October 2016

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Test Discontinuation
Helicobacter pylori IgG serology
Effective 12/01/2016

TECHNICAL BULLETIN

Effective **December 1, 2016**, the present Helicobacter pylori IgG serology test will no longer be available. To support high quality care, the *Helicobacter pylori* Breath Test or *Helicobacter pylori* stool antigen test will continue to be available to order. These changes support the current diagnostic guidelines recommended by the American College of Gastroenterology and the American Gastroenterology Association.

Antibody tests cannot distinguish between active and past infection with adequate sensitivity and specificity. Despite older literature suggesting that IgG serology can be used as a test of cure after 18 months, this has been proven to be inaccurate. Both the urea breath test and stool antigen are FDA cleared for use as a test of eradication. They are both currently offered at DMCUL.

Inactivated test codes
Helicobacter pylori IgG

Sunquest code: HELI **Antrim code: 125153**

See attached Technical Bulletins for ordering information for Breath Test and Stool antigen EIA

Technical inquiries:

Michael Long, PhD, Technical Director, Immunodiagnostic Laboratory
Technical inquiries: 7:00 AM - 3:00 PM: DMCUL Immunodiagnostic Laboratory,(313) 993-0712;
Medical Director: Barbara Anderson, MD: Email: banderso@dmc.org

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September 2013

TECHNICAL BULLETIN

Helicobacter pylori Urea Breath Test (BreathTek™ UBT®)

Now available in house, note new test code

Helicobacter pylori (*H. pylori*) is a Gram Negative bacilli that has been identified as an important pathogen in the upper GI tract. The *H. pylori* causes chronic active gastritis, duodenal and gastric ulcer. *H.pylori* Urea Breath Test (BreathTek™ UBT®) is a non-invasive, non-radioactive method for detecting urease activity of *H. pylori* infection. The assay is FDA approved and offers 95.2% sensitivity and 89.7% specificity compared with endoscopic methods for diagnosis of active *H.pylori* infection or confirmation of the cure.

Clinical Use: Diagnosis of *H pylori* infection and therapeutic monitoring/test of cure in patients with *H. pylori* infection

Principle of the test: The assay indirectly detects the presence of *H pylori*-associated urease by measuring CO_2 in the patient's breath. A baseline breath sample is collected before (blue bag) the patient ingests **Pranactin®-citric** (^{13}C-urea, ie, urea labeled with a naturally occurring, non-radioactive carbon isotope). A second sample is collected shortly after (pink bag) the ingestion. *H pylori*-associated urease degrades the urea, producing ammonia and CO_2. The resultant CO_2 is absorbed in the blood and then exhaled. An increase in the ratio of $^{13}CO_2$ to $^{12}CO_2$between the pre- and post-ingestion samples indicates the presence of *H pylori*-associated urease.

Ordering Information: **Test name:** BreathTek™ UBT®): **CPT code:** 83013 **Antrim Code**: 335695
Sunquest Code: BRETEK **CIS Code:** Breathtek

Sample collection kit: BreathTek UBT® Collection Kit is available through DMCUL sales representatives or client services at (313) 745-4100
Patient preparation and Sample collection: Please see the back page of this Technical Bulletin.

Limitations: 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 specimen or an alternate method.
False negative results could be due to:

1. Antibiotics, proton pump inhibitors, and bismuth preparations use within the two weeks preceding the test.
2. Administration of the breath test less than 4 weeks after completion of therapy to eradicate *H. pylori.*
3. Premature or late collection of the post-dose specimen.

False positive results could be due to:

1. Patients with achlorhydria.
2. Rinsing the Pranactin citric in the mouth allowing contact with urease positive bacteria.
3. The presence of other gastric spiral organisms such as *Helicobacter heilmanii.*

Result reporting: The assay is qualitative and the results are reported as Positive or Negative.

Reference range: Negative

Storage/Transport Temperature: Ambient (room temperature)

Unacceptable specimens: Bags not fully inflated or only one of the two bags submitted. Specimens from individuals 18 years or younger will not be accepted.

