Heliprobe® BreathCard™

Instructions For Use

Product name

Heliprobe® BreathCard™

Reference: HPC-001

Classification

The Heliprobe® Breathcard™ is a Class A *in vitro* diagnostic medical device as per Regulation (EU) 2017/746.

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1. Product overview

1.1. General description

Heliprobe® BreathCard™ is a single-use device for ^{14}C Urea Breath Test sampling allowing *Helicobacter pylori* detection. Heliprobe® BreathCard™ is only compatible with the Heliprobe® Analyzer.

Heliprobe® BreathCard™ consists of an aluminum foil integrating a mouthpiece for exhaling, two reactivity filters (upper and lower) for adsorbing CO_2 and a color indicator to show completion of sampling. Two air outlets allow the exhaled air to pass through. Heliprobe® BreathCard™ is single packed in an aluminum envelope to protect it from damage and humidity, then packed by 5 in a secondary packaging. Each breath sample on Heliprobe® BreathCard™ can be identified using a non-erasable pen.

1.2. Intended purpose

The Heliprobe® BreathCard™ is intended for the manual collection of breath specimen from lay persons under the supervision of healthcare professionals in clinical or laboratory environments, in order to capture ^{14}C-labelled CO2.

The Heliprobe® BreathCard™ is a device of the Heliprobe® System that is intended, with a non-invasive ^{14}C Urea Breath Test (^{14}C UBT), for the qualitative detection of *Helicobacter pylori* causing infections in the gastrointestinal tract (stomach and duodenum).

1.3. Intended users and operating environment

For sample collection, the Heliprobe® Breathcard™ is intended to be used by lay persons from the general adult population, excluding pregnant women, under the supervision of healthcare professionals.

After sample collection, the Heliprobe® Breathcard™ is intended to be used by healthcare professionals that have been trained to the use of the entire Heliprobe® System, especially for the connection of the Heliprobe® Breathcard™ to Heliprobe® Analyzer.

This device is intended to be used in clinical or laboratory environments.

1.4. Contraindications

There is no specific contraindication for the use of the device.

1.5. Adverse effects

There is no adverse effect associated with the normal use of the device.

2. Overview of the medical condition

2.1. Indication

Qualitative detection of *Helicobacter pylori* infection in the gastrointestinal tract (stomach and duodenum).

2.2. Target patient population

Lay persons with a suspected or diagnosed *Helicobacter pylori* infection from the general adult population, excluding pregnant women.

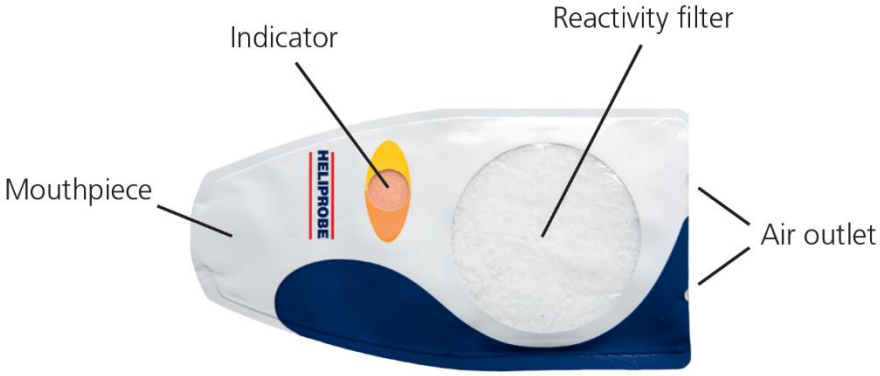
2.3. Principle of the procedure

Helicobacter pylori produces urease, an enzyme that catalyzes the hydrolysis of ^{14}C-urea to $^{14}CO_2$ and NH_3. $^{14}CO_2$ is excreted in exhaled air while NH_3 and excess ^{14}C-urea are excreted in urine. Under healthy conditions (absence of *Helicobacter pylori*), ^{14}C-urea is not hydrolyzed and no $^{14}CO_2$ will be present in exhaled air. Hence, $^{14}CO_2$ is only present in exhaled air during *Helicobacter pylori* infection.

For Urea Breath Test (UBT) sampling, the patient swallows a HeliCap™ capsule containing ^{14}C urea (1 µCi) and wait 10 minutes before exhaling into Heliprobe® BreathCard™ where the reactivity filters adsorb the CO_2. The indicator changes color from orange to yellow to indicate when the reactivity filters are saturated, and sampling completed. The sample analysis is then performed using Heliprobe® Analyzer.

