

Revision Nov05



Introduction and Test Instructions

Note: This "Introduction and Test Instructions" contains information for:

<i>Test Collection Kit</i>	<i>Breath Test Instrument</i>
BreathTek™ UBT for <i>H. pylori</i>	1. UBiT ³⁰ -IR 300 Infrared Spectrophotometer
	2. POcone™ Infrared Spectrophotometer

Intended Use

The BreathTek™ UBT Collection Kit is intended for use in the qualitative detection of urease associated with *Helicobacter pylori* in the human stomach and as an aid in the initial diagnosis and post-treatment monitoring of *Helicobacter pylori* infection in adult patients. The test may be used for monitoring treatment if used at least four (4) weeks following completion of therapy. For these purposes, the system utilizes an Infrared Spectrophotometer for the measurement of the ratio of $^{13}\text{CO}_2$ to $^{12}\text{CO}_2$ in breath samples.

This test should be administered by health care professionals and under a physician's supervision.

Warnings and Precautions

- A. For in vitro diagnostic use only. The Pranactin®-Citric drug solution is taken orally as part of the diagnostic procedure.
- B. Phenylketonurics: Contains Phenylalanine, 75 mg per dosage unit. (For reference, 12 ounces of typical diet cola soft drinks contain approximately 80 mg of Phenylalanine.)
- C. A negative result does not rule out the possibility of *Helicobacter pylori* infection. False negative results do occur with this procedure. If clinical signs are suggestive of *H. pylori* infection, retest with a new sample or an alternate method.
- D. Antimicrobials, proton pump inhibitors, and bismuth preparations are known to suppress *H. pylori*. Ingestion of these within two (2) weeks prior to performing the BreathTek™ UBT may give false negative results.
- E. A false positive test may occur due to urease associated with other gastric spiral organisms observed in humans such as *Helicobacter heilmannii*.
- F. Premature POST-DOSE breath collection time can lead to a false negative diagnosis for a patient with a marginally positive BreathTek™ UBT result.
- G. A false positive test could occur in patients who have achlorhydria.⁷
- H. If particulate matter is visible in the reconstituted Pranactin®-Citric solution after thorough mixing, the solution should not be used.

Shelf Life and Storage

The BreathTek™ UBT Collection Kit should be stored at 15°-30°C (59°-86°F). Pranactin®-Citric has an expiration date. Do not use beyond the expiration date stated on the label.

Patient Preparation

- A. Remind the patient that Pranactin[®]-Citric contains phenylalanine. Phenylketonurics restrict dietary phenylalanine.
- B. The patient should have fasted at least one (1) hour before administering the BreathTek[™] UBT.
- C. The patient should not have taken antimicrobials, proton pump inhibitors, or bismuth preparations within two (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.
 - 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 fifteen (15) minutes
- Scissors for opening the Pranactin[®]-Citric pouch.

Note: An Infrared Spectrophotometer (UBiT[®]-IR3000 or PO Cone[™], Otsuka Pharmaceutical Co., Ltd.) is required for analysis of breath sample.

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 as specified in Section VI.
2. Open the BreathTek™ UBT Collection Kit, which should contain all the materials listed in Step VII. 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 sixty (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 *two (2) minutes* to dissolve the packet contents; typically, only one (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 fifteen (15) minutes. The patient should sit quietly and should not eat, drink or smoke during the fifteen (15) minute interval.
 7. After fifteen (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 VII 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 seven (7) days of breath sample collection. If desired, use the plastic sample transport bag for transport of the breath samples.

Quality Control

Complete operating information, including self-diagnostic instrument routines and user maintenance procedures, is provided in the Instruction Manuals for the UBiT[®]-IR300 Spectrophotometer, the UBiT[®]-AS10 Autosampler and the POCon[™] Spectrophotometer, respectively. Additionally, each office laboratory or test facility should follow its own internal procedures for quality control.

Limitations of the Test

- A. The BreathTek[™] UBT should not be used until four (4) weeks or more after the end of treatment for the eradication of *H. pylori* as earlier post-treatment assessment may give false negative results.
- B. The performance characteristics for persons under the age of eighteen (18) have not been established for this test.
- C. The specimen integrity of breath samples and reference gases stored in breath bags under ambient conditions has not been determined beyond seven (7) days.
- D. A correlation between the number of *H. pylori* organisms in the stomach and the BreathTek[™] UBT result has not been established.
- E. The predicate device (Meretek UBT[®]) was standardized in asymptomatic healthy volunteers and subsequently validated in clinical trials limited to patients with documented duodenal ulcer disease.