A/ Did you know?
The interrelation between Helicobacter pylori and the erosion of stomach wall, gastritis, gastric ulcer and stomach cancer was discovered by Barry Marshall in 1993. He was awarded the Nobel Prize for this discovery in 2005. The HelicoSense test machine can be widely used for diagnosis of this and of certain paediatric diseases. «Maastricht-4» at the XXIV-th International Workshop on Helicobacter and related bacteria in chronic digestive inflammation and gastric cancer in Dublin, Ireland, September 11-13, 2011, has recommended the urease breath test as a basic procedure for H.pylori diagnostics. http://www.helicobacter.org/2011/

B/ HelicoSense Helicobacter pylori diagnostics and why to choose it:

It has the **Highest Accuracy** among the existing Helicobacter pylori non-invasive breath-diagnostic methods
Only with the advent of **HelicoSense** one part in a hundredth accuracy became attainable in the area of breath test diagnostics! It is handy with a friendly innovative interface
There are no calculations or complicated procedures required. At the end of the test there will be presented an infection rate accurate to two decimal places.

**BENEFITS**
- Easy to exchange patient cartridge
- result in 10 minutes
- high-accuracy

The results of testing from the HelicoSense are more informative because the test data takes into account the reference ammonia level of the patient. HelicoSense method accuracy is on average 8-10% higher than similar C13 breath urease tests as well as being at least as accurate as immunological and helic-test methods.

The Helicobacter pylori infection diagnosis method with HelicoSense device is precise, non-invasive and it is easy to use.
It does not require high staff qualification, is a rapid test (performed within 10 minutes), safe and comfortable for surveyed patients (urea of normal isotopic composition is swallowed and there is no other patient contact by the device apart from the mouth piece).

The HelicoSense non-invasive method gives comparable results to invasive test methods. This makes it the most effective diagnostic method for HP diagnosis, leading to target eradication or control for gastric and duodenal ulcer patients.

**Methodological foundations and applicability limits of Helicobacter pylori infection diagnostic methods**

<table>
<thead>
<tr>
<th>Method</th>
<th>Principle</th>
<th>Traits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacteriological</td>
<td>Incubation of sample material on nutrient media, followed by a specific reaction, causing the test material color change</td>
<td>Invasive, time limited on the sample delivery. Long (5-7 days) sample preparation. 97% for accuracy and specificity</td>
</tr>
<tr>
<td>Method</td>
<td>Description</td>
<td>Characteristics</td>
</tr>
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<tr>
<td><strong>Histological</strong></td>
<td>Specific reaction causing the test material color change</td>
<td>Invasive, time limited on the sample delivery. High degree of dependence on the morphologist experience. The most precise method.</td>
</tr>
<tr>
<td><strong>Polymerase chain reaction</strong></td>
<td>Identification of a species-specific DNA HP fragment</td>
<td>Invasive \ noninvasive, high technological complexity, expensive equipment.</td>
</tr>
<tr>
<td><strong>Detection of HP specific Ig</strong></td>
<td>Presence of specific IgG, IgA, IgM antibodies</td>
<td>Invasive \ noninvasive. Inconclusive for children Seropositivity: occurs for 60 days after infection, continues up to one year after a successful HP eradication</td>
</tr>
<tr>
<td><strong>Urease breath tests based on the $^{12}$C $^{13}$C $^{14}$C isotopes</strong></td>
<td>Splitting of xxC labeled urea by HP, to ammonia and carbon dioxide, which are transferred into the blood</td>
<td>High cost of equipment. Time consuming. Isotope tracing urea intake. Does not fit for children.</td>
</tr>
<tr>
<td><strong>HelicoSense</strong></td>
<td>Urea of normal isotopic composition</td>
<td>Rapid – 10 minutes, reasonable price. Suitable for primary care offices, hospitals, eradication control</td>
</tr>
</tbody>
</table>

**C/ What do clinical studies state**

The device has high Sensitivity – 93% for children and 94% for adults.

