

Use this card when shipping breath samples from pediatric patients 3-17 years old to a laboratory for analysis.

Place the completed card inside the sample transport bag along with the collected breath samples and the laboratory's test requisition form.

Pediatric UHR Calculation Information	
Sample Information	Patient's Information
[Affix barcode sticker here.]	Patient ID _____
Collection Date _____	Gender <input type="radio"/> (Male) <input type="radio"/> (Female) Age _____ (Years)
	Height _____ (Inches) <input type="radio"/> (Centimeters) Weight _____ (Pounds) <input type="radio"/> (Kilograms)



Patient Preparation:

- The patient should have no food or drink for at least 1 hour before the test.
- The patient should have not taken antibiotics, proton pump inhibitors (PPIs) or bismuth preparations for 2 weeks prior to the test. If PPIs are used within 2 weeks of BreathTek UBT testing, false negative test results may occur, and the test should be repeated 2 weeks after discontinuation of PPI treatment. A positive result for a patient on PPI could be considered positive and be acted upon.
- The effect of histamine 2-receptor antagonists (H₂RAs) may reduce urease activity on urea breath tests. H₂RAs may be discontinued for 24-48 hours before the BreathTek UBT.
- Use of antacids does not appear to affect the accuracy of the BreathTek UBT.
- Remind the patient that PranaActin-Citric contains phenylalanine (one of the protein components of Aspartame). Phenylketonurics restrict dietary phenylalanine.
- For administration by a healthcare professional only. Do not provide this kit to the patient for self-administration.
- If repeat testing is needed, BreathTek UBT can be administered again on the following day.

For Pediatric Patients:

Complete the attached Pediatric UHR Card, and send it with the patient's breath samples to the laboratory for analysis.

For more information, please visit www.BreathTek.com, or call 1-888-637-3835.



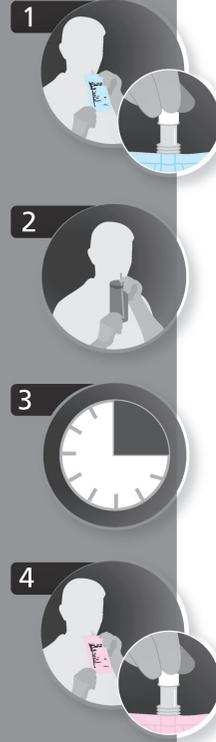
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October 2021



4 simple steps



Rx ONLY



How to Administer BreathTek UBT in Just 4 Simple Steps!

For BLUE Baseline Collection Bag:

1. Collect baseline sample by having the patient inhale, hold their breath momentarily, then exhale into the **blue** bag. Place cap on the bag and press down until it snaps to prevent sample loss.

For Solution Administration:

2. Thoroughly mix the entire PranaActin-Citric packet with water in the plastic container. Close the lid securely by pressing down until you hear a click and swirl until dissolved up to 2 minutes. The patient must drink the solution using the plastic straw provided.

3. Wait 15 minutes.

For PINK Post-Dose Collection Bag:

4. Collect the second breath sample in the **pink** bag using the same procedure as Step 1. Breath sample may be collected no later than 30 minutes POST-DOSE. Place cap on the bag and press down until it snaps to prevent sample loss.

Samples are good for 7 days, at room temperature, after collection.

Brief Summary about BreathTek UBT

Intended Use

The BreathTek® UBT for *H. pylori* Kit (BreathTek UBT Kit) is intended for use in the qualitative detection of urease associated with *H. pylori* in the human stomach and is indicated as an aid in the initial diagnosis and post-treatment monitoring of *H. pylori* infection in adult patients and pediatric patients 3 to 17 years old. The test may be used for monitoring treatment if used at least 4 weeks following completion of therapy. For these purposes, the system utilizes an Infrared Spectrophotometer for the measurement of the ratio of ¹³CO₂ to ¹²CO₂ in breath samples, in clinical laboratories or point-of-care settings. The Pediatric Urea Hydrolysis Rate Calculation Application (pUHR-CA), provided as a web-based calculation program, is required to obtain pediatric test results.

The BreathTek UBT Kit is for administration by a health care professional, as ordered by a licensed health care practitioner.

Warnings and Precautions

- For *in vitro* diagnostic use only. The Pranactin-Citric solution is taken orally as part of the diagnostic procedure and contains Phenylalanine (one of the protein components of Aspartame), 84 mg per dosage unit. (For reference, 12 ounces of typical diet cola soft drinks contain approximately 80 mg of Phenylalanine.)
- A negative result does not rule out the possibility of *H. 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.
- False negative test results may be caused by:
 - Ingestion of proton pump inhibitors (PPIs) within 2 weeks prior to performing the BreathTek UBT. If a negative result is obtained from a patient ingesting a PPI within 2 weeks prior to the BreathTek UBT, it may be a false-negative result and the test should be repeated 2 weeks after discontinuing the PPI treatment. A positive result for a patient on a PPI could be considered positive and be acted upon.
 - Ingestion of antibiotics, or bismuth preparations within 2 weeks prior to performing the BreathTek UBT.
 - Premature POST-DOSE breath collection time for a patient with a marginally positive BreathTek UBT result.
 - Post-treatment assessment with the BreathTek UBT less than 4 weeks after completion of treatment for the eradication of *H. pylori*.

- False positive tests may be caused by urease associated with other gastric spiral organisms observed in humans such as *Helicobacter heilmannii*, achlorhydria or oral contamination associated with urease containing bacteria especially when not using the straw provided in the kit.
- If particulate matter is visible in the reconstituted Pranactin-Citric solution after thorough mixing, the solution should not be used.
- Patients who are hypersensitive to mannitol, citric acid or Aspartame should avoid taking the drug solution as this drug solution contains these ingredients. Use with caution in patients with difficulty swallowing or who may be at high risk of aspiration due to medical or physical conditions.
- Pregnancy/Lactation: The safety of using the BreathTek UBT kit during pregnancy and lactation is not established.
- For pediatric test results, the Urea Hydrolysis Rate (UHR) results must be calculated. DOB results in conjunction with Pediatric Urea Hydrolysis Rate Calculation Application (pUHR-CA), provided as a web-based calculation program, is required to obtain pediatric test results. DOB results **cannot** be used to determine the infection status of pediatric patients. Use the web-based pUHR-CA (<https://BreathTekKids.com>) to calculate the UHR.
- Safety and effectiveness has not been established in children below the age of 3 years.

Adverse Events

During post-approval use of the BreathTek UBT in adults, the following adverse events have been identified: anaphylactic reaction, hypersensitivity, 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 a causal relationship to drug exposure.

In two clinical studies conducted in 176 (analyzed) pediatric patients ages 3 to 17 years to determine the initial diagnosis and post treatment monitoring of *H. pylori*, the following adverse events experienced by ≥1% of these patients were: vomiting (5.1%), oropharyngeal pain (4.5% to include throat irritation, sore throat, throat burning), nausea (2.3%), restlessness (2.3%), stomach ache/belly pain (1.1%), and diarrhea (1.1%). Most of the adverse events were experienced by patients within minutes to hours of ingestion of the Pranactin-Citric solution.

In another clinical study comparing the UBiT®-IR300 and POCone® in pediatric patients ages 3 to 17 years, the following adverse events were observed among the 99 subjects enrolled: 2 incidences of headache, and 1 incidence each of cough, dry mouth and acute upper respiratory infection.