Sysmex Parameters—Enhancing Patient Care Quality One Laboratory Test at a Time

“Better Outcomes. Fewer Complications” is what distinguishes America’s 50 Best Hospitals 2009 according to HealthGrades, the leading healthcare independent ratings organization. Community Hospital, Munster, Indiana has been named to this elite list based on the objective analysis of patient care data of more than 5,000 hospitals nationwide. Contributing to this milestone is Community Healthcare System’s operational excellence philosophy.

“Since early 2007, our organization, Community Healthcare System, has been in an operational excellence mode, initiating a ‘pillar of services’ mindset and challenging each hospital department to enhance its service levels. In our clinical laboratory, we responded to the challenge by asking ourselves, ‘How do we make our CBC service offering better?’ The answer was a clear one—the implementation of Sysmex parameters RET-H, IG, and IPF,” said Ethel Urbi, MPA, MT (ASCP) SH, DLM, Regional Laboratory Director and Hematology Technical Advisor of Community Hospital and Healthcare System.

Ethel was aware that Sysmex instruments were able to offer additional, clinically relevant parameters that were automatically measured in the course of a routine CBC. Three were of particular interest to her: Immature granulocyte (# and %), RET-H (hemoglobin content of reticulocytes), and IPF (Immature platelet fraction). Ethel’s query to Sysmex America for literature regarding Sysmex parameters set the ball in motion.

“Our pathologists are innovative leaders who do not shy away from technology advancements that could better serve patients. This mindset, coupled with the fact that the implementation of these additional Sysmex parameters would not require additional capital, additional training, or additional reagents, made our July 2007 conversion an easy one,” said Ethel.

Not wedded to tradition, Ethel looked beyond the 5-part differential. “Band neutrophils have been tricky to report because they lack standardization. But since the Sysmex instrument helps us standardize Immature Granulocytes (IG) between different laboratories within the Health System, a 6-part differential, which includes IG, is now part of our standard CBC offering.

President’s Message

The theme of my last two messages has been on reshaping the laboratory, with the focus given to operational efficiency and clinical excellence respectively. This issue’s message, the last of my three-part series, will give critical eye to the financial aspect of laboratory reshaping.

In a July 2009 Gallup Poll, it was reported that an overwhelming 79% of Americans say that they are dissatisfied with the total costs of healthcare in this country. Poll results also noted that the push for healthcare reform is occurring in an environment characterized by high levels of concern about fiscal responsibility, government spending, and the growing federal deficit. No matter which way you cut it, one cannot scrutinize healthcare services without considering the costs associated with those services. At Sysmex America we have considered these costs.

In October 2008, the Centers for Medicare and Medicaid Services introduced significant restructuring of the diagnostic related groups (DRGs) to MS-DRG (Medical Severity - Diagnosis Related Groups) used in the inpatient prospective payment system (IPPS). New Present on Admission (POA) rules require evidence-based, patient diagnosis on admission. This will impact how hospitals code patients upon admission and, consequently, the way in which hospitals are reimbursed. This, along with an aging population, increasingly complex cases and diminished human and financial resources, makes accurate patient diagnosis and instrument capability critical elements to adequate reimbursement and hospital survival.

As such, hospitals must be committed to a best-in-class philosophy. Why? By thoroughly considering quality, reliability and the ability to provide advanced, clinically relevant results, laboratory managers can impact overall healthcare efficiencies—operationally, clinically and financially. It is within this careful consideration where one looks to Sysmex—a best-in-class hematology products manufacturer and services provider.

One must also consider Sysmex’s commitment to research and development. Clear evidence suggests that laboratory developments will move us away from the traditional paradigm of chronic disease diagnosis and management to one of disease prevention, early treatment, tailored therapy, and genome/proteome/cellulome-guided disease management.

Sysmex quality, reliability and our ability to provide advanced, clinically relevant results will be as crucial to the financial health of your clinical laboratories and institutions in this new paradigm as they are today. A commitment to a best-in-class philosophy takes care of you today and tomorrow.

As we approach this holiday season, we want to personally thank you, our customers, for always pushing us to greater heights. Your demands for clinical excellence are reflected in our best-in-class product offering. And it will be your demands for maneuverability in a changing clinical laboratory environment that will reflect our advancement in technology.

Happy holidays.

