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|---|---|---|---|---|
| Article | 3,500 | S: 250 | 40 | 6 |
| Brief Communication | 1,500 | S: 250 | 20 | 1 each |
| Citation Classics | 600 | Non Applicable | 6 | Non Applicable |
| Clinical Case Study<br>*Case description with 3–5 questions and up to 5 Points to Remember* | 1,500<br>(500) | Non Applicable | 10 | 2 |
| Clinical Case Study Commentary | 300 | Non Applicable | Non Applicable | Non Applicable |
| Editorial | 1,500 | Non Applicable | 15 | Non Applicable |
| Letters to the Editor / Reply | 750 | Non Applicable | 5 | 1 |
| Mini-Review Article | 3,500 | S: 250 | 40 | 4 |
| Opinion | 1,500 | Non Applicable | 15 | 1 |
| Perspective | 1,500 | Non Applicable | 5 | 1 |
| Review Article | 5,000 | S: 250 | 75 | 6 |
| What Is Your Guess?<br>*Case description w/ 3 Questions*<br>*Case discussion* | >75<br>>75 | Non Applicable | 5 | 1 |

*This chart represents common types of submissions to *Clinical Chemistry*.

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- ☐ Numbered pages with references numbered sequentially in main text
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AACC Presents a Webinar

# Antinuclear Antibody Screening:
## Issues and Answers

**Wednesday, September 22, 2010 ~ 2:00-3:30 pm Eastern U.S. Time**

The antinuclear antibody (ANA) test is the mainstay for screening for a number of autoimmune disorders, which affect approximately 13-22 million people in the US. The immunofluorescence (IF) ANA Assay has long been considered the gold standard for the detection of ANAs. This method uses cell lines, in particular HEp-2 cells, which contain approximately 100 to 150 autoantigens and can provide both a pattern and a titer to assist in diagnosis.

In recent years, enzyme immunoassays (EIA) and solid phase multiplex immunoassays have been introduced for ANA screening. These assays can process specimens more quickly and at less cost than the traditional IF technique. However, they are less sensitive for some conditions because they can detect only specific autoantibodies that are directed against autoantigens included in the assay. Further, the composition of the EIA and multiplex assays varies from as few as 8-12 antigens to a much larger number when extracts from HEp-2 cells and /or chromatin material is included.

The decision as to which of the tests to use to screen patient serum for the presence of autoantibodies is highly controversial. This program will provide both the laboratory's and the rheumatologist's perspective on the pros and cons of different methodologies used to screen for ANAs. Key components of each technology will be reviewed, including false positives and false negatives. Strategies to overcome these limitations and improve screening, diagnosis and test result communications will be discussed.

Attend and you will know:

- Why the American College of Rheumatologists considers the immunofluorescence ANA assay to be the gold standard for ANA screening
- The importance of standardization of ANA laboratory testing and results
- How to compare the different methodologies currently available
- How to evaluate which testing method is best for your lab
- What to include with your ANA test results to ensure proper test interpretation

**The Experts:**

*David Keren, MD, Medical Director, Warde Medical Laboratory, Ann Arbor, MI*

*Donald Bloch, MD, Associate Physician, Massachusetts General Hospital, Assistant Professor of Medicine, Harvard Medical School, Boston, MA*

*John L. Carey, MD, Vice Chair, Clinical Pathology, Henry Ford Hospital, Detroit, MI*

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# Critical Issues in Alcohol and Drugs of Abuse Testing

## Edited by Amitava Dasgupta

*2009, 319 pages, softcover*
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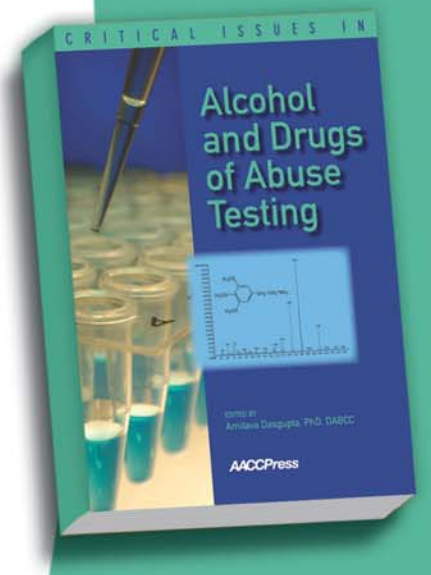


*Critical Issues in Alcohol and Drugs of Abuse Testing* addresses problems encountered in workplace alcohol and drug testing and how to resolve such problems. People try to pass drug tests by using a variety of urinary adulterants, and this book reviews, in detail, how to catch these cheaters. Ingestion of certain prescription medications or poppy seed-containing food, however, may also cause positive results in drug testing. Two chapters are devoted to reviewing true analytical positive results in drugs of abuse testing. In addition, drug testing using alternative specimens such as hair, saliva, and sweat is also addressed. Additional chapters review the following:

- Pharmacogenomics of alcohol abuse
- Pharmacogenomics of drugs of abuse
- Abuse of magic mushrooms, peyote cactus, khat, and volatiles
- Sports drug testing

*Critical Issues in Alcohol and Drugs of Abuse Testing* will be helpful to toxicologists, medical review officers, pathologists, and medical technologists as a quick handbook and reference book to address problems encountered in alcohol and drugs of abuse testing.

