A guideline-recommended testing method


Business Card to go here

3.5x2

Please see accompanying BRIEF SUMMARY and enclosed Current Package Insert.
**H. pylori:**
A common chronic infection...

Affects at least 30% of adults and 1 in 4 children* in the United States1-3

- When symptoms occur in adults, they may include burning, bloating, belching, vomiting, flatulence, abdominal pain, halitosis, nausea, and loss of appetite6-8
  - Children may present with gnawing or burning pain in the epigastrum, nausea, vomiting, or loss of appetite6-8
  - Infection is not often clinically apparent6,7

...that may lead to more serious medical conditions

- *H. pylori* infection is also associated with a 2- to 6-fold increase in the risk for stomach cancer6

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**H. pylori** can’t hide from BreathTek UBT

Approved as an aid in the initial diagnosis and post-treatment monitoring of *H. pylori* infection in adults and children ages 3 to 17 years

Use a Test–Treat–Confirm Approach1,2,9

- **TEST**
- **TREAT**
- **4 WAIT 4 WEEKS**
- **CONFIRM**

- **Guidelines recommend**1 a test-and-treat strategy using noninvasive methods, such as UBT, for adults with uninvestigated dyspepsia2,10-12
  - Adults under the age of 55 years and with no alarm features12
- UBT is also **recommended to confirm eradication in adults**2,11,12 and **children** §13

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1. Data from the National Health and Nutrition Examination Survey (NHANES) III of children ages 6 to 19 years.
3. Alarm features include bleeding, anemia, early satiety, unexplained weight loss, progressive dysphagia, odynophagia, recurrent vomiting, family history of GI cancer, and previous esophagogastric malignancy.1
4. North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) and the European Society for Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN).
BreathTek UBT:
simple, convenient, noninvasive

Excellent sensitivity (96%) and specificity (96%) when confirming eradication in adults*14

<table>
<thead>
<tr>
<th>BreathTek UBT</th>
<th>STOOL (HpSA)**</th>
<th>SEROLOGY (ELISA)**</th>
<th>Endoscopic Biopsy (Routine Histology)**</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRE</td>
<td>POST</td>
<td>PRE</td>
<td>POST</td>
</tr>
<tr>
<td>SENSITIVITY</td>
<td>95%</td>
<td>96%</td>
<td>93%</td>
</tr>
<tr>
<td>SPECIFICITY</td>
<td>90%</td>
<td>96%</td>
<td>93%</td>
</tr>
</tbody>
</table>

*Data are weighted mean values. Compilation of data is not the result of a comparative study.
† Serology is not effective in post-treatment testing because it cannot distinguish between active and past infection.
ELISA, enzyme-linked immunosorbent assay.

When using BreathTek UBT, 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 test results may be caused by:
- Urease associated with other gastric spiral organisms observed in humans such as Helicobacter heilmannii or achlorhydia.
- Oral contamination associated with urease containing bacteria especially when not using the straw provided in the BreathTek UBT kit.

BreathTek UBT may be administered to patients currently taking PPIs:
- It is still recommended that antibiotics, PPIs, or bismuth preparations not be taken within 2 weeks prior to administering BreathTek UBT14.
- If patients currently taking PPIs test positive for H. pylori, the result is considered positive and eradication therapy can be started immediately. If the test is negative, it may be a false negative and results should be confirmed with a second breath test 2 weeks after discontinuing PPIs14.
- 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 UBT14.
- Use of antacids does not appear to affect the accuracy of the BreathTek UBT14.

Citric acid–based UBT methods minimize false negative results by reducing pH effects of PPIs17

- Pooled data from 9 published studies of H. pylori–positive patients (N=626) confirm the performance of the UBT method in patients taking PPIs17.

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Please see accompanying BRIEF SUMMARY and enclosed Current Package Insert.
Symptom resolution does not always mean treatment success

Eradication therapy may fail in 25% of patients—partly because of increased antibiotic resistance.

- Antibiotic resistance is on the rise—and may be the strongest predictor of treatment failure.
- Patients may not complete their full course of therapy.

ACG* calls the UBT method “the most reliable nonendoscopic test...” to confirm H. pylori eradication.

ACG guidelines do not support serologic testing in populations with low H. pylori prevalence.

- Serologic tests cannot distinguish active H. pylori infection from past infection.
- If serology is used, positive results should be confirmed with a test of active infection.

With serologic testing, 1 out of every 3 positive test results may be wrong†.

†Assumes a 30% H. pylori prevalence rate.

Stool testing is associated with relatively low patient compliance.

- In one study, more patients returned for a post-treatment UBT vs a stool test (N=29).
- In a separate study of fecal occult blood testing, the overall compliance rate was 17.9% (N=1940).

*ACG, American College of Gastroenterology.

Please see accompanying BRIEF SUMMARY and enclosed Current Package Insert.
The patient experience with fecal antigen testing (FAT)

Your patient is responsible for completing the 5 steps of testing

<table>
<thead>
<tr>
<th>FAT</th>
<th>BreathTek UBT</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>STEP 1</strong></td>
<td>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.</td>
</tr>
<tr>
<td>Patient inserts dish in toilet and ensures the sample does not touch water or urine</td>
<td></td>
</tr>
<tr>
<td><strong>STEP 2</strong></td>
<td>2. Thoroughly mix the entire Pranactin®-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.</td>
</tr>
<tr>
<td>Patient uses a collection spoon to scoop a sample</td>
<td></td>
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<tr>
<td><strong>STEP 3</strong></td>
<td>3. Wait 15 minutes.</td>
</tr>
<tr>
<td>Patient washes hands with soap and water</td>
<td></td>
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<tr>
<td><strong>STEP 4</strong></td>
<td>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.</td>
</tr>
<tr>
<td>Patient places sample container in bag and refrigerates</td>
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<tr>
<td><strong>STEP 5</strong></td>
<td></td>
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<tr>
<td>Patient transports sample to physician or lab within 24 to 48 hours</td>
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</tbody>
</table>

Please see accompanying BRIEF SUMMARY and enclosed Current Package Insert.
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 $^{13}$CO$_2$ to $^{12}$CO$_2$ 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 test results may be caused by:
  — Urease associated with other gastric spiral organisms observed in humans such as *Helicobacter heilmannii* or achlorhydria.
  — Oral contamination associated with urease containing bacteria especially when not using the straw provided in the BreathTek UBT 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.
- 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. Delta over Baseline (DOB) results in conjunction with the 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.
Use a Test-Treat-Confirm approach with BreathTek UBT

A simple, convenient, noninvasive test that can help diagnose active *H. pylori* infection and confirm treatment success

Learn more at BreathTek.com or call 888.637.3835.