3. Materials

3.1. Heliprobe® BreathCard™



Component	Function
Mouthpiece	Air inlet facilitating the breath sample collection.
Indicator	Colored indicator allowing the user to know when the sampling is completed by changing its color from orange to yellow. The indicator pad is protected by a thin, resistant membrane. ⚠ Contains LiOH.
Reactivity filter	Core pad of the Heliprobe® BreathCard™ that chemically adsorbs the CO_2 from the exhaled air. The reactivity filter is protected by a thin, resistant membrane (mylar). ⚠ Contains LiOH.
Air outlet	Outlets allowing the reduction of the pressure inside of the Heliprobe® BreathCard™ during sample collection, while retaining enough air to ensure an adequate capture of the $^{14}CO_2$.
Bodyfoil	Outer layer of the Heliprobe® BreathCard™ for easy handling.

LiOH

Hazard statement(s)

H301	Toxic if swallowed.
H314	Causes severe skin burns and eye damage.

Precautionary statement(s)

P260	Do not breathe dusts or mists.
P270	Do not eat, drink or smoke when using this product.
P280	Wear protective gloves/ protective clothing/ eye protection/ face protection.
P303 + P361 + P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.

P304 + P340 + P310	IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER/ doctor.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

3.2. Materials required but not provided

The following equipment is required for use but not provided with the Heliprobe® Breathcard™:

Manufacturer	Product name	Reference
Kibion GmbH	Heliprobe® Analyzer	HPU-011

The following substrate is required for use but not provided with the with the Heliprobe® Breathcard™:

Market Authorisation Holder(1)	Product name
Mayoly Spindler Laboratories	HeliCap™, 37 kBq, capsule, hard

(1) Note: The Market Authorisation Holder may vary depending on your country. Please contact your local distributor for further information.

4. Storage and transport

4.1. Before sample collection

- Heliprobe® BreathCard™ should be transported and stored at 15-25°C(2) in its primary packaging (envelope with 1 unit) and secondary packaging (box of 5 units)
- Heliprobe® BreathCard™ should not be exposed to humidity or direct sunlight

(2) If maintained in its original packaging, and no later than 6 months after the manufacturing date that is written on its label, Heliprobe® Breathcard™ may be transported and stored at up to 40°C and 75% RH.

4.2. After sample collection

- Heliprobe® BreathCard™ should be processed immediately
- If not processed immediately, Heliprobe® BreathCard™ should be placed back in its original primary packaging (envelope). Heliprobe® BreathCard™ should then be transported, stored at 15-25°C and must be processed no later than 24 hours after the sample collection.

5. Instructions for use

In the following instructions :

- Indicates when the step is to be performed directly by the patient under the supervision of a healthcare professional.
- Indicates when the step is to be performed exclusively by the healthcare professional.

SWALLOW

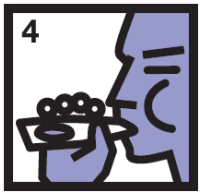
Swallow a substrate (see section 3.2) with a glass of water.

WAIT

Wait for 10 minutes.

OPEN PACK

Open the package and remove the Heliprobe® BreathCard™.
Identify the patient and the sample directly onto the bodyfoil of the Heliprobe® BreathCard™ with a non-erasable pen with smooth tip.



EXHALE

Exhale into the Heliprobe® BreathCard™ until the indicator changes color from orange to yellow (1–4 minutes).
Ensure that the two air outlets are free and allow exhaled air to pass through.

⚠ Do not exhale too hard into the Heliprobe® Breathcard™.

INSERT

Gently squeeze out any excess air without touching the plastic filter shield (mylar).
Remove the Protection Card and insert Heliprobe® BreathCard™ into the slot with the mouthpiece facing outwards and the indicator side facing upwards.

START

The display shows: “**ready to measure, standard program**”.
Press the Start/Stop key to start the measurement and analysis.
The display shows “**measuring**” and indicates the time remaining (seconds).

The final analysis steps are further detailed in the User Manual of the Heliprobe® Analyzer.