John Kershaw
President
Sysmex America, Inc.
Sysmex Latin America & the Caribbean Makes Showing at Brazilian Congress of Clinical Pathology

Sysmex attended one of the year’s most important congresses in Brazil – The 43rd Brazilian Congress on Clinical Pathology (CBPC/ME). The congress provided an environment of scientific exchange and offered Sysmex to showcase Sysmex hematology, urinalysis and coagulation instruments. Sysmex’s partner, Colabions, also was present at the congress to discuss the sophisticated digital morphology system CellVision DMS9. More than 400 clinical laboratory professionals benefited from Sysmex booth presentations and informative talks, according to Leonardo Amaral, Sysmex Media and Events Coordinator for Latin America & the Caribbean. This year’s congress marked Sysmex Brazil’s first appearance at this prestigious event.

Sysmex Latin America & the Caribbean at a Glance
Sysmex Brazil Lays Foundation for Social Accountability Certification

Sysmex operations in the Americas include a manufacturing reagent plant in Brazil and a São Paulo office overseeing Latin America & the Caribbean distributors – all of which include a Sysmex team of professionals dedicated to standards of social responsibility.

As such, Sysmex Brazil has recently laid the groundwork for the company’s SA8000 Social Accountability certification by reaching out to its major suppliers with an official presentation of Sysmex Brazil’s SA8000 certification program initiatives.

SA8000 is a universal standard for companies interested in auditing and certifying labor practices in their facilities and those of their suppliers and vendors; and is designed for independent third-party certification.

“The SA8000 is the most widely recognized and auditable standard for managing human rights in the workplace for organizations of all sizes anywhere in the world,” said Sandra Forat, Quality and Regulatory Affairs Manager, Sysmex Brazil. “Sysmex Brazil’s interest in achieving this voluntary certification further demonstrates the company’s core behavior as a responsible member of society – a core behavior found in the Sysmex Way.”

In 2008, the Centers for Medicare and Medicaid Services introduced significant restructuring of the diagnostic related groups (DRGs) to MSS-DRGs (Medicare Severity–Diagnosis Related Groups) used in the inpatient prospective payment system (IPPS). New Present on Admission (POA) requirements set evidenced based, patient diagnosis on admission. This will impact how hospitals code patients upon admission; and consequently, the way in which hospitals are reimbursed. This, coupled with an aging population, increasingly complex cases and diminishing human and financial resources, makes accurate patient diagnosis and instrument capability critical elements to adequate reimbursement and hospital survival. To provide accurate information in this process, clinical laboratories must assess their instrument capability relative to their effect on service line, care pathways, medical errors and patient flow.

“Community Hospital is one of the three hospitals that comprise Community Healthcare System which services Northwest Indiana and the south suburbs of Chicago. The hospitals have been Sysmex customers since the late 1980s,” said Urbi.

Community Hospital’s pathologists also played a key role in the development of a printed newsletter which was used to create awareness of the parameters at the hospital and physician levels. The pathologists then followed up with one-on-one meetings with physicians in specialty areas such as oncology, nephrology, infectious diseases and pediatrics, among others.

“The validation and implementation of the new advanced clinical parameters was easy and well accepted by our clinicians. Immediate standardization in measurement is part of our standard automated differential and we receive approximately 20-40 RET-H and 20-IPF orders each month. Good validation planning and communication to our physicians can be attributed to our success,” said Urbi.

FDA Clears Sysmex XE-2100D Hematology Analyzer for QC Release Testing in Blood Processing Centers

The United States Food and Drug Administration (FDA) has cleared the Sysmex XE 2100D for blood processing center Quality Control release testing of post-processed red blood cell and platelet components collected using a variety of anticoagulants. Historically, the Sysmex XE-2100D had been cleared for in vitro diagnostic use in clinical laboratories and donor centers as a multi-parameter hematology analyzer for white blood cells using EDTA anticoagulant.

“The nation’s blood centers play a critical role in serving the needs of patients. As blood centers face increasing blood donation needs across the country by a level in-class hematology instrument provider, Sysmex continued development based on blood center customer input. We invested the time and money necessary to conduct the extensive studies required by the FDA to achieve this clearance milestone. The ability to use the XE-2100D with these anticoagulants enables blood centers to meet the FDA’s rigorous manufacturing classification demands. It streamlines the validation and documentation process necessary to meet these requirements, providing the potential for improving efficiency and labor utilization,” said John Kerns, President & CEO, Sysmex America, Inc.

Since blood centers are classified as manufacturing organizations, they are highly regulated by the FDA. All instruments and products are to be used according to the manufacturer’s intended use and instructions. Any deviation from any of the manufacturer’s intended use statements requires extensive validation and documentation by the blood centers. This intended use clearance for the Sysmex XE-2100D greatly reduces the validation effort needed prior to placing the XE-2100D into production. This means significant savings in time, materials and labor, explained Kerns. No other currently available hematology analyzer has been cleared for such use.

