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Quality Assurance in Hemostasis

AACC understands that your job demands results as quickly as possible and your time for career enrichment is limited. To fit into this strained schedule, AACC is holding three Quick Take webinars in August. All webinars take place at lunch time, 1:00–1:30 PM ET. Recordings of missed sessions will be provided. You get all three webinars for the price of one and 1.5 ACCENT credits.

Expert George Fritsma, author of AACC Press’ Quick Guide to Hematology Testing, understands the importance of valid coagulation testing. Fritsma will present three webinars discussing QC and QA issues that relate specifically to hemostasis.

Over the course of three webinars, to be held August 7, 14, and 21, learn:

- How to develop a Brill-Edwards curve to establish the partial thromboplastin time (PTT) unfractionated heparin therapeutic range
- How to determine PTT sensitivity to factor VIII and IX deficiency
- Specimen management for coagulation and platelet aggregometry
- How to employ local calibration for prothrombin time/international normalized ratio (PT/INR) monitoring of warfarin therapy

EXPERT: George Fritsma, MS, MLS
Associate Professor and consultant to the Department of Laboratory Medicine, University of Alabama at Birmingham, proprietor of The Fritsma Factor, your Interactive Hemostasis Resource, www.fritsmafactor.com, and co-editor of Hematology, Clinical Principles and Applications, Elsevier Press

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- Therapy monitoring of IBD patients

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Clinical Chemistry is pleased to announce a special upcoming theme issue on Molecular Diagnostics edited by Drs. Rossa W.K. Chiu, Frank R. Cockerill, Y.M. Dennis Lo, and Carl T. Wittwer titled “Molecular Diagnostics: A Revolution in Progress.” 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 molecular diagnostics that focus on either: (1) clinical applications that use molecular diagnostics to reach novel conclusions about disease and/or therapy; or (2) new technologies that improve high-volume needs, test turnaround time, comprehensive analysis, or ease of use.

Clinical Chemistry invites authors to submit original articles related to molecular diagnostics for potential publication in this special issue. In general, manuscripts must be quantitative rather than descriptive. Article selection will be based on the overall quality and potential impact of the manuscript.

Potential topics of interest include:

- New technologies that further advance the utility of molecular diagnostics
- Significant applications of molecular diagnostics that improve patient care
- Sample-to-answer platforms that can be used at the point of impact
- Informatics advances to analyze genomes, exomes, transcriptomes, epigenomes, or microbiomes
- Generic technologies that depend less on proprietary instruments and reagents
- Novel massively parallel sequencing approaches
- Methods and applications of cell-free nucleic acid analysis
- Guidelines for using specific molecular diagnostic techniques

Be a part of this exciting issue!

Submissions must be received through our online submission system at submit.clinchem.org. We welcome submissions after June 2014, but cannot guarantee the inclusion of late submissions for the Special Issue. Your cover letter should express your interest in submitting your paper for consideration for the Molecular Diagnostics theme issue. Journal guidelines for submission apply as described in the Information for Authors on the submission website.
Now Available!

**DIAZYME’S 25-OH VITAMIN D ASSAY FOR CLINICAL CHEMISTRY ANALYZERS**

**Principle and Procedure**

The test is based on the principle of \( \alpha \)-complementation of the enzyme \( \beta \)-galactosidase and the competition between an enzyme donor-25-OH Vitamin D conjugate, an anti-Vitamin D antibody and the 25-OH Vitamin D content of a serum sample. Samples with higher 25-OH Vitamin D concentrations produce higher \( \beta \)-galactosidase activities and vice versa. A nitro-phenyl-\( \beta \)-galactoside derivative (NPG) is used as the enzyme substrate. The reaction's product has maximum absorbance at 415 nm. The 25-OH Vitamin D concentration of a sample is proportional to the measured \( \beta \)-galactosidase activity.

