

PATIENT PREPARATION

BreathTek® UBT for *H. pylori* test

FOR BEST TEST RESULTS:



1. Do not eat or drink for 1 hour prior to taking the test.
2. Do not take any of the following medications for 2 weeks prior to the test:



- a. All antibiotics
 - b. Bismuth preparations such as Pepto-Bismol®
 - c. Proton pump inhibitors (PPIs)*
3. The effect of histamine 2-receptor antagonists (H₂RAs) such as Axid® (nizatidine), Pepcid® (famotidine), Tagamet® (cimetidine), and Zantac® (ranitidine) or their generic versions may reduce urease activity, which could interfere with test results. H₂RAs may be discontinued 24 to 48 hours before testing.
 4. You may continue taking antacids such as sodium bicarbonate (Alka-Seltzer®) or calcium carbonate (Rolaids®, Tums®) prior to testing.

IF YOU ARE CURRENTLY TAKING A PPI:



- Consult your doctor about whether you need to stop taking a PPI before testing
- If you continue taking a PPI and the test is positive, your doctor can start you on antibiotic treatment. If the test is negative, it may be a false negative (meaning the test may say there's no infection when there really is), and the test should be repeated 2 weeks after you stop taking the PPI

TESTING PROCEDURE:



- At the lab you'll be asked to exhale into a blue bag (this is the "baseline" breath sample)
- You will be given a drug solution to drink with a straw
- After drinking the drug solution, you will sit quietly for 15 minutes
- Then you will be asked to exhale into a pink bag

WHEN TESTING TO CONFIRM CURE:

- If antibiotic treatment is prescribed by your doctor, a second test may be administered at least 4 weeks after completion of the treatment, to confirm cure. If you get retested, follow the same directions

*The names of some common brands of PPIs are listed under Warnings and Precautions, on the back of this card.

FOR OFFICE USE:

Pre-treatment testing:

Appointment date _____ time _____

Post-treatment testing:

Appointment date _____ time _____

Please see accompanying BRIEF SUMMARY and enclosed Current Package Insert.

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 are Phenylketonuric (PKU), as 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
- 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
 - 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
- The safety of using the BreathTek UBT Kit during pregnancy and lactation is not established
- 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 or call 1-800-FDA-1088.

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Please see enclosed
Current Package Insert.



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