Is H. pylori infection... 
the culprit behind your stomach symptoms?
What’s really going on in your stomach?

You may often have stomach symptoms that you blame on certain foods or stress. You may take over-the-counter medications to get some relief, but it doesn’t last long. If you have stomach symptoms that keep returning, it’s important to identify the root of the problem.

Up to 40% of adults in the United States suffer from dyspepsia (indigestion) each year, but fewer than 10% ever see their doctor about it.1

Figuring out the cause of stomach symptoms may not always be easy. Stomach problems such as heartburn, stomach inflammation (gastritis), indigestion (dyspepsia), and peptic ulcer all share similar symptoms,2,3 including those listed below.

- Burning
- Bloating (feeling too full)
- Belching/burping
- Loss of appetite
- Nausea
- Passing gas
- Bad breath
- Vomiting
- Gnawing pain

You might think that the source of your symptoms is heartburn or indigestion, but the root cause may be something you haven’t considered: infection with *Helicobacter pylori* (pronounced hell-ee-ko-back-ter pie-lore-ee) or *H. pylori*.

Please see accompanying BRIEF SUMMARY and enclosed Current Package Insert.
What is *H. pylori*?

*H. pylori* is a bacterium that can cause infection in the stomach and upper part of the small intestine (the duodenum). It can live in the stomach for many years and damage the stomach’s lining (epithelium) and protective mucus. This allows gastric acid to reach and harm the stomach’s wall (see picture below). Ulcers can develop as a result.

*H. pylori* causes more than 90% of duodenal ulcers and up to 80% of gastric ulcers. *H. pylori* infection can also cause gastritis and dyspepsia, and, without proper treatment, these conditions will probably not go away. Recent studies have linked *H. pylori* infection with an increased risk of developing certain stomach cancers.
H. pylori is a common chronic infection that:

- Affects 30%–40% of adults and 1 in 4 children in the United States
- Usually develops in childhood and may spread within families
- Can last a lifetime unless it is properly treated

Most people with H. pylori do not have symptoms of infection. If symptoms occur—like the examples listed on page 2—they usually come from the conditions that H. pylori causes. As with many other infections, antibiotics are prescribed to treat H. pylori. Treating the stomach symptoms alone could mask the infection and delay more effective treatment.

Finding out if you have an H. pylori infection is simple.

Medical experts agree that people suffering with dyspepsia should be considered for H. pylori testing because there is some evidence to support the opinion that curing an infection could help ease their symptoms.

**If your stomach symptoms are bothering you, ask your doctor about a test that is convenient and easy—BreathTek® UBT for H. pylori.**

Please see accompanying BRIEF SUMMARY and enclosed Current Package Insert.
BreathTek UBT can identify an active infection in your stomach.

BreathTek UBT uses patient breath samples to find out if an *H. pylori* infection is present. BreathTek UBT is:

- **Convenient**—Can be done in your doctor’s office or at a lab
- **Easy**—Simple to do, no invasive procedures, no messy collection cups, no painful needles
- **Fast**—The entire testing process takes about 20 minutes

Testing with BreathTek UBT is covered by most national and regional health plans.

BreathTek UBT can help you feel confident that you’re cured after treatment.

After being diagnosed with an *H. pylori* infection, you’ll most likely be prescribed antibiotics as treatment. Because these medications are prescribed often to cure infection, some bacteria may have developed a resistance to certain antibiotics. To feel confident that your infection is cured, ask your doctor if you need to retest with BreathTek UBT. The retest should be administered at least 4 weeks after you completed your treatment.
The benefits of confirming that you are cured

• Ulcers are less likely to return once an H. pylori infection is cured\(^2\)

• Curing the infection is less expensive than staying on medicines to treat the symptoms\(^2\)

• You may reduce the risk of developing stomach cancer, especially if stomach cancer already runs in your family\(^2\)

The American College of Gastroenterology states that UBT is the most reliable nonendoscopic test for confirming that H. pylori infection has been cured.\(^5\)

Ask your doctor to test with BreathTek UBT.

