AMA Co Ltd ®

Instruction for Use

HELIC ABT Reader Indicator Tube Kit

CE

IVD

+5°C +40°C

EC REP

REF 0106, 0107, 0109

Authorized Representative in Europe
"CMC Medical Devices & Drugs S.L."
C/ Horacio Lengo no 18, CP 29006,
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Manufacturer
"Association of Medicine and Analytics
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17 line of Vasilievsky Island, 4-6,
Saint-Petersburg, 199034, Russia

Intended Use and Principle of Operation

HELIC Ammonia Breath Test (HELIC ABT) is a ready-to-use test for qualitative detection of *Helicobacter pylori* (*H.pylori*) urease activity in patients with suspected *H.pylori* infection. The test is applied by gastroenterologists, general practitioners, by staff of primary health centers and dispensaries and allows implementing Near Patient Testings (NPT) in any place and situation. The packaging and size of the HELIC ABT make the test easy to transport in regions with various climate conditions. Sensitive composition inside the indicator tube allows the *H.pylori* infection to be detected without using complicated equipment or radioactive isotope markers. The procedure of analysis lasts about 15 minutes. The test can also be recommended for children and pregnant women without any special precautions.

The Method

The test is based on a change of ammonia level in a patient's mouth cavity air. *H.pylori* produces large amounts of urease, which degrades urea to ammonia. The ammonia is detected in the mouth cavity air by a change of the indicator tube color from yellow or orange to blue, violet or grey-green. The analysis consists of 2 parts. In Part I the basal ammonia level is detected. In Part II the load ammonia level is detected. After that the basal and load levels are compared and the conclusion regarding the *H.pylori* infection presence is made.

Warnings and Precautions

For in vitro diagnostic use only. The indicator tube is a single-use device. Do not use device beyond the expiry date. Discard the used devices as potentially infected waste according to the local and national regulations.

Preparations before the Test

1. The test is to be performed on an empty stomach: it is necessary to exclude taking food and water before the test. The last meal should be no less than 12 hours before the test. The last meal should be "light": it's necessary to avoid such products as meat, fish and mushrooms.
2. The test can be fulfilled:
• 4-6 weeks after antibacterial therapy;
• 2 weeks after last dose of antisecretory agents, anti-inflammation agents, acid inhibiting drugs (PPI or H2 blockers), bismuth drugs and analgetics.
3. It's necessary to avoid strong alcohol for 3 days before the test.
4. It's necessary to avoid legumes (such as peas, kidney beans, lentil, soy) for 3 days before the test.
5. It's necessary to avoid chewing gum on the test day.
6. It's necessary to avoid smoking for 3 hours before the test. It is necessary to brush teeth and rinse mouth cavity thoroughly after smoking.
7. It's necessary to brush teeth and rinse mouth cavity thoroughly before the test.

***Attention!* A patient shall strictly observe the preparation rules!**

Test Procedure

Please refer to the “HELIC Ammonia Breath Test (HELIC ABT) with HELIC ABT Reader” Instructions for use and follow the steps of the “New test” mode.

***Attention!* Please pay particular attention to the requirement for rinsing mouth cavity before basal and load aspirations!**

Limitations

Inaccurate test results may occur in cases where the patient failed to comply with the test preparation requirements stated in the Patient’s notice. As with any diagnostic procedure the HELIC ABT results must be interpreted in light of the patient’s clinical presentation and any other information available to the physician.

Storage and Stability

Store the HELIC ABT Reader indicator tube kit at temperature from +5 °C to +40 °C in the dark place in the manufacturer pack. Keep the devices away from ammonia vapor, direct sunlight, moisture and heaters. The storage place must be protected from mechanical action (friction, pressure, strokes) and aggressive chemicals. In the case of storage / transportation at low temperatures it is necessary to keep the devices at temperatures from +15 °C to + 45 °C for at least 1 hour before use. When stored under the above mentioned conditions the device is stable until the expiration date printed on the immediate container label.

Warranty

The Manufacturer shall remedy all defects discovered in any Product (the “Defective Product”) that result from unsuitable materials or negligent workmanship and which prevent the mechanical functioning or intended use of the Products including, but not limited to, the functions specified in the Manufacturer’s specifications for the Products.
Any warranty will, however, be deemed as void if the fault is found to have been caused by maltreatment, misuse, accidental damage, incorrect storage or use of the product for operations outside their specified limitation or outside their specifications, contrary to the Instructions for use. The period of this warranty is 24 months from the date of manufacture.

Ordering information

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• Manufacturer: "Association of Medicine and Analytics" Company Limited ("AMA" Co., Ltd) 17 Line of Vasilievsky Island, 4-6, 199034, Saint-Petersburg, Russia.Tel: (007) 812 321-7501; Fax: (007) 812 380-7699; E-mail: ama@sp.ru; Web: www.amamed.ru

Explanation of the symbols, used in labels


Manufacturer

Authorized Representative in the European Community

Batch code


Use by


Do not reuse

Catalogue number


Date of manufacture


Contents sufficient for N tests

Temperature limitation

In vitro diagnostic medical device


Consult Instructions for use