

PATIENT PREPARATIONBreathTek® UBT for *H. pylori* (BreathTek UBT)**IN PREPARATION FOR A BREATHTEK UBT TEST:**

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. Proton Pump Inhibitors or their generic versions such as Zegerid® (omeprazole/sodium bicarbonate), Prilosec® (omeprazole) and Prilosec OTC® (omeprazole), Prevacid® (lansoprazole), Aciphex® (rabeprazole), Protonix® (pantoprazole) and Nexium® (esomeprazole)
- c. Bismuth preparations such as Pepto Bismol®

Histamine blockers (H2 antagonists) may be substituted for Proton Pump Inhibitors. These medications do not appear to affect the accuracy of UBT. These medications include Zantac® (ranitidine), Tagamet® (cimetidine), Pepcid® (famotidine) and Axid® (nizatidine). Many labs suggest that you do not use H2 antagonists 24 to 48 hours prior to testing.

BEFORE TEST ADMINISTRATION, ALL PATIENTS SHOULD BE ASKED THE FOLLOWING QUESTIONS:

1. Have you had anything to eat or drink in the last hour?
2. Are you on any antibiotics, proton pump inhibitors or bismuth preparations?
3. Do you have PKU or are you on a phenylalanine restrictive diet (one of the protein components of Aspartame)?

WHEN TESTING TO CONFIRM CURE:

The test should be administered at least 4 weeks after completion of treatment therapy. The above conditions also apply.

FOR OFFICE USE:

Appointment date: _____

Appointment time: _____

PS 55877

IMPORTANT SAFETY INFORMATION**INTENDED USE:**

The BreathTek® UBT for *H. pylori* Kit (BreathTek UBT Kit) is used in adult patients to detect urease (an enzyme that breaks urea down into carbon dioxide and ammonia) associated with the *H. pylori* bacteria in the stomach and is indicated to help in the initial diagnosis and post-treatment monitoring of the *H. pylori* bacterial infection. The test may be used for monitoring the treatment of the bacterial infection if used at least 4 weeks following completion of treatment. The BreathTek UBT test is administered by a healthcare professional, as prescribed by a physician.

Some symptoms of an *H. pylori* infection include upset stomach, nausea, stomach pain or burning or gnawing feeling in the stomach. Stomach pain may occur several hours after eating when the stomach is empty, may be worse at night, may last from a few minutes to several hours, or may be relieved by food, antacids or vomiting. You should talk to your healthcare provider about how this test can help in the treatment of your symptoms.

You should not administer this test to yourself. It should only be administered to you by a healthcare professional.

WARNINGS AND PRECAUTIONS:

BreathTek UBT is an in vitro diagnostic test requiring you to provide breath samples.

- You should not eat or drink for at least 1 hour before taking this test.
- You should not take any antibiotics, proton pump inhibitors (acid blockers such as Zegerid®, Prilosec®, Prilosec OTC®, Prevacid®, Aciphex®, or Nexium®) or bismuth preparations (Pepto Bismol®) within 2 weeks prior to taking this test.
- You must wait at least 4 weeks after completing the treatment to eliminate the *H. pylori* infection before taking this test again.

The drug component of the test is Pranactin®-Citric. It is taken by mouth as a drug solution as part of the diagnostic procedure.

- For Phenylketonurics (PKU) patients, this drug contains Phenylalanine (one of the protein components of Aspartame). For reference, 12 ounces of typical diet cola drinks contain approximately the same amount of Phenylalanine.
 - For diabetic patients, use with caution as Pranactin-Citric contains Aspartame.
 - Use with caution if you have difficulty swallowing or may be at high risk of aspiration due to medical or physical conditions.
 - For patients who are hypersensitive to mannitol, citric acid or Aspartame, you should avoid taking the drug solution as it contains these ingredients.
- False negative and false positive results may occur with this test.
- Tell your healthcare provider if you continue to have symptoms. You may need to be retested with a new sample or a different method.

No information is available on use of the Pranactin-Citric solution during pregnancy.

POSTMARKETING EXPERIENCE:

During the post-approval use of the BreathTek UBT, the following adverse reactions have been identified: allergic reaction, rash, burning sensation in the stomach, tingling in the skin, vomiting and diarrhea. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to establish whether the reaction is related to use of the drug.

You should talk with your healthcare provider if you have questions about the safety of the BreathTek UBT.

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 Otsuka
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Urea Breath Test for *H. pylori*
BreathTek®
Detection made convenient

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