Scan to learn more at BreathTek.com.

Please see accompanying BRIEF SUMMARY and enclosed Current Package Insert.
Schedule your follow-up test

First day of antibiotic treatment (date)

__________________________________________

Last day of taking your antibiotics (date)

__________________________________________

Appointment to confirm treatment outcome 4 weeks later (date)

__________________________________________
Find out if your treatment worked. Ask your doctor about retesting for H. pylori.

Please see accompanying BRIEF SUMMARY and enclosed Current Package Insert.
My stomach symptoms:
Consumer Brief Summary about BreathTek UBT

Intended Use
The BreathTek UBT for *H. pylori* Kit is a breath test that detects a common infection of the stomach called *Helicobacter pylori* (*H. pylori*). A licensed health care practitioner may prescribe BreathTek UBT to test for *H. pylori* infection in patients aged 3 years and older. A patient may need to take the test again 4 weeks after completing antibiotic therapy to monitor whether *H. pylori* has been wiped out.

BreathTek UBT is always administered by a health care practitioner, as ordered by a licensed health care practitioner.

Warnings and Precautions

- BreathTek UBT is an in vitro diagnostic test requiring you to provide breath samples and drink a drug solution called Pranactin®-Citric.
- If you are sensitive to mannitol, citric acid, or Aspartame, avoid drinking the drug solution (Pranactin-Citric).
- Tell your health care practitioner if you have diabetes or are Phenylketonuric (PKU).
  - For PKU patients, this drug contains Phenylalanine (a component of Aspartame). For reference, 12 ounces of a typical diet cola drink contains approximately the same amount of Phenylalanine.
  - For diabetic patients, use with caution, as drug solution (Pranactin-Citric) contains Aspartame.
- False negative and false positive results may occur with this test.
  - Tell your health care practitioner if you continue to have symptoms. You may need to be retested with a new sample or a different method.
- Inaccurate results may be caused by drugs you are taking within 2 weeks prior to this test. These may include:
  - Proton pump inhibitors (PPIs) such as Aciphex® (rabeprazole), Nexium® (esomeprazole), Prevacid® (lansoprazole), Prilosec® (omeprazole), Prilosec OTC® (omeprazole), Protonix® (pantoprazole), Zegerid® (omeprazole/sodium bicarbonate), and Dexilant® (dexlansoprazole).
  - Antibiotics.
  - Bismuth-based drugs (Pepto-Bismol®).
- Inaccurate test results can also occur if:
  - The second breath sample is collected too soon.

Please see enclosed Current Package Insert.
— You were treated for *H. pylori* with antibiotics, but take your confirmation test with BreathTek UBT less than 4 weeks after completing your therapy

• Tell your health care practitioner if you have trouble swallowing because of a medical or physical condition

• No information is available on the use of the drug solution during pregnancy

• BreathTek UBT is not to be used with children under the age of 3

**Adverse Events**

The following adverse events in adults have been identified: anaphylactic (allergic) reaction, oversensitivity and rash, burning sensation in the stomach, tingling in the skin, vomiting, and diarrhea.

In one study, the following adverse events in children 3 to 17 years old have been identified: throwing up, mouth and throat pain (including irritation, soreness, and burning), unsettled stomach, restlessness, stomach ache/belly pain, and diarrhea. Most of these adverse events were experienced within minutes to hours of ingestion of the drug solution (Pranactin-Citric). In another study, some patients also experienced headache, cough, dry mouth, and acute upper respiratory tract infection.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

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**References:**

Ask your doctor today about BreathTek UBT for *H. pylori*…

and find out if *H. pylori* infection is the cause of your stomach symptoms.

Learn more at BreathTek.com

Please see accompanying BRIEF SUMMARY and enclosed Current Package Insert.