<table>
<thead>
<tr>
<th>Instrument</th>
<th>REF</th>
<th>Kit Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemistry Analyzers</td>
<td>DZ688C-K</td>
<td>Diluent: 1 x 17 mL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>R1: 1 x 6.5 mL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>R2: 1 x 17 mL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>R3: 1 x 6.5 mL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Cal: 5 x 1 mL</td>
</tr>
</tbody>
</table>

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**Diazyme FemtoQuant™ Vitamin D Assay**

- **Method**: Enzyme-Immunoassay
- **Instrument**: General Chemistry Analyzers
- **Precision %CV**: 2.9-14.0% 40 ng/mL: 4.7% 90 ng/mL: 3.7%
- **Accuracy**: \( R^2 = 0.96 \) against DiaSorin Liaison
- **Sensitivity**
  - LoB: 2.0 ng/mL
  - LoD: 3.5 ng/mL
  - LoQ: 7.6 ng/mL
- **Measuring Range**: 7.6 - 147.8 ng/mL
- **Time to First Result**: 15-19 min
  - *Analyzer Dependent*
- **Throughput**: For example:
  - Hitachi Modular P >100 tests/hr
  - Ace Alera > 50 tests/hr
  - Pentra 400 > 50 tests/hr
- **Fully Automated**: Yes
- **D2 and D3 Equal**: Yes
- **Accuracy**: Yes
- **Directly Traceable**: NIST SRM 972 Yes
- **Regulatory Approvals**
  - 510(k) Cleared
  - EU CE IVD

---

**Diazyme vs. Predicate**

\[
y = 0.9892x + 0.465 \\
R^2 = 0.9689
\]

**Linearity**

(recovered values versus expected values)
Newly released guidelines are changing the lab’s role in the management of patients at risk of having a cardiac event. Researchers continue to discover new markers or novel ways to use existing assays to identify cardiovascular events earlier. Early diagnosis of both conditions allows clinicians to intervene and prevent further damage, leading to better patient outcomes.

AACC keeps laboratorians on the cusp of these new developments with three exclusive webinars featuring lectures, question-and-answer sessions, and research selections with experts from the Clinical Chemistry journal.

WEBINARS INCLUDE:

**JULY 8 The Drive to Define “Normal”: The 99th Percentile Value of Cardiac Troponin**
Fred Apple, PhD, Medical Director of Clinical Laboratories, Clinical Chemistry, POC Testing and Clinical And Forensic Toxicology Laboratories at Hennepin County Medical Center, and Professor of Laboratory Medicine and Pathology, University of Minnesota School of Medicine, Minneapolis, MN

**SEPTEMBER 2 Stroke Biomarkers: Current Status, Future Promise**
Robert Christenson, PhD, Professor of Pathology and of Medical and Research Technology at the University of Maryland School of Medicine, and Director of the Clinical Chemistry, Toxicology, and Core Laboratories and Point of Care Services at the University of Maryland Medical Center, Baltimore, MD

**SEPTEMBER 9 CVD Risk Prediction: The Evolving Role of Laboratory Testing**
Paul Ridker, MD, MPH, Director, Center for Cardiovascular Disease Prevention at Brigham and Women’s Hospital and Eugene Braunwald Professor of Medicine at Harvard Medical School, Boston, MA

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Najwa Adlan, CPHHA(AIHQ)
King Faisal Specialist Hospital & Research Center,
Riyadh, Saudi Arabia

The award is sponsored by the AACC Critical and Point-of-Care Testing Division with support from Ortho Clinical Diagnostics.
CREATIVE DESTRUCTION OF MEDICINE – THE DIGITAL REVOLUTION CREATES BETTER HEALTH CARE  
Eric J. Topol, MD

The past year has witnessed tectonic advances in technology. We can now sequence a whole genome in a few hours using a handheld device and access the capabilities of a supercomputer through the cloud. While such feats are yet to impact routine clinical practice, signs point to movement within the field. Cancer patients are more frequently asking for their tumor sample to be sequenced for targeted therapy. Nearly every week a new report is published of an individual with a rare or unknown condition which has been unraveled through genomics. The consumer use of online health social networks is steadily increasing. People are also starting to download medical apps and such features are growing in popularity. We have seen a proliferation of hardware “adds” to the phone for blood pressure, blood sugar, heart rhythm, eye refraction, and other medical metrics. The public is learning that a new form of medicine – one that is individualized – is well within our reach.


