

## The BreathTek™ Urea Breath Test for *Helicobacter pylori* Infection

a report by

**Meretek Diagnostics, Inc.**

Meretek Diagnostics offers an extremely accurate, non-invasive urea breath test for detecting active *Helicobacter pylori* (HP) infection in the adult human stomach, aiding in the initial diagnosis and post-treatment monitoring of *H. pylori* infections, the leading cause of gastritis and peptic ulcers. With 95% sensitivity and specificity compared to endoscopy, the BreathTek™ UBT delivers benefits over other testing methodologies. It is easily administered in-office in about 15 minutes, requiring only that the patient give an initial breath sample, drink a Pranactin®-Citric solution, and give another breath sample. Analysis is available in approximately 5 minutes. No special staff training is needed, and there is no exposure to radioactive or biohazardous materials. The 2005 American Gastroenterological Association (AGA) Guidelines state that, “*H. pylori* testing is optimally performed by a <sup>13</sup>C-urea breath test or stool antigen test.”<sup>1</sup>

Meretek Diagnostics Inc., a subsidiary of Otsuka America Inc., is a healthcare company engaged in the development of advanced, non-invasive, non-radioactive breath tests and instrumentation. Meretek was founded in 1993 by a group from the Baylor College of Medicine in Houston, TX. The company holds exclusive licenses to patents involving <sup>13</sup>C urea breath test technologies.

### BreathTek™ UBT Lets you Practice Evidence-Based Medicine for *H. Pylori*-Based Diseases in Adult Patients.

The test can provide definitive evidence of the presence of active *H. pylori* infection and can be used for the post-treatment monitoring of *H. pylori* infection to confirm eradication. The Cleveland Clinic Journal of Medicine commented that,

*Repeat testing after H. pylori eradication therapy should be offered to all patients to confirm that infection has been cured.<sup>2</sup>*

### The Contents of a BreathTek™ UBT Kit

Each kit includes:

- One plastic tray
- Package Insert

- How To Guide
- Pranactin®-Citric powder (3 grams)
- Self-adhesive bar-code stickers (4, all with the same number)
- Blue bag (for baseline sample)
- Pink bag (for post-dose sample)
- Transport bag
- Plastic straw
- Drinking cup

### The POCone™ In-Office Analyzer

The POCone™ analyzes the breath samples collected from the BreathTek™ UBT using infrared spectrophotometry;

- Insert baseline sample bag
- Insert post-dose sample bag
- Enter patient ID
- Start test
- LCD displays progress of test
- Printout of test delivered
- “Positive” or “Negative” result clearly displayed on printout

In-office testing for *H. pylori* infection can benefit your patients and your practice. Begin “Test and Treat” best practice in one patient visit.

### The UBiT®-IR300 Laboratory Analyzer

The UBiT®-IR300 analyzes the breath samples collected from the BreathTek™ UBT using infrared spectrophotometry



**Table 1: BreathTek™ UBT Provides Benefits over Other H. pylori Testing Methodologies**

	<b>BreathTek UBT</b>	<b>Serology (ELISA)</b>	<b>Stool (HpSA)</b>	<b>Endoscopy</b>
<b>Accuracy</b>	95% sensitivity <sup>3</sup> 95% specificity <sup>3</sup>	85% sensitivity <sup>4</sup> 79% specificity <sup>4</sup>	93% sensitivity <sup>4</sup> 93% specificity <sup>4</sup>	90-95% sensitivity <sup>5</sup> 100% specificity <sup>5</sup>
<b>Administration</b>	Non-invasive	Requires drawing blood	Inconvenient, requires handling fecal material	Requires invasive procedure
<b>Consistent results</b>	Tests for active infection reducing the chance of false positives <sup>6</sup>	“Serologic testing [for H. pylori] is not accurate enough for use in routine clinical practice.” <sup>5</sup>	Considerable lot-to-lot variation in tests <sup>5</sup>	Careful sample preparation is necessary for optimal results <sup>5</sup>
<b>Scope of test</b>	Tests the entire gastric mucosa for active H. pylori infection <sup>3</sup>	Inactive antibody testing is 17 times more likely to cause unnecessary treatment <sup>1</sup>	Second office visit is required	Endoscopic biopsies only target small areas of the stomach <sup>5</sup>
<b>Eradication</b>	Indicated for the post-treatment monitoring of H. pylori infection to confirm eradication 4 weeks following completion of therapy <sup>3</sup>	Cannot confirm eradication <sup>5</sup>	Must wait 6 to 8 weeks after therapy to confirm eradication <sup>5</sup>	Requires second invasive procedure to confirm eradication

