MassTox® IMMUNOSUPPRESSANTS BY TANDEM-MS

- Reagent Kit
- Deuterated Internal Standards
- Trap Column Technology

> STABLE DEUTERATED INTERNAL STANDARDS FOR ALL FOUR ANALYTES

> HIGH INTRA-ASSAY PRECISION

> FULLY AUTOMATED SAMPLE PREPARATION

> VALIDATED IN ACCORDANCE WITH REGULATORY REQUIREMENTS

6PLUS1®
Multilevel Calibrator Sets

For safe diagnostics worldwide.

Certified according to
DIN EN ISO 9001:2008
DIN EN ISO 13485:2007-10
ISO 13485:2003 CMDR (Canada)

Chromsystems GmbH · Munich · Germany
Phone: +49 89 18930-300 · Fax: +49 89 18930-399
www.chromsystems.de · mailbox@chromsystems.de
Information for Authors

Clinical Chemistry is published by the American Association for Clinical Chemistry (AACC). The journal welcomes contributions of original information, experimental or theoretical, that advance the science of clinical chemistry. Submissions should adhere to the “Uniform Requirements for Manuscripts Submitted to Biomedical Journals” (http://www.icmje.org/).

Manuscript Review. Manuscripts are evaluated by anonymous peer reviewers. Authors are usually notified of the disposition of a manuscript within three to four weeks of its receipt. Equal consideration is given to manuscripts in English from any country, whether or not the author is a member of the AACC.

Copyright. Manuscripts are considered with the understanding that each author has participated in the work and assumes responsibility for the content; that the authors have disclosed any potential conflicts of interest; that the same information has not been and will not be submitted for concurrent review; nor published elsewhere; that other than as an abstract, preliminary report, or poster cited in the manuscript; that unique materials necessary to reproduce the results are available to readers; and that if the manuscript is accepted, copyright will be transferred to the publisher. To convey these assurances, all authors must sign the copyright form provided at acceptance.

Unpublished Work. When citing unpublished work or opinions of others, provide a permission letter from them.

Manuscript Preparation. Text. Most common word-processing software formats are accepted; Microsoft Word is preferred. Use 12-point font, 1-inch margins, and double spacing throughout. Do not use headers or footers, but do number the pages, starting with the title page as page 1. For guidance on manuscript preparation and style, consult our Information for Authors at http://www.clinchem.org/info_ar/info_authors.shtml.

Images: The acceptable image file formats for print publication are TIFF (tagged image file format) and EPS (encapsulated postscript) both at 600 dpi resolution. The figures must be submitted as independent files, not embedded within a word processing document. Microsoft PowerPoint (PPT) files are also acceptable, but each file must have embedded fonts and only one image per slide, one slide per file. Verify that symbols and legends will be legible when reduced to publication size. Figures should be redesigned or recreated if they do not appear sharp and clear on paper. Authors are advised to use our online Digital Expert evaluation tool to test print figures before submitting them.

The author will be required to bear the full cost of the preparation and publication of color illustrations, invited contributions excepted. The charge for the first color figure is $1500. Subsequent color figures or parts of figures are $500 each.

Tables: Tables should be created in a common word-processing format. Spreadsheet-generated or embedded image tables should be recreated in the word-processing document and included with the text of the manuscript.


The complete Information for Authors is available at http://www.clinchem.org/info_ar/info_authors.shtml.

Clinical Chemistry (ISSN 0009-9147) is published monthly by the American Association for Clinical Chemistry, 1850 K Street, NW, Suite 625, Washington, DC 20006.

© 2010 The American Association for Clinical Chemistry
Quick Guide to Submission

For additional article types and detailed instructions, please see the Information for Authors at http://www.clinchem.org/info_ar/info_authors.shtml.