UNDERSTANDING BIG DATA AND ITS IMPACT ON YOUR LABORATORY  
Viktor Mayer-Schönberger

“Big Data” is the idea that we can now do with a vast amount of data things that we simply could not do when we had less. At its core, Big Data is not about change in technology, it is about a shift in mindset. This talk looks at the potential of Big Data and its defining characteristics in general and in the lab research context. It will also look at long-term consequences, from how lab research is being organized and institutionally situated, how funders will evolve and how we disseminate and access it. It will also look at the important limitations – what Big Data cannot do – and why understanding these limitations is of critical import not just for the research community but for society as a whole.

NEWBORN SCREENING FOR INBORN ERRORS OF METABOLISM IN THE 21ST CENTURY  
Piero Rinaldo, MD, PhD

Since the 2010 adoption of the recommended uniform screening panel by the HHS Secretary as a national standard, virtually all newborns in the United States are tested by MS/MS for >40 metabolic disorders. These disorders have in common abnormal concentrations of either amino acids or acylcarnitines. A few other inherited conditions are screened using dedicated assays. Many other disorders are being considered as possible candidates for addition to the panel. This session will discuss the possible expansion of newborn screenings, the medical, ethical and financial issues that need to be addressed by a multitude of stakeholders and the pursuit of new solutions to old problems.
LEPTIN AND THE BIOLOGICAL BASIS OF OBESITY  
Jeffrey M. Friedman, MD, PhD

The discovery of leptin has led to the elucidation of a robust physiologic system that maintains fat stores at a relatively constant level. Recessive mutations in the leptin gene are associated with massive obesity in mice and some humans. Treatment with recombinant leptin markedly reduces food intake and body weight. The low leptin levels in patients with leptin mutations are also associated with multiple abnormalities including infertility, diabetes and immune abnormalities. All of these conditions can be corrected by leptin treatment. These findings have established important links between energy stores and many other physiologic systems. They have led to the use of leptin as a treatment for an increasing number of other human conditions. Identification of a physiologic system that controls energy balance establishes a biologic basis for obesity and further establishes links between leptin and numerous other physiologic responses.


TACKLING HIV LATENCY: MOVING TOWARD A CURE FOR HIV  
Sharon Lewin, MD, PhD

Combination antiretroviral therapy (cART) has led to a major reduction in HIV-related mortality and morbidity, but HIV still cannot be cured. The most significant barrier to cure is the establishment of a latent or “silent” infection in resting CD4+ T cells. In latently infected T-cells, the virus is able to integrate into the genome but does not proceed to active replication. Reactivation of latently infected resting CD4+ T cells can then re-establish infection once cART is stopped. Other significant barriers to cure include residual viral replication and anatomical reservoirs. Achieving either a functional cure (long-term control of HIV in the absence of cART) or a sterilizing cure (elimination of all HIV-infected cells) remains a major challenge. Dr. Lewin will discuss possible approaches to eliminating latently infected cells in HIV patients.


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THE CLINICAL TOXICOLOGY LABORATORY
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Edited by Tai Kwong, Barbarajean Magnani, Tom Rosano, and Les Shaw

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Critical and Point-of-Care Testing:
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SEPTEMBER 17-20, 2014
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Sponsored by the AACC CPOCT Division in cooperation with CSCC and EFLM, and under the auspices of IFCC.

The conference is supported by educational grants from Accriva Diagnostics, Alere, Instrumentation Laboratory, Medica Corporation, Nova Biomedical Corporation, Radiometer, Roche, and Siemens Healthcare Diagnostics.
New online certificate program from AACC, with strategies and tools to implement patient safety measures.

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For information on content, special pricing for AACC members, and registration, please visit [www.aacc.org/cert_prog](http://www.aacc.org/cert_prog)
Quick Guide to Hematology Testing, 2nd Edition

By Vishnu Reddy, Marisa B. Marques, and George A. Fritsma

2013, 180 pages, spiral binding
ISBN 9781594251559
Product # 8290
Price only $24; AACC Member $20

The Quick Guide to Hematology Testing is a speedy reference for anyone who orders, performs, or interprets hematology laboratory tests, including complete blood counts, bone marrow aspirate and biopsies, flow cytometry, cytogenetics, and molecular diagnosis. Clear understanding of the significance of hematology laboratory results is critical, and awareness of the effect of confounding factors leads to clinically sound interpretations.

