

**Technical Note**

# Introducing the HeliGuide: Urea Breath Tests System for Detecting Helicobacter Pylori

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## ABSTRACT

**Purpose-** In this report the design concept and experimental evaluation of the performance of HeliGuide have been illustrated.

**Methods-** 14C-UBT system designed for detecting Helicobacter pylori. In order to assess the capability of the system, results of 221 reference cards have been analyzed.

**Results-** Results of the HeliGuide system are matched with the reference.

**Conclusion-** Results of the evaluation indicated that HeliGuide is adequate as a Urea Breath Test system for detecting helicobacter pylori.

## 1. Introduction

**H**elicobacter pylori (HP) is a spiral shaped gram-negative bacterium which colonizes the human gastric mucosa [1]. This bacterium plays an important role in many human diseases, especially duodenal ulcers, gastric ulcers and stomach cancer. The prevalence of H. pylori infection is 25%-50% in developed countries and 70%-90% in developing countries [2,3].

Today, the presence of HP in the gastrointestinal tract is most conveniently detected non-invasively using either the 13C- or 14C-UBT [4-6]. The accuracy of UBT is comparable to the invasive tests, and it is recommended for situations when endoscopy is not needed [7]. UBT is a highly standardized, sensitive and specific test [8]. It detects the metabolically active bacteria, which makes the test suitable for pretreatment detection as well as for monitoring results after eradication treatment against H. pylori. The validity of the UBT is generally high, with a reported sensitivity of 90-98% and specificity of 92-100% [5, 9-11].

Although 13C-UBT is an alternative method in comparison with 14C-UBT with high diagnostic

precision and accuracy [4, 6, 8-10], it seems to complicate the analysis by requiring a centralized, expensive mass spectrometer with a continuous need for maintenance and calibration [12]. That's why 14C-UBT is preferred. In 14C-UBT method HP infection detection has 96.6% sensitivity and 100% specificity and has the best diagnostic performance compared with other methods like RUT, PCR, and HP-HE [13].

## 2. Methods

Our developed system, the HeliGuide UBT, has been designed based on 14C-UBT technology where the traditionally used liquid  $\alpha$ -scintillator has been replaced with an detector containing two built-in Geiger-Mueller counters operating in parallel mode. This has made it possible to design a cheap, small, and fully automatic analyzer that can be easily operated by the nurse or physician in clinic [12].

HeliGuide UBT is a completely dry system consisting of two components, a breath-card and an analyzer (Figure 1). The patient exhales into the breath-card and the analyzer counts the activity of 14C in the breath-card.

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Figure 1. The HeliGuide system.

The HeliGuide analyzer consists of two shielded Geiger-Muller counters mounted face-to-face. An opening in the shield allows the insertion of the breath-card between the two counters. When the breath-card is fully inserted, its two pads are perfectly lined up with the two counters. The correct positioning of the breath-card is verified with an optical sensor. The analysis sequence can only be initiated if the card is properly inserted.

The microprocessor- controlled electronics in the analyzer steer the measurement cycle. The system keeps continuous track of and compensates for variations in the background radiation that are not blocked by the shielding around the Geiger-Muller counters. It also compares the result with programmed cut-off levels for determination of test results, calculates and presents the result on its LCD display. The picture in Figure 2 shows the inside of the system consisting of shielded detectors and the mother board.

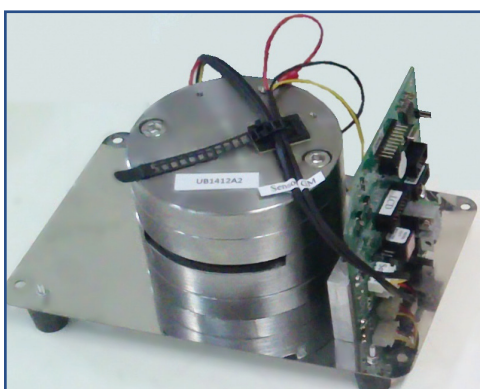


Figure 2. Inside of HeliGuide analyzer.

The test procedure is simple; 10 minutes after the patient has swallowed  $^{14}\text{C}$  labeled urea, he/she exhales into the breath-card until it is fully saturated. This

will be indicated by the built-in indicator, which changes color from orange to yellow. The breath-card is then inserted into the analysis unit and a single button press starts the analysis. The result is presented 250 seconds later as “HP= 2” (infected), “HP= 0” (not infected), or “HP= 1” (borderline).

The amount of radiation used in these tests is extremely low, much lower than the amount a pregnant woman is absorbing through natural sources. The ionizing radiation dose associated with the  $^{14}\text{C}$ -UBT is very small and requires no restrictions in adults and young children (3 years old and older) or upon repeated testing [14].

The accuracy of this device is evaluated with 221 reference breath-cards that consist of 103 positive, 115 negative and 3 borderline cases.

Another test has also been taken from 141 volunteers, both men and women, with ages between 24 to 61 years old.

### 3. Results

Figure 3 shows the results of HeliGuide system on the reference cards.

Between 141 tests which are taken from the selected population, 77 cards were positive and 64 cards were negative.

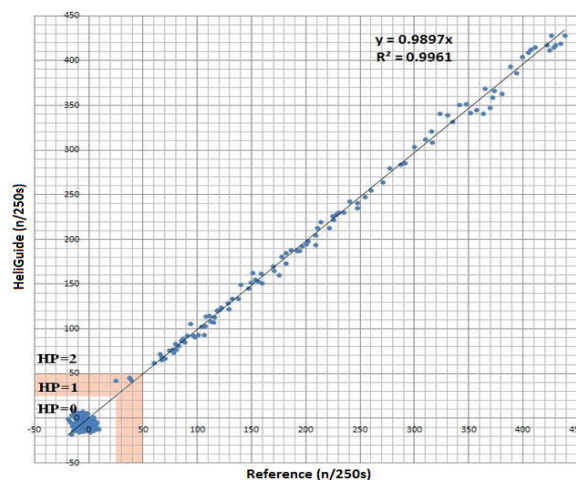


Figure 3. Results of HeliGuide system on the reference cards.

### 4. Discussion

The HeliGuide system reported the results properly and the results were matched with the references in 100% of cases.

In the selected population statistical 54% of results were positive and 46% negative.

## 5. Conclusion

Results of the evaluation indicated that HeliGuide is adequate as a 14C-UBT system for easy, simple and cheap non-invasive test for supporting the diagnosis and monitoring for the treatment of HP infection and has high sensitivity, specificity and accuracy.

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