<table>
<thead>
<tr>
<th>Type of Submission*</th>
<th>Word Limit</th>
<th>Structured (S) or Unstructured (U) Abstract: Word Limit</th>
<th>Maximum Number of References</th>
<th>Total Number of Tables/Figures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Article</td>
<td>3,500</td>
<td>S: 250</td>
<td>40</td>
<td>6</td>
</tr>
<tr>
<td>Brief Communication</td>
<td>1,500</td>
<td>S: 250</td>
<td>20</td>
<td>1 each</td>
</tr>
<tr>
<td>Citation Classics</td>
<td>600</td>
<td>Non Applicable</td>
<td>6</td>
<td>Non Applicable</td>
</tr>
<tr>
<td>Clinical Case Study</td>
<td>1,500</td>
<td>Non Applicable</td>
<td>10</td>
<td>2</td>
</tr>
<tr>
<td>Case description with 3–5 questions and up to 5 Points to Remember</td>
<td>(500)</td>
<td>Non Applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical Case Study Commentary</td>
<td>300</td>
<td>Non Applicable</td>
<td>Non Applicable</td>
<td>Non Applicable</td>
</tr>
<tr>
<td>Editorial</td>
<td>1,500</td>
<td>Non Applicable</td>
<td>15</td>
<td>Non Applicable</td>
</tr>
<tr>
<td>Letters to the Editor / Reply</td>
<td>750</td>
<td>Non Applicable</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>Mini-Review Article</td>
<td>3,500</td>
<td>S: 250</td>
<td>40</td>
<td>4</td>
</tr>
<tr>
<td>Opinion</td>
<td>1,500</td>
<td>Non Applicable</td>
<td>15</td>
<td>1</td>
</tr>
<tr>
<td>Perspective</td>
<td>1,500</td>
<td>Non Applicable</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>Review Article</td>
<td>5,000</td>
<td>S: 250</td>
<td>75</td>
<td>6</td>
</tr>
<tr>
<td>What Is Your Guess?</td>
<td>75</td>
<td>Non Applicable</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>Case description w/ 3 Questions</td>
<td>75</td>
<td>Non Applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Case discussion</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

Manuscript Formatting
- Double-spaced text, 1-inch margin, 12-point font size in Arial, Helvetica, or Times New Roman
- Numbered pages with references numbered sequentially in main text
- Title page listing title, authors (first name, middle initial, last name), each author’s affiliation during the study, corresponding author’s contact information, running title, keywords, list of any previous presentation of manuscript, and any disclaimers
- Reference list formatted according to Information for Authors with Journal abbreviations in the reference list checked against the National Center for Biotechnology Information database (http://www.ncbi.nlm.nih.gov/)
- SI units used throughout manuscript according to Information for Authors

Metadata (to be entered online)
- A valid and unique e-mail for each author
- Authors’ current institution, address, telephone, and fax
- Author Disclosure Forms and Contribution Forms to be completed by each author before submission.
- Copyright Transfer Agreement to be completed by each author after acceptance.
- Clinical Chemistry manuscript number of any companion papers (if applicable)

Compliance with Guidelines
- A STARD checklist is required for all studies or trials of the diagnostic accuracy or performance of a diagnostic test, a CONSORT diagram is required for all randomized and Phase III trials, a MIAME checklist is required for all studies that present data for microarray experiments.
- All studies involving human subjects must indicate that they are in compliance with the Declaration of Helsinki ethical principles for medical research involving human subjects.

A statement must be included in the text that Institutional Review Board approval was obtained and written informed consent obtained from study subjects.

Permissions
- Written permission from the copyright holder is required to reproduce any copyrighted material
Clinical Chemistry is pleased to announce a special upcoming theme issue on Diabetes Mellitus edited by Drs. Vivian Fonseca, Allison Goldfine and David Sacks entitled Diabetes: Advances and Controversies. Clinical Chemistry, published by the American Association for Clinical Chemistry, is the most highly cited forum for peer-reviewed, original research in the fields of Clinical Chemistry and Laboratory Medicine.

The purpose of this issue is to highlight recent advances in the pathophysiology of diabetes and the use of novel markers in the diagnosis or treatment of patients with diabetes. New technological developments provide opportunities for the institution of approaches using personalized medicine.

Clinical Chemistry invites authors to submit original articles related to diabetes to be considered for publication in this special issue. Manuscripts are most likely to be favorably received if they address novel technologies to diagnose, treat or prevent type 1 or type 2 diabetes or their complications.

Potential topics of interest include:

- Assessment of the risk of diabetes or diabetes complications using “omics”
- Measuring biomarkers of diabetes complications—oxidative stress, AGEs, RAGE
- Predictive models for developing diabetes and prediabetes
- Role of the gut in the pathogenesis of diabetes: hormones or microbiome
- Advances in glucose monitoring (clinical cases on this topic are welcome)
- Predicting drug responses in diabetes using clinical chemistry and pharmacogenomics

Be a part of this exciting issue!

Submissions must be received through our online submission system at http://submit.clinchem.org no later than August 10, 2010. Your cover letter should express your interest in submitting your paper for consideration for the diabetes theme issue. Journal guidelines for submission apply as described at the submission website in Information for Authors.
A New Biomarker for Ovarian Cancer

HE4 is available in the United States for use as an aid in monitoring recurrence or progressive disease in patients with epithelial ovarian cancer.

