

ASCLS Annual Meeting 2016: Official Abstracts of Submitted Papers, Case Studies and Posters

Philadelphia, PA

The following abstracts have been accepted for presentation at the 2016 American Society for Clinical Laboratory Science (ASCLS) Annual Meeting and Clinical Laboratory Exposition to be held August 1 through August 4 in Philadelphia, PA. Abstracts are reviewed by members of the ASCLS Abstract and Proposal Review Committee. They are the final authority in selecting or rejecting an abstract.

Papers, case studies and posters will be presented during the following times at the annual meeting.

POSTER PRESENTATIONS

Tuesday and Wednesday, August 2 and 3, 10:00am-4:30pm at the Pennsylvania Convention Center in the Terrace Ballroom located on the 400 level. *Authors will be present on Wednesday, August 3 from 10:30am to Noon to discuss their work and answer questions.*

ORAL RESEARCH PRESENTATIONS

Tuesday, August 2nd at 10:30am in room 122B at the Pennsylvania Convention Center

Poster Presentation Abstracts

Combating Specimen Label Issues Leading to Barcode Scan Failures

Travis Bicher, B.S., MLS(ASCP)^{CM}, Pennsylvania Hospital, Philadelphia, PA

A significant number of specimens received by laboratory staff at Pennsylvania Hospital in the fall of 2015 had barcode labels that were failing to be scanned by the automated instruments. These scan failures required tube relabeling or manual programming to run, which increased turnaround time and the risk of patient mix-up, could cause sample depletion, possibly leading to cancellation, and put extra stress on the laboratorians. Root cause analysis revealed that the staff was experiencing an

average of 103 scan failures per week, which equated to an average of 7.92 scan failures per 1000 tests received in the laboratory. Problem locations were identified as well as the issues with the labels themselves: print quality in the form of fading/spotting or white lines through the print, writing or smeared ink through or near the barcode, and label misalignment, though this one did not contribute directly to scan failures. A reporting system was implemented to ensure collection of all relevant information, and other interventions included (1) inspection of the barcode scanner on the instrument with the majority of the scan failures, which was particularly sensitive to barcodes obscured in any way but otherwise functional, (2) coordination with supervisors of outpatient locations to find problem printers, (3) discussion with and dispatch of Information Services staff to find causes of issues and make adjustments and repairs, and (4) education of location staff on what issues to watch for and how to report them. These changes resulted in a drop in the average scan failure rate from 7.92 per 1000 to 1.12, or 15 failures per day down to 2. Future efforts will focus on raising awareness of the issues among staff who collect specimens.

Acceptability of Current Patient Risk

Zoe Brooks, ART, AWESome Numbers Inc., Ontario, Canada, **Kim Przekop, MBA, MLS(ASCP)^{CM}**, AWESome Numbers Inc., Ontario, Canada, **Rania Mohamed El Sharkawy, MD**, Medical Research Institute, Alexandria University, Alexandria, Egypt, **Eman El Hadidi, MD**, Ein Shams University, Alexandria, Egypt, **Eman Elattar, MD**, Medical Research Institute, Alexandria University, Alexandria, Egypt, **Noha S Kandil, MD**, Medical Research Institute, Alexandria University, Alexandria, Egypt, **Eman Shaheen, PhD**, Alexandria University, Alexandria, Egypt, **Omneya Ahmed Ibrahim, MSc**, Medical Research Institute,

Alexandria University, Alexandria, Egypt, Basma Wagdy, MSc, Private laboratory, Alexandria, Egypt, Eman Farrag, MSc, Private laboratory, Alexandria, Egypt

Clinical & Laboratory Standards Institute's (CLSI) Guideline EP23A states that risk is acceptable when it is "small enough such that patients, physicians, institutions, and society are willing to risk the consequences." This study was designed: 1) To evaluate acceptability of risk in four laboratories for urea, alkaline transaminase (ALT), and alkaline phosphatase (ALP); 2) to identify the predominant source of analytical faults; and 3) to compare the effectiveness of existing quality control (QC) processes to those recommended 'Mathematically-Optimized Risk Evaluation™. Each laboratory set total allowable error (TEa) limits according to common practice. We set the acceptable current risk level at 2.275% to reflect the practice of considering a 2-sigma method acceptable. We calculated current risk as the percent, number, and existing cost of medically-unreliable results (MURs) from sigma values for each QC sample based on verified QC data and patient test volumes. We assigned the average cost of errors reported at \$10US (90LE) per /MUR. We applied the process of Mathematically-Optimized Risk Evaluation™ to assess the acceptability of risk, identify faults and advise action. Seventeen of the 24 QC samples had error rates less than 2.275%; 10 samples reflected methods currently producing <1 medically-unreliable result /year; and 7 samples failed the TEa limits set. Selected TEa limits varied from 11.7% to 30% for ALP. This practice is incongruous with recommendations to set medical goals. Evaluation of risk and recommended action varied between laboratories and between analytes. Faults creating imprecision were more common than those causing imprecision. We concluded that the calculated risk level is generally not accepted in healthcare. Adjustment of these procedures is mandatory. Mathematically-Optimized Risk Evaluation™ detects laboratory risks that are missed by commonly used statistical QC.

