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SOMAGEN QUARTERLY SUMMER 2006

Automation of Urine Microscopy in Canadian Labs

The option to automate urine microscopy requires careful consideration of the challenges and benefits of such automation: What are the goals of automation? What benefits will automation offer the lab? Will any benefits be offered to the clinician?

Solid Technology

The Sysmex UF-100 is a fully automated urine cell analyzer which is used in over 2000 laboratories worldwide. The UF-100 uses Fluorescent Flow cytometry and is designed to bring efficiency and quality to routine urine microscopic analysis. The same technology which has been used in Hematology cell counters for decades is now available for urine microscopy. The use of a fluorescent dual stain (cytoplasmic and nuclear) combined with adaptive cluster flow cytometry allows this technology to produce the highest quality results in urine microscopy.

Extensive Analysis

The UF-100 will automatically classify 10 classes of formed elements. Of these, the following are enumerated: RBC, WBC, Epithelial Cells, Hyaline Casts and Bacteria. The remaining elements (Pathological Casts, Small Round Cells (renal and transitional epithelial cells), Yeast, Crystals, and Sperm) are flagged parameters which require microscopic confirmation by a skilled technologist. The review involves a simple confirmation of the presence or type of cellular element which has been flagged and not a full microscopic review of all cellular elements.

Sensitivity

An important consideration in urine microscopy is the sensitive detection of pathological casts. The use of an uncentrifuged sample together with the analysis of a large sample volume (9ul volume) is a key factor in the quality of results obtained with the UF 100.

The combination of a dual fluorescent stain, adaptive cluster analysis and the use of an intelligent algorithm allows the UF system to "see" more than what we can view on a standard microscope. This is especially important in the detection of rare pathological formed elements such as casts. The cellular dimensions which are considered in the classification algorithm are size, cross sectional area, length of cell, length of stained portion, volume, chromogenesity, index of refraction and stability of centroid. Thus the UF-100 provides a very sensitive screen for the detection of rare pathological events such as the detection of casts and microhematuria.

Early Indications of Disease

Apart from providing data on the above formed elements, the UF-100 can also provide accessory information such as flags for RBC morphology. This sensitive flag allows for the follow up of samples with dysmorphic red cell populations which may be an early indicator of kidney disease. The number of RBC populations and the number of lysed cells (ghost cells) are also available and this information may aid in the classification of glomerular bleeds.

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Automation of urine microscopy in Canadian Labs [continued from page 1](#)

Early diagnosis of kidney disease is key in the potential treatments options for renal patients, it is important to consider factors which may help increase the early detection of this disease. Examining current laboratory protocols are important. For example, if chemical urinalysis (dipstick) is used to screen samples prior to microscopic analysis, we may potentially miss samples with low level intact RBCs, Small Round Cells (renal tubular, renal transitional cells) and oval fat bodies as these are not detected by dipsticks. The unsurpassed sensitivity of the UF-100 will ensure that even low level cellular elements are detected so that appropriate follow up may be initiated.

Efficiencies

The introduction of automated urine microscopy will allow the laboratory to screen a large number of samples with a reduction in valuable technologist time. Most samples are

auto validated by the analyzer; this includes samples which contain particles above the reference values for the enumerated elements. The samples which require confirmation of a pathological element are flagged for review by the skilled technologist. The introduction of automation helps target samples which require attention and with the introduction of appropriate review criteria we can eliminate unnecessary reviews.

Potential

The UF-100 offers many promising future applications such as the use of a WBC and Bacteria count for UTI applications and the identification of WBC populations to determine if an active UTI is present.

Sysmex technology offers high quality automation for urine microscopics and provides benefits to both the lab and the clinician. The use of Fluorescent Flow Cytometry allows for



unattended operation in batch or continuous mode, superior formed element identification and enumeration bring new levels of efficiency and standardization by automating the entire analytical process. The unmatched sensitivity of this system also offers important information which may serve the clinician in the assessment of the origin of hematuria.

Somagen Continuing Education

We are pleased to present Dr. Kenneth Blick, Dept. of Pathology, University of Oklahoma Health Sciences Center, Oklahoma City to share his laboratory's experience with BNP and Point of Care implementation as an industry workshop at the upcoming Canadian Society of Clinical Chemist's (CSCC) meeting in Victoria B.C. Tuesday, June 6, 4 – 6 p.m.

Presentation Overview

“Economics of Point-of-Care (POC) Testing for Cardiac Markers and B-Natriuretic Peptide (BNP)”

The focus of this presentation is the clinical, economic and operational benefits achieved after implementing the combination of rapid protocols with POC testing of BNP, TnI, CK-MB and Myo in the Emergency Department.

Discussions will highlight a study authored by this Laboratory Director as it was the Lab that took the lead in investigating, justifying and implementing POC testing in the E.D. for cardiac markers and BNP

The laboratory performed cardiac markers (TnI, CK-MB, Myo) on (4) different systems, (Triage MeterPlus, Abbott AxSYM, Bayer Centaur, Dade RxL).