In summary, blood centers using the Sysmex XE-2100D Automated Hematology Analyzer can expect to realize improved efficiency and labor utilization, enhanced validation efficiency and decreased validation cost, as well as a wealth of support tools and services from Sysmex America, Inc.

The Sysmex TS-2000 Tube Sorter – Managing up to 800 Samples Hourly

Sysmex America unveiled its new Sysmex TS-2000 Tube Sorter during last year’s AACC Annual Conference and Clinical Lab Expo. As a part of the Sysmex Lavender Top Management® system, the TS-2000 is capable of automatically redirecting lavender top tubes for reticulocyte and MPV parameters into the Bio-Rad VARIANT™ II TURBO Link.

The handling of the lavender top tests used in such as hematology and diabetes testing, slide making and staining, sorting and archiving, repeat testing and decision processes can be combined into a single automation platform - Sysmex’s Lavender Top Management (LTM) solution. LTM combines the power of Sysmex’s automation platform (HST-N) with decision logic software, Sysmex WAM Hematology Clinical Decision Support Software, to optimize data and sample management efficiency through a higher level of LIS collaboration. This solution offers clinical laboratories quality results, superior instrument and automation performance (uptime and improved productivity turn-around times (both hematology and A1c results) and labor utilization.

Bio-Rad Laboratories, Inc. manufactures and distributes a broad range of products for the life science research and clinical diagnosis. Bio-Rad is renowned worldwide among hospitals, universities, major research institutions, as well as in vitro diagnostic and pharmaceutical companies for its commitment to quality and customer service. Founded in 1952, Bio-Rad is headquartered in Hercules, California, and serves more than 150,000 industry customers worldwide through its global network of operations.

Lavender Top Management™

Lavender Top Management™ is a turn-key solution which combines the Sysmex HST-N hematology automation platform and the Bio-Rad VARIANT™ II TURBO Link, enabling on-demand, automated diabetes testing in a random access setting. The integrated testing solution also utilizes automated decision logic software, Sysmex WAM Hematology Clinical Decision Support Software, to maximize efficiencies in the area of data and sample management and labor utilization. Lavender Top Management enables the automation of testing and data management of blood results performed on EDTA samples and automated sample management of virtually 100% of all EDTA samples, i.e. CBC, DHR, Retic, ESR and other esoteric tests. This integrated testing solution became available to hospitals across the nation in April 2008.

Sysmex XE-2100D Blood Center Anticoagulant FDA Clearance

The System XE-2100D Automated Hematology Analyzer is intended for in vitro diagnostic use in clinical laboratories and donor centers on EDTA anticoagulated whole blood.

Also, in blood processing centers the XE-2100D can now be used as a multi-parameter hematology analyzer and for QC release testing of the following post-processed components:

• Red blood cell components for HGB, HCT and parameters using CPD, CPD2, ACD-A, CPDA-1 and ACD antisera.

• Platelet components for PLT and MPV parameters using CPD and ACD-A as anticoagulants.

Cytometric Tube Sorter during this year’s AACC Annual Conference and Clinical Lab Expo.
In October, Sysmex America announced the appointment of Tom Lindsay as its National Director of Sales. In his new role, Tom is responsible for sales strategy development and implementation, customer loyalty initiatives and professional development; and retention of the company’s sales professionals.

“Tom’s heart of leadership at Sysmex America will focus on cross-functional collaboration that enables Sysmex to achieve its growth objectives.

His strong leadership skills in strategic planning and organizational development and his financial acumen will serve well as the company continues its pursuit as a world leader in diagnostics and information systems,” said Robert Degnan, Vice President of Sales. Lindsay will report directly to the Vice President of Sales. The company’s five regional sales directors and the non-acute segment director will report to Lindsay.

Prior to joining Sysmex America, Lindsay served in the IVD market for more than twenty years and most recently, as a regional business manager for Roche Diagnostics Corporation. His tenure with Roche included key roles in sales, international collaboration projects, professional development, and merger integration. While with Roche Diagnostics Corporation, Lindsay was the recipient of many professional awards including the Principle Quest Award and the Hubert Rehkaemper Award. He was also a five-time recipient of the President’s Award.

Lindsay received his bachelor’s of science in biology with a minor in chemistry from St. Cloud University, Minnesota. He has professional training in the areas of executive and economic value selling and building competitive immunity, among others.

Sysmex America Names National Sales Director

Sysmex Canada Continues Webinar Educational Outreach to Customers

Sysmex America is continuing its complimentary web-seminars series (webinars) for its customer-laboratories interested in learning more about receiving education credit in the convenience of their home or office. The webinars provide a quick, easy and inexpensive means for clinical laboratory professionals to optimize their learning on a variety of topics relevant to survival in a changing healthcare environment.