Serum Versus Urine Cotinine in Predicting Smoking Status

Janelle Chiasera, Ph.D, Tera Webb, MS, Kinigra Cohill, BS, Laura Herrington, BS, Brittany McCracken, BS, Lauren Spivak, BS, Li Zhang, BS, University of Alabama at Birmingham, Birmingham, AL

Smoking is the number 1 cause of preventable deaths in the U.S. and smoking, both acute and chronic, is associated with the increased risk for surgical complications. Current preanesthesia guidelines recommend that people abstain from smoking at least 24 hours prior to surgery as this has shown to improve surgical outcomes and reduce costs for surgical procedures. Timely notification of patient smoking status is critical to allow smoking cessation to begin sooner or to alert physicians of the potential for surgical complications. Our current method to measure smoking status involves the serum analysis of cotinine, a batched test performed once per week, which limits our ability to provide timely notification. The purpose of this study was to determine if urine cotinine results, results that can be generated same day, can correctly classify smokers and nonsmokers compared to serum cotinine. Blood and urine samples were collected from 20 subjects (10 smokers and 10 nonsmokers) and were analyzed for serum (Microplate immunoassay kits, OraSure Technologies) and urine (AU 5822 analyzer, Beckman Coulter) cotinine. The cut point for identification as positive for cotinine in serum was > 0.457 ng/mL and positive for cotinine in urine was > 500 ng/mL. All subjects classified as nonsmokers (n=10) tested negative for serum and urine cotinine. All subjects classified as smokers (n=10) tested positive for serum and urine cotinine. There was 100% agreement between the urine and serum cotinine values in correctly classifying all subjects (n=20). It was concluded that all subjects were correctly classified using both serum and urine cotinine assays and that there was 100% agreement in how subjects were classified using serum and urine cotinine results. The urine cotinine test can be used to assess smoking status and can do so on an as needed basis providing more timely notification to physicians.

Skin Bank: Surgery and MLS Communication

Ninive Costa, MLS(ASCP)^{CM}, University of Michigan, School of Public Health, Ann Arbor, MI

Work of Medical Laboratory Scientists (MLS) often goes unnoticed and it is not surprising that very little is known about the work in a Skin (or Tissue) Bank. The American Association of Tissue Banks (AATB), which has certifications for Tissue Banking and conferences annually is attended mostly by practitioners in the field, not by Skin Bank staff, who share information about current trends in the burn patient population, care barriers, or innovations in skin grafting and placement. Burn patients rely as much on their providers as on the adequate monitoring of skin banks where MLS serve as an integral part of the health care team. Effective communication is key between MLS and Providers, Nutritionists, Social Workers, PT/OT, Nursing, and Administrative Staff. Often, when new residents learn about skin banking there is little knowledge regarding MLS staff responsibilities. Errors occur when surgeon and Skin Bank staff do not communicate or there is little training and the laboratory is unable to provide its best practices. This leads to wastage of expensive products (skin replacements cost thousands of dollars), patients can be harmed if inappropriate supplies are given or important cultures to determine infections, as a result this can be a costly expenditure to society. A key way to prevent these errors from occurring is by accurately communicating through well written clinical documentation and by giving new providers or staff a tour of physical or virtual nature of the skin bank to serve as a reminder of policies and procedures. These processes will serve preliminarily to help in emergencies, during training of new residents and medical students, and new staff. Patient care is as much a concern for a provider as it is for an MLS, thus it is critically important that all means of clinical documentation be recorded accurately between staff.

Seroprevalence of *Babesia microti* in Patients with Lyme Disease

Sabino R. Curcio, M.S., Azad L. Gucwa, Ph.D., MT(ASCP), Long Island University, Post Campus, Department of Biomedical Sciences, Brookville, NY

