

# Helikit<sup>®</sup> Breath Test for the Diagnosis of *Helicobacter pylori* Infection



# Principle of $^{13}\text{C}$ Urea Breath Test (UBT)

- The principle of the UBT is based on the large amount of urease produced by *H. pylori*.
- When urea labeled with a carbon isotope is ingested, it is broken down in the stomach into ammonia and labeled  $\text{CO}_2$ .
- The labeled  $\text{CO}_2$  is absorbed in the blood and expired in the breath.
- This test provides accurate diagnosis of active infection and can also be used for confirmation of eradication post therapy.

# Advantages

- Non-Invasive & Non-Radioactive
- Safe for use with children 6 years of age and older
- Helikit<sup>®</sup> is practical and features high sensitivity and specificity.

# Helikit® MS01



# Helikit<sup>®</sup> MS01

- Read through the Directions for Use insert provided in the kit including
  - Patient Preparation
  - Warnings and Precautions
- The Helikit MS01 utilizes specimen tubes to collect breath samples for analysis on an Isotope Ratio Mass Spectrometer (IRMS) (must be sent in to a central testing facility equipped with a Mass Spectrometer).

# Helikit<sup>®</sup> MS01 contents


- 1 pre-mixed Cup
- 1 set of Directions for Use
- 1 Set of **Green** and **Yellow** labels for tubes
- 1 **Green** Capped Breath Collection Tube
- 1 **Yellow** Capped Breath Collection Tube
- 2 individually wrapped straws
- 1 mailing box
- 1 registration card

# Helikit<sup>®</sup> Patient Preparation

- Patients should not drink or eat for at least **4 hours** before taking this test.
- Helikit<sup>®</sup> test should be scheduled prior to barium tests if both are scheduled for the same day.
- No other breath tests should be scheduled at the same time as Helikit<sup>®</sup>.
- Some medications are known to suppress *H. pylori*. Patients must discontinue the use of the following groups of medications for the specified time to avoid false negative results:
  - **Proton pump inhibitors (H<sup>+</sup>, K<sup>+</sup>-ATPase Inhibitor) – 3 days**
  - **Histamine H2 receptor antagonists – 1 day**
  - **Antibiotics – 4 weeks**
  - **Bismuth Preparations – 2 weeks**

# Helikit® procedure

- Complete the **registration card** with the patient and physician information.
  - This information should correspond to the information provided on the green/yellow labels.
- Complete the **green/yellow labels** with the patient name and identification number.

 <b>Isodiagnostika</b> a division of Paladin Labs Inc. 100 ALEXIS-NIHON BLVD., SUITE 800, ST-LAURENT, CANADA, H4M 2P2 • TOLL FREE 1-888-867-7426		<b>LAB</b> <input type="text"/>
<b>PATIENT</b>	Name: _____	DOB: _____ (DDMMYY)
	Address: _____ City Province Postal Code	<input type="checkbox"/> Male <input type="checkbox"/> Female ID# _____
<b>SAMPLE</b>	Test Requested: <input type="checkbox"/> Helikit® Urea Breath Test <input type="checkbox"/> Other - Specify _____	
	Sample Collected Date: _____ (DDMMYY)	
<b>PHYSICIAN</b>	Name: _____	Phone: _____
	Address: _____ City Province Postal Code	Fax: _____
Physician Comments: _____		

<b>HELIKIT®-MD</b> Baseline - First breath sample Premier échantillon d'air expiré
PATIENT NAME/NOM DU PATIENT: _____
IDENTIFICATION NUMBER/NUMÉRO D'IDENTIFICATION: _____
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<b>HELIKIT®-MD</b> Second breath sample (after 30 minutes) Deuxième échantillon d'air expiré (après 30 minutes)
PATIENT NAME/NOM DU PATIENT: _____
IDENTIFICATION NUMBER/NUMÉRO D'IDENTIFICATION: _____
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# Procedure: Step 1

## Collect the baseline breath sample

Collect the first breath sample into the **GREEN** capped collection tube as follows:

- Remove screw cap from the collection tube.
- Ask the patient to:
  - Take a normal breath.
  - Then **exhale fully for 4 seconds** through a straw into the bottom of the collection tube.
  - While exhaling, withdraw the straw. Do not exceed 8 seconds total.
- **Immediately** replace screw cap on the collection tube.
- Tighten until snug and affix completed **green** label to the tube. This is the BASELINE sample.



# Procedure: Step 2

## Prepare and drink the solution

- Shake the plastic container to loosen powder which may have settled upon storage.
- Prepare solution by adding tap water to fill line on the plastic container.
- Mix until completely dissolved.

Note: If particulate matter is visible in the reconstituted  $^{13}\text{C}$ -urea solution after thorough mixing, the solution should not be consumed.

- Instruct the patient to drink the entire solution.
- Start the 30 minute time period once the solution has been consumed.
- **Instruct the patient to not drink or eat anything during the 30 minutes.**



# Procedure: Step 3

## Collect the second breath sample

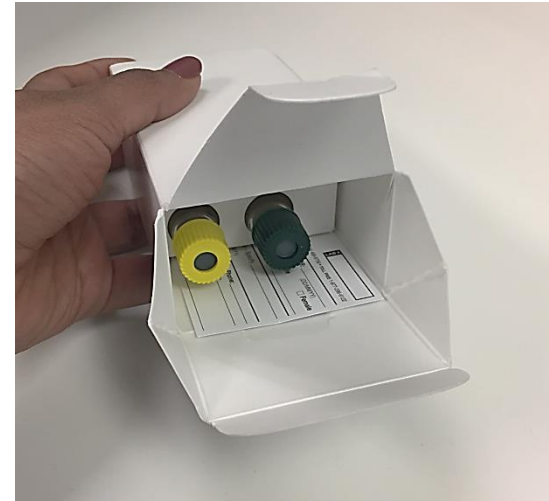
- 30 minutes after drinking the solution, instruct the patient to:
  - Take a normal breath.
  - Then **exhale fully for 4 seconds** through a straw into the bottom of the **yellow** collection tube.
  - While exhaling, withdraw the straw. Do not exceed 8 seconds total.
- Immediately replace screw cap on the collection tube.
- Tighten until snug and affix completed **yellow** label to the tube.



# Procedure: Step 4

## Send the samples to a testing facility

- Insert the two collection tubes into the mailing box provided
- Include the completed patient registration card
- Send the mailing box to a testing facility for analysis.



Note: The breath test samples, if stored between 15°C and 30°C (59° to 89°F), are stable up to 6 months from the collection date.

For further information on Helikit<sup>®</sup> , please visit: [www.helikit.com](http://www.helikit.com)

