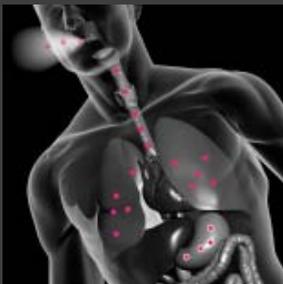


# When diagnosis is just a breath away

Heliprobe® System – a quick, reliable and painless test

Doctor's office test – for diagnosis of *Helicobacter pylori*



## The golden standard

*Helicobacter pylori* is extremely common in humans, infecting around 50 % of the world's population. It is recognized as the main etiological factor for chronic gastritis, peptic ulcer and also gastric cancer. Much suffering and even ulcer related deaths can be easily prevented through accurate diagnosis and appropriate treatment with antibiotics.

Urea Breath Test (UBT) is considered to be the gold standard for the diagnosis of *Helicobacter pylori*. It is non-invasive and it measures active infection.

# Heliprobe® UBT

RAPID RELIABLE RESULTS



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# Accurate diagnosis within minutes

*Heliprobe® System is a <sup>14</sup>C-Urea Breath Test perfectly suited for primary diagnosis and for post treatment follow-up of *Helicobacter pylori* infection. It is a reliable, safe and cost-effective near-patient testing system consisting of three components – HeliCap™, BreathCard™ and Heliprobe® Analyzer.*

## Heliprobe® System A method with unique advantages

- Convenience – Easy to use, near patient testing, no need to send sample for analysis
- Comfort – Painless, no invasive gastroscopic tubing
- Speed – Samples are ready for analysis in only 10 minutes with test result available in 5 minutes
- Reliability – Sensitivity 95 %, specificity 100 %

## The most reliable test is also the easiest to perform

Heliprobe® is a test system which is easy to use for both patients and health care providers. No special training or experience is required. The test result is available on-site within 15–20 minutes after the patient has swallowed HeliCap™. This capsule contains 1 µCi <sup>14</sup>C-labelled urea. The radioactive dose is very low – significantly lower than a normal x-ray dose.

## The advantage of solid capsule formulation

HeliCap™ solid capsule formulation minimizes false positive results in early breath samples by eliminating urea hydrolysis in the mouth and on the way to the stomach. In addition there is no need for a test preparation or a test-meal.



## How Heliprobe® System works in the patient

- On an empty stomach, the patient swallows a HeliCap™ capsule with a glass of water.
- HeliCap™, containing <sup>14</sup>C-labeled urea, disintegrates rapidly in the stomach and the <sup>14</sup>C-urea is dissolved.
- In the presence of *Helicobacter pylori*, the <sup>14</sup>C-urea is metabolized into carbon dioxide and ammonia by the enzyme urease, produced by *Helicobacter pylori*.
- The available <sup>14</sup>C isotopes, now in the form of <sup>14</sup>CO<sub>2</sub>, diffuse into the blood to be transported to the lungs, where it is exhaled in the breath to be captured during sampling. A positive answer offers conclusive evidence that the patient is infected with *Helicobacter pylori*.
- In the absence of *Helicobacter pylori*, the administered urea is absorbed from the gastrointestinal tract and subsequently voided.

## Heliprobe® System – Simply swallow, breathe and analyze



1) Swallow HeliCap™



2) After a 10-minute wait, breathe into BreathCard™



3) Insert BreathCard™ into Heliprobe® Analyzer



4) Result is available in a few minutes

### References:

1. The European *Helicobacter pylori* Study Group (EHPG). Current concepts in the management of *Helicobacter pylori* infection – The Maastricht 2-2000 Consensus Report.
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3. Ken McKoll et al. Current opinion in Gastroenterology 2000, 16 (suppl) pp. 29-32.
4. Olga Hegedus et al. Validated accuracy of a novel urea breath test for rapid *Helicobacter pylori* detection and in-office analysis. European Journal of gastroenterology & Hepatology 2002, 14:1-8.
5. W.A. de Boer et al. Validation of a new portable near patient urea breath test; the Heliprobe system. European *Helicobacter* Study Group, XVIth International Workshop, Sep 2003, Sweden.