The Guide’s pocket size provides immediate access at the time and place that tests are ordered, performed, and interpreted. The text discusses benign and malignant conditions of the three cell lineages, including anemias, leukemias, and thrombocytopenia, emphasizing their diagnosis, treatment, and laboratory-based treatment monitoring. Disease descriptions and assays are adjacent so that all conditions may be correlated. The extensively updated second edition has new sections and expands on newly described phenotypes and genotypes of hematologic disorders and new methods, providing a current list of cell markers and mutations.

Although the Guide reviews clinical conditions, treatment, and laboratory assays, it should not be used alone to make final diagnoses. Many current references are provided for further reading. The authors’ local experience helps make the Guide a valuable resource for physicians, physician assistants, nurse practitioners, nurses, pharmacists, and medical laboratory scientists.

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Quick Guide to Immunoassay Interference

By Pradip Datta, Adetoun A. Ejilemele, and John R. Petersen

2013, 75 pages, spiral binding
ISBN 9781594251566
Product # 8289
Price only $22; AACC Member $18

The Quick Guide to Immunoassay Interference is a valuable resource for medical laboratory scientists and directors, physicians, and other clinical support personnel to identify how laboratory immunoassay results may be affected by different types of interference. The Guide’s pocket size provides immediate access about what to watch for and how to correct such aberrant results, which are now ever dependent on clinical laboratory results, and maintain the integrity of patient care.

Starting from the basics of both immunoassays and assay interference, the Guide presents various sources of assay interference: cross-reactivity, prozone effects, heterophilic antibodies, endogenous serum components, system components, and analyte heterogeneity. The Guide also includes the various sources of preanalytical interference and is intended to be used as a reference for the diagnostics and pharmaceutical industries with regard to choosing an assay design to minimize interferences and to product support specialists so they can respond to reports of erroneous results from their customers.

The Guide can be used to assist physicians, pharmacists, pathologists, physician assistants, and medical fellows, residents, and students in understanding not only how to detect erroneous immunoassay results before making clinical decisions based on them but how such interference can be resolved and correct results may be obtained. The information contained in this Quick Guide also clarifies laboratory assay utilization to help predict, diagnose, and monitor therapy for clinical conditions and disease.
The Quick Guide to Molecular Diagnostics is intended for physicians, residents/fellows, allied medical health professionals, nonmedical professionals, and students who wish to better understand the complex field of molecular diagnostics. The Guide is intended to be a quick, informative reference for individuals who order molecular tests in the fields of genetics, oncology, and infectious disease. For each of these fields, information about common molecular diagnostic tests is provided to assist in ordering and results interpretation. Molecular laboratory techniques are also discussed to help readers better understand their advantages and limitations. The pocket size of this text offers immediate access when and where tests are ordered. Our experience suggests that this Guide will be a useful reference for individuals in many different fields.
Quick Guide to Clinical Chemistry, 2nd Edition

By Janelle M. Chiasera, Robert W. Hardy, and John A. Smith
2013, 150 pages, spiral binding
ISBN 9781594251443
Product # 7293
Price only $24; AACC Member $20

The Quick Guide to Clinical Chemistry, Second Edition, is a pocket-sized reference intended for physicians, nurses, physician assistants, nurse practitioners, medical technologists, pharmacists, and residents and students in those professions. This Guide focuses on the selection and use of chemistry laboratory tests for diagnosing and managing emergent conditions such as poisonings, acute abdominal pain, sepsis, and acute myocardial infarction.

The Guide’s small size allows it to be used in situations when quick decisions must be made regarding the ordering and interpretation of chemistry tests. The emergent clinical conditions and the associated laboratory tests are described together for quick reference.

Although this Guide reviews several clinical conditions, it is not intended to be a comprehensive guide to all clinical laboratory tests, nor is it intended to dictate what constitutes reasonable, appropriate, or best care in a given situation. Comprehensive references for such information currently exist. Instead, it should be seen as it is clearly named, a “Quick Guide” to clinical chemistry.
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