Cost per reportable result (CPRR) calculations will be discussed. Data mining for outcome was analyzed from computer records and peer comparison data was acquired from Cardiac Data Solutions (MedPAR, 2002, CMS), using CPRR calculations obtained from HealthTrust Purchasing Group.

Points of Review:

1. Summary of the tangible clinical, economic and operational benefits achieved since implementing POC cardiac markers, BNP, and rapid protocols in the E.D.
2. Qualitative summary of the benefits associated with POC testing of cardiac markers and BNP.
3. Review mean in-laboratory TAT for cardiac markers during high-volume testing periods (Range: 33 to 84 minutes). **Main point:** the mean of 41.6 minutes was pretty good, however, that's the mean, the problem is the outliers, which never go away. (This lab was continually striving “to do better” with regard to Cardiac TAT)
4. Reference NACB Guidelines recommending TAT of 30 minutes or less for cardiac markers. **Main point:** the 30-minute guidelines are not 30 minutes for the mean TAT across all patients, rather the guidelines are 30 minutes or less for every cardiac patient's markers.
5. Identify most of the major variables that can comprise the total cost of running a test. **Main point:** to make an apples-to-apples comparison of the costs for POC methods and traditional lab instruments, the cost per reportable result (CPRR) of the assay (or panel of assays) should be determined by including all contributors to cost as opposed to simply comparing the cost per test of the reagent.
6. MedPAR and hospital data reflects high NSTEMI population (58.1%) as well as relatively high PCI/CABG intervention rates (42.1%/19.5%) for ACS patients. **Main point:** this patient population mix increases pressures to reduce the duration of indecision and to reduce ED LOS.
7. Restate the tangible benefits of POC testing. In addition, this hospital has experienced benefits in managing ED ACS patients through the use of rapid BNP measurements. **Main point:** rapid BNP measurements are useful in evaluating ACS patients for possible emergency PCI or CABG interventions.

8. Review the impact of indecision regarding “when” to discharge patients from the CCU. Lack of bed space for new admissions is also cited as a common problem. **Main points:** length of stay in the CCU directly impacts the hospital's bottom line as does the appropriate initial disposition of patients into the CCU. This hospital has experienced a reduction in LOS for CCU CHF patients of 2.0 days, a potential savings of over \$1,000 per day, per patient. The decrease in CCU CHF LOS has amounted to an estimated savings of 440 CCU patient days. Rapid POC testing combined with rapid protocols contributed to achieving these improved outcomes. BNP test volumes have increased, however, significant improvements in outcomes have proven the value of investing in POC testing.

9. Review CAP's accreditation program requiring labs to pursue a documented CQI program. This lab is documenting, with outcomes studies, how enhancements in services (POC testing + rapid protocols) have resulted in improved patient outcomes. We will discuss metrics being measured to assess the impact of Cardiovascular POC testing.

Full article and reference material on this presentation are available through Somagen Diagnostics.

We look forward to seeing you at the CSCC in June!





IFA Automation – Total Flexibility for Workload Management

In today's busy laboratory, the need to consolidate and automate testing is top priority. Technologists must multitask like never before – in other words spend as little time as possible running many different assays.

Highly labor intensive tests such as Immunofluorescent (IFA) ANA testing where manual dilutions, titrations and slide processing must be performed, put demands on technologist's valuable time – at a cost to productivity. Today, automation of these steps reduces potential slowdown and frees up precious time. The Immuno Concepts AFT2000 (Autoimmune FastTrack) delivers high throughput processing and flexibility to IFA

testing. Designed for flexible high-workload management, the AFT2000 performs all of the steps in an IFA ANA test from sample diluting, sample pipetting, titrations, slide washing, reagent addition and timed incubations. Easy to use software allows for fast start up – once underway, the graphical interface provides the operator with continuous information on the progress of the batch. Up to 16 IFA slides of various configurations may be set up. Single or serial dilutions may be performed. System features include a dual nozzle PTFE coated probe to minimize carryover; automatic liquid tracking which minimizes needle submersion - pipetting imprecision is less than 0.5% CV!

The AFT2000 from Immuno Concepts is an affordable and reliable solution to your serology testing. Contact Somagen Diagnostics today for more information.



CVA/CVA for CELL-DYN... Ensuring confidence in every patient result

Somagen Diagnostics is proud to profile Streck Laboratories, manufacturer of hematology, chemistry and immunology products for the clinical laboratory.

Known as a leading developer and manufacturer of hematology control products, Streck excels in producing some of the most commonly used controls worldwide. One of these products is the Calibration Verification Assessment (CVA) and CVA for Cell-Dyn. These are assayed linearity control kits that can be used to assess calibration and to verify reportable range of three and five part hematology instruments, as well as, automated and semi-automated non-differential analyzers. In addition to assessing calibration and reportable range, the kits may be used to measure the linear performance of a hematology analyzer.

Simply using daily QC controls tests only a small portion of an instrument's reportable range. By using CVA, a laboratory is able to test the extreme upper and lower limits of an instrument. This expanded range assures that abnormal patients' results are valid.

