

A detailed 3D rendering of Helicobacter pylori bacteria. The bacteria are shown as long, pinkish-red, spiral-shaped organisms with numerous small, dark, granular structures (likely flagella or surface proteins) along their length. They are set against a background of soft, out-of-focus pink and orange spheres, suggesting a cellular or tissue environment. The entire image is framed by a large, curved white border that separates the microscopic view from the solid purple background on the right.

Diagnosing *Helicobacter pylori*

*A clinical guide to urea
breath testing and
alternative methods*

Helicobacter pylori (H. pylori)

H. pylori is a Gram-negative bacillus that is found as a natural coloniser of the human gastric mucosa in about 50% of adults worldwide. *H. pylori* was first identified in Australia by Marshall and Warren in 1983, who established the association with gastric and duodenal ulcers.¹ More than 80% of duodenal ulcers and more than 60% of gastric ulcers (see Figure 1) are associated with *H. pylori*, as well as some cancers of the stomach.

“More than 80% of duodenal ulcers and more than 60% of gastric ulcers are associated with *H. pylori*.”

Most infections are acquired during early childhood, postulated to be due to transmission from close family members by oral-oral or faecal-oral routes.² In Australia, 25 to 30% of the population is infected, with the prevalence increasing with age. Acute infection may be asymptomatic or associated with mild dyspeptic symptoms. Acquisition of infection in adulthood is uncommon. Once acquired, the infection usually persists, resulting in chronic gastritis with the potential to cause gastroduodenal complications, including peptic ulcer disease, gastric atrophy, and intestinal metaplasia, as well as increasing the risk of gastric cancer and gastric mucosa-associated lymphoid tissue (MALT) lymphoma.

H. pylori may also be associated with iron and/or vitamin B12 deficiency due to reduced absorption caused by gastric atrophy and hypochlorhydria induced by chronic infection.

In adults, once *H. pylori* is diagnosed, eradication treatment is recommended.

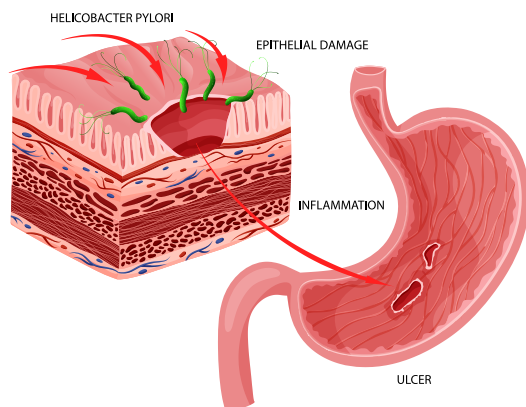


Figure 1. Gastric ulcer caused by *H. pylori* infection.

Diagnosis of *H. pylori*

The choice of test used to diagnose *H. pylori* is dependent on whether the patient requires an endoscopy to evaluate their symptoms. If an endoscopy is not required on the basis of clinical presentation, non-invasive tests for *H. pylori* are recommended.

Non-invasive tests are also useful where there is a potential false negative test during endoscopy (due to use of certain medications or active peptic ulcer bleeding) and for follow-up to confirm successful eradication after treatment.

Indications for testing (adults)^{3,4}

- Established peptic ulcer disease
- Non-ulcer dyspepsia
- Monitoring the success of eradication of *H. pylori* after treatment
- Prior to chronic treatment with nonsteroidal anti-inflammatory drugs (NSAIDs) or low-dose aspirin
- Unexplained iron deficiency anaemia (after investigation for other causes)

In children, testing is generally only recommended where there is established peptic ulcer disease or during endoscopy if treatment is intended. Such patients should be under specialist care.

Urea breath testing for *H. pylori*

The urea breath test is an accurate, non-invasive way to diagnose active *H. pylori* infection.

The test relies on the fact that *H. pylori* produces bacterial urease, which hydrolyses urea to produce CO₂ and ammonia. This helps to neutralise gastric acid and allows *H. pylori* to survive in the gastric environment.

In the ¹⁴C Urea Breath Test, a capsule containing ¹⁴C-labelled urea is given by mouth, and 10 minutes later, exhaled breath is collected into a balloon. If *H. pylori* is present, ¹⁴CO₂ will be produced, and this can be detected in the breath sample. If *H. pylori* is not present, the labelled urea will not be broken down, and the breath will not contain ¹⁴CO₂.

Is the test safe?

¹⁴C is a naturally occurring radioactive form of carbon, present in very small amounts in all living things, with the more common form being ¹²C. The dose of radiation in the ¹⁴C Urea Breath Test is approximately equivalent to one day of background radiation exposure, far less than a standard X-ray.⁵

However, as studies have not been performed to determine safety in pregnancy, breastfeeding, and for children under 12 years, testing is not routinely performed in these groups. A stool antigen test is available as an alternative when testing for *H. pylori* is indicated.