Babesiosis is an emerging tickborne disease (TBD) caused by the protozoa *Babesia microti*, an intracellular parasite of red blood cells. *B. microti* is currently the highest-ranked pathogen transmitted by blood transfusion primarily because most infected with *Babesia* are often asymptomatic at the time of donation. *B. microti* is transmitted by *Ixodes scapularis* ticks, the same vector that carries *Borrelia burgdorferi*, the proponent of Lyme disease. Co-infection with these two pathogens has been reported with individuals often presenting with atypical symptoms of increased severity and duration. In this study we aimed to determine the co-infection rate of *B. microti* in patients who tested positive for Lyme disease. Sera obtained from 154 individuals in New York, an area endemic for TBDs, was collected from May through September and tested by immunofluorescence assay (IFA) for the presence of IgM antibodies against *B. microti*. Previous reports have cited infection rates with *Babesia* to be between 10-32%. Of the 59 individuals who tested positive for IgM antibodies directed against *B. burgdorferi*, 55.9% also tested positive for antibodies directed against *B. microti*, suggesting recent co-infection of both TBDs. In those who had previously been exposed to Lyme disease and were positive for the IgG antibodies against *B. burgdorferi*, 62.2% were also positive for antibodies against *B. microti*. Both of these groups were significantly increased ($p > 0.05$) as compared to our Lyme disease-free control group, which had 26.7% testing positive for IgM antibodies against *B. microti*. Our findings suggest co-infection of *B. microti* and Lyme disease is more prevalent than previously estimated. A more extensive study investigating the occurrence of *Babesia* infections is needed, particularly in areas where it is endemic. In addition, these findings further support the need to implement an FDA-approved screening test for blood donation to help prevent transfusion-transmitted babesiosis.

Biochemical Changes Associated with HbA1c levels in Diabetes

Gabriel Diaz, Undergraduate Student, Mark Kirby, Undergraduate Student, Maria Quintanilla, BS, Jean Sparks, PhD, Felix Omoruyi, PhD, Texas A&M University, Corpus Christi, TX

The use of hemoglobin A1c (HbA1c), also known as glycated hemoglobin in the management of diabetes is well established. It is currently an important marker for the long-term assessment of glycemic status and monitors the effect of therapy in diabetic patients. Hemoglobin A1c levels between 5.7% and 6.4% indicate increased risk of diabetes, and levels of 6.5% or higher indicate diabetes. Mean blood glucose (MBG) as estimated by HbA1c is the main parameter for diabetes control as it relates to risk of diabetic complications. There is strong data supporting the association of HbA1c variability with the development and progression of diabetic complications. However, in some individuals with hemoglobin variants, HbA1c levels have been reported not to correlate with their MBG levels. In this pilot study, we assessed some biochemical indices in diabetic patients with > 5.7% HbA1c – separated into five groups as follows: group 1 (< 5.7% - non-diabetic group); group 2 (5.8 – 6.4%); group 3 (6.5 – 8.5%); group 4 (8.6 – 11.9%); group 5 (\geq 12%). Our data showed significant increases in alanine amino transferase and aspartate amino transferase activities in diabetic patients with > 8.6% of HbA1c levels. We also noted a significant increase in total cholesterol levels in patients with \geq 12% HbA1c compared to the other groups. There was a significant increase in serum globulin levels in patients with > 8.6 % of HbA1c compared to the other groups. We noted a decreasing trend in the albumin: globulin ratio with increasing HbA1c levels. Overall, our data showed that patients with > 8.6 % HbA1c levels may be progressing towards the development of diabetic complications. The observed changes in albumin: globulin ratio may be helpful in the prevention of diabetic complications in patients whose HbA1c levels may not correlate with their blood glucose levels- patients with hemoglobin variants.

Implementation of Bone Marrow Processing Quality Improvement

Joshua Edwards, MBA, Darrin Jengehino, MT(ASCP), Megan Lim, MD, PhD, Division of Hematopathology, Department of Pathology and Laboratory Medicine, Hospital of the University of Pennsylvania, Philadelphia, PA

Introduction: Evaluation of the bone marrow is a critical component in the diagnostic workup of hematologic disorders and provision of high complex results with rapid turn-around is critical for appropriate patient management. With increasing volumes and enhanced complexity of ancillary testing, there is a continued need to improve the efficiency and quality of bone marrow processing. **Objective:** Identify strategic areas for process improvement and standardization in bone marrow processing. **Methods:** Process mapping of the bone marrow work flow including pre-analytical, analytical, and post-analytical phases was used to identify key opportunities for improvement. **Results:** In each phase of the work flow, we identified several areas that provided opportunities for improvement. In the pre-analytical phase, the physical path from the clinic to the laboratory was causing significant delays in specimen delivery. Working with our client services, we instituted an electronic tracking system to monitor the delivery of specimens. To assess bone marrow quality, we implemented an IT-based process to gather quality descriptions of the specimens. Using the data collected in this evaluation, we will monitor the specimen quality, and we will continue to work with submitting locations to provide feedback and educational support. Post-analytically, we identified a processing bottleneck between the hematology lab and the gross room. In collaboration with the Anatomic Pathology Division, grossing times were adjusted to accommodate a larger portion of the daily bone marrow specimens. This change has increased the capacity of same-day processing to over 80% of the cases. **Conclusions:** Evaluation of the bone marrow workflow identified strategic areas of process improvement. Modifications to the work flow have led to significant decreases in turnaround time and overall quality of the results. With continued collaboration and monitoring of the process,

additional improvements to turnaround time can be achieved while ensuring that we are providing high quality results.