Streck CVA is composed of stabilized human red blood cells* and simulated platelets, maintaining an open vial stability (OVS) of 5 days and a closed vial stability (CVS) of 120 days. The 5-day OVS allows CVA to be rerun if an instrument problem is detected.

Once data is collected, Streck offers an inter-laboratory quality control program where customers can submit their data for a complete linearity and reportable range analysis, saving laboratories time to perform other tasks. These STATS® reports are clear and concise and an excellent tool to show compliance with Clinical Quality Management Programs such as the Ontario Laboratory Accreditation (OLA).

For more information on CVA and other Streck products, please contact Somagen Diagnostics.

CVA Assayed Instruments

- Beckman Coulter® STKS™, MAXM™, STKR/S Plus Series, A^c T™ 5diff, Gen S™, LH 750/LH 755
- Bayer Diagnostics ADVIA® 120, Advia 70, Advia 60 Hematology system
- ABX Diagnostics Pentra 60C+
- Danam™/Infolab Excell 16™, Excell 22™
- HemoCue, Inc. B-Hemoglobin Photometer

CVA for CELL-DYN Assayed Instruments

- Abbott CELL-DYN 4000, CELL-DYN 3500/3700, CELL-DYN 3200, CELL-DYN 3000, CELL-DYN 1600, CELL-DYN 1700, CELL-DYN 1800

***All human source material used to manufacture this product was nonreactive for antigens to Hepatitis B and HIV-1, negative by tests for antibodies to HIV and Hepatitis C, and nonreactive to Serological Test for Syphilis using techniques specified by the U.S. Food and Drug Administration.**





SEE YOU THERE!

Watch for Somagen at these upcoming conferences:

**AMMIQ – Association des Médecins
Microbiologistes Infectiologues du
Québec**

Rivière du loup, Québec
May 30 – June 2, 2006

**OPTMQ – Ordre Professionnelle des
Technologistes Médicaux du Québec**

Laval, Québec
June 1 – 3, 2006

**CAEP – Canadian Association of
Emergency Physicians**

Halifax, Nova Scotia
June 3 – 7, 2006

**CSCC – Canadian Society of Clinical
Chemists**

Victoria, British Columbia
June 4 – 7, 2006

**CAP – Canadian Association of
Pathologists**

St. John's, Newfoundland
July 15 – 19, 2006

**AACC – American Association of Clinical
Chemists**

Chicago, Illinois
July 23 – 27, 2006

**NSH – National Society for
Histotechnologists**

Phoenix, Arizona
September 9 – 14, 2006

**Kenora Rainy River Regional Lab
Program Annual Fall Symposium**

Kenora, Ontario
September 19 – 21, 2006

Somagen Partner Profiles

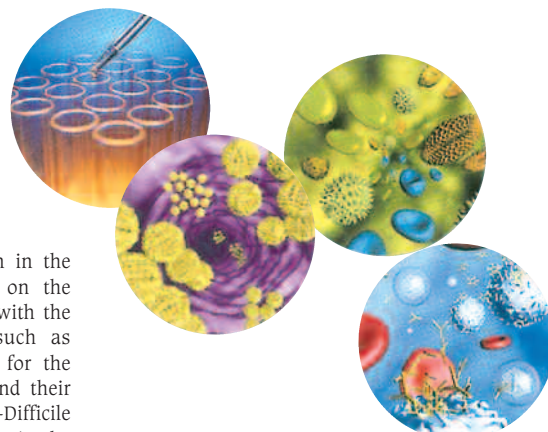
Somagen Diagnostics is pleased to present Somagen Partner Profiles. This feature highlights the many supplier partnerships within Somagen Diagnostics. We will review the company and let you know what special benefits their products provide your industry.

Founded in 1988, r-Biopharm, (Germany) is a leading developer of solutions for clinical diagnostics. The company's innovative test kits are relied upon by laboratories in many countries for their analytical precision and ease of use. Since 1988 r-Biopharm has grown to include subsidiaries in the UK, USA, Italy, and France and is represented by a worldwide distribution network of over 80 distributors.

r-Biopharm products fall under the trade names RIDASCREEN and RIDA and for products presently sold by Somagen Diagnostics all have undergone Health Canada regulatory approval.

r-Biopharm's long standing reputation in the diagnostics industry has been built on the quality of their EIA and rapid assays with the focus on stool diagnostics. Tests such as RIDASCREEN Norovirus a novel EIA for the detection of Norwalk virus in stool and their improved EIA kit for the detection of c-Difficile have made r-Biopharm a leading player in the Infectious Disease market.

*To learn more about r-Biopharm products,
please visit our website at
www.somagen.com or contact us at
1-800-661-9993.*



Rounding out the list of products offered by r-Biopharm are EIA and rapid stool assays which include...

Adenovirus	Entamoeba
Astrovirus	Giardia
Campylobacter	Norovirus
C. Difficile	Rotavirus
Cryptosporidium	Verotoxin

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Visit our website at www.somagen.com



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