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# Using **serology** to test for *H. pylori* is **no better** than a coin toss.

*"… in a community with an H. pylori prevalence of less than ~20%, as is the case in much of the United States…*

*a positive [antibody] test is **no better than a coin toss** in predicting the presence of active infection.*

*In low prevalence populations, **antibody tests should be avoided altogether.***

*Positive results should be confirmed with a test that identifies active infection, such as the UBT."* [1]

**Fact:** Serology is not accurate enough for use in routine clinical practice.[2]

**Fact:** Because serology cannot distinguish between active and passive infection, it cannot be used as a test for eradication.[2]

**Fact:** The $^{13}C$ urea breath test (UBT) is recommended by both the AGA and ACG.[1,3]

**Fact:** The UBT is the most reliable non-endoscopic test to document eradication of *H. pylori* infection.[1]

Despite the evidence, serologic testing is still used by the majority of physician practices. There is a better way: BreathTek® UBT. It is easy for your staff to administer, convenient for your patients and widely available as either a laboratory or in-office test.

BreathTek UBT is also covered by Medicare and most insurance providers using the following codes*: 83014 drug administration, and 83013 *Helicobacter pylori* breath test analysis for urease activity, non-radioactive isotope.

*Urea Breath Test for H. pylori*

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**Learn more at www.BreathTekFacts.com, or contact us at 1-888-637-3835.**

[1] Chey and Wong, American College of Gastroenterology Guideline on the Management *Helicobacter pylori* Infection. Am J Gastroenterol 2007; 102: 1808-1825.

[2] Vakil N, Fendrick M. How to test for *Helicobacter pylori* in 2005. Cleve Clin J Med. 2005; 72 (Suppl 2): S8–S13.

[3] American Gastroenterological Association Medical Position Statement: Evaluation of Dyspepsia. Gastroenterol. 2005; 129: 1753-1755.

* This reimbursement information is being provided to help the health care professional understand and comply with billing and reimbursement requirements that may apply to products. Use of codes identified here does not guarantee coverage or payment at any specific level.

April 2010 0510A-0397

## Brief Summary

**Intended Use:**
The BreathTek™ UBT Collection Kit is intended for use in the qualitative detection of urease associated with *Helicobacter pylori* in the human stomach and as an aid in the initial diagnosis and post-treatment monitoring of *H. pylori* infection in adult patients. The test may be used for monitoring treatment if used at least 4 weeks following completion of therapy. For these purposes, the system utilizes an Infrared Spectrophotometer for the measurement of the ratio of $^{13}CO_2$ to $^{12}CO_2$ in breath samples. For administration by health care professionals. To be administered under a physician's supervision.

**Warnings and Precautions:**
1. For in vitro diagnostic use only. The Pranactin®-Citric drug solution is taken orally as part of the diagnostic procedure.
2. Phenylketonurics: Contains Phenylalanine (one of the protein components of Aspartame), 84 mg per dosage unit. (For reference, 12 ounces of typical diet cola soft drinks contain approximately 80 mg of Phenylalanine.)
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 alternative method.
4. Antimicrobials, proton pump inhibitors, and bismuth preparations are known to suppress *H. pylori*. Ingestion of these within 2 weeks prior to performing the BreathTek UBT may give false negative results.
5. A false positive test may occur due to urease associated with other gastric spiral organisms observed in humans such as *Helicobacter heilmannii*.
6. Premature POST-DOSE breath collection time can lead to a false negative diagnosis for a patient with a marginally positive BreathTek UBT result.
7. A false positive test could occur in patients who have achlorhydria.
8. If particulate matter is visible in the reconstituted Pranactin®-Citric solution after thorough mixing, the solution should not be used.

**Limitations:**
1. The BreathTek UBT should not be used until 4 weeks or more after the end of treatment for the eradication of *H. pylori* as earlier post-treatment assessment may give false negative results.
2. The performance characteristics for persons under the age of 18 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 7 days.
4. A correlation between the number of *H. pylori* organisms in the stomach and the BreathTek UBT result 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.

December 2009 0508L-0177B

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