

Urea Breath Test for *Helicobacter pylori* by Meretek

Principle:

The Breath Tek UBT collection kit is intended for use in the qualitative detection of urease associated with *Helicobacter pylori* infection in the human stomach and as an aid in the initial diagnosis and post-treatment monitoring of *Helicobacter pylori* infection in adult patients. The causal relationship between *H. pylori* and chronic active gastritis, duodenal ulcer, and gastric ulcer is well documented. In the Breath Tek UBT -IR300 for *H. pylori*, 3g of reconstituted Pranactin –Citric containing 75 mg of ^{13}C -urea is ingested by the patient. In the presence of urease associated gastric *H. pylori*, ^{13}C -urea is decomposed to $^{13}\text{CO}_2$ and NH_4 . The $^{13}\text{CO}_2$ is absorbed in the blood and then exhaled in the breath. This results in an increase in the ratio of $^{13}\text{CO}_2$ and $^{12}\text{CO}_2$ in a POST-DOSE breath sample taken after the Pranactin –Citric solution was consumed, compared to a BASELINE sample taken before the Pranactin –Citric was consumed. In the absence of gastric *H. pylori* the ^{13}C -urea does not produce $^{13}\text{CO}_2$ in the stomach and the ratio $^{13}\text{CO}_2$ and $^{12}\text{CO}_2$ in the POST-DOSE breath sample remains essentially the same as the BASELINE.

Specimen Requirements:

Each specimen must contain at least 1.5 volume percent CO_2 to assure the tube contains adequate breath for analysis.

Interferences:

1. Antimicrobials, proton pump inhibitors and bismuth preparations taken within two weeks prior to performing the BreathTek UBT may give false negative results.
2. Premature post-dose breath collection time can lead to false negative results for a patient with marginally positive results.
3. A negative result does not rule out the possibility of *Helicobacter pylori* infection. False negative results do occur with this procedure. If clinical signs are suggestive of *H. pylori* infection, retest with a new sample or an alternate method.
4. A false positive test could occur in patients who have achlorhydria.
5. Other gastric spiral organisms producing urease such as *Helicobacter heilmannii* may cause false positive results.
6. Patients with achlorhydria may show false positive results.
7. Phenylketonurics: Contains Phenylalanine.
8. If particulate matter is visible in the reconstituted Pranactin-Citric solution after thorough mixing, the solution should not be used.

Critical Values:

None defined

Interpretation of Results:

1. A result ≥ 2.4 Delta/Baseline is interpreted as diagnostically positive for the presence of urease associated with *H. pylori*.
2. A result < 2.4 Delta/Baseline is interpreted as diagnostically negative for the presence of urease associated with *H. pylori*.

Quality Control:

1. Reproducibility test to be performed ONCE PER MONTH
 - a. Reproducibility tests the accuracy and precision of the POCone breath analyzer, as well as checking the components of the device itself.
 - b. This test is performed by in-house testing personnel either using their own breath or staff volunteer's. Do not perform reproducibility on patient samples.
 - c. Select YES in the "5 Reproducibility" screen.
 - d. Detach sample ports from the instrument and attach the Y-tube ends into the now vacated inlet holes.
Prepare the 5L Mylar breath collection bag by holding the breath for 5-10 seconds then exhaling into the bag.
 - e. The bag should be $\geq 50\%$ full. You may take several breaths to complete this step.
 - f. Attach the third Y-tube end into the 5L breath collection bag.
 - g. The screen will prompt "Please input meas. Repeat 10 times". Enter the number
 - h. Select YES at "Test start?"
2. Evaluating Results of Reproducibility Test:
 - a. The expected range of the $^{13}\text{CO}_2/^{12}\text{CO}_2$ ratio for human breath is 1.000 ~ 1.150. The average difference for the 10 measurements must fall within (-0.3% and +0.3%). The standard deviation of the 10 measurements is $\pm 0.3\%$.