The two remaining seminars in the Sysmex Fall 2009 Web-based Educational Conferences include a November 18, 2009 webinar titled, “Laboratory Hematology: Providing Clinicians What They Need” and a December 16 webinar titled, “Health Reforms and the Role of the Laboratory: Meeting the Multi-setting Care Coordination Challenge.” Each conference will be held from noon to 1 p.m. CST. See complete information for each in webinar sidebar.

Sysmex’s educational conferences are designed to assist clinical laboratory professionals in addressing issues such as healthcare reform, advanced hematology technologies and strategic planning. Pathologists, lab managers, lab supervisors and bench technologists are all appropriate audiences. Each webinar is provided by experts in their fields. Each registrant will be able to receive 1.0 P.A.C.E./Florida C.E.U. per session.

Sysmex Canada to Standardize Hematology for Canadian Healthcare Network

Reliability. Ease-of-use. Enhanced patient data. Multi-site standardization capability. These are some of the reasons that The Eastern Ontario Regional Laboratory Association (EORLA) has signed an exclusive-five-year Vendor Supply and Capital Equipment Service Agreement with Sysmex Canada, Inc. (SCI). SCI will standardize hematology instruments, reagents, training, services and support for the Canadian hospitals, reference laboratory and allied health facilities regulated by EORLA within the Champlain Local Health Integration Network (LHIIN).

“EORLA was formed to create better performance and reliability, parameters, quality control and calibration and maintenance were considerations. Professional recommendations from a clinical laboratory working group consisting of Champlain’s medical technologies, administrative directors and pathologists contributed to Champlain’s decision. “Our decision to partner with Sysmex Canada was driven by our need to seek out a laboratory equipment manufacturer that had a proven track record of instrument uptime and one that enabled greater work efficiency while cost-effectively producing accurate results. Sysmex’s reliability and its standardization capability enables us to meet these needs across 16 multi-sized, multi-sites while sustaining a quality of patient care that meets standards set forth by EORLA,” said Antonio Giusti, M.D. Division Head, Hematology and Transfusion Medicine, Department of Pathology and Laboratory Medicine, The Ottawa Hospital.

Due to Sysmex’s instruments utilizing similar technology, even though offering different levels of sample throughput at the sixteen sites within the network, EORLA will achieve hematology standardization. The labs will be able to produce the same quality results (using the same reagents, the same software-management system) and have the ability to scale up or down, depending on the test volume at the individual lab location. Applied rules will be the same 24/7 and across all instrumentation, regardless of shift or day of the week.

Headquartered in Ottawa, Canada, EORLA is a member owned non-profit corporation providing hospital-based clinical laboratory and pathology services to the 16 acute care Hospital Members located in the Champlain Local Health Integration Network of Eastern Ontario. The Member Hospitals of EORLA provide a variety of patient care services including, but not limited to, oncology, pediatrics, surgery/cardiac surgery, internal medicine, emergency services/trauma-level patient care and psychiatry/mental health services. EORLA Member Hospitals include; Almonte General, Winchester District Memorial, The Ottawa Hospital (Riverdale, General and Civic Campuses), St. Francis Memorial, Renfrew Victoria, Queensey Carleton, Pembroke Regional, Kemp-ville District, Montfort, Glengarry Memorial, Hawkesbury and District, Deep River and District, Cornwall Community, Children’s Hospital of Eastern Ontario (CHEO), Carlton Place, and Amoritt and District Memorial.

“The proven performance reliability and results accuracy of our instruments will serve Champlain well as its network of hospitals and clinics balance the need to provide quality patient care with the need to deliver that care as efficiently and cost-effectively as possible,” said Antonio Giusti, M.D. Division Head, Hematology and Transfusion Medicine, Department of Pathology and Laboratory Medicine, The Ottawa Hospital.

Of note are Dr. Giles’ observations regarding the use of mathematical approaches to gain reliable and appropriate insight into the relevance of specific processes and current instrument performance in any setting. “Traditionally, instrument specification decisions relating to new instruments have been based almost exclusively on competitive analysis, and final decisions have been made by individuals or consensus without the luxury of being able to design instruments according to clinically relevant performance goals. By applying simple Sigma calculations to data sets from multiple components of the laboratory / manufacturing system, assessments and comparisons can be made that enable realistic change relative to clinical diagnostic performance requirements, and varying regulatory restrictions.”