Patient preparation

The patient will need to fast for a minimum of 6 hours before the test. The following medications should be discontinued before the test to prevent false negative results.

| Medication | Exclusion period |
|---|--|
| Antibiotics and bismuth containing products | 4 weeks |
| Sucralfate | 2 weeks |
| Proton Pump Inhibitors | 7 days |
| Antacids and H2 Antagonists | No exclusion period, other than during fasting and during the test |

Testing to confirm eradication following treatment should be performed at least 4 weeks following completion of treatment.

Alternative tests

Invasive tests

Invasive tests require upper endoscopy to obtain gastric tissue biopsies, which can be used for bacterial culture, susceptibility testing, and histopathology. The main limitation of these methods is their invasiveness and the ability to analyse only a small part of the gastric mucosa.⁶ These tests are of value in the management of recurrent infection and in patients who are failing therapy, where specialist consultation is required.

Non-invasive tests

In addition to the urea breath test, non-invasive tests include serology and stool antigen tests. These tests provide high reliability in the detection of *H. pylori* due to their high sensitivity and specificity (Table 1). However, all of these methods have limitations, and the selection of test will depend on the clinical circumstances. Only the urea breath test and stool antigen test identify active infection.

The Stool Antigen Test (SAT) is based on the direct identification of *H. pylori* in stool samples. SAT is recommended for both the primary diagnosis of *H. pylori* infection and for the monitoring of therapy effectiveness. The test is non-invasive, quick, and easy to use, with a sensitivity of 95% and specificity of 97%. It is suitable for the diagnosis of *H. pylori* in children.

Serology: Antibodies to *H. pylori* appear in the blood 3 to 4 weeks after infection and may be present for life. Serologic tests are widely available to diagnose *H. pylori*. They are non-invasive, rapid, and can be used in screening populations. However, there are a number of limitations. Serology may be positive due to the presence of an active infection at the time of the test, a previous infection, or non-specific cross-reactive antibodies. The results must therefore be interpreted within the context of the clinical illness. Antibodies do not decline following treatment, so the test is of no value in monitoring therapy.

Table 1: Accuracy of *H. pylori* diagnostic methods⁶

| Specimen type | Sensitivity (%) | Specificity (%) |
|-------------------------------|-----------------|-----------------|
| Non-invasive tests | | |
| Urea Breath Test | 96-100 | 93-100 |
| Stool Antigen Test | 95 | 97 |
| Serology | 76-84 | 79-80 |
| Invasive (requires Endoscopy) | | |
| Rapid Urease Test | 85-95 | 95-100 |
| Histology | 91-93 | 100 |
| Culture | 76-90 | 100 |

Requesting the ¹⁴C Urea Breath Test with Clinical Labs

- How to order:** Request ‘Urea Breath Test’ on a Clinical Labs General Pathology Request Form.
- Follow-up testing:** Testing to confirm eradication following treatment should be performed at least 4 weeks following completion of treatment.
- Cost:** The Urea Breath Test is bulk-billed subject to Medicare criteria, which includes both confirmation of *H. pylori* colonisation and monitoring of successful eradication.
- Alternative non-invasive tests** (for pregnancy, breastfeeding and children):
- The Stool Antigen Test (SAT) – Specify ‘Stool Antigen Test (SAT)’ on the request form.
 - Serology – Specify ‘Serology for *H. pylori*’ on the request form.

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About the authors:



Dr Phoebe Stanford

MBBS FRCPA FRACP

Lab: Bella Vista (NSW)

Speciality: Chemical Pathology

Areas of Interest: Endocrinology

Phone: (02) 8887 9999

Email: phoebe.stanford@clinicallabs.com.au



Dr Stella Pendle

MSc MBChD DTM&H FRCPA

Lab: Bella Vista (NSW)

Speciality: Microbiology

Areas of Interest: General bacteriology, infectious serology, VRE and hepatitis

Phone: (02) 8887 9999

Email: stella.pendle@clinicallabs.com.au

Local pathologists:



Dr David Deam

MBBS MAACB FRCPA

Lab: Clayton (Vic)

Speciality: Chemical Pathology

Areas of Interest: Endocrine function testing, protein abnormalities, laboratory automation

Phone: (03) 9538 6777

Email: david.deam@clinicallabs.com.au



Dr Linda Dreyer

MBChB MMED (Path) (South Africa)
FRCPA

Lab: Clayton (Vic)

Speciality: Infection Control, Microbiology

Areas of Interest: Antimicrobials, infection control, and molecular diagnostic assays in contemporary clinical microbiology

Phone: (03) 9538 6777

Email: linda.dreyer@clinicallabs.com.au



Dr Tony Mak

MBBS MBA FRCPA FRCPATH

Lab: Osborne Park (WA)

Speciality: Chemical Pathology

Areas of Interest: Toxicology

Phone: (08) 9442 7663

Email: tony.mak@clinicallabs.com.au



Dr Sudha Pottumarthy-Boddu

MBBS FRCPA D(ABMM)

Lab: Osborne Park (WA)

Speciality: Clinical Microbiologist, microbiology

Areas of Interest: Antimicrobial susceptibility trends and molecular methods in the diagnosis of infectious diseases

Phone: 1300 134 111

Email: sudha.pottumarthyboddu@clinicallabs.com.au