LEXINGTON MEDICAL CENTER
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Department of Pathology and Laboratory Medicine

Protocol for Urea Breath Test Collections:

4 simple steps

Urea Breath Test for H. pylori

BreathTek®
DEFINITIVE EVIDENCE

How to Administer BreathTek® UBT in Just 4 Simple Steps!

1. Collect baseline sample by having the patient inhale, hold their breath for 4-5 seconds, then exhale into the **blue** bag.
2. Thoroughly mix the entire Pranactin®-Citric packet with water in the plastic container. The patient must drink the solution using the plastic straw provided.
3. Wait 15 minutes, then collect the second breath sample in the **pink** bag using the same procedure as Step 1.
4. Place caps tightly on the bags to prevent sample loss. Samples are good for 7 days after collection.

Patient Preparation:

- The patient should have no food or drink for at least 1 hour before the test.
- The patient should have not taken antimicrobials, proton pump inhibitors (PPIs) or bismuth preparations for 2 weeks prior to the test.
- Remind the patient that Pranactin®-Citric contains phenylalanine (one of the protein components of Aspartame). Phenylketonurics restrict dietary phenylalanine.

Patient Preparation

A. Remind the patient that Pranactin-Citric contains phenylalanine (one of the protein components of Aspartame). Phenylketonurics restrict dietary phenylalanine.

B. The patient should have fasted at least 1 hour before administering the BreathTek UBT No smoking during test administration.

C. The patient should not have taken antimicrobials, proton pump inhibitors, or bismuth preparations within 2 weeks prior to administering the BreathTek UBT.

Procedure for Collecting Breath Samples Using BreathTek UBT Kit, for Analysis by Infrared Spectrophotometer

A. **Materials**

1. Materials provided

Each sealed single-patient BreathTek UBT Collection Kit contains:

□ One (1) plastic kit tray containing:

- One (1) "How To" guide
- Test instructions
- One (1) pouch of Pranactin-Citric powder (3 g)
- A set of four (4) self-adhesive bar-code stickers. All bar-codes should bear the same number.
- Two (2) breath collection bags, one (1) blue bag for the BASELINE sample and one (1) pink bag for the POST-DOSE sample.

BreathTek® UBT for *H. pylori*

- One (1) sample transport bag
- One (1) plastic straw
- One (1) plastic drinking cup

2. Materials needed but not provided

□ A timer capable of timing an interval up to 15 minutes

□ Scissors for opening the Pranactin-Citric pouch

Note: An Infrared Spectrophotometer (UBiT-IR300 or POCone, Otsuka Pharmaceutical Co., Ltd.) is required for analysis of breath samples.

B. **Step-By-Step Procedure**

Time intervals listed in the following step-by-step procedure are critical. They are highlighted by the timer icon:

1. Verify that the patient has been prepared for the test.
2. Open the BreathTek UBT Collection Kit. Slide out the kit tray. Label each breath collection bag to maintain patient identification using the bar-code labels provided, or according to your laboratory or office procedure.

3. Collect the BASELINE breath sample according to the following procedure:

a. Remove the blue breath collection bag from the kit tray.

b. Remove the pull-off cap from the mouthpiece of the breath collection bag.

c. Instruct the patient to: (1) breathe normally; (2) take a deep breath then pause momentarily; (3) exhale into the mouthpiece of the bag.

d. Replace the cap firmly until it clicks on the mouthpiece of the bag.

4. Prepare the Pranactin-Citric *solution no more than 60 minutes before administering it to the patient. Urea slowly decomposes in water.*

a. Remove the Pranactin-Citric pouch from the kit tray. Tap the upright packet of Pranactin-Citric to settle the contents in the bottom half.

b. With clean scissors, cut off the top of the packet and carefully empty the contents into the drinking cup provided, making sure to transfer all of the contents by tapping on the bottom of the pouch.

c. Add potable water to the fill line indicated on the outside of the cup by a raised plastic ridge.

d. Replace the lid securely and swirl the mixture for up to *2 minutes* to dissolve the packet contents; typically, only 1 minute is required for complete dissolution. *The resulting solution should be clear with no particulate matter. If particulate matter is present after thorough mixing, the solution should not be used.*

5. Instruct the patient to drink all of the solution with the straw provided, without stopping. Advise the patient NOT to 'rinse' the inside of his/her mouth with the solution before swallowing. *Discard the straw.*

6. Set the timer for 15 minutes. The patient should sit quietly and should not eat, drink or smoke during the 15 minute interval.

7. After 15 minutes have elapsed, remove the pink breath collection bag from the kit tray. Collect the POST-DOSE breath sample according to the procedure described in Steps VIII B.3.b through B.3.d.

8. Store the specimens at 15°-30°C (59°-86°F) until analysis is performed.

9. Perform breath sample analysis within 7 days of breath sample collection. If desired, use the plastic sample transport bag for transport of the breath samples.