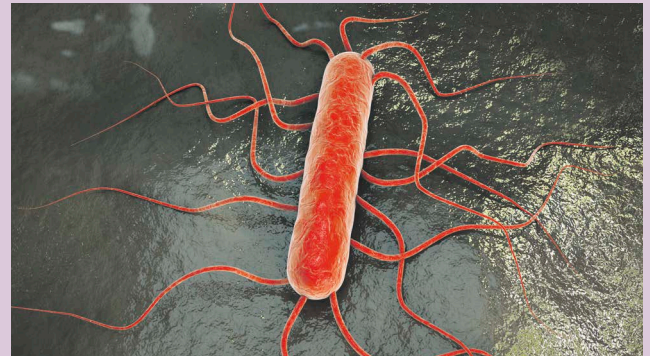


HELICOBACTER PYLORI

The PathFlow™ *H. pylori* Antigen Cassette is a rapid chromatographic immunoassay for the qualitative detection of *H. pylori* antigens in human faeces specimens to aid in the diagnosis of *H. pylori* infection.



What is the Test?

- The PathFlow™ *H. pylori* Cassette is a qualitative, lateral flow immunoassay for the detection of *H. pylori* antigens in human faeces specimens.

What is the Disease?

- *H. pylori* is a small, spiral-shaped bacterium that lives in the surface of the stomach and duodenum.
- It is implicated in the aetiology of a variety of gastrointestinal diseases, including duodenal and gastric ulcers, non-ulcer dyspepsia and active and chronic gastritis.

Symptoms

- Many individuals have no symptoms (around 50% of the world's population are infected); others may have occasional episodes of: belching, bloating, nausea and vomiting and abdominal discomfort.
- In more serious cases *H. pylori* can cause symptoms of nausea and vomiting, fatigue and anaemia, dark-tarry-like stools, diarrhoea, heartburn/bad breath and peptic ulcers.

Mortality/Morbidity – Clinical Implications

- Transmission of the disease has not been definitively proven; suggested route is oral-oral or faecal-oral.
- The most serious consequence of *H. pylori* infection is gastric cancer. *H. pylori* is considered a type 1 carcinogen and the most common cause of infection-related cancer (5.5% of global cancer burden).
- Prognosis for infections is usually good/excellent, but up to 20% affected individuals may have reoccurring infection.

- Complete system, no additional reagents required.
- Simple and easy to use; only two steps involved.
- Rapid result offered. Available after 10 minutes or within 10-20 minutes.
- Can be used for both solid and liquid specimens.
- In-built procedural control.
- Non-invasive test allowing for rapid detection of *H. pylori* infections to create effective treatment solutions.

Why use PathFlow™

- Both invasive and non-invasive methods are used to diagnose *H. pylori* infection in patients with symptoms of gastrointestinal disease.
- Specimen-dependent and costly invasive diagnostic methods include gastric or duodenal biopsy followed by urease testing (presumptive), culture, and/or histologic staining.
- Non-invasive methods include faecal antigen testing, serological testing and UBT (urea breath test). The UBT is the most expensive diagnostic technique and serological testing does not distinguish past and current infections.
- The PathFlow™ *H. pylori* Antigen Cassette provides a non-invasive method, for the qualitative detection of *H. pylori* antigens in human faeces allowing for a more cost effective, rapid diagnostic procedure.

Performance – Tested vs. Endoscope-based methods

Sensitivity – 98.8%

Specificity – 98.4%

Accuracy – 98.6%

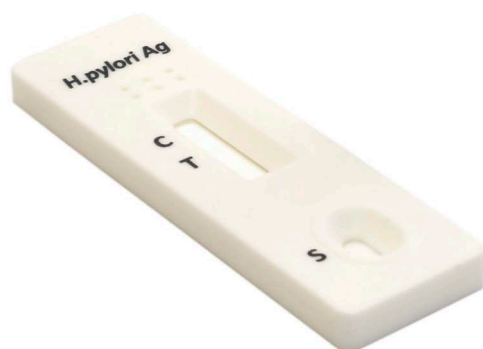
Ordering Information

Code – M587CE

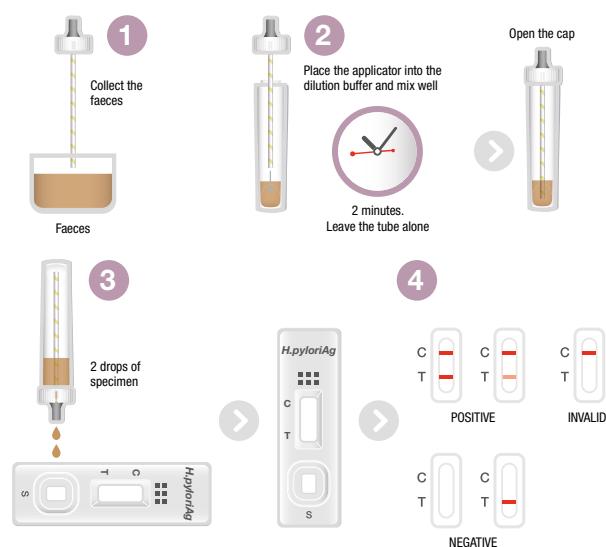
Description – PathFlow™ *H. pylori* Antigen

Size – 25 Test Kits

Storage – 2°C-30°C



Procedure



Step 1. Collect sufficient quantity of faeces (1-2ml/g). Optimum results will be obtained if the assay is performed within 6 hours.

Step 2. Solid Specimens – Unscrew the cap on the sample collection tube and collect approximately 50mg of faeces. Liquid Specimens – Hold the dropper vertically, aspirate faecal specimens and then transfer 2 drops (approximately 80µl) into specimen collection tube. Tighten the cap on the specimen collection tube and shake vigorously, leave for 2 minutes. Bring the pouch to room temperature before opening it, remove the cassette and use within one hour.

Step 3. Hold the specimen collection tube upright and open the cap onto the specimen collection tube. Invert the collection tube and transfer 2 full drops of extracted specimen (approximately 80µl) to the specimen well on the test cassette and start the timer.

Step 4. Read the result after 10 minutes, do not read after 20 minutes.

Distributed by:

MICROGEN
BIOPRODUCTS



PathFlow™ - Leading The
Way to a Better Diagnosis



Microgen Bioproducts Ltd, Unit 1, Watchmoor Point, Camberley, Surrey GU15 3AD, United Kingdom
T: +44 (0)1276 600 081 F: +44 (0)1276 600 151 E: enquiries.microgen@novacyt.com
www.microgenbioproducts.com

GMM134, Revision -1

Part of the
NOVACYT
GROUP