Helikit® Breath Test for the Diagnosis of Helicobacter pylori Infection
**Principle of 13C 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 CO$_2$.

- The labeled 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® is practical and features high sensitivity and specificity.
Helikit® MS01
Helikit® 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® 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® Patient Preparation

- Patients should not drink or eat for at least 4 hours before taking this test.
- Helikit® 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®.
- 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⁺, K⁺-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.
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 13C-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®, please visit: www.helikit.com