Measuring Osmolality to Assess the Effectiveness of Commercial Hydration Products

Jeannie Guglielmo, MS, MAT, MLS(ASCP)^{CM}, Stony Brook University, School of Health Technology and Management, Stony Brook, NY

This research reports for the first time a comprehensive study of the osmolality of commercial hydration products, including comparisons between lots and differences between liquid products and powder products prepared by the user. The purpose of this study was to determine the measured osmolality in commercial hydration products and assess whether each was hypotonic, isotonic, or hypertonic. This information is valuable for rehydrating athletes, for helping parents and health care workers care for sick children and the elderly, and for general consumer knowledge when it comes to making educated commercial hydration product choices. Physiology dictates that the osmolality of an ingested sports drink is directly related to gastric distress and the speed of gastric emptying, intestinal absorption, and hydration. By avoiding hypertonic drinks whose osmolality exceeds 300 mOsm/kg, hydration and performance should be improved. The osmolality of 81 commercial products were measured using the Advanced Instruments Model 3320 Micro-Osmometer. Data was collected for various liquid sports drinks like Gatorade Thirst Quencher and Sqwincher ranging from 125-482 mOsm/kg and powder sports drinks like PowerBar Perform and Gatorade Thirst Quencher ranging from 173-333 mOsm/kg. The investigators found that in general, liquid sports drinks should be avoided before or during an athletic event due to their elevated osmolalities. The exception was Gatorade G2 which was hypotonic even with the addition of ½ teaspoon salt. Most hypotonic coconut water based drinks contain low levels of sodium and as such would be less effective at sodium replacement. Although several sports drink powders were hypotonic, their high cost (\$8.00/32 oz) may make them unaffordable to many athletes. Gatorade Thirst Quencher powder which is hypotonic and inexpensive may be the best

choice. Regarding pediatric hydration; Pedialyte or Drip Drop were hypotonic and should be effective. Store brand grape flavored products were all hypertonic and should be avoided.

Biometric, Physical and Psychological Assessment of an Adolescent Population: A Wellness Initiative for Student Health

April Harkins, PhD, MLS(ASCP)^{CM}, Marie Hoeger Bement, PhD, PT, Sandra Hunter, PhD, PT, Astrida Kaugars, PhD, Stacy Stolzman, PhD, PT, Marquette University, Milwaukee, WI

Adolescents in college-preparatory high schools have a high prevalence of stress and unhealthy behaviors such as inadequate sleep. This study aimed to identify biological and psychological components impacting health and wellness in an all-female college-preparatory high school population. 243 adolescent females (15.8 ± 1.1 years) completed the following testing: 1. *Biometrics*: for weight status, body composition, AM and PM salivary cortisol, and fasting blood sample (glucose, total cholesterol [TChol], high-density lipoprotein [HDL], and non-HDL), 2. *Physical Fitness*: FitnessGram Progressive Aerobic Cardiovascular Endurance Run (PACER), strength (hand grip, curl-ups and push-ups), leg flexibility (sit and reach), 3. *Psychological Assessments*: self-reported surveys for sleep (SLEEP), body image (Body Appreciation Scale-2), quality of life (Pediatric Quality of Life Inventory) and physical activity (Physical Activity Questionnaire--Adolescents), and 4. *Physical Activity/Sleep Monitoring*: (Actigraphs). Adolescents had high levels of TChol (14.4%), non-HDL (12.2%), AM cortisol levels (12.4%) and PM cortisol levels (10.6%) and low levels of HDL (31.7%). Insufficient sleep (<7 hours per night) was reported by 34%. Total quality of life was significantly below national cut-offs for healthy youth populations. Students with higher non-HDL demonstrated lower academic achievement and quality of life, less positive body image and fewer hours of weekday sleep. Students with higher physical fitness levels demonstrated higher academic achievement, quality of life, body image, and sleep efficiency with less stress and sedentary time. Biometric testing is feasible in a high-school setting and can provide a unique

perspective of health and wellness that can be linked to psychological components of health where targeted interventions can be used. Opportunities for physical activity may improve physical fitness and promote good psychological and metabolic health in adolescents.

Interprofessional Education and Practice, What Does This Mean for the Medical Laboratory Scientist?

