

Effective Thursday, March 17, 2022, ACL Laboratories will implement a new test system for urea breath testing (Test Order Code LAB11090). The new test system will include a new testing kit that will be available to order beginning Monday, March 14, 2022. Please discard any old kits you have on Thursday, March 17, 2022. (Note: There are no special instructions for disposal of unused kits as there are no hazardous materials in the kit.) Information about the new system is provided below, as well as a photo of the new kit.



BreathID® Kit

Clinical Background:

The urea breath test is a non-invasive, fast, and extremely accurate test (95% sensitivity, 92% specificity) detecting the presence of active *H. pylori* infection.

It has a higher diagnostic accuracy and lowest false-negative rate for the detection of *H. pylori* when compared to the *H. pylori* stool antigen test (84% sensitivity, 91% specificity).

Testing for *H. pylori* should be performed only if the clinician plans to offer treatment for positive results. Indications for testing include:

- Detect and diagnose for *Helicobacter pylori* infection in patients suspected to have active *H. pylori* infection
- Monitoring response to therapy

This test **is not appropriate** for asymptomatic people. A negative result **does not** rule out the possibility of *H. pylori* infection. If clinical signs are suggestive of *H. pylori* infection, retest with a new sample or an alternate method.

Specimen Collection Requirements remaining the same:

- Required 1 hour fasting prior to testing
- Discontinuation of proton pump inhibitors (PPI), Bismuth preparations, and antibiotics two weeks prior to testing. (This helps reduce false negative results.)
- The drink contains Phenylalanine (84 mg/dose) and should not be used in patients with phenylketonuria (PKU).
- Post dose sample is collected at 15 minutes after drink ingestion
- Testing is restricted for use in patients < 3 years of age.

Important Differences/Changes with the New System:

New Method (Meridian- Breath ID) Effective Thursday, March 17, 2022	Current Method
<ul style="list-style-type: none"> • Bag Color: Blue (baseline), gray (post dose) • Drink: Citrica Powder + ¹³C-enriched urea 75mg tablet • Recommended retest 6 weeks after treatment • Testing during pregnancy is not recommended (insufficient data) 	<ul style="list-style-type: none"> • Bag color: Blue (baseline), pink (post dose) • Drink: Pranaactin Citric Powder • Recommended retest 4 weeks after treatment • No information on testing during pregnancy

References:

Fashner J, Gitu A. Diagnosis and treatment of peptic ulcer disease and *H. pylori* infection. *Am Fam Physician*. 2015; 15(91): 236-242.

<https://www.uptodate.com/contents/indications-and-diagnostic-tests-for-helicobacter-pylori-infection-in-adults>

For additional information regarding these tests, as well as specimen collection requirements, please contact ACL Client Services at 1.800.877.7016 or visit our website at www.acllaboratories.com/test-catalog/.