Dear Reader,

Welcome to Lab-trendz, your clinical platform that keeps you updated on the latest advances in laboratory diagnostics. We, at Siemens understand the value of the quality of reagents used in the clinical chemistry laboratory. The AUTOPAK® brand name resonates with every clinic in India.

We pride ourselves most on the millions of lives we impact each year with over 9 billion laboratory diagnostics tests sold worldwide, reaching over 800 million patients per year with chemistry and immunoassay tests alone. To continue this reach, Siemens has recently partnered with pharmaceutical companies where pharmaceutical company makes the medication and Siemens makes the companion diagnostics test.

According to the U.S. Food and Drug Administration (FDA), companion diagnostics occurs when the prescription of a particular medication is closely coupled to a specific test. This is one of the greatest benefits for the healthcare system, where companion diagnostics uncovers the most likely treatment in a given case, instead of spending on procedures that may not work for some patients. This would further help Siemens to enhance our personalized medicine portfolio benefitting our customers and their patients.

The month of August witnessed a great start with Siemens’ participation in the 2013 AACC and ASCLS Annual Meeting and Clinical Lab Expo, held in Houston, Texas. Here we displayed Siemens’ innovative and comprehensive portfolio in laboratory diagnostics.

In the coming months, you will witness new innovative products from Siemens catering to small and mid-size laboratories. For instance, Manual Scan microbiology system, capable of performing identification and susceptibility testing and AUTOPAK® liquid stable open chemistry reagents manufactured in our ISO 13485:2003 certified Vadodara plant.

In this issue of Lab-trendz, we have compiled interesting articles from our industry stalwarts. We would like to thank Dr. Sunita Kapoor from City X-Ray and Scan Clinic (P) Ltd., Delhi, Dr. Ravindra Patwadkar from Dr. Hedgewar Rugnalaya, Aurangabad and Dr. Sudip Roy from Medica Superspecialty Hospital, Kolkata for their valuable contribution.

Lastly, hearty congratulations to all our quiz winners and thank you for your valuable feedback and suggestions towards making Lab-trendz even more informative and insightful. Please continue writing to us at labtrendz.in@siemens.com.

Sushant Kinra
Vice President – South Asia Diagnostics Division Healthcare Sector, Siemens Ltd.

Key benefits of AUTOPAK®:
- Provides accurate results
- Has a wide range of testing parameters
- Offers flexibility of pack sizes
- Longer reagent stability
- Proven quality and reliability
Diabetes is one of the most challenging health problems of the 21st century. The International Diabetes Federation estimates that about 366 million people around the world have diabetes. The Siemens DCA Vantage® analyzer is a portable analyzer for the quantitative measurement of hemoglobin A1c (HbA1c) in whole blood at the point of care. The DCA Vantage® Analyzer helps monitor glycemic control and detect early kidney disease in environments ranging from the physician's office to remote, point-of-care coordinated sites in hospitals and multisite practices.

**Key benefits of AUTOPAK® liquid stable reagents:**
- Excellent workflow – No additional man-hour required
- Save time – No reconstitution required
- Manual errors eliminated – Limited handling
- Economical – Ready to use liquid reagent, stability till expiry

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Launch Status</th>
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<tr>
<td>Albumin, Amylase, Bilirubin, Calcium, Chloride, Creatinine, Phosphorous &amp; Total Protein</td>
<td>Available in Liquid Stable format</td>
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<tr>
<td>Cholesterol, BUN, GGTP and HDL-C (Precipitating)</td>
<td>Newly launched Liquid Stable parameters</td>
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<tr>
<td>Triglyceride, Uric Acid, SGPT, SGOT, CK, CK-MB, LDH and Direct LDL &amp; HDL</td>
<td>Ongoing work for future launch</td>
</tr>
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</table>

Table 1: AUTOPAK® Liquid Stable Portfolio

Did you know?

**Why measure HbA1c?**
HbA1c measurements represent the degree of glucose exposure over a three-month period and are more useful than relying upon a single or episodic measurement of glucose levels to guide patient management and therapy adjustment. Measuring HbA1c levels every three months is a useful tool for monitoring glycemic control.