Specificity – 86,7% for children and 85,5% for adults

Clinical studies made in:

- Saint Petersburg State Pediatric Medical Academy (SPbSPMA) – http://www.gpma.ru/
- Peoples’ Friendship University of Russia- http://www.rudn.ru/en/
- Scientific Research institute of SPA treatment and physical medicine of the Armenia Republic Ministry of Health http://www.fizecomed.com/
- Technical testing and calibration done at All-Russia D.I. Mendeleev Scientific and Research Institute for Metrology (VNIIM, acknowledged by TUV) - http://www.vniim.ru/index.en.html
- Universidad de Santiago de Chile – http://www.usach.cl/portada.php

Clinical studies results and scientific publications at http://helicosense.ru/specialists/

**D/ About the device**

Breath Test Analyzers (BTA) «HelicoSense» are designed for express measurement of ammonia mass concentration in the exhaled air.
BTA are designed for application in medical institutions for express diagnostics and monitoring of Helicobacter pylori infected patients’ treatment course. It is an automatic self-contained device. Its working principle is based on using an electrochemical sensor for measuring ammonia mass concentration in the analyzed sample of air. Regarding its mode of application, BTA are the devices of multiple cyclic use. The «HelicoSense» expired air analyzers have been produced since 2003 in two versions – «HelicoSense Routine» and «HelicoSense Scientific».

«HelicoSense Routine» is designed for primary diagnostics in **Outpatient offices** and wide scale screening examinations

«HelicoSense Scientific» – is intended for a follow-up of a patient after diagnosis until the final victory over the disease. It is for **Inpatient institutions** where a patient is treated from primary diagnostics until eradication control – hospitals, sanitariums, private and industry-sponsored clinics

«HelicoSense» is a multipurpose, easy-to-use device that combines precision and high throughput capacity.

The device construction, microprocessor, and PC programs are protected with seven RF patents. We have applied for an international PCT procedure. http://en.helicosense.ru/patents/

Since 2004 all aspects of our activity have been regulated by quality management system ISO 9001-2000. In 2011 we have introduced and successfully implemented quality management system ISO 9001-2008 and have obtained the CE mark.

**CONSTRUCTION AND WORK PRINCIPLE**

An electrochemical sensor, provides an electrical signal, proportional to a concentration of ammonia. The sensor has a high resolution – 0.025 mg/m³

Accurate sensor selectivity provides to avoid the influence of other gases on the test result. Built-in microprocessor administers all the measuring process and transforms output signals of the sensor into the display readings.

Besides the measuring results, display provides with a timeline of ammonia concentration change, instructions for an operator and reports on Gas analyzer operating modes.

It is well known, that for any kind of heliobacteriosis, availability of ammonia in the exhaled air of a patient is a distinctive cue.

Diagnosis is carried out by measuring of the ammonia concentration in the exhaled air of a patient after the intake of a fluid – a water solution of normal isotopic composition urea. 500 mg pelleted urea is a part of a device complete set. Calculation of ammonia basal concentration (a concentration, specific for a certain patient and not caused by an interaction of diagnosticum and bacteria) provides a reference taking into account the individual characteristics of a patient and increasing the accuracy of the analysis.

1. **HelicoSense Scientific**

The HelicoSense Scientific does not require a periodic verification!

The detector element system is designed as an easily replaceable unit.

Once a year, one has just to replace the old for the new one, which has passed factory calibration, thus not interrupting the tests in order to send HelicoSense Scientific back for periodic verification.
Your HelicoSense Scientific will work all the year – you will not miss any patient.

High resolution HelicoSense Scientific measuring system takes into account miniscule changes in the concentration of a tested sample (down to hundredths of milligram).

HelicoSense Scientific provides quantitative data on ammonia concentration in figures as well as in a graph.

Whilst elaborating HelicoSense Scientific, we tried to reduce the burden on the doctor and also tried to increase the diagnostics accuracy. Leading to the processes of sensor cleansing, quality control, and sampling being completely automated.

Universal power supply excludes influence on the test of supply voltage fluctuations.

One can work even when supply voltage fluctuations are ranging from 90 to 265 volt.

2. HelicoSense Routine

Routine breath test measuring device is a universal, handy, accurate and high capacity device.

If Your medical institution provides a substantial amount of medical services and You consider it worth implementing express diagnostics methods for Primary Care Physicians – Routine model is Your option!

FEATURES

- Obtaining the results rapidly after the test
- Intuitive interface with sound and text reminders
- Operation time not more than 10 minute
- Device weight – just 380 gram
- Completed with a practical bag with all necessary consumables
- Designed for testing in office and at home
- Sensor replacement once every two years
- Sensor is protected from exhaled air humidity
- Periodic testing of the device – once a year