Dr. Giles commentary further explores hematology QC concerns and instrument performance utilizing Sigma-metrics. “Calculating Sigma-metrics of different processes, at different places in the value chain, allows owners to isolate and identify areas for improvement and document quality assurance.”

Guest Essay Reveals Sysmex Perspective on Sigma-metrics

Ian Giles, M.D. Director of Scientific Affairs for Sysmex America was recently invited to submit guest commentary from a manufacturing perspective on Sigma-metrics. Sigma-metrics or Six Sigma Metrics can be defined as important tools that help to create better performance and improved processes through data analysis. Dr. Giles commentary can be found at http://www. westgard.com/sysmex-perspective-on-sigma-metrics.htm.

Westgard QC
$20,000 Sysmex America and Customer Donation to Benefit Research

As part of its customer appreciation dinner held this year during the AACC annual meeting in Chicago, Illinois, Sysmex America and its customers donated $20,000 to the Illinois Chapter of The Leukemia & Lymphoma Society (LLS). The donation was earmarked for a general fund which supports blood cancer research and patient services. The check was accepted by LLS Executive Director Pam Swenk and LLS Board President Scott Saxe.

“The Leukemia & Lymphoma Society is proud to partner with Sysmex, and honored to be the beneficiary of their generosity,” said Pam Swenk, Executive Director, Illinois Chapter of the Leukemia & Lymphoma Society. “It is somehow appropriate that the global leader in healthcare testing equipment and technology be paired with the leader in the fight against blood cancer to meet the mission of the LLS. Our heartfelt thanks go to Mr. Kershaw and Sysmex.”

The Leukemia & Lymphoma Society® (LLS) is the world’s largest voluntary health agency dedicated to blood cancer. The LLS mission: Cure leukemia, lymphoma, Hodgkin’s disease and myeloma, and improve the quality of life of patients and their families. LLS funds lifesaving blood cancer research around the world and provides free information and support services. Founded in 1949 and headquartered in White Plains, NY, LLS has chapters throughout the United States and Canada.

“On behalf of Sysmex, our board of directors and our employees, we want to thank our customers for their generosity in joining us in our efforts to support the Leukemia & Lymphoma Society as they work to eradicate hematological cancers. I trust our joint donation will be especially meaningful to the organization in these challenging economic times. We are all honored to have been given the opportunity to help,” said John Kershaw, President & CEO, Sysmex America, Inc. Mr. Kershaw and Sysmex Corporate President & CEO Hisashi Ietsugu presented the check to LLS on behalf of Sysmex and its customers.

Ohio Health Improved TAT, Lower Review Rates with Sysmex WAM 4.0

Ohio Health, a nationally recognized healthcare organization of 17 hospitals and 23 health and surgery centers has completed its implementation of Sysmex’s latest software release, Version 4.0, of its Sysmex WAM hematology data management system. OhioHealth plans to leverage the new features in Version 4.0, including an alerts module and the re-designed user interface software to enhance the user experience. Currently, Ohio Health processes nearly 2,500 hematology orders per day.

“This new version of Sysmex WAM includes all the features I could have ever wanted,” explains Kim Moser, Laboratory Supervisor. “It’s unusual to work with a vendor that really listens to customers and incorporates our feedback into its products.”

“We were very impressed with the energy, hard work and professionalism of our Sysmex implementation team,” said Michael Wiles, Laboratory Manager at Ohio Health. “Our go-live was smooth and uneventful, just as it should be.”

Five of OhioHealth’s hospitals have been using Sysmex hematology analyzers, automation and Sysmex WAM since August 2007. Four of its hospitals, Riverside Methodist Hospital, Grant Medical Center, Dublin Methodist Hospital and Doctors Hospital, are each equipped with the Sysmex HST-N™ automation line (most with two XE-2100™ automated hematology analyzers and a slidemaker/stainer) and the fifth, Grady Memorial Hospital, uses the Sysmex XE-2100 hematology analyzer and XS-1000™ analyzer. All of these hospitals’ hematology equipment and automation are connected to OhioHealth’s enterprise network and are interfaced to a single Sysmex WAM system with both multi-site and multi-LIS capability. Sysmex WAM interfaces to two laboratory information systems at OhioHealth: McKesson’s Horizon Lab and Soft Computer Corporation’s Softlab. Sysmex expects to officially launch the Sysmex WAM Version 4.0 to its prospective customers later this fall. “With nearly 100 Sysmex WAM systems installed in the U.S. and Canada, OhioHealth represents one of our larger and more complex implementations,” explains John Kershaw, President and CEO for Sysmex America, Inc. “This is a proving ground for future customers. We are excited to get such positive, early feedback.”