**What are the accepted clinical guidelines for HbA1c?**
- An HbA1c level above 6.5% (48 mmol/mol) is an indicator of diabetes: Diabetic patients should keep HbA1c levels below 7% to minimize the risk of diabetes complications.
- Levels between 5.7% and 6.4% (39 mmol/mol to 46 mmol/mol) may indicate pre-diabetes: Pre-diabetic or at-risk patients should make lifestyle changes or explore pharmacologic treatment.

DCA Vantage® Analyzer: Ensures clinical confidence and enhances laboratory productivity

DCA Vantage® Analyzer: Proven system with a track record spanning nearly two decades
- Whole blood sample obtained by finger prick or venepuncture
- Self-contained cartridges facilitate easy, walkaway operation after sample loading
- No sample or reagent preparation required
- Barcode scanner for safer and faster patient/operator ID entry
- Minimal maintenance requirements with automatic reminders to alert you when maintenance is due
- Versatile data management and reporting options
- Onboard printed patient results minimize the need for subsequent visits and tests, thus improves workflow
- Largest memory stores up to 4000 records, easily downloaded and transferred to a computer
- Oversee and troubleshoot multiple connected analyzers in real time especially in hospitals when supported by Siemens RAPIDComm® Data Management System

DCA Vantage® Analyzer: Proven system with a track record spanning nearly two decades

Diabetes is one of the most challenging health problems of the 21st century. The International Diabetes Federation estimates that about 366 million people around the world have diabetes.

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The DCA Vantage® Analyzer helps monitor glycemic control and detect early kidney disease in environments ranging from the physician's office to remote, point-of-care coordinated sites in hospitals and multisite practices.

**References:**
2. Standards of Medical Care in Diabetes - Diabetes Care, Volume 35, Supplement 1, January 2012.

Figure 1: AUTOPAK® Reagent portfolio

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<td>Urea</td>
<td>Calcium</td>
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<tr>
<td>Uric Acid</td>
<td>Chloride</td>
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<tr>
<td>Renal Profile</td>
<td>Inorganic Phosphorus</td>
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<td>Lipid Profile</td>
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<td>HDL-Cholesterol</td>
<td>LDH</td>
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<td>Cardiac Profile</td>
<td>Electrolyte Profile</td>
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<td>Lipid Profile</td>
<td>Metabolic Profile</td>
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<td>Alkaline Phosphatase</td>
<td>Amylase</td>
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<tr>
<td>Bilirubin (Total &amp; Direct)</td>
<td>Glucose</td>
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<tr>
<td>GGTP</td>
<td>Calcium</td>
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<tr>
<td>SGPT (ALT)</td>
<td>Choline</td>
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<tr>
<td>SGOT (AST)</td>
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</tbody>
</table>
Customer Experience:

Dr. Ravindra Patwadkar  
M.D. Pathology  
Dr. Hedgewar Rugnalaya, Aurangabad  
Senior Pathologist  
ravindra-patwadkar@hedgewar.org

HbA1c testing in a small medium sized laboratory faces many challenges—

- Sample constraints – EDTA sample
- Sample preparation outside the equipment
- Poor reproducibility and reliability
- High turnaround time
- Satisfaction of diabetic patients who are always scrutinizing their results under lens

At our lab over the period, we tried direct enzymatic method and particle enhanced immunoturbidimetric method (PEIT) for HbA1c estimation. The problems we faced were poor reagent stability, short calibration stability, poor accuracy and reproducibility and hence unsatisfied clients. PEIT also caused rapid loss of cuvette transparency and poor quality results.

With addition of DCA Vantage® we have overcome the above disadvantages. The method has got sample flexibility (EDTA or Fluoride or Citrate sample can be used with the same quality results), low sample volume (1 µl), excellent reproducibility and accuracy of results with ease of processing. This has resulted in satisfied patients and clinicians. There is improvement in workload of the laboratory.

