Helicobacter Test INFAI®

\(^{13}\text{C}-\text{urea breath test}

for Helicobacter pylori detection

Helicobacter pylori infection:
A worldwide problem
**Helicobacter pylori infection**

A worldwide problem

On average, 50% of the world’s population is already infected with *Helicobacter pylori.*

Infection rate in Europe ranges from 35-40%.

*Helicobacter pylori* infection places the affected person under considerable physical and emotional strain. High economic costs lead to the necessity for eradication of the bacterium.

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**Facts**

- Internationally approved medicinal product subject to medical prescription
- The best test for the diagnosis of *H. pylori* infection with high accuracy and easy performance (the Maastricht IV/ Florence Consensus Report)
- Suitable for diagnosis and control after eradication treatment of an infection with *H. pylori*
- Registered in more than 35 countries worldwide
- Reimbursement by health insurance in most European countries
- Easy handling, cost-effective and non-invasive
- Analysis via mass spectrometry or infrared spectroscopy
- The only approved 13C-urea breath test for children of the age 3 - 11
- **NEW:** for patients with dyspepsia taking PPIs, INFAI offers the test with Refex® as a special test-meal, no withdrawal of PPIs medication necessary
- **NEW:** CliniPac Basic (only 50 13C-urea containers) for general practitioner, laboratory and hospital use

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**References**

Performance of the test

Sampling of the 00-minute value $t_0$

Before performing the test, the patient should have fasted 4-6 hours, preferably overnight. The test starts with the collection of the baseline breath samples ($t_0$). The breath is collected either in a sampling tube (MS-version) or in a breath bag (IR-version) by gently blowing through a straw.

Administration of $^{13}$C-urea (test solution)

After drinking 200 ml of pure orange juice (100 ml of pure orange juice for children) or a solution of 1 g citric acid (for adults and adolescents) diluted in 200 ml of water to delay gastric emptying, the test solution is prepared. The enclosed $^{13}$C-urea (45 mg for children or 75 mg for adults and adolescents) is dissolved in 30 ml of water and taken immediately.

Sampling of the 30-minute value $t_{30}$

30 minutes after administration of the test solution, the second breath samples are collected ($t_{30}$). Barcoded labels are provided to ensure safe and distinctive identification during analysis. Breath samples should be dispatched to INFAI or other qualified laboratories in the box provided.

Basic principle

To establish an infection with *Helicobacter pylori*, $^{13}$C-labelled urea is administered, which is then split up into $^{13}$C-labelled carbon dioxide and ammonia in the presence of the bacteria.

Quality criteria

Specificity of 98.5 % and sensitivity of 97.9 %. Helicobacter Test *INFAI®* surpasses all other non-invasive diagnostic methods for *Helicobacter pylori* detection.

References

- Validity of a novel biopsy urease test (HUT) and a simplified $^{13}$C-urea breath test for diagnosis of *H. pylori* infection and estimation of the severity of gastritis, Labenz J., Aygen S. and; Digestion, 1996, 57(6):391.
An infection with Helicobacter pylori is regarded as proven if the difference in \(^{13}\text{C}/^{12}\text{C}\) of 00-minute-value \(t_0\) and 30-minute-value \(t_{30}\) exceeds 4‰.

Analysis of the breath test

Helicobacter Test INFAI\(^\circ\) is safe, reliable, cost-saving, and can be performed easily and fast. The analysis of the breath samples can be carried out either by means of Isotope Ratio Mass Spectrometry (IRMS) or Non-Dispersive Infrared Spectroscopy (NDIR). For both analytical methods, the European Medicines Agency (EMA) approved specifications for their execution.

Evaluation

An infection with Helicobacter pylori is regarded as proven if the difference in \(^{13}\text{C}/^{12}\text{C}\) of 00-minute-value \(t_0\) and 30-minute-value \(t_{30}\) exceeds 4‰.
MACHINES: Helicobacter Test recommended to take notice of the product information of eradication therapy products for expected that the test procedure may be harmful during pregnancy or lactation. It is Helicobacter pylori status or urease activity. PREGNANCY AND LACTATION: It is not.

See Summary of Product Characteristics before prescribing. PHARMACEUTICAL FORM: Powder for oral solution. CLINICAL PARTICULARS: Therapeutic indications: Helicobacter Test INFA® may be used for in vivo diagnosis of gastrroduodenal Helicobacter pylori infection in adults and adolescents, who are likely to have peptic ulcer disease. PRINCIPAL CHANGES AND PRECAUTIONS FOR USE: A positive test alone does not constitute indication for eradication therapy. Differential diagnosis with invasive endoscopic methods might be indicated in order to examine the presence of any other complicating conditions, e.g. ulcer, autoimmune gastritis and malignancies. There are insufficient data on the diagnostic reliability of the Helicobacter Test INFA® to recommend its use in patients with gastritis. For children from the age of 3, Helicobacter Test INFA® for children aged 3 to 11 is available. In individual cases of A-gastritis (atrophic gastritis) the breath test may have false positive results; other tests may be required to confirm the Helicobacter pylori status. If the patient vomits during the test procedure, necessitating the repetition of the test, this should be done in fasted condition and not before the following day. INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION: Helicobacter Test INFA® will be affected by all treatments interfering with Helicobacter pylori status or urease activity. PREGNANCY AND LACTATION: It is not. INCOMPATIBILITIES: Not applicable. SHELF-LIFE: 3 years. SPECIAL PRECAUTIONS FOR STORAGE: Do not store above +25°C.

The Company

Development and production of non-invasive methods for in vivo gastrointestinal diagnosis

INFAI is a research-based pharmaceutical company, offering new and innovative methods in the field of life science, as well as medicinal products, for the in vivo diagnosis of different widespread common diseases. These in vivo diagnostics are non-invasive and offer competitive advantages in comparison with other diagnostic tools.

In 1997, the $^{13}$C-urea breath test Helicobacter Test INFAI® was approved for all of Europe by the European Medicines Agency. Its use was subsequently extended to many other countries worldwide. Helicobacter Test INFAI® is now the most widely used test for the non-invasive diagnosis of infection with Helicobacter pylori.

In 1998, an automated production line was installed at our facility in Bochum, Germany, complying with all pharmaceutical quality guidelines. The production line was adapted in 2013 with new techniques conforming to the best state of pharmaceutical technology.

Additionally to Helicobacter Test INFAI®, the company is developing other innovative tests for the diagnosis of functional and metabolic disorders. These include:

- **Gastromotal®** - gastric emptying test - **approval in progress** -
- **Pancreo-Lip®** - test for slight to moderate degree of pancreatic insufficiency
- **Pancreo-Amyl®** - test for moderate to severe degree of pancreatic insufficiency
- **Lactoin®** - lactose intolerance test
- **Metabo Test®** - for congenital metabolic diseases - **available** -
- **Cardio Test INFAI®** - for cardio risk assessment - **available** -

All tests were already used in several clinical trials worldwide.

Quality management

INFAI has established an integrated quality management system based on ISO 9001:2015, in compliance with national and international regulations. The high quality standards defined within this framework ensure the production of reliable and high-quality pharmaceutical products. Customer satisfaction is at the centre of all our activities. The permanent improvement of our quality management system enables us to act quickly upon changing market conditions.