- 75% of patient samples with no change in HE4 value correlated with no progression of disease\(^1\)
- 60% of patient samples with a positive change in HE4 value correlated with disease progression\(^1\)
- HE4 should be used in conjunction with other clinical methods to determine disease status

For more information visit: www.taketherightpath.com
Our new advances in VITROS® technology are driven by your impact on patients.

Quality lab results touch lives. Millions of them, every day. That’s the global magnitude of what you do—and the reason why Ortho Clinical Diagnostics supports you with innovative systems that help you do it better than ever. To make your lab more productive without compromising quality results, we studied laboratories around the world and created two new high-capacity VITROS® systems.

As the next generation in our standardized family of systems, the VITROS® 5600 Integrated System and the VITROS® 3600 Immunodiagnostic System feature patented enabling technologies, innovative sample handling, and a world-class menu for exceptional accuracy, efficiency, and result integrity. We’re committed to shaping the future of diagnostics, because what you do shapes the future of countless lives around the world. Learn more at www.orthoclinical.com.

The science of knowing shapes the art of living.
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

Target Audience: Laboratory administrators, directors, and managers; pathologists; rheumatologists, and IVD professionals involved in immunoassay testing.

This program is approved by AACC for 1.5 Category 1 ACCENT credit hours.

Invite your rheumatologist colleagues to attend! Register today!

TO REGISTER
Go to www.aacc.org and under “Upcoming Events,” select this webinar.
Then, click “Register” to register online or print a registration form.
From large scale laboratories,

...to bedside patient care,
Randox has you covered.

The Evidence series of analyzers provides complete laboratory solutions to a wide range of settings. We know how important fast, reliable diagnosis is to you and that’s why we continue to develop revolutionary diagnostic solutions of unbeatable quality.

Our dedication to Research & Development is continually improving not only our diagnostic analyzers, but also looks towards the world’s need for effective diagnosis. With ever increasing prevalence of infectious diseases, cardiovascular disease and cancer; our Biochip Arrays are key to providing early diagnosis in order to save lives - and the menu is growing bigger and bigger.

Our former list of biochip arrays remains unchanged
- Cytokines & Growth Factors • Cerebral • Metabolic • Adhesion Molecules • Cardiac
- Thyroid • Drugs of Abuse • Fertility • Tumour Monitoring • Colorectal Cancer SNP Array

Our new list now includes
- STI and STI Pathogen Arrays • Respiratory Pathogen Array
- Endocrine Array • Synthetic Steroids Array • Metabolic Array
Call For Abstracts

New Directions in Point-of-Care and Critical Care Testing: Innovation, Controversies, and Partnerships

23rd International Symposium
September 22-25, 2010 • Marriott Copley Place Hotel • Boston, MA, USA

Abstract Submission Deadline: May 1, 2010

Abstracts are invited in the following categories:
• Integrating POCT into Patient Care Pathways and Patient Outcomes
• Microbiology and Infectious Disease Testing
• Innovation in New Technologies
• Point-of-Care Partnerships
• Controversies in POC and Critical Care Testing

Oral Presentations
8-10 abstracts will be selected for oral presentation during the symposium.

Poster Session
Posters of accepted abstracts will be displayed throughout the symposium.

Award for Best Abstracts
The CPOCT Division will award two travel grants of $500 each for best abstracts. One of the listed authors must attend the meeting.

Publication of Proceedings
Accepted abstracts and meeting proceedings will be published in Point of Care: The Journal of Near-Patient Testing & Technology.

For abstract specifications and the electronic abstract submission form, visit: http://www.aacc.org/events/meetings
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.”

**Fact:** Serology is not accurate enough for use in routine clinical practice.¹
**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.¹³
**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.

---

**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.

---

Learn more at [www.BreathTekFacts.com](http://www.BreathTekFacts.com), or contact us at 1-888-637-3835.

See us at AACC 2010 in booth #6620.
One team. One shared vision: to treat not just the child, but the entire family. At Nationwide Children’s Hospital, we are committed to creating a haven for children of all ages and with every need. We are recognized as a leader in pediatric health care by Parent’s Magazine (10 Best Children’s Hospitals) and U.S. News and World Report 2009-2010 (Best Children’s Hospitals). Join us, as we look forward to 2012 and the opening of our new, 12-story main hospital building. We have an immediate need for an:

ASSOCIATE OR ASSISTANT DIRECTOR OF CORE LABORATORY SERVICES

GENERAL SUMMARY
The Associate (Assistant) along with the Director of Core Laboratory Services is responsible for the scientific and clinical administration of the area including basic chemistry, metabolic disease testing, endocrine testing, special chemistry, TDM/toxicology testing, basic hematology, and decentralized testing. They will maintain the “core lab” concept as an efficient, rapid-response laboratory operating 24 hours a day, 7 days a week.