ELISA = Enzyme-linked Immunosorbent Assay, HpSA = Helicobacter pylori Stool Antigen Test

**Table 2**

<b>Specifications</b>	<b>POCone™</b>
Size	8.6" w x 10" h X 12.75" d
Weight	23lbs.
Warm-up time	10mins.
Analysis time	2.5mins.
Batching	No
Internal timer	Yes
Sleep mode	No

**Figure 1: POCone™**



- Insert baseline sample bag
- Insert post-dose sample bag
- Enter patient ID
- Start test
- LCD displays progress of test

**Table 3**

<b>Specifications</b>	<b>UBiT®-IR300</b>
Size	12.2" w x 12.2" h x 24.4" d
Weight	60lbs.
Warm-up time	5mins.
Analysis time	5.5mins.
Batching	Yes*
Internal timer	No
Sleep mode	Yes

\*The UBiT-AS10 allows for the testing of up to 10 samples when installed on the UBiT-IR300. All 10 tests can be run at once (batch mode). Fewer than 10 tests can be run as needed (continuous mode).

- Printout of test delivered
- “Positive” or “Negative” result clearly displayed on printout

The UBiT® -AS10 allows for testing up to 10 samples when installed on the UBiT® -IR300 and all 10 tests can be run at once (batch mode). Fewer than 10 tests can be run as needed (continuous mode).

**Warnings and Precautions<sup>3</sup>**

- For *in vitro* diagnostic use only. The Pranactin®-Citric drug solution is taken orally as part of the diagnostic procedure.
- Phenylketonurics: Contains Phenylalanine, 75mg per dosage unit. (For reference, 12 ounces of typical diet cola soft drinks contain approximately 80mg of phenylalanine.)
- 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.

- Antimicrobials, proton pump inhibitors, and bismuth preparations are known to suppress *H. pylori* and ingestion of these within two weeks prior to performing the BreathTek™ UBT may give false negative results.
- A false positive test may occur due to urease associated with other gastric spiral organisms observed in humans such as *Helicobacter heilmannii*.
- Premature Post-Dose breath collection time can lead to a false negative diagnosis for a patient with a marginally positive BreathTek™ UBT result.
- A false positive test could occur in patients who have achlorhydria.
- If particulate matter is visible in the reconstituted Pranactin®-Citric solution after thorough mixing, the solution should not be used. ■

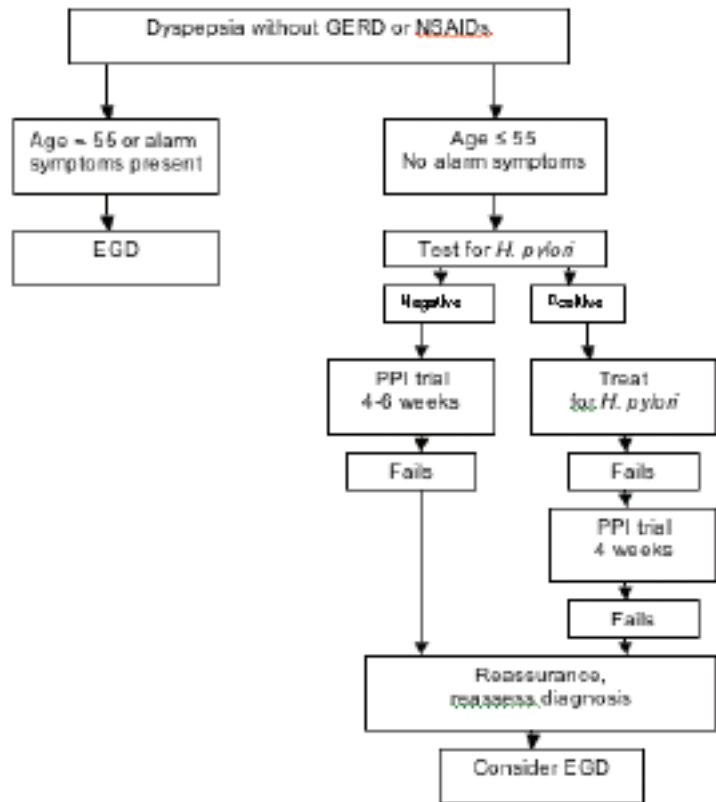
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Figure 2: Algorithm for the Management of Uninvestigated Dyspepsia.' Medical Position Statement, American Gastroenterological Association (AGA), 2005



EGD = esophagogastroduodenoscopy, GERD = gastroesophageal reflux disease, NSAIDs = non-steroidal anti-inflammatory drugs

Figure 3: The BreathTek UBT Mechanism of Action

