

# NEW

EXPANDED TESTING OPTION  
FOR PEDIATRIC PATIENTS

Dear Healthcare Practitioner,

Otsuka America Pharmaceutical, Inc., is excited to announce BreathTek® UBT for *H. pylori* has a NEW expanded testing option for pediatric patients.

On April 18, 2014, the FDA announced the approval for BreathTek UBT and the Pediatric Urea Hydrolysis Rate Calculator Application (pUHR-CA) for testing children 3 to 17 years of age, when used with the POCon® Infrared Spectrophotometer.



## ***H. pylori* is a common chronic infection affecting 1 in 4 children in the United States<sup>1\*</sup>**

\*Data from an NHANES III survey of children aged 6 to 19 years.

### **Diagnosing *H. pylori* in children**

- Children may present with persistent gnawing or burning pain in the epigastrium, nausea, vomiting, or loss of appetite<sup>2,3</sup>
- *H. pylori* may cause duodenal ulcers, atrophic gastritis, and gastric ulcers in children<sup>2,4</sup>
- Eradicating *H. pylori* reduces recurrence of duodenal ulcers and risk of precancerous lesions in adulthood<sup>2,4,5</sup>
- International studies suggest *H. pylori* may cause growth delay in children<sup>4,6</sup>
- Look for transmission between mother and child and siblings, which is most common. Another determinant is living in or originating from high-prevalence areas<sup>7</sup>

### **BreathTek UBT delivers excellent sensitivity (96%) and specificity (99%) for diagnosing *H. pylori* in pediatric patients<sup>8</sup>**

	AGE			ALL AGE GROUPS
	3–5 YEARS	6–12 YEARS	13–17 YEARS	COMBINED
SENSITIVITY	100%	100%	92%	96%
SPECIFICITY	100%	100%	95%	99%

**Study design:** A multi-center, open-label study. The primary endpoint analysis was conducted to determine the sensitivity and specificity of the BreathTek UBT UHR to the composite reference method criteria for the 176 evaluable cases. The table demonstrates the diagnostic performance of the BreathTek UBT (expressed as UHR) compared to the composite reference method criteria in pediatric patients aged 3 to 17 years old.

Please see accompanying BRIEF SUMMARY  
and [Current Package Insert](#).

Urea Breath Test for *H. pylori*  
**BreathTek®**

### **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 antimicrobials, 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.

### **NASPGHAN and ESPGHAN<sup>†</sup> recommend the use of UBT in children<sup>5</sup>**

- 94% of a joint NASPGHAN and ESPGHAN panel strongly agreed that the <sup>13</sup>C-UBT is a reliable noninvasive test to determine *H. pylori* eradication<sup>5</sup>
- 9 in 10 declared serology is not reliable for use in the clinical setting<sup>5</sup>

<sup>†</sup>North American Society for Pediatric Gastroenterology, Hepatology and Nutrition; European Society of Paediatric Gastroenterology, Hepatology and Nutrition.

### **While testing procedures will not change, an analysis calculation is needed for pediatric test results**

To obtain pediatric test results, you or your lab technician will need to use the pUHR-CA to conduct the analysis. For your convenience you can access this web-based application at: [BreathTekKids.com](http://BreathTekKids.com). The Delta-over-Baseline results from the POCone or UBiT®-IR300 cannot be used to determine infection status in pediatric patients, and is used to calculate the Urea Hydrolysis Rate (UHR) metric to provide a positive/negative result.

To complete the analysis, the pUHR-CA requires the following patient information:

Age<sup>‡</sup> (years)

Gender

Collection Date

Analysis Date

Height (inches or centimeters)

Weight (pounds or kilograms)

Patient ID

<sup>‡</sup>Use the patient's current age and do not round up.

For your convenience, we will be including the pediatric UHR Card in the BreathTek UBT Kits to capture this patient-specific information and accompany breath samples for analysis. Expect 2-3 months for this card to become part of the kit. In the interim, download a copy of the pUHR Card [here](#).

### **First-time users must request access to pUHR-CA**

When visiting [BreathTekKids.com](http://BreathTekKids.com), first-time access must be requested to be granted a user name and password. User name and password generation requires the following information:

- Customer ID (account number with OAPI)  
— Call 888.637.3835 if a Customer ID is needed
- Customer's name (as it appears in the contract with OAPI)
- Customer's city and state
- Name of person requesting access
- Business e-mail

Allow some time to ensure processing and account validation for a new user name and password.

For more information, visit [BreathTek.com](http://BreathTek.com) or call **888.637.3835** for an appointment with your BreathTek UBT representative.

Thank you for your continued partnership,

**Julie Kang, RPh**

Director of Marketing  
Medical Device Division

Please see accompanying BRIEF SUMMARY  
and [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  $^{13}\text{CO}_2$  to  $^{12}\text{CO}_2$  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, and should be used with caution in diabetic patients. (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 antimicrobials, 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.
- 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.
- No information is available on use of the Pranactin-Citric solution during pregnancy.
- For pediatric test results, the Urea Hydrolysis Rate (UHR) results must be calculated. The Delta over Baseline (DOB) results are only used to calculate the UHR metrics to determine *H. pylori* infection in pediatric patients. DOB results **cannot** be used to determine the infection status of pediatric patients. Use the web-based pUHR-CA (<http://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  $\geq 1\%$  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 POCon® 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.

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**References:** 1. Staat MA, Kruszon-Moran D, McQuillan GM, Kaslow RA. A population-based serologic survey of *Helicobacter pylori* infection in children and adolescents in the United States. *J Infect Dis.* 1996;174(5):1120-1123. 2. *Helicobacter pylori*. Centers for Disease Control and Prevention Web site. <http://www.cdc.gov/ulcer/files/hpfacts.pdf>. Accessed August 7, 2013. 3. Uc A, Chong SK. Treatment of *Helicobacter pylori* gastritis improves dyspeptic symptoms in children. *J Pediatr Gastroenterol Nutr.* 2002;34(3):281-285. 4. Pacifico L, Anania C, Osborn JF, Ferraro F, Chiesa C. Consequences of *Helicobacter pylori* infection in children. *World J Gastroenterol.* 2010;16(41):5181-5194. 5. Koletzko S, Jones NL, Goodman K, et al; *H pylori* working groups of ESPGHAN, NASPGHAN. Evidence-based guidelines from ESPGHAN and NASPGHAN for *Helicobacter pylori* infection in children. *J Pediatr Gastroenterol Nutr.* 2011;53(2):230-243. 6. Goodman KJ, Correa P, Mera R, et al. Effect of *Helicobacter pylori* infection on growth velocity of school-age Andean children. *Epidemiology.* 2011;22(1):118-126. 7. Kivi M, Tindberg Y. *Helicobacter pylori* occurrence and transmission: a family affair? *Scand J Infect Dis.* 2006;38(6-7):407-417. 8. Package Insert for BreathTek UBT. Otsuka America Pharmaceutical, Inc; 2014

Learn more at [BreathTek.com](http://BreathTek.com) or call 888.637.3835.

Please see [Current Package Insert](#).



Medical Device Division of  
Otsuka America Pharmaceutical, Inc.

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