Procedure:

1. Patient Instructions
 - a. Two weeks prior to testing, instruct the patient not to ingest antimicrobials, proton pump inhibitors, or bismuth preparations.
 - b. Verify that the patient has fasted for 1 hour prior to the test.
 - c. Verify that the patient is NOT on a phenylalanine restricted diet.

2. Kit Instructions

- a. Verify that the patient has been prepared for the test as specified in step 1.
- b. Prepare the Pranactin®-Citric no more than sixty minutes prior to administering the patient test.
- c. Ensure all contents of the Pranactin®-Citric pouch are settled at the bottom of the bag.
- d. With clean scissors, cut off the top of the packet and empty all the contents into the drinking cup provided in the BreathTek kit. Make sure to transfer all of the contents by tapping on the bottom of the pouch.
- e. Add potable water to the fill line indicated on the outside of the container.
- f. Replace the lid securely and swirl up to two minutes to dissolve the packet contents completely. The resulting solution should be clear with no particulate matter.

****If particulate matter is present after thorough mixing, do not use the solution****

3. Collect the baseline sample

- a. Label the blue breath collection bag with the patient's name, medical record number and one of the provided bar code labels.
- b. Remove the pull-off cap from the mouthpiece of the collection bag.
- c. Instruct the patient to breath normally.
- d. Take a deep breath in then pause momentarily.
- e. Exhale into the mouthpiece of the bag.
- f. Replace the mouthpiece cap on the bag.

4. Administer the Pranactin-Citric solution

- a. Instruct the patient to drink all of the Pranactin-Citric solution in one sip with the provided kit straw.
- b. Advise the patient not to rinse the mouth with the solution before swallowing.
- c. The patient should sit quietly without ingesting food, drink, or tobacco products for 15 minutes.

5. Collect the post-dose sample

- a. Prepare the pink breath collection bag with the patient's name, medical record number, and the remaining bar code label.
- b. Repeat the collection technique used for collecting the baseline sample.

6. Specimen storage

- a. The specimen may be stored at 15-30°C for up to seven days in the plastic sample transport bag until analysis can be performed.

7. Measuring samples

- a. Insert the baseline sample bag onto the Baseline port. Insert the post-dose sample bag onto the Sample port. Push the breath collection bags towards the instrument until the black O-ring is no longer visible.
- b. From “Continue QC sample” screen, Select NO.
- c. Enter the patient medical record number, confirm the bags are securely attached, then confirm the patient medical record number is correct and select YES.
- d. POCono will print two copies of patient results.
- e. From “Continue patient sample” screen you may continue to run patient tests by selecting YES.

Limitations of Test:

1. The BreathTek UBT should not be used until four weeks or more after the end of treatment for the eradication of *H. pylori*, as earlier post-treatment assessment may give a false negative result.
2. The performance characteristics for persons under the age of eighteen have not been established for this test.
3. The specimen integrity of breath samples and reference gases stored in breath bags under ambient conditions has not been determined beyond seven days.
4. A correlation between the number of *H. pylori* organisms in the stomach and the BreathTek UBT results has not been established.
5. The predicate device (Meretek UBT) was standardized in asymptomatic healthy volunteers and subsequently validated in clinical trials limited to patients with documented duodenal ulcer disease.

Results reporting:

Results are reported as negative or positive.

Calibration:

No calibration is required.

Reagents:

1. Breath Tek UBT collection kit: should be stored at 15-30°C. Pranactin[®]-Citric has an expiration date. Do not use beyond the expiration date stated on label.

Reference:

1. $^{13}\text{CO}_2$ Breath Analyzer POCone Infrared Spectrophotometer Instruction Manual. Meretek Diagnostics, Inc. February, 2005.2. Urea Breath Test for *H. pylori*: Introduction and Test Instructions. Meretek Diagnostics, Inc. November, 2005.
2. BreathTek package insert.

Revised 2/2/11