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.

- **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. 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. 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. 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 -0.8 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.

<table>
<thead>
<tr>
<th>Method</th>
<th>ADVIA Centaur XP</th>
<th>DiaSorin RIA</th>
<th>DiaSorin LIAISON</th>
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<tr>
<td>Pearson coefficient (r)</td>
<td>0.92</td>
<td>0.94</td>
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<td>Slope</td>
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<tr>
<td>Intercept (ng/mL)</td>
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<td>1.86</td>
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Figure 1. Deming regression by method compared to LC/MS/MS (n = 113).

Australian method comparison study results

The ADVIA Centaur Vitamin D Total assay and DiaSorin LIAISON 25-OH Vitamin D TOTAL assay were compared using 188 samples in Australia. Discordant samples (n = 60) with enough sample volume were sent for LC/MS/MS analysis in the U.S. In comparison to LC/MS/MS for the 60 discordant samples, the ADVIA Centaur assay demonstrated a Deming regression of -0.58 ng/mL + 0.77x and a Pearson correlation coefficient of 0.92. The DiaSorin LIAISON assay demonstrated a Deming regression of -13.94 ng/mL + 1.91x and a Pearson correlation coefficient of 0.84. Of the 60 samples, some samples (n = 7) had yielded divergent results by different immunoassay methods such that the patient’s reported total 25(OH) vitamin D status (deficient, insufficient, or sufficient) varied according to the method used.

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, >375–500 nmol/L. Samples highlighted below had a >40% difference in value from LC/MS/MS.

<table>
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<tr>
<th>Sample</th>
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<th>DiaSorin LIAISON</th>
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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.

References:


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

Order No. A91DX-9187-A1-4A00 | 07-2012 | All rights reserved | © 2012 Siemens Healthcare Diagnostics Inc.
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!

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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
- 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/)
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**Compliance with Guidelines**
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- All studies involving human study participants must indicate that they are in compliance with the Declaration of Helsinki ethical principles for medical research involving human study participants. A statement must be included in the text that Institutional Review Board approval was obtained and written informed consent obtained from study participants.

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In recent years, new anticoagulant drugs have been introduced into clinical practice, expanding the number of therapies available to treat conditions such as atrial fibrillation, recurrent venous thrombosis, and acute coronary syndrome. Since the adoption of these drugs has changed clinical practice, it is also changing the role labs play in assessing and monitoring patients who are taking anticoagulants.

Of particular concern are surgery patients. Lab testing may be necessary to determine if a patient is taking an anticoagulant prior to surgery, or to identify which anticoagulant a patient is using. In cases where a patient is already taking an anticoagulant, transitioning to a different anticoagulation therapy prior to surgery may be indicated, and lab testing plays a role in that process as well.

Attend this program and know:
- How anticoagulants—both old and new—are currently being used by clinicians to treat various conditions and diseases
- The physiological mechanics of how each anticoagulant affects the coagulation cascade
- What assays should be used to monitor various anticoagulants
- Recommended treatment, monitoring and testing algorithms for traditional anticoagulants such as warfarin and heparin
- How newer anticoagulants such as Dabigatran and Rivaroxiban work, and what their addition to the list of FDA-approved anticoagulation therapies means for laboratorians

Program Faculty:
Michael Laposata, MD, PhD, Edward and Nancy Fody Professor, Executive Vice Chair of Pathology, Microbiology, and Immunology and Professor of Medicine at Vanderbilt University School of Medicine; Pathologist-in-Chief, Vanderbilt University Hospital, Nashville, TN

Target Audience: Clinical laboratory directors, managers and lead technologists; hematologists; pathologists; and IVD industry professionals who are involved in testing for or monitoring anticoagulants.

This program is approved by AACC for 1.0 Category 1 ACCENT credit hours.

Learn more about the lab’s role in measuring and monitoring anticoagulants. Register today!
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University of Minnesota School of Medicine

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DeCode Genetics

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David Morrow, MD  
Harvard Medical School

K. Srinath Reddy, MD  
Public Health Foundation of India

This program is offered under the auspices of the IFCC and is co-sponsored by the Asian Pacific Federation of Clinical Biochemistry and Laboratory Medicine, Indonesian Heart Association, Japan Atherosclerosis Society, Japan Society of Clinical Chemistry, Korean Society for Laboratory Medicine, Singapore Association of Clinical Biochemists, Singapore Cardiac Society, and Taiwan Society of Cardiology.

Generous corporate funding for this program has been received from the Committee of Cardiovascular Pharmacology of the Chinese Pharmacological Society, Denka Seiken Co., Ltd., Health Diagnostic Laboratory, Inc., Randox Cardiology, Roche Diagnostics, and Siemens Healthcare.
Developing a Quality Control Plan Based on Risk Management

Wednesday, November 28, 2012 ~ 2:00-3:30 pm Eastern U.S. Time

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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Mass Spectrometry in the Clinical Lab: Best Practices and Current Applications

Mass spectrometry is fast becoming the analytical method of choice for many clinical assays. Attend this conference to find out if mass spec has a place in your lab, and learn about clinical applications where it is now being routinely used.

Our leading lab experts will show you:
- Advantages and challenges of mass spec
- Keys to implementing mass spec tools in the clinical lab
- New guidelines for MS method development and validation
- Pros and cons of mass spec vs. immunoassay

In addition, conference faculty will examine some of the applications already in use in the clinical lab, including:
- LC-MS for drug analysis
- TDM
- Steroid and vitamin D analyses

…and offer a look at emerging applications in microbiology, molecular diagnostics and protein quantitation.

Don’t miss this informative program! Early bird registration ends August 16.

AACC would like to thank Agilent Technologies, Thermo Fisher Scientific, and Waters Corp. for their support of this event.

For more information or to register, please visit the AACC web site at www.aacc.org.