DCA Vantage® Analyzer: Actionable results in 7 minutes or less

Minimize the need for follow-up visits with a full spectrum of results

- **Monitor glycemic control**
  - Simplicity: HbA1c from a small (1 µL) whole blood sample in 6 minutes to result and no reagent preparation; NGSP certified and IFCC certified/CLIA waived
  - Flexible reporting of HbA1c% (NGSP, JDS and Mono-S units) and IFCC (mmol/mol)
  - Reporting of HbA1c results as Estimated Average Glucose* values in the same units (mg/dL) that patients’ home glucose meters display
  *check the availability in your country

- **Detect early kidney disease**
  - Albumin, Creatinine and Albumin-to-Creatinine (A:C) ratio from a urine specimen in 7 minutes to report a quantitative protein status with automatic creatinine adjustment
  - Onboard GFR calculator indexes kidney function to help you monitor kidney disease progression and recommend the most effective treatment plan
**Advances in Acridinium Ester (AE) technology on ADVIA Centaur® Systems**

Driving innovation in chemiluminescent immunoassay design and meeting evolving clinical needs

The AE chemiluminescence technology featured on Siemens ADVIA Centaur® Immunoassay Systems has successfully resolved many challenges in terms of greater assay sensitivity, specificity and precision and is pushing the innovation barrier through the innate characteristics of the AE molecule.

The AE molecule is extremely flexible because it is based on a family of chemiluminescent structures that can be selectively optimized for each individual assay. Benefits include direct labeling with a small molecule that uses a rapid and uncomplicated mechanism for high quantum yield light emission, hydrophilicity and stability.

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**Features of acridinium ester chemistry**

- **High quantum yield (HQY).** High signal-to-noise ratio for improved sensitivity and low-end precision.
- **Hydrophilicity.** Improved efficacy of wash step for low non-specific binding.
- **Hydrolytic stability.** Long reagent shelf life and extended onboard stability.
- **Versatility.** Labeling versatility for an extensive assay menu.
- **Small size.** Direct labeling with AE for use in a broad range of assays.
- **Rapid Kinetics.** Light emission complete in 1 to 5 seconds for high throughput.

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The advances in AE technology have resulted in significant improvements in the performance and reliability of commonly used clinical assays. Robust AE molecule evolution is also enabling the introduction of novel assays and is facilitating their design through reliance on well-proven principles and performance.

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**ADVIA Centaur® Enhanced Liver Fibrosis (ELF™)* test: First fully automated Liver Fibrosis Assessment**

Siemens AE-related research has helped in the development of the innovative Enhanced Liver Fibrosis (ELF™) test that measures direct biomarkers of liver fibrosis to assess the severity of liver fibrosis in patients with chronic liver disease. The current standard of care to assess liver fibrosis is an invasive liver biopsy, which has its own limitations. The ELF™ test combines three direct serum biomarkers to obtain a single ELF score calculated by ADVIA Centaur® Systems that correlates with severity of fibrosis as assessed by liver biopsy. The test has been clinically validated in an international multi-center study with a mix of patient groups and was found to be accurate in differentiating mild, moderate and severe fibrosis.

- Uses a routine blood serum sample
- First standardized direct marker panel of liver fibrosis
- Standardized component assays - hyaluronic acid (HA), amino-terminal propeptide of type III procollagen (PIIINP) and tissue inhibitor of metalloproteinase 1 (TIMP-1)
- Clinically validated for liver fibrosis assessment in mixed, HCV and NAFLD patient groups

*Check the availability in your country

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**ADVIA Centaur® Vitamin D Total Assay: Fast, Accurate Vitamin D Results on a Primary Analyzer**

A modified AE molecule is the central component of the Siemens Vitamin D Total assay, which offers the equimolar detection of both D2 and D3 necessary for assessment of vitamin D status. In recent years, vitamin D has become an assay of general health status and multiple publications have linked vitamin D deficiency to several disease states, such as cancer, cardiovascular disease, diabetes and autoimmune diseases.

The AE-reliant ADVIA Centaur® Systems Vitamin D Total Assay eliminates the need for a specialty analyzer for vitamin D testing. The assay measures total 25(OH) Vitamin D to ensure accurate results with good precision and offers clinical concordance with LC/MS/MS methods. Results are available in 18 minutes, representing a significant improvement in turnaround time over legacy methods.