Production schedule: Testing will be performed 7 days a week. Results are available within 24 hours after receipt of sample in the laboratory.

Michael Long, PhD, Technical Director, Immunodiagnostic Laboratory
Technical inquiries: 7:00 AM - 3:00 PM: DMCUL Immunodiagnostic Laboratory, (313) 993-0712

Patient preparation: The patient should fast and abstain from smoking for 1 hour prior to test administration. The patient should not have taken antibiotics, proton pump inhibitors (e.g., Prilosec®, Prevacid®, Aciphex®, Nexium®), or bismuth preparations (e.g., Pepto-Bismol®) within the previous 14 days. When used to monitor treatment, the test should be performed four weeks after cessation of definitive therapy. Pranactin®-citric contains a small amount of aspartame sweetener. Test may not be suitable for patients with phenylketonuria whose dietary phenylalanine should be restricted.

Specimen Collection: Paired breath samples (pre and post) collected collection kit bags and must be submitted together. Follow instructions provided with kit.

1) Label breath collection bags with patient name, MRN, date and time of collection, and designate Pre (blue) or Post (pink).

2) Collect the baseline breath specimen:
-Remove cap from collection bag (blue).
-Have patient take a deep breath, pause momentarily then exhale into the mouthpiece of the bag filling it completely.
-Replace cap on the bag.

3) Prepare Pranactin®-Citric solution:
-Empty packet from test kit into the cup provided.
-Add drinking water up to the fill line (raised ridge).
-Replace lid; swirl for up to two minutes until completely dissolved. Solution should be clear. The solution is stable up to 60 minutes at room temperature.

4) Instruct patient to drink the solution without stopping using the straw provided. Advise the patient not to "rinse" the mouth with the solution before swallowing.

5) Set timer for 15 minutes. Start timer as soon as the patient has completed drinking. Patient should sit quietly without eating, drinking, or smoking.

6) Prepare the post specimen collection (pink) bag. At exactly 15 minutes, have the patient take a deep breath, pause momentarily and then exhale to fill the second sample collection bag (pink). Note: for a valid result, the post specimen must be collected 15 minutes after administration of the Pranactin®-Citric Solution.

July 2013

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New Test Notification

Helicobacter pylori Stool Antigen

TECHNICAL BULLETIN

Effective 8-5-2013, the Detroit Medical Center University Laboratories will begin performing the *Helicobacter pylori* Stool Antigen assay in-house, with next-day results after receipt in lab.

- **Detect active *Helicobacter pylori* infection** - *Helicobacter* stool antigen detection is intended to aid in the diagnosis of active *H. pylori* infection. Serologic testing is not specific to active infection and is not recommended for that purpose.
- **Utility as a test of cure** - Conventional medical practice recommends that testing to confirm the loss of *H. pylori* stool antigen be done at least four weeks following completion of therapy.
- **Can be used in all age groups** - The *Helicobacter* stool antigen test has been evaluated extensively and has been accepted as an accurate noninvasive test for active infection both before and after treatment for patients of all ages.
- **Fully compliant with ACG and AGA guidelines for *H. pylori* testing** – Furthermore, the recent Maastricht 2 Consensus Report recommends the use of the stool antigen as an aid in the diagnosis of *H. pylori* disease in the primary care setting.
- **Limitations** - Antimicrobials, proton pump inhibitors and bismuth preparations are known to suppress *H. pylori*, and ingestion of these prior to *H. pylori* testing may cause false negative results.
    - However, a positive result for a patient ingesting these compounds prior to performing the *Helicobacter* stool antigen test, should be considered accurate.

- **Order " HELICOBACTER PYLORI STOOL ANTIGEN" (335471)**
- **Submit a minimum of 1 g of stool in an airtight container and store/transport at 2-8° C until tested.**
    - ***Reference Value: Negative***
    - ***CPT code: 87338***

Technical inquiries:

- DMCUL Microbiology Laboratory, (313) 993-0700
- Hossein Salimnia, PhD, Chief Technical Director, Microbiology, (313) 745-2130
- Paul Lephart, PhD, Associate Technical Director, Microbiology, (313) 993-0490