



LABORATORY UPDATE

October 29, 2018

UREA BREATH TEST NOTIFICATION COLLECTION KIT CHANGE

Dear Physicians and Staff,

Effective October 29, Enzo Clinical Labs will be changing collection kits for Urea Breath Test (order code 8832) to the IDkit Hp™ Two collection kit (Blue and Gray bags). To collect the sample, the patient first blows a breath of air into the Blue bag, drinks a solution, and after 15 minutes breathes into the Gray bag. The bags are then sent at room temperature to the lab to be analyzed. Detailed instructions for sample collection are found in the kit, on Enzo Clinical Lab's website or on the reverse side of this Lab update.

We will accept the current collection kit (Blue and Pink bags) for a short transition period after which they will no longer be accepted for testing.

For *H. pylori* testing guidelines please access <http://www.exalenz.com/recommended-guidelines/>

Test Name	Test code	Specimen requirements	Turnaround Time
Urea Breath Test	8832	Blue and Gray breath collection bags.	3 days



We appreciate the continued opportunity to serve you and your patients and welcome any questions or concerns you may have. You can reach us at 631-755-5500 or talk to your ECL sales or service representative for more information.

Sincerely,

Dieter Schapfel, MD
Medical Director

INSTRUCTIONS FOR PERFORMING THE BreathID® H. pylori test, using the IDkit Hp™ Two single-use kit.

Inform the patient that the Citrica contains 84mg of phenylalanine per packet of Citrica Powder. Phenylketonurics restrict dietary phenylalanine.

The patient should have fasted at least one hour before administering the solution. The patient should not have taken antimicrobials, proton pump inhibitors or bismuth preparations within two weeks prior to administering the test.

1. Collection of the BASELINE breath sample
 - a. Label each bag with patient identification, date and fill time.
 - b. Remove cap from the mouthpiece of the blue BASELINE bag.
 - c. Instruct the patient to take a deep breath, hold their breath for 4 to 5 seconds and then exhale directly into the mouthpiece of the blue BASELINE breath bag until completely full.
 - d. If the bag is not full repeat step II.
 - e. Replace the cap on the bag mouthpiece and firmly press until it clicks and is securely locked into place.
2. Preparing the test drink
 - a. Dissolve the Citrica Powder and the 13C-enriched urea tablet in 5.1 to 6.8 oz. (150 to 200 ml) of tap water in a single drinking cup of at least eight ounces (236 ml) in capacity.
 - b. Stir thoroughly with the provided straw for a few minutes, until the Citrica Powder and the 13C-urea tablet are completely dissolved.
 - c. Keep the stirring straw in the cup to serve for drinking.

(Tiny particles may remain visible after thorough mixing. However, if more substantial particulate matter is still present after five minutes of stirring, discard the solution and repeat the procedure with a new kit.)

3. Administering the test drink.
 - a. Give the prepared test drink to the patient.
 - b. Ensure that the patient drinks the solution through the straw.
 - c. The patient must drink the solution within two minutes and consume the entire amount.
 - d. Start a timer for 15 minutes.
 - e. After the patient finishes drinking the solution, record the present time plus (+) another 15 minutes in the Time to Fill field on the gray POST INGESTION bag.
4. Collection of the POST INGESTION breath sample:
 - a. Fifteen minutes after the administration of the test drink (but not later than 20 minutes after administration) remove the cap from the mouthpiece of the gray POST INGESTION bag.
 - b. Instruct the patient to take a deep breath, hold their breath for 4 to 5 seconds and then exhale directly into the mouthpiece of the gray POST INGESTION bag until it is full.
 - c. If the bag is not full repeat step II.
 - d. Replace the cap on the bag mouthpiece and firmly press until it clicks and is securely locked into place.
5. Storage of Breath Sample Bags
 - a. Assure both filled Breath Sample Bags are correctly labeled and all fields are complete for future identification.
 - b. Place both filled Breath Sample Bags (the blue BASELINE bag and the gray POST INGESTION bag) into the provided sample transport bag.
 - c. Until analyzed, Breath Sample Bags should be stored at room temperature (15-30°C, 59-86°F), protected from direct sunlight and sharp objects. Refrain from applying any external pressure on the Breath Sample Bags.