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**ADVIA Centaur® TnI-Ultra Assay: Five Times More Sensitive than its Predecessor**

Cardiac troponin I measurements determined by high-sensitivity assays may be used as an aid in the diagnosis of acute myocardial infarction (AMI) and in the risk stratification of patients with acute coronary syndromes. The AE-based ADVIA Centaur® TnI-Ultra™ assay is a highly precise assay that can measure very low concentrations of cardiac troponin I. This excellent precision exceeds the industry benchmark established by the Joint European Society of Cardiology/American College of Cardiology Committee of ≤10% CV at the 99th percentile of normal. The assay uses the HQYAE molecule to help improve analytical sensitivity by a factor of 5 over the previous ADVIA Centaur® cTnl assay.
Dr. Sunita Kapoor is the Director of the NABL accredited, state-of-the-art diagnostic laboratory at City X-Ray and Scan Clinic (P) Ltd. The lab has an array of fully automated equipments in Hematology, Biochemistry, Immunoassay, Microbiology and Serology. Impressed by immunoassay solutions from Siemens, Dr. Kapoor shares her opinion:

In the year 2000, we had the opportunity to start a diagnostic laboratory at City X-Ray and Scan Clinic (P) Ltd. We started with Enzyme immunoassay (ELISA) method to handle various tests like T4, T3, FreeT4, Free T3, TSH, FSH, LH, Prolactin, etc. We then switched over to Siemens IMMULITE® analyzer, a fully automated system. We were impressed by extensive test menu and its throughput.

As the workload and patient demands further increased, we decided to upgrade the laboratory with even faster throughput analyzers like the 180 tests per hour ADVIA Centaur® CP analyzer and currently the highest throughput in the class with ADVIA Centaur® XP 240 tests per hour analyzer.

The major advantage using automated analyzers is that we can run any test or combination of tests when required. The ADVIA Centaur® XP allows continuous loading of samples and it can accommodate 30 reagents on board. These can be changed on the fly without disturbing other assay processes.

ADVIA Centaur® provides a wide menu and can perform TFT’s (both free and total), fertility parameters (eg. FSH, LH, PRL), cancer markers, bone markers (25 OH Vitamin D, PTH), anemia markers (ferretin), therapeutic drugs (eg. valproate, carbamazepine) and other endocrine parameters (eg. GH, Cortisol) on a single platform. The equipment maintenance is very easy.

Major advantages on the ADVIA Centaur® XP are:

- Shorter TAT on routine and STAT tests
- Broad linearity range and auto-dilution for results beyond linearity
- Multi-parameter calibrators help in efficient inventory management
- Alarms for calibration
- Ease of switch over to back up instrument even with partially used kits, in case of breakdown

The equipment maintenance is very easy. The Centaur analyzer handles 95 percent of our laboratory workload and has given us efficient service over the years.

Stenotrophomonas Maltophilia - a concern in tertiary care hospital

Authors: Roy Sudip, Ghosh-Mitra Arpita, Chakraborty Sanchita, Banerjee Partha, Paul Srabanti

Dr. Sudip Roy
Consultant Clinical Microbiologist
Chairperson Hospital Infection Control Committee
Medica Superspecialty Hospital, Kolkata
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Introduction

Stenotrophomonas maltophilia exists in nature as a motile, aerobic, glucose non-fermenting, non-sporulating, gram-negative bacillus. Several events and outbreaks of healthcare associated infections were reported associated with Stenotrophomonas as it has got the capacity to colonize the inanimate hospital environment. Although these infections are typically polymicrobial, monomicrobial infections are also gaining importance. Considering its inherent resistance to many antimicrobials and increasing trends of resistance to drug of choice Cotrimoxazole, antimicrobial management is often problematic in these instances. The purpose of this study is to evaluate the incidences of S. maltophilia infection with its clinico-microbiological profile and demographic characteristics.