S. Renee Hodgkins, PhD, MT(ASCP), University of Kansas Medical Center, Kansas City, KS

Interprofessional education (IPE) and interprofessional collaborative practice (IPCP) are more than just buzzwords in healthcare. Interprofessionalism has been adopted by the Institute of Medicine (IOM) standards as a competency for all health professions. In the fall of 2015, the IOM published a report on improving diagnosis in health care that demonstrates a need for more laboratory information and consultation in patient care. Medical laboratory scientists (MLS) produce 70-80% of the data that directly impacts diagnosis and therapy. The current model of healthcare has reflected the educational approach of learning in silos. Professionally, there is a lack of understanding of roles and responsibilities of other professions, an inability to communicate, and a lack of teamwork among all professions. To prepare for the new healthcare model, changes are needed in the education system and the professional role of the MLS. The education model must expand to allow for professional interaction prior to practice. While traditionally the MLS has not had an active voice in patient care, the new model of healthcare requires a more active role in test selection, interpretation, and consultation. At The University of Kansas Medical Center (KUMC), a campus-wide foundational interprofessional program that includes bachelor's degree-seeking CLS students has been developed and implemented to address the Interprofessional Education Collaborative (IPEC) competencies. This program has two levels that lay the foundation for interprofessional collaboration. A third level, still in development, integrates the healthcare professions in patient simulations. Through the foundational program, the role of the MLS can be expanded and

incorporated into the healthcare team. This foundational program will be presented along with some of the lessons learned. The data generated will show that we are achieving a new mental model with enhanced knowledge of roles and responsibilities of other professions and the ability to communicate in an interprofessional team.

Advancing a Culture of Quality

Jennifer Dawson, MHA, DLM(ASCP)SLS, QLC, QIHC, Sonic Healthcare USA, Austin, TX

Sonic Reference Laboratory (SRL) is a newly established state-of-the-art reference laboratory specializing in Immunology, Chemistry, Analytical Chemistry, Molecular and Hematology testing. The lab's executive team built the lab from the ground up with a go live date of December 1st, 2014. A primary goal was to establish a culture of quality and a comprehensive best practice Quality Management System (QMS) striving for best practice and ISO 15189 conformance. Laboratory leadership employed a variety of methods to create a culture that fosters quality and patient safety including, but not limited to, the establishment of an organizational quality policy and manual, comprehensive quality onboarding program, Hippocratic pledge, electronic non-conforming event management, aggressive internal audit program, wireless temperature monitoring, heatmaps, real-time metric dashboards and interactive management review of quality reports. 93.0% of SRL staff responded that management fosters a quality culture in year one, which improved to 100% in year 2. This significantly exceeded the 60% overall benchmark and 81% world-class organization benchmark published by the American Society for Quality. The lab reported more than 5 times fewer serious non-conforming events per employee and more than 7 times fewer serious non-conforming events per test volume reported monthly than the average reported in a survey of 16 clinical labs. The number of minor non-conformities reported per test volume at the lab slightly exceeded the average for all labs. This suggests that SRL is a learning organization. Cost of Poor Quality savings to the laboratory in just in non-conforming event cost avoidance in year 2 is estimated at \$300,000. SRL's quality program has

been successful in establishing a proactive, learning organization with a culture of quality.

A Simple Spectrophotometric Method for the Determination of Cyanide in Blood

Jerome Smith, PhD, Deborah Sammons, BS, Christine Toennis, BS, Barbara MacKenzie, BS, Cynthia Striley, PhD, John Snawder, PhD, Marissa Alexander-Scott, DVM, Shirley Robertson, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, Cincinnati, OH

Cyanide poisoning occurs with exposure to cyanide compounds, such as hydrogen and potassium cyanide, present in insecticides, smoke, car exhaust, and some industrial processes, resulting in weakness, paralysis, hypothyroidism, miscarriages or even death. Cyanide blood levels are a marker of exposure often measured by gas chromatography-mass spectrometry, which is accurate, but expensive. We have adapted an autoanalyzer technique for cyanide measurement in equine blood, using human blood and low reagent volumes by using an Enzyme Linked Immunosorbant Assay (ELISA) plate reader. Cyanide in a 350 μ l water or blood sample is converted to hydrogen cyanide by adding the sample to 1 ml of 1 M H₂SO₄ in a 10 ml test tube, which is rapidly capped with a rubber cap containing a small collection cup with 350 μ l of 0.25 N NaOH which captures the generated hydrogen cyanide as cyanide ion. After collecting overnight, the cyanide ion is reacted with chloramine-T, in a 96-well plate, to convert it to cyanogen chloride which is then reacted with pyridine-barbituric acid to form a red-blue complex, whose intensity is measured spectrophotometrically at 570 nm using an ELISA plate reader. Since color development by these reagents is without a definite endpoint, but reaches a maximum intensity and then fades, the absorbance measurement is started immediately after addition of pyridine-barbituric acid reagent and the plate is read kinetically for 20 minutes. Maximum absorbance in each well is determined. Preliminary data indicates the method has linear response from 31.2 to 2000 ng/ml for prepared solutions and spiked water samples and the data from the spiked samples is well correlated with prepared solutions. Further study

will better define the range and precision of the method as well as study the recovery from spiked blood samples and determine if this method may be used for application in biomonitoring.

