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) such as Aciphex®
   d. Histamine 2-receptor antagonists (H2RAs) such as Axid® (nizatidine), Pepcid® (cimetidine), and Zantac® (ranitidine) or their generic versions

3. The effect of histamine 2-receptor antagonists (H2RAs) such as Axid® (nizatidine), Pepcid® (cimetidine), Tagamet® (cimetidine), and Zantac® (ranitidine) or their generic versions may mask the enzyme (usually produced by the stomach) that breaks down ammonia, 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®), calcium carbonate (Rolaids®, Tums®), sodium citrate (Citrus-C®) or calcium carbonate/magnesium oxide/Gas-x® 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 with the knowledge that the test may be a false negative (meaning the test may say there’s no infection when there is). 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 procedures as you did the first time.

Testing Procedure:

• At the lab you’ll be asked to exhale into a blue bag (this is the “baseline” breath sample)
• 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:

• The BreathTek® UBT for Helicobacter pylori (H. pylori) test
• Proton pump inhibitors (PPIs) such as Aciphex® (rabeprazole), Zegerid® (omeprazole/sodium bicarbonate), and Dexilant® (dexlansoprazole)
• Bismuth-based drugs (Pepto-Bismol®
• Histamine 2-receptor antagonists (H2RAs) such as Axid® (nizatidine), Pepcid® (cimetidine), and Zantac® (ranitidine) or their generic versions

For Office Use:

Pre-treatment testing:
Appointment date___________ time______________

Post-treatment testing:
Appointment date___________ time______________
All antibiotics

Appointment date_______________ time______________

Post-treatment testing:
Appointment date_______________ time______________

Pre-treatment testing:

FOR OFFICE USE:
Please see accompanying BRIEF SUMMARY and enclosed

WHEN TESTING TO CONFIRM CURE:

TESTING PROCEDURE:

IF YOU ARE CURRENTLY TAKING A PPI:

FOR BEST TEST RESULTS:

BreathTek® UBT for

PATIENT PREPARATION

1. Do not eat or drink for 1 hour prior to taking the test. You may continue taking antacids such as sodium bicarbonate (Alka-Seltzer®) or calcium carbonate (Rolaids®, Tums®) prior to testing. You may continue taking PPIs such as proton pump inhibitors (PPIs), including Aciphex® (lansoprazole), Nexium® (esomeprazole), Prevacid® (lansoprazole), Prilosec® (omeprazole), Protonix® (pantoprazole), Zegerid® (omeprazole/sodium bicarbonate), and Dexilant® (dexlansoprazole). These may interfere with test results. H2RAs may be taken the same directions to confirm cure. If you get retested, follow the same directions as per your doctor, a second test may be administered at the time of your appointment.

2. If antibiotic treatment is prescribed by your doctor, a test could be performed to monitor whether the infection in patients aged 3 years and older. A patient can have testing on BreathTek UBT for Helicobacter pylori (H. pylori) with antibiotics, but take your confirmation test with BreathTek UBT less than 4 weeks after completing your therapy.

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

4. The names of some common brands of PPIs are listed under Warnings and Precautions.

• Aerohal® (nabazepam), Nexium 24HR® (esomeprazole), Prevacid® (lansoprazole), Prilosec® (omeprazole), Protonix® (pantoprazole), Zegerid® (omeprazole/sodium bicarbonate), and Dexilant® (dexlansoprazole)

• Antibiotics

• Biuret-based drugs (Pepo-Bismuth®)

• Inaccurate results may be caused by drugs you are taking within 2 weeks prior to this test. These may include:

  a. Bismuth preparations such as Pepto-Bismol®

  b. H2RAs such as Zantac® (ranitidine) or their generic versions

  c. Interferes with test results. H2RAs may be taken the same directions to confirm cure. If you get retested, follow the same directions as per your doctor, a second test may be administered at the time of your appointment.

5. Tell your health care practitioner if you have difficulty swallowing. 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.

6. 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.

7. If you are currently taking a PPI, consult your doctor about whether you need to stop taking a PPI before testing.

8. Do not take any of the following medications for 2 weeks prior to the test:

   a. Antacids such as sodium bicarbonate (Alka-Seltzer®) or calcium carbonate (Rolaids®, Tums®) prior to testing.

   b. Do not eat or drink for 1 hour prior to taking the test. You may continue taking PPIs such as proton pump inhibitors (PPIs), including Aciphex® (lansoprazole), Nexium® (esomeprazole), Prevacid® (lansoprazole), Prilosec® (omeprazole), Protonix® (pantoprazole), Zegerid® (omeprazole/sodium bicarbonate), and Dexilant® (dexlansoprazole) and H2RAs such as Zantac® (ranitidine) or their generic versions. These may interfere with test results. H2RAs may be taken the same directions. If you get retested, follow the same directions as per your doctor, a second test may be administered at the time of your appointment.

   c. Interferes with test results. H2RAs may be taken the same directions. If you get retested, follow the same directions as per your doctor, a second test may be administered at the time of your appointment.

   d. Consult your doctor about whether you need to stop taking a PPI before testing.

8. 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.

9. In one study in children, the following adverse events in children 3 to 17 years old have been identified: throwing up, mouth and throat pain (including irritation, soreness, and swelling), vomiting, diarrhea and stomach aching/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 cold symptoms.

10. In one study in children, the following adverse events in children 3 to 17 years old have been identified: vomiting, 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 cold symptoms.

11. 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.

12. Please see enclosed Current Package Insert.

13. Warning: BreathTek UBT 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 can have testing on BreathTek UBT for Helicobacter pylori (H. pylori) with antibiotics, but take your confirmation test with BreathTek UBT less than 4 weeks after completing your therapy. If antibiotic treatment is prescribed by your doctor, a test could be performed to monitor whether the infection in patients aged 3 years and older. A patient can have testing on BreathTek UBT for Helicobacter pylori (H. pylori) with antibiotics, but take your confirmation test with BreathTek UBT less than 4 weeks after completing your therapy.

14. In one study in children, the following adverse events in children 3 to 17 years old have been identified: vomiting, mouth and throat pain (including irritation, soreness, and swelling), vomiting, diarrhea and stomach aching/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 cold symptoms.

15. 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.