Materials & Methods

A retrospective analysis of all incidences of S. maltophilia at Medica Superspecialty Hospital, Kolkata, India between January 2010 to July 2012 was performed. Identification and antimicrobial susceptibility testing of isolates was performed on MicroScan® autoSCAN®-4 with Negative Break Point Combo Panel 34. The results were interpreted according to the Clinical and Laboratory Standards Institute (CLSI) guidelines. Escherichia coli ATCC 25922 and Pseudomonas aeruginosa ATCC 27853 were used as quality control strains.

Results

Eleven patients with confirmed S. maltophilia infection were included in this study. The median age was 55 years with a male preponderance (63.63%). The most common infections were blood stream related (54.54%, half of which was central line related) followed by respiratory tract infection (45.45%). (Ref: Table 2)

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<tr>
<th>Sample</th>
<th>n (%)</th>
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<tr>
<td>Blood</td>
<td>6 (54.54)</td>
</tr>
<tr>
<td>Bronchial secretion/lavage</td>
<td>5 (45.45)</td>
</tr>
<tr>
<td>Pus</td>
<td>1 (9.09)</td>
</tr>
<tr>
<td>Central line tip</td>
<td>3 (27.27)</td>
</tr>
</tbody>
</table>

Table 2: Sample Types and Occurrence

Antibiotic susceptibility: The highest in-vitro susceptibility (including susceptible and intermediate status) was observed with levofloxacin (54.54%), followed by cotrimoxazole (36.36%). (Ref: Chart 1)
Quiz #3

1. The DCA Vantage® analyzer is a portable point-of-care analyzer for the quantitative measurement of HbA1c. With a finger prick sample collection, it provides HbA1c result:
   a) From a small (1 µL) whole blood sample in 6 minutes without any reagent preparation time
   b) From a small (1 µL) whole blood sample in 10 minutes without any reagent preparation time
   c) From a small (2 µL) whole blood sample in 6 minutes without any reagent preparation time

2. AUTOPAK® liquid stable reagents suitable for clinical chemistry laboratories:
   a) Save time, eliminate manual errors, improve workflow and are economical
   b) Are suitable for any semi automated analyzer
   c) Both a) and b)

3. ADVIA Centaur®'s Enhance Liver Fibrosis (ELF) test is the first fully automated non-invasive test that measures direct biomarkers of liver fibrosis to assess the severity of liver fibrosis in chronic liver disease patients.
   True False

Please send your answers along with your contact details and the lucky five will receive a special prize.
E-mail to labtrendz.in@siemens.com
If you have interesting cases to be shared, please e-mail us at labtrendz.in@siemens.com

Lab-trendz Issue#2 March 2013 Quiz 2
Answers:
   b, d, true

Winners
Dr. Prashant K. Naik, SRL Diagnostics - Abha Laboratory, Surat
Dr. Arun Kumar Sharma, PGIMER, Chandigarh
Dr. Abha Gupta, Indraprastha Apollo Hospital, New Delhi
Dr. Pallab Basu, Sagar Dutta Medical College & Hospital, Kolkata
Dr. Santhi Silambanan, Sri Ramachandra Medical College and Research Institute, Chennai

Siemens at AACC and ASCLS

Siemens participated in the 2013 AACC and ASCLS Annual Meeting and Clinical Lab Expo, held in Houston, Texas. More than 17,000 participants attended this expo, where Siemens displayed its innovative diagnostics portfolio of solutions that can help them to "test smarter and run faster". Visitors had the opportunity to visualize their laboratory’s full potential via on-floor solution displays and the interactive Augmented Reality Zone. Our products*, which were in the spotlight at AACC include the newly launched VersaCell® X3 Solution, Aptio™ Automation system, syngo Lab Inventory Manager (cloud-based technology that streamlines and automates the inventory management process), key assays including IMMULITE® Systems Anti-CCP assay, RAPIDLab® 348EX Blood Gas System, CLINITEK Status® Connect System, and Copan WASP® WalkAway Specimen Processor.

*Product availability varies by country

Technological innovations spur new clinical applications. This gives the medical community an edge in diagnosis and helps detect / treat diseases at an early stage. This in turn will help the society at large. These are the primary objectives with which we developed Lab-trendz. We would like to know how we can make this initiative more valuable for your practice and the wellbeing of patients.

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