Timeliness of Critical Results Reporting

Kate Bernhardt, MS, MLS(ASCP)^{CM}, LSSGB, Loyola University Medical Center, Maywood, IL

Timely reporting of critical results is a TJC requirement and CAP Key Indicator of Quality. Our laboratory target stated 90% of critical results should be called to the RN within 30 minutes. This target was not always met, fluctuating between 84% and 94%. Reduction of lab notification time supports the nursing target for critical notifications to physicians. A new goal was set: Within 90 days, meet a target of 95% of laboratory calls within 30 minutes, with a stretch goal of 100% within one year. Collaborative efforts among Lab Administration, Core Lab, LIS staff, and the Laboratory Call Center, using Lean Six Sigma tools such as SIPOC, Process Mapping, Run Charts, Pareto Charts, and Fishbone Analysis, identified root causes such as (1) Laboratory Staff – Partner communication and distracted by other responsibilities, (2) Callback Issues – No reminders, wrong numbers in the system, and (3) Critical Results Policy – How many unsuccessful attempts at calling the nurse until the laboratory asks to speak to a charge nurse? What if no one answers the phone? The Core Lab produces about 1,400 inpatient critical results requiring notification per month. A pareto chart showed 43% of critical calls were made between 3 – 7 am, so team efforts focused on helping Midnight shift. By using Lean Six Sigma tools, we identified underlying issues with the current process and implemented the following: (1) Call Center making critical calls from 4 – 7 am, (2) Callback system changes – Flashing and beeping, correction of wrong phone numbers, and (3) Policy Revision – After two unsuccessful notification attempts to the nurse, contact the floor's charge nurse. If the charge nurse cannot be located, page the hospital nurse supervisor. Before implementation, Midnight shift made 95% of their calls within 53 minutes. After changes were implemented, 95% of calls were made within 18 minutes.

Leptin-Induced Monocyte Chemoattractant Protein-1 Secretion

Michael Lavantucksin, MHS, Gloria Sloan, MS, Miriam Cortez-Cooper PhD, Joseph Cannon, PhD, Augusta University, Augusta, Georgia

Leptin is a regulatory hormone known to promote satiety, monocyte migration, and cytokine secretion. It is linked to atherosclerotic plaque development by stimulating the release of pro-inflammatory cytokines, such as TNF- α , IL-6, and IL-1 β . The purpose of the study was to define more completely the range of cytokines induced by leptin. Frozen plasma and leptin-treated peripheral blood mononuclear cell (PBMC) supernatant samples collected from healthy men (n = 13) and women (n = 21) in a previous study (Physiological Reports DOI: 10.14814/phy2.12177) were assayed for monocyte chemoattractant protein-1 (MCP-1) using a cytometric bead array assay. In vitro, leptin induced MCP-1 in a dose-related manner (P = 0.0003). In vivo, plasma MCP-1 correlated with circulating leptin (P = 0.050), in a manner that depended upon sex (P = 0.046) and plasma cortisol (P = 0.013) interactions. Plasma MCP-1 also correlated with beta-stiffness, an indicator of preclinical atherosclerosis (R = 0.60, P = 0.0003, measured in the original study by ultrasound). These observations support the concept that leptin may promote atherosclerosis, in part, by stimulating MCP-1 secretion. This work was funded by NIH grant HL093663.

Molecular Basis of Arrested Liver Stage Development of Gamma-irradiated *Plasmodium yoelii* exo-erythrocytic Form

George Asanga Ndeti, PhD, MSc, MT(ASCP), University of Texas Rio Grande Valley, Edinburg, TX

Sporozoites isolated from irradiated mosquitoes and injected into Balb/c mice, will infect hepatocytes and transform to trophozoites. Infected mosquitoes that are irradiated as well as infected mosquitoes that are not irradiated will introduce sporozoites into a host during a blood meal and the sporozoites will also infect hepatocytes. However, while irradiated

mosquito-inoculated sporozoites invade hepatocytes and only transform to trophozoites, the non-irradiated mosquito-inoculated sporozoites invade hepatocytes and transform to trophozoite, then to schizonts that rupture later and release merozoites into the blood stream. Arrest of irradiation-attenuated sporozoites in hepatocytes when used as a vaccine candidate has been observed to induce protection against challenge with infectious sporozoites for up to seven weeks. The effect of radiation on gene expression has only minimally been accessed. In this study, suppression subtractive hybridization, semi-quantitative RT-PCR and dot blot analysis were used so as to understand the molecular basis for the arrest in the development of the exo-erythrocytic stage as a result of exposure to 12,000 rads of radiation from a ¹³⁷Cesium source.

