Notification of Method Change

February 2022

Laboratory Testing Updates

H.Pylori method change:

UCHealth laboratories will be changing the method of testing for H.Pylori Breath Testing. UCHealth is transitioning from Otsuka Breathtek UBT testing kit to Meridian BreathID® IDKit HPTwo. UCHealth will run both methods during the transition period. As of June 3rd, 2022, the Otsuka BreathTek UBT kit will no longer be acceptable.

There are a few differences between collection kits. Thoroughly review collection instructions within the BreathID IDKit HP Two prior to use. Results obtained on the new method will include change of method result comment. Contact MCR laboratory with further questions regarding method or collection practices. The following QR code leads to an online training video for the BreathID IDKit HP Two.



Scan to watch video

Method	BeathID® Meridian IDKit HP Two **New Method Meridian Item number AC00063	Otsuka BreathTek UBT
Technology	Molecular Correlation Spectroscopy	Infrared Spectrophotometry
Specimen Stability	14 Days	7 Days
Sensitivity	100%	95.2%
Specificity	97.9%	89.7%
Patient testing	Validated for patients 3 years and older. Height and weight is not required.	Validated for pediatric patients ages 3-17yo following adjustment calculation for height and weight. Validated for patients ages 18 and older without a calculation.

Limitations for H.Pylori BreathID® IDKit HP Two include:

1. A negative result does not rule out the possibility of H. pylori infection. False negative results can occur with this procedure. If clinical signs suggest H. pylori infection, retest with a new sample or an alternate method.

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For more information or questions, please call 970.495.8715

UCHealth Northern Colorado

Laboratory Services

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- 2. A false positive test may (rarely) occur due to urease associated with other gastric spiral organisms observed in humans such as Helicobacter heilmanni.
- 3. A false positive test could occur in patients who have achlorhydria.
- 4. Antimicrobials, proton pump inhibitors, and bismuth preparations are known to suppress H. pylori. Ingesting these medications **within two weeks** prior to performing the breath test may produce false negative test results.
- 5. Post treatment monitoring of H. pylori should be performed after at least six weeks of treatment for H. pylori infection. Earlier assessment may give false results.
- 6. Data is insufficient for recommending the use of this test on patients with total or partial gastrectomy.

The following contacts for each region can be utilized for supply fulfillment and education throughout the transition. Please review the timeline below regarding the method change.

Resources and contacts:

North region: Robyn Boswell Located at Medical Center of the Rockies 970-624-1512

Central region: Kathi Wilcox at UCHealth Central 720-848-7031

South region: Aaron Nuttall at UCHealth Memorial Central 719-365-2626

UCHealth Teams Page *H.Pylori Method Switchover*: can be used for inventory management, education resources, and communication.

February 22, 2022

• Lawson number # 85163 for BreathTek UBT kits will freeze. UCHealth Kits will need to be shared between sites.

February 28, 2022

• New kits will be distributed to one main location in each region. Please share old kits with those within your region before using new kits.

March 1, 2022

- •Testing will be available on the new and old kit.
- BreathID acceptable!
- BreathTek acceptable!

April 3, 2022

- •The new item will be orderable in Lawson. Please continue to use up the old kit prior to ordering the new kit.
- BreathID acceptable!
- BreathTek acceptable!

June 3, 2022

- •Otsuka BreathTek UBT testing will be discontinued. This will require a recollection if the BreathTek kit is used.
- BreathID acceptable!
- BreathTek no longer acceptable!

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