AN EASY TO USE DOCTOR’S OFFICE TEST

HELIProbe™ UBT
FOR THE DIAGNOSIS
OF HELICOBACTER PYLORI INFECTION
SIMPLE AND NON-INVASIVE. AN ACCURATE TEST RESULT IN MINUTES

TWO NOBEL PRIZE WINNERS REDEFINED A DISEASE TO OPEN NEW DOORS FOR DIAGNOSIS AND TREATMENT

SIMPLY SWALLOW, BREATHE AND ANALYSE

HOW HELIPROBE™ WORKS IN THE PATIENT

NO INVASIVE GASTROSCOPES OR DIFFICULT TO HANDLE LIQUIDS, JUST A SIMPLE CAPSULE

ABOUT KIBION
Now it is possible to perform a simple test for the ulcer bacterium *Helicobacter pylori* in the doctor’s office. The Heliprobe™ UBT is a reliable, safe and cost-effective near-patient testing system for the presence of *H. pylori* infection. This Swedish invention is perfectly suited for use in the test & treat strategy in primary care and obviates the need for patient referral. The system consists of three components; HeliCap™, BreathCard™ and Analyser.
Breath testing for *Helicobacter pylori* is a non-invasive diagnostic technology with enormous potential. This bacterium is extremely common in humans, infecting around 50% of the world’s population. It is recognised as the main etiological factor for chronic gastritis, peptic ulcer and possibly also gastric malignancies. Much suffering and even death related ulcers can be easily prevented through accurate diagnosis and appropriate treatment with antibiotics. A post-treatment check is recommended to ensure eradication of the infection.

Heliprobe™ is an accurate urea breath test system for primary diagnosis and for post-treatment follow-up of *Helicobacter pylori* infection. It fulfils the growing clinical demand for a cost-effective method for *Helicobacter pylori* diagnosis in the doctor’s office.

**Heliprobe™ offers the following advantages:**

- **CONVENIENCE**
  - Easy to use, near patient testing, no need to send samples for analysis.

- **COMFORT**
  - No invasive gastroscopic tubing.

- **SPEED**
  - Samples are ready for analysis in only 10 minutes and test result within 5 minutes.

- **RELIABILITY**
  - Sensitivity 95% and specificity 100%.

- **COST-EFFECTIVENESS**
  - No need for complex and expensive test equipment, analysis made on-site.
Two Nobel Prize winners redefined a disease to open new doors for diagnosis and treatment.
OVERTURNING MISCONCEPTIONS
For generations, the medical community accepted the conventional wisdom that gastric ulcers were strongly coupled to personality traits, lifestyle and stress. These impressions were firmly ingrained in spite of the fact that Helicobacter pylori is a highly common bacteria.

TRUE CAUSALITY
Yet it wasn’t until 1983 that Helicobacter pylori’s significance as a causal agent for gastro-duodenal ulcers was recognised by Barry Marshall and Robin Warren. These two pioneers finally managed to convince the medical community of the pathological implications of Helicobactor pylori and that such an infection can be cured in just a few weeks by a treatment of antibiotics. In 2005, the two men were awarded the Nobel Prize in medicine for their accomplishment.

NEW DIAGNOSTIC NEEDS
Today it is accepted that Helicobacter pylori infection is responsible for the pathogenesis of gastro-duodenal ulcer disease and possibly gastric cancer and non-ulcer dyspepsia. Consequently, there is a global need for a simple and accurate diagnostic test for this infection.
Heliprobe™ is a test system which is easy to use for both patients and health care providers. No extra help is required from external facilities. The test results are available within 15-20 min after the patient has swallowed the HeliCap™. This capsule contains 1µCi ¹³C-labeled urea. The radioactive dose is very low, significantly less than the dose given during a normal X-ray.

The results are obtained on-site, so there is no need to send samples to an external laboratory. The Heliprobe™ System is simple, rapid, practical and cost-effective and designed for the doctor's office.

Simply swallow, breathe and analyse

THE PROCEDURE IS FAST AND SIMPLE WITH THE FOLLOWING STEPS:

1) The HeliCap™ is swallowed

2) After a 10-minute wait, the patient exhales into the BreathCard™

3) The Breathcard™ is then inserted into the Heliprobe™ Analyser, a small desktop GM-counter.
How Heliprobe™ works in the patient

**A)** On an empty stomach the patient swallows a HeliCap™ Capsule with a glass of water.

**B)** HeliCap™, containing $^{14}$C-labeled urea, disintegrates rapidly in the stomach and the $^{14}$C-urea is dissolved.

**C)** In the presence of *Helicobacter pylori*, the $^{14}$C-urea is metabolized to carbon dioxide and ammonia by the enzyme urease, produced by *Helicobacter pylori*.

**D)** The available $^{14}$C isotopes, now in the form of $^{14}$CO$_2$, 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*.

**E)** In the absence of *Helicobacter pylori*, the administered urea is absorbed in the gastrointestinal tract and subsequently voided.

**VALIDATION OF THE METHOD**

The Heliprobe™ system has been validated and found to be comparable to conventional UBT, with the advantage of being a diagnostic system for detection of *H. pylori* directly in the doctor’s office.

Results are expressed as 0 = patient not infected, 2 = patient infected, 1 = borderline.
How Heliprobe™ works in the patient
No invasive gastroscopes or difficult-to-handle liquids, just a simple capsule, easy sampling and analysis.
Comparing the benefits: Heliprobe™ is superior to other diagnostic methods for detection of Helicobacter pylori infection.

GOLDEN STANDARD
Urea breath testing (UBT) is currently considered to be the golden standard for non-invasive diagnosis of Helicobacter pylori infection. It is highly reliable for pre- and post-treatment follow-up of infection. However, tests in liquid form have several disadvantages compared to HeliCap™ solid-capsule formulation.

CLINICAL EVALUATION
Heliprobe™ System has been compared to other UBTs. The conclusions from the clinical evaluations were:

- the HeliCap™ capsule minimizes false positive results by eliminating urea hydrolysis in the mouth and on the way to the stomach.
- The solid capsule eliminates the need for a pre-test meal.
- Short time to sampling, only 10 minutes after capsule intake.
- Results obtained on site, within 5 minutes after sampling.
- Acid supplementation in the capsule reduces the risk of false negative results.
- Sensitivity and specificity are 95% and 100%.

In conclusion, the Heliprobe™ system in comparison with liquid-based urea breath tests is more accurate, rapid and easy to use. The simplicity and handiness of the system makes it ideal for detection of Helicobacter pylori directly in the doctor’s office.
About Kibion

Founded in 2005, Kibion AB markets and distributes the urea breath tests Heliprobe™ system and Diabact® UBT world-wide. Both test methods are protected by patents and trade marks. Kibion pursues an active intellectual property protection program to ensure that its current and future products have maximum protection in key territories.

A wholly owned subsidiary of the pharmaceutical company Orexo AB, Kibion is based in Uppsala, Sweden.

REFERENCES:


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