Mathematically-Optimized Risk Evaluation™

Kim A. Przekop, MBA MLS(ASCP)^{CM}, Zoe C. Brooks, ART, Awesome Numbers, Inc., Ontario, Canada

Laboratories have used quality control (QC) concepts and theories based on the same statistical calculations and assumptions for decades. Risk management, as stated in Clinical & Laboratory Standards Institute's (CLSI) EP23A Guideline, adds an 'acceptable risk criteria.' Now there is a way to comply with EP23A and also save time, reduce risk to patients, and diminish analytical lab errors and their costs. The Mathematically-Optimized Risk Evaluation™ (M.O.R.E.) method enhances existing QC concepts, while risk metrics unveil a wealth of new understanding - just 'beyond sigma.' M.O.R.E. is an Excel-based software that can consistently evaluate QC results and propel the QC process to meet locally-defined quality standards. The M.O.R.E. method begins with basic QC values: target and current mean, the QC chart mean, target and current SD, frequency of QC runs, and any QC rules applied. Then, the medical director and/or clinicians sets medical goals and acceptable risk levels for quantitative analytes, while the administrative director sets costs/test and the average cost of harm to the patient if a medically-unreliable result (MUR) is released from the laboratory for those analytes. Medical goals are similar to allowable

error limits; however, clinicians set the goals with their patients in mind. The acceptable risk level drives the number of patients a laboratory is willing to expose to an MUR.

Currently, SQC (Statistical QC) reports a numerical indicator of the level of quality which is subject to variations in calculation and interpretation. The new M.O.R.E. method answers the question, "Is risk acceptable?" with a clear "Yes" or "No." The M.O.R.E. method increases the effectiveness of the QC process and its ability to reduce the number of MURs, and also alerts the laboratorian immediately when the analytical process changes enough to allow more than the acceptable number of MURs to be released.

Assessment of Relationship between Hemoglobin A1c and Highly Sensitive C- Reactive Protein Levels in Pre-Diabetic Individuals

Masih Shokrani, Ph.D., MT(ASCP), Jamie Phan, Judith Lukaszuk, Ph.D, RDN, Victoria Flores, Northern Illinois University, DeKalb, IL

The progression from normal state to pre-diabetic or pre-diabetic to a diabetic state in individuals can often go unnoticed. There are millions of people who are not aware they are pre-diabetic. While studies exist that link inflammation to the diabetic disorders, the link between inflammation, risk for cardiovascular events and pre-diabetic state remains vague. Measurements of blood hemoglobin A1c (HbA1c) levels were used to determine whether the subjects were pre-diabetic. The hsCRP (highly sensitive C-reactive protein) levels in the blood are related to inflammation and also used for cardiovascular risk stratification. In addition to HbA1c and hsCRP levels, anthropometric measurements such as body mass index (BMI) and percent body fat (PBF) of 76 study participants were determined. The levels of HbA1c of the 76 participants ranged from 4.6 to 6.3 percent. The levels of hs-CRP of the participants ranged from <0.2 – 18.5 mg/L. Pearson correlations were used to test for relationships among HbA1c, hsCRP, BMI, and PBF levels. There were significant positive relationships between HbA1c and hsCRP, $p = .026$, between HbA1c and BMI, $p = .001$, and between HbA1c and PBF, $p < .01$. In addition, there were

significant positive relationships between hsCRP and BMI, $p = .001$, and between hsCRP and PBF, $p < .01$. The data in this pilot study suggest that high levels of HbA1c are related to a greater risk for inflammation and cardiovascular events. Larger studies in the future will elucidate this relationship further.

Hemolysis in Blood Collection Using S-Monovette® Versus Evacuated Tube System

Vi Thompson, Latrice Smith, Jennifer Kuckarchuk, **Lester Pretlow, PhD, CLS(C), NRCC(CC)**, Augusta University, Augusta, GA

The purpose of this study was to document the occurrence of hemolysis in the S-Monovette® collection tube system (Sarstedt, Inc., Newton, NC) compared to a standard vacuum tube system when used to draw blood specimens from arterial lines. In the MICU (medical intensive care unit), at Georgia Regents Health System, nurses collected a standard lithium heparin vacuum tube and an S-Monovette® lithium heparin tube from consented patients with arterial-lines. The order of collection (S-Monovette® versus standard vacuum tube) was randomized using computer software. Both specimens were sent to the hospital's clinical laboratory and aliquotted into two specimen containers. The first container was analyzed in the hospital's clinical laboratory and assessed for hemolysis indicators (K, CK, and LD). The second container was analyzed in the Transitional Research Laboratory using spectrophotometry for the measurement of free hemoglobin (mg/dL). The investigators collected and analyzed 86 S-Monovette® and standard vacuum tube sets. The study was powered for 200 sets, however this number sets was not reached. The occurrence of hemolysis between the two systems was analyzed using Wilcoxon signed-rank and t-test statistics. The mean values of hemolysis indicators were compared using the appropriate statistic based on the population distribution. Final analysis shows no statistical difference between the standard vacuum tube system and the S-Monovette® collection tube system for any hemolysis indicators and for free hemoglobin values. Since the original power of this study was not reached, it is possible that a type II error exists.