6. Warnings and precautions for use

Preparation of the Heliprobe® BreathCard™
Do not use the Heliprobe® BreathCard™ if the single package is damaged.
Keep Heliprobe® BreathCard™ in the single package (envelope) until use.
Avoid scratching the plastic filter shield (mylar) when removing Heliprobe® BreathCard™ from the package.
Use a non-erasable pen for the identification of the sample.
Do not use a sharp pen for the identification of the sample. Where the bodyfoil shows signs of alteration (*e.g.* punctures) after the identification of the sample, do not use Heliprobe® BreathCard™.
Sample collection with the Heliprobe® BreathCard™
Handle Heliprobe® BreathCard™ with care.
Avoid touching the plastic filter shield (mylar) when handling Heliprobe® BreathCard™ as it is is very thin and sensitive to damage.
The reactivity filter and the indicator pad inside Heliprobe® BreathCard™ contain lithium monohydroxide (LiOH), which may cause irritation in the respiratory tract and eyes on contact. To avoid contact with LiOH: - Do not disassemble Heliprobe® BreathCard™ - Never inhale through Heliprobe® BreathCard™. Remove Heliprobe® BreathCard™ Card from the mouth if you must take a fresh breath. - Do not bite the Heliprobe® BreathCard™. - Exhale into Heliprobe® BreathCard™ with an even pressure. Avoid blowing too hard. - Ensure that the two air outlets on Heliprobe® BreathCard™ are free so that exhaled air can pass freely through. Do not damage the plastic filter shield (mylar).
NOTE In case of contact or suspected contact with LiOH, rinse the affected area immediately with water. Contact your local sales representative for further information and to report adverse effects. Further information regarding the hazards associated with LiOH are available in the section “Materials” of these “Instructions for Use”.
Do not expose Heliprobe® BreathCard™ to humidity or fluids.
Avoid getting saliva into Heliprobe® BreathCard™ during exhalation.
Do not drink or eat between exhalations during the test.
Only use the validated substrate (see section 3.2) for the sample collection.
Do not use the Heliprobe® BreathCard™ too early or too late after swallowing the substrate.
Exhale into the Heliprobe® BreathCard™ until the indicator changes color from orange to yellow.
Analysis of the Heliprobe® BreathCard™
Gently squeeze out any excess air without touching the plastic filter shield (mylar).
Insert the Heliprobe® BreathCard™ into the Heliprobe® Analyzer with care.
Only use the validated instrument (Heliprobe® Analyzer) for the analysis of the Heliprobe® BreathCard™.

Disposal
Replace Heliprobe® BreathCard™ in its package/envelope prior to disposal.
Dispose according to local rules or guidelines.
NOTE Sampled Heliprobe® BreathCard™ from an infected patient typically gives about 200–2000 counts. This is expected to contain between 0.2–1.6 kBq 14C (0.005–0.05 µCi).
Miscellaneous
Heliprobe® BreathCard™ is for single-use only.
Do not use expired Heliprobe® BreathCard™.
Heliprobe® System ^{14}C Urea Breath Test radioactivity is very low. ^{14}C emits low energy ß-radiation with a range of 24 cm in air and 0.25 mm in plastic. 1 capsule of substrate (see section 3.2) contains 37 kBq (1 µCi) ^{14}C-urea, which gives a dose of 2.5 µSv. Most of the ^{14}C urea is excreted in the urine. Only a minor part is exhaled as $^{14}CO_2$. Heliprobe® BreathCard™ sampled from an infected patient typically contains 0.2–1.6 kBq (which corresponds to 200–2000 counts) and gives a maximal dose of 0.2 µSv. The upper limit for occasional exposure is < 20 µSv/hour. The upper limit for continuous exposure is < 2 µSv/hour.
NOTE No protection or precautions are required for the safe handling of Heliprobe® BreathCard™.

7. Additional information

7.1. Key features

Heliprobe® BreathCard™ belongs to the Heliprobe® System and must only be used with its substrate (see section 3.2) and Heliprobe® Analyzer.

Correct sample collection can be qualitatively assessed by the change in color of the marker from orange to yellow.

7.2. Device disposal

After use, the device must be placed in its initial individual packaging and destroyed in accordance with local laboratory and healthcare facility procedures and in accordance with local regulations for the disposal of clinical waste.

NOTE

Sampled Heliprobe® BreathCard™ from an infected patient typically gives about 200–2000 counts. This is expected to contain between 0.2–1.6 kBq 14C (0.005–0.05 µCi).

7.3.Symbols

	Manufacturer
	In vitro diagnostic medical device
	Catalogue number
	Batch code
	Caution
	Do not use if package is damaged and consult *instructions for use*
	Do not re-use
	Use-by date
	Temperature limit
	Keep away from sunlight
	Keep dry
	Consult *instructions for use* or consult electronic *instructions for use*

7.4. Customer support and contact information

Please contact your local distributor or Kibion GmbH for support.

- ⇨ info-bremen.kibion@mayoly.com
- ⇨ +49 421 278650

7.5. Serious incidents

Any serious incident that as occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

The manufacturer must be contacted at the following email address:

- ⇨ quality.kibion@mayoly.com

For Europe, the contact points of the competent authorities are available on the website of the European Commission:

- ⇨ https://ec.europa.eu/tools/eudamed

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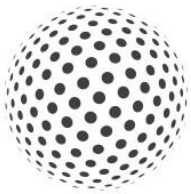

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