

# BreathID® Performance for Detection H. pylori in a US Pivotal Study

The Urea Breath Test (UBT) can detect the presence of the H. pylori bacteria in a non-invasive simple manner. The BreathID® technology enables accurate and immediate results, at a Point of Care (POC) environment.

## Experimental Design

The data presented here was collected from a prospective, open-label clinical trial, designed to assess the sensitivity and specificity of the BreathID® test compared to other methods in determining the status of gastrointestinal infection with H. pylori (pre-therapy phase) and to evaluate the ability of the BreathID® System to monitor the efficacy of therapy for H. pylori (post-therapy phase).

There were 315 adult pre-therapy patients at two United States hospitals (Brigham and Women's and Massachusetts General Hospital in Boston) in the study.

There were 77 post-therapy patients, who were positive for infection and who had undergone eradication therapy at least 4 weeks previously. 19 of these post-therapy patients participated in the pre-therapy phase as well.

Patients were evaluated by at least two of four diagnostic methods:

1. **Histopathology:** Biopsy specimens, fixed with 10% buffered formalin, were cut into 4 mm sections, stained with Giemsa stain and examined by an experienced pathologist.
2. **Rapid Urease Test (CLOtest®):** Biopsy specimens were tested for urease activity with the CLOtest® according to the instructions in the package insert.
3. **Meretek UBT®** Breath Test for H. pylori (post-therapy only): The Meretek UBT® was performed according to the instructions in its package insert.
4. **Exalenz BreathID® test:** The Exalenz BreathID® test was performed in accordance with the procedures described in its package insert.

<sup>1</sup> Contents taken from the BreathID IDkit: Hp™ Package Insert

## Pre-Therapy

Table 1 and Table 2 compare the BreathID® to rapid urease test and histological exam, respectively. In Table 3, the BreathID® outcome is compared to congruent results from the two endoscopy biopsy-based methods (rapid urease test and histological exam).

**Table 1: Comparison of BreathID® Test to Rapid Urease Test (Clotest®)<sup>1</sup>**

BreathID® Test			
ClOtest®	Positive	Negative	Total
<b>Positive</b>	50	0	50
<b>Negative</b>	2	259	261
<b>Total</b>	52	259	311*

Relative sensitivity: 100% [95% CI (94.2, 100)]

Relative specificity: 99.2% [95% CI (97.3, 99.9)]

*\*Four patients out of the 315 were missing either the rapid urease test or BreathID® test results and therefore were not included in the table.*

**Table 2: Comparison of BreathID® Test to Histology Pre-Therapy**

BreathID® Test			
Histology	Positive	Negative	Total
<b>Positive</b>	47	2	49
<b>Negative</b>	6	251	257
<b>Total</b>	53	253	306*

Sensitivity: 95.9% [95% CI (86.0, 99.5)]

Specificity: 97.7% [95% CI (95.0, 99.1)]

*\*Nine patients out of the 315 were missing either histology or BreathID® test results and therefore were not included in the table.*

**Table 3: Comparison of BreathID® Test to Congruent Endoscopic Tests (Clotest® and histological exam) Pre-Therapy**

BreathID® Test			
Congruent Endoscopic Tests*	Positive	Negative	Total
<b>Positive</b>	47	0	47
<b>Negative</b>	2	251	253
<b>Total</b>	49	251	300

Sensitivity\*\*: 100% [95% CI (92.5, 100)]

Specificity\*\*: 99.2% [95% CI (97.2, 99.9)]

*\*H. pylori positive is defined as positive rapid urea test and positive histology. H. pylori negative is defined as negative rapid urea test and negative histology.*

*\*\*These calculations of sensitivity and specificity do not include 15 patients. In five of these patients, results obtained from the rapid urease test and histology did not match and in 10 of these patients at least one of the three tests was missing.*

## Post Therapy

Table 4 compares the BreathID® to congruent results from the two biopsy based methods (rapid urease test and histological exam) or urea breath test (Meretek UBT®).

**Table 4: Comparison of BreathID® Test to Endoscopic Tests or Meretek**

BreathID® Test			
Endoscopic Tests or Meretek UBT®*	Positive	Negative	Total
<b>Positive</b>	21	1	22
<b>Negative</b>	0	50	50
<b>Total</b>	21	51	72

Percent agreement with positive patients: 95.5%

Percent agreement with negative patients: 100%

*\*H. pylori positive is defined as at least one positive on either of the endoscopic tests or Meretek UBT®.*

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