Emerging Cases of *Plasmodium falciparum*

Anietie Uko, MLS (ASCP)^{CM}, Tufts Medical Center, Boston, MA

The purpose of this study is to take into account the number of Malaria cases are occurring in countries that are not considered endemic for this particular parasite. In November of 2015 a patient was seen in a Level One trauma facility suffering from initially seemed to be septic shock. The routine blood smear showed a high number of blood parasites present later identified as *Plasmodium falciparum*. With an initial diagnosis the patient was asked about their travel history but there was no indication of travel to a heavily endemic country that carries this parasite. Throughout the duration of their stay the patient received quinine and doxycycline for the parasitic treatment. This presentation will gather data on countries with a rising number of parasitic infections focusing on the Plasmodium Species.

Effects of Tip60 and Paclitaxel on Breast and Lung Cancer

Himali Vashishtha, Daniel S. Ginsburg, PhD, LIU Post, Brookville, NY

Tip60 is a protein, coded by the KAT5 gene, which is involved in transcription, DNA repair, and apoptosis. It acetylates histones, the ATM protein kinase, and the p53 tumor suppressor, among other targets, making it a key regulator of cell homeostasis. Tip60 has been shown to be a tumor suppressor in most cancers but an oncogene in prostate cancer. We were interested in exploring Tip60's potential as a therapeutic agent, either through epigenetic regulation of transcription in the nucleus or acetylation of cytoplasmic targets. We investigated whether the nuclear localization of Tip60 is important for its tumor suppressor function. Our hypothesis was that decreasing Tip60 nuclear localization would reduce its anti-proliferative effect in breast and lung cancer cells. To test this hypothesis, we mutated a putative Tip60 nuclear localization signal (NLS) and measured nuclear localization by immunofluorescence, as well as proliferation of transiently transfected breast and lung cancer cells lines. Tip60 lacking the putative

NLS (Tip60ΔNLS) had a significantly different localization pattern compared to the wild type Tip60 in all of the cell lines we tested, suggesting that we mutated the correct NLS. Although Tip60ΔNLS showed significantly less nuclear localization than WT Tip60, neither construct reduced proliferation of breast and lung cancer cell lines in combination with paclitaxel treatment. These results suggest that we have identified the Tip60 NLS, but that the effects of changing Tip60 localization are more subtle than large changes in cell growth.

Sustaining the Laboratory Workforce: Lessons Learned from Evaluation of the Association of Public Health Laboratories (APHL)/Centers for Disease Control and Prevention (CDC) Emerging Infectious Disease (EID) Laboratory Fellowship Program

K. Leigh Inge Vaughan, MPH, Centers for Disease Control and Prevention, Atlanta, GA, Heather Roney, MA, Association of Public Health Laboratories, Silver Spring, MD, Sierra Finnie, BS, Clayton State University, Morrow, GA

Concerns about sustaining a proficient laboratory workforce have existed for a number of years and remain an ongoing issue. Options for increasing laboratory workforce sustainability and/or competency have included laboratory training programs and fellowships. We summarize a recent evaluation of the APHL/CDC's EID Laboratory Fellowship program, which operated for 20 years, focusing on aspects of results arising from this evaluation relevant to this sustainability. Data were obtained from narrative in a sample of 70 "final reports", which were supplied by participating fellows in response to an end-of-fellowship questionnaire survey. The sample used in the analysis was randomly selected from 202 final reports submitted between 2004 and 2014. The data obtained included information on the fellows' fellowship experiences, laboratory and research-related training, public health and public health laboratory-related activities, as well as fellows' program objectives. The data were qualitatively analyzed by using applied thematic analysis, with the final reports being iteratively read, memoed, and coded. Themes, sub-themes, codes and related frequencies were examined to investigate potential

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thematic relationships and to help find patterns in the data. Four major themes arose from the analysis: Professional Capability: tangible professional laboratory or laboratory-related products (specific laboratory testing/analysis skills, publications); benchmarks of experience (fiscal, leadership, speaking skills); Understanding Public Health: knowing what the public health field is