

H. PYLORI BREATH TEST

Date: _____

Time: _____

Location: _____

This test takes approximately 20 minutes

Preparation for the Test

Two (2) Weeks prior to the test, do not take:

- Antibiotics
- Pepto Bismol or Bismuth
- Aciphex (rabeprazole)
- Carafate (Sucralfate)
- Dexilant (dexlansoprazole)
- Nexium (esomeprazole magnesium)
- Prevacid (Lansoprazole)
- Prilosec (Omeprazole)
- Protonix (pantoprazole)
- Zegrid (omeprazole sodium-bicarb)

24 Hours prior to the test:

- Stop taking Tums (calcium carbonate), Tagamet (Cimetidine), Zantac (ranitidine HCl), Axid (nizatidine) and/ or Pepcid (famotidine)

Day of the test:

- 2 Hours prior to the test, do not eat or drink anything (including water and ice chips) until after the test is complete
- No medications, supplements or vitamins
- No breath mints, chewing gum or mouthwash (you can brush your teeth up to 1 hour prior to test)
- No tobacco products including chewing tobacco and e-cigarettes

After the test:

- You can resume all activities and eat immediately after the test.
- You will receive the results of your test on our portal at www.washgi.com. If you are not using the portal, you will receive test results by letter, phone or a follow up office visit.

How does the BreathID Breath Test work?

The test consists of two phases, the Sampling phase, at which time two Breath Sample Bags are inflated by the patient, and the Analysis phase at which time the two Breath Sample Bags are analyzed together using the BreathID Hp Lab System.

Sampling phase begins with the collection of a baseline breath sample. The patient inflates the Baseline Breath Sample Bag. The patient then ingests a test drink consisting of 13 C-urea tablet 75mg and 4.3g of Citrica Powder (4g citric acid). After 15 minutes a post-ingestion sample is collected by inflation of the Post Ingestion Breathe Sample Bag.

The average adult body normally contains about 9.0 grams of urea, which is a product of protein metabolism. Urea in the body is referred to as a natural isotopic abundance urea since it is composed of 98.9% 12C-urea and 1.1% 13C-urea. Greater than or equal to 99% of the carbon molecules in the supplied tablet are in the form of 13C; a stable, naturally occurring, non-radioactive isotope of carbon. 13C-urea is the diamide of 13C carbonic acid and is highly soluble in water.

What risks are involved with the BreathID Breath Test?

Following FDA clearance of the IDkit:HpTM One kits (using the identical 13C-urea tablet and Citrica powder), the following adverse events have been identified: anaphylactic reaction, diarrhea and vomiting. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to establish a casual relationship to drug exposure. In two clinical studies conducted in 465 patients' of at least 18 years-old and older to determine the initial diagnosis and post treatment monitoring of *H. pylori* infection using the IDkit HpTM Two kits, the following adverse events experienced by 1.5% of those patients were nausea (0.6%), throat burning (0.4%), and lightheadedness (0.4%). The last one was reported after blowing into the bags. The potential for adverse events were experienced by the patients within minutes of the 13C-Urea tablet and Citrica powder.

What is Helicobacter pylori?

Helicobacter pylori (*H. pylori*) is a bacteria which lives only in the lining of the stomach and is one of the most common chronic infections in humans. The importance of *H. pylori* was unrecognized until 1982, when an Australian physician, Dr. Barry Marshall, discovered that the germ was almost always present in patients with gastritis (inflammation of the stomach) and ulcers. Doctors now believe that *H. pylori* is associated with most stomach ulcers and most all duodenal ulcers.

H. pylori causes inflammation of the stomach lining and weakens the natural protection against stomach acid, which may then cause an ulcer. If stomach acid is reduced with medication, an ulcer may heal, but it tends to come back once the medication is stopped. However, if *H. pylori* is treated successfully with antibiotics, an ulcer can be permanently cured. This means that ulcer medication may no longer be needed.

Does H. pylori always cause ulcers?

H. pylori does not always cause ulcers to form, but almost always produces inflammation of the stomach lining. Some people with *H. pylori* infection do not have any symptoms, but may report nausea, gas, bloating, and burning stomach pain. These symptoms occur twice as often in people with *H. pylori* compared to those who are not infected. Doctors believe that *H. pylori* may be responsible for many of these symptoms.

How common is H. pylori infection?

H. pylori infection occurs throughout the world, in every part of society, and in every age group. About 30% of the United States population has the infection, which is more common with advancing age (50% will have it by age 60) and is rare in children. Once infected with *H. pylori*, a person usually continues to carry the germ unless certain medications are used to cure the infection.

How did I get it and can I spread it?

H. pylori appears to be passed from person-to-person. It is more common in spouses of infected patients than in the general population. It is also common in places where sanitation is poor and where crowded living conditions exist. It is not clear exactly how a person gets *H. pylori*, but it may be through swallowing infected food or water. *H. pylori* is not found naturally in animals, so pets do not seem important in the spread of the infection. Careful personal hygiene (through hand washing, use of separate personal items such as eating utensils, glassware, etc.) probably is the best way to reduce person-to-person spread of *H. pylori*.

How is H. pylori infection diagnosed?

There are several very accurate ways to determine the presence of *H. pylori*:

1. Blood tests can be used to determine the presence of antibodies to the bacteria. These tests tell if a person has ever had the infection but do not tell if the infection is active.
2. A biopsy of the stomach can be used to determine the presence of *H. pylori*. A biopsy is obtained during an examination of the stomach with a flexible scope. The biopsy is examined by a pathologist under a microscope for the presence of *H. pylori*.
3. The urea breath test (the **BreathID***) is a diagnostic test that can determine the presence of *H. pylori* without the use of a scope. It is safe, accurate, easy to perform and much less expensive than a scope and biopsy for diagnosis.
4. A stool antigen for *H. pylori* can be performed to determine the presence of the active organism.