The Associate Director will be available to manage daily technical and medical/scientific issues including quality control and consultations. Teaching of allied medicine students, residents and fellows as well as cooperation with research endeavors by NCH researchers is expected.

MINIMUM QUALIFICATIONS
Knowledge of laboratory medicine practices, research theory, and technical personnel management, generally gained by completing a Ph.D. in Clinical Chemistry or related biomedical science, board eligible, with a minimum of a two year post-doctoral training program preferred.

For additional information please contact Marc Mercurio at (614) 355-4160 or to apply online, please visit our web site at www.NationwideChildrens.org.
Handbook of Workplace Drug Testing, 2nd Edition

Edited by Jeri Ropero-Miller and Bruce Goldberger

Published 2008, 506 pages, softcover, ISBN 9781594250903, Product #5176
Price only $89; AACC Member $71

The Second Edition of *Handbook of Workplace Drug Testing* builds on the knowledge included in the first edition and offers considerable updates and enhancements. It remains a valuable resource for understanding the complexity of the science, law, and interpretation of workplace drug testing. The information that has been compiled in the second edition was obtained through extensive laboratory study and literature surveys. As leaders in their fields, the authors provide a historical perspective of workplace drug testing and an understanding of analytical procedures and theory, drug class overviews, adulteration and specimen validity testing, alternative matrices, quality assurance and quality control, result interpretation for medical review officers, and laboratory accreditation.

This book is a “must have” for all workplace drug testing laboratories and practitioners in forensic toxicology, clinical toxicology, and clinical chemistry. A complete subject index is included for easy referencing of topics.
Critical Issues in Alcohol and Drugs of Abuse Testing

Edited by Amitava Dasgupta

2009, 319 pages, softcover
ISBN 9781594250934
Product # 5629

Price only $90; AACC Member $75

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.

HOW TO ORDER

ONLINE:
http://www.aacc.org and click on the AACC Store button

CALL:
(800) 892-1400
or (202) 887-0717

FAX:
(202) 887-5093

MAIL:
AACC Customer Service
1850 K Street NW, suite 625
Washington, DC 20006

www.aacc.org
Solutions for Clinical Research from the Leader in LC/MS/MS Technology

**AB SCIEX** offers the most comprehensive portfolio of pre-configured methods and software, a reputation for the most reliable LC/MS/MS systems available, and the most comprehensive service and support organization in the industry. All designed to get you up and running faster and generating quality results.

**Therapeutic Drug Monitoring**
- Inborn Errors of Metabolism

**Steroids**
- Vitamin D

**Clinical Toxicology**
- Amino Acids

**Catecholamines**
- and many more

**AB SCIEX QTRAP® 5500**, the most sensitive LC/MS/MS system for trace level quantification of steroids, 1,25-dihydroxy vitamin D and other analytes requiring low levels of detection.

©2010. AB SCIEX. For Research Use Only. Not for use in diagnostic procedures. The trademarks mentioned herein are the property of AB Sciex Pte. Ltd. or their respective owners. AB SCIEX™ is being used under license.
Attend the premier education and networking event for the clinical lab community
• Keep up with the latest trends and advances in the profession
• Learn from colleagues and peers from around the world
• Stay current on continuing changes in the health care environment
• Choose from 5 full days of scientific sessions

See new science and technology at the largest Clinical Lab Exposition in the world
• Evaluate products of nearly 700 vendors in 1,900 booths
• Learn about new technologies in clinical, molecular and genetic diagnostics, automation, informatics, POCT, OEM, biotech, and more
• Make informed clinical lab purchase decisions
• Earn Continuing Education credit for attending the Clinical Lab Expo

Registration opens April 2010
www.aacc.org/2010am
See what we see.

At Phadia, we see things differently. Since we invented specific IgE blood testing more than 40 years ago, our perspective has offered a new outlook for patients with rhinitis, asthma, rheumatoid arthritis, celiac disease, and many other challenging conditions. We are driven to equip laboratories and clinicians with the best possible assays for allergic and autoimmune diseases.

For cutting-edge testing technologies for allergic and autoimmune diseases...

Look no further than Phadia.