Increasing Demand for Vitamin D Testing Requires Accurate Results and Improved Workflow

New Vitamin D Total Test from Siemens Demonstrates Concordance with LC/MS/MS

Vitamin D testing volumes continue to grow, making it one of the most commonly requested assays. Current testing methods for vitamin D include manual immunoassays, automated immunoassays, and direct detection methods (liquid chromatography tandem mass spectrometry (LC/MS/MS) and high performance liquid chromatography). Automated assays are typically the best choice for many laboratories.

When considering an automated vitamin D testing solution, clinical concordance to LC/MS/MS and other key questions must be considered:

- **Will the test measure total 25(OH) vitamin D?** Labs need to provide accurate assessment of vitamin D status through the equimolar measurement of total 25(OH) vitamin D—the sum of 25(OH) vitamin D2 and 25(OH) vitamin D3.1-3
- **How will this test improve the turnaround time to clinicians?** Effective workflow management of high-volume testing includes fast turnaround time, minimal labor, and high instrument throughput.1 The additional ability to test in-house can significantly improve turnaround time.
- **How does the test provide reproducible results?** Laboratories have reported discrepancies between assays. In one lab, 60% of the results from an immunoassay method indicated insufficiency; compared to only 30% by LC/MS/MS.2 Another laboratory had similar discrepancies for sample classification: 80% of samples had levels below 32 ng/mL by immunoassay, but only 46% of samples by LC/MS/MS.3 In the absence of an international standard for vitamin D, it is important that assays be traceable to LC/MS/MS.

French and Australian Method Comparison Studies Demonstrate Concordance between the Siemens ADVIA Centaur Vitamin D Total Assay and LC/MS/MS

Two independent method comparison studies evaluated concordance to LC/MS/MS by comparing the ADVIA Centaur® Vitamin D Total assay to LC/MS/MS, Diasorin 25-OH Vitamin D radioimmunoassay, and Diasorin LIAISON 25-OH Vitamin D TOTAL assays. The data were evaluated by Deming regression and Pearson correlation coefficient analyses.

French method comparison study results

113 samples with known Diasorin 25-OH Vitamin D radioimmunoassay (Diasorin RIA) values were sent for ADVIA Centaur measurement at Siemens Healthcare Diagnostics (Tarrytown, NY, USA), Diasorin LIAISON 25-OH Vitamin D TOTAL assay (Diasorin LIAISON) measurement at the Research and Development Institute, Calabasas, CA, USA, and to a U.S. accredited laboratory for LC/MS/MS.

The ADVIA Centaur and Diasorin RIA demonstrated good agreement with LC/MS/MS; Pearson correlation coefficients, 0.92 and 0.94, and Deming regressions, -1.80 ng/mL + 0.98x and 1.86 ng/mL + 0.88x, respectively (Table 1 and Figure 1).

The Diasorin LIAISON assay demonstrated a Pearson correlation coefficient of 0.77 and a Deming regression of -0.80 ng/mL + 0.87x (Table 1 and Figure 1).

Table 1. Pearson correlation coefficient and Deming regression results by method compared to LC/MS/MS.

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Table 2. Summary of clinically relevant discordant results by assay type compared to LC/MS/MS. All results are reported in nmol/L. Deficiency, <50 nmol/L; Insufficiency, 50–75 nmol/L; Sufficiency, 75–250 nmol/L; Toxicity, >250 nmol/L. Samples highlighted below had a >40% difference in value from LC/MS/MS.

New Vitamin D Total test from Siemens provides highly accurate, reproducible results in 18 minutes

Vitamin D test volumes continue to grow rapidly, requiring laboratories to adopt a robust solution to meet their vitamin D testing needs. When laboratories consider implementing a new methodology, it is important to include clinical concordance to LC/MS/MS as an acceptable evaluation criteria to ensure correct assessment of vitamin D status—deficiency, insufficiency, sufficiency, or toxicity.

In two studies, vitamin D results from Siemens’ ADVIA Centaur systems demonstrated concordance to LC/MS/MS. Additionally, the Siemens’ Vitamin D Total assay can be run on a routine analyzer with results in 18 minutes.

To learn more about the Siemens ADVIA Centaur Vitamin D Total assay, please visit www.siemens.com/vitaminDtotal

References:

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*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
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Managing the Challenges of Biological Variation

Wednesday, September 19, 2012 ~ 2:00-3:30 pm Eastern U.S. Time

Lab statistics aren’t sexy, but performing the right calculations to produce clinically appropriate and correctly interpreted test results can be life-altering for patients. For example, using statistics to adjust for biological variation in serial troponin results can mean the difference between a patient being diagnosed with an AMI and getting the appropriate care, or that same patient being sent home with a “missed” acute cardiac episode, putting them at further risk of a second adverse event.

As cardiac markers and other laboratory assays improve and are better able to detect very low analyte concentrations, calculating and understanding the impact of biological variation on test results is imperative for labs.

Attend this program and know:
- How to incorporate data on biological variation into your quality control goals
- The effects of biological variation on test precision and accuracy
- Tips for selecting and applying QC rules that will help you meet your QC goals
- How biological variation can influence the results of common laboratory tests
- Strategies for measuring reference change values (RCVs) and reducing RCVs that are too high

Program Faculty:
Alan H.B. Wu, PhD, DABCC, Chief of Clinical Chemistry and Toxicology, San Francisco General Hospital; Professor of Laboratory Medicine, University of California, San Francisco, CA

Roy Gerona, PhD, Research Scientist, Department of Laboratory Medicine, San Francisco General Hospital and the University of California, San Francisco, CA

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

Learn how to incorporate data on biological variation into your QC program. Register today!
Improving the Efficiency of Critical Value Reporting: The Clinician/Lab Partnership

Tuesday, October 16, 2012 ~ 2:00-3:30 pm Eastern U.S. Time

Finding ways to make your critical value reporting more efficient requires a systems approach—one in which laboratorians, clinicians and others involved in the process collaborate. During this webinar, two laboratory experts explain what they’ve done in their hospital to create efficiencies in the critical value reporting process. Dr. Gordon Schiff, Associate Director of the Center for Patient Safety Research and Practice at Harvard, will provide the physician’s perspective on critical values reporting, discussing approaches you can take to find and fix the vulnerabilities in your critical value reporting systems.

Attend this program and know:
• Where to find the “failure mode” areas in your process that are prone to error
• The physician’s and lab director’s perspective on striking the appropriate balance for reporting critical values, managing the “subcritical” value, and reporting critical results from sendout tests
• The advantages and disadvantages of using clinical decision support and other electronic tools to improve critical result reporting
• How current regulations and accreditation requirements affect the way labs build their critical value reporting processes
• Strategies for measuring the effectiveness of your critical value reporting system and improving its efficiency

Program Faculty:
Gordon Schiff, MD, Associate Director, Center for Patient Safety Research and Practice; Internist, Division of General Internal Medicine, Brigham and Women’s Hospital; and Associate Professor of Medicine, Harvard Medical School, Boston, MA

Corinne R. Fantz, PhD, Co-director of the Core Laboratory, Emory Crawford Long Hospital, Director of Point-of-Care, Emory Medical Laboratories, and Associate Professor, Pathology and Laboratory Medicine, Emory University School of Medicine, Atlanta, GA

Crystal Evans, MT(ASCP), Regulatory Coordinator, Department of Pathology and Laboratory Medicine, Emory University Hospital, Atlanta, GA

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Learn what you can do to make the process of critical value reporting work better for your lab and your clinicians. Register today!

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• Circulating cancer cells, circulating free DNA, and micro-RNAs

Don’t miss this exciting issue!
Available January 2013!
Clinical labs now have a new option for quality control (QC) compliance programs based on risk management principles.

Risk management principles can improve laboratories’ QC programs by evaluating regulatory requirements, information provided by the manufacturer, information pertaining to the laboratory environment, and medical requirements for the test result. The result is a QC plan designed specifically for the particular combination of measuring system, laboratory environment, and clinical application.

In this program you will hear from CLSI guideline developers and world leaders in the field of QC. Through case studies they will share with you how they have implemented effective QC plans using risk management principles to improve the practice and safety of laboratory medicine.

After attending you will be able to:

- Describe the CLSI document EP23 and understand risk management’s role in QC
- Develop a QC plan for moderate complexity POCT and central lab-based tests
- Identify benchmarks for monitoring the effectiveness of a QC plan after implementation
- Use EP23 to refine an existing QC plan for a testing process not performing up to expectations

The Experts:

Valerie Ng, MD, PhD, Immediate Past Chief, ACMC Medical Staff; Chair, Laboratory Medicine & Pathology; Director, Clinical Laboratory, Alameda County Medical Center/Highland General Hospital, Oakland, CA

James H Nichols, PhD, Professor of Pathology, Tufts University School of Medicine; Medical Director, Clinical Chemistry, Baystate Health, Springfield, MA; Chairholder, CLSI EP23 Document Development Committee

Curtis Parvin, PhD, Manager, Advanced Statistical Research, Bio-Rad Laboratories, Plano, TX

This program is approved by AACC for 1.5 Category 1 ACCENT credit hours, and is supported by Bio-Rad Laboratories.

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Go to www.aacc.org and under “Events” select “Conference and Event Calendar.”
Quick Guide to Renal Disease Testing

George A. Fritsma

2011, 76 pages, spiral binding
ISBN 9781594251252
Product # 6654
Price only $20; AACC Member $16

The time-honored “routine” urinalysis test is perhaps the humblest of laboratory assays, yet it provides a wealth of renal and metabolic information when appropriately performed and applied. Likewise, creatinine clearance, urea, glomerular filtration rate, and osmolality assays generate irreplaceable results.

The Quick Guide to Renal Disease Testing assists physicians, nurses, physician assistants, nurse practitioners, clinical laboratory scientists, and office personnel to properly collect, manage, and analyze urine and to apply and perform renal function tests. The Guide is a useful teaching reference for fellows, residents, and students, and is a quick-access reference for practitioners who order, collect, perform, or interpret urinalysis and renal disease laboratory tests.

The author is a member of the University of Alabama (UAB) Department of Pathology Division of Laboratory Medicine. The Guide arose from experiences in teaching clinical laboratory science students and practitioners, medical students, residents, fellows, and physicians at the UAB University Hospital. AACC Press and UAB make no warranties concerning contents of the Guide.

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Authors: Martin Ehrenschwender, Juergen Koessler, Kirsten Brunner, and Udo Steigerwald

Institut fuer Klinische Biochemie und Pathobiochemie mit Zentrallabor,
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Drug and alcohol abuse is a serious public health and safety issue, resulting in losses of $100 billion annually in the United States. Workplace drug testing programs have been instituted to deter employees from abusing drugs.

Written in less technical language than comparable reference books in this field, Pre-Employment Drug and Alcohol Testing: A Pocket Guide examines all topics related to testing for drug and alcohol abuse, including:

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- impact of foods, industrial hemp products, herbal teas, and passive marijuana inhalation on drug tests;
- ways individuals try to beat the system;
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Medical professionals such as medical technologists, toxicologists, clinical chemists, and laboratory administrators, as well as human resources professionals, will find Pre-Employment Drug and Alcohol Testing: A Pocket Guide a useful reference.
The seventh edition of *Pediatric Reference Intervals* is a valuable reference providing instant and accurate reference intervals for over 250 chemistry and hematology analytes in an alphabetized, user-friendly format. New analytes to this edition include C-peptide, haptoglobin, insulin, hemoglobin A, hemoglobin A2, hemoglobin F, immature platelet fraction, and reticulocyte hemoglobin equivalent. Reference intervals for steroids, free thyroxine, and free triiodothyronine measured by tandem mass spectrometry have been added, as well as reference intervals employing new platforms such as the Abbott Architect® ci8200 and the Roche cobas® 6000 analyzer.

Since the first edition was published in 1995, *Pediatric Reference Intervals* (formerly *Pediatric Reference Ranges*) has been a must-have for clinical chemists, hematologists, pathologists, endocrinologists, and pediatricians. It enhances interpretation of patient results, allows comparison of test results using different methods, and helps optimize patient care.

*Pediatric Reference Intervals* provides the following information: age- and sex-related reference ranges, methodology, type of specimen, references, statistical basis, population sources, and, in most cases, SI units.
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- Integrating middleware and autoverification
- Unlocking the power of QC: Your key to lab excellence

Laboratories all over the world are facing many of the same challenges: integrating lab processes into an increasingly IT-focused healthcare world, improving efficiency and quality, assuring patient safety, and managing cost constraints. Attend this meeting and learn how fellow laboratorians have harnessed the power of automation to meet these challenges head on.

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For information on corporate partnership opportunities, please contact David Sainato at AACC (dsainato@aacc.org).
AACC’s very popular High-Value Tests for High-Impact Diseases webinar series continues to offer monthly 60-minute programs featuring low-cost, high-value tests for the clinical laboratory. The next two series focus on kidney and thyroid disease and provide the information you need to help empower clinical decision making and guide patients with highly prevalent diseases avoid downstream complications and costs.

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  - Sept 11 – Biomarkers for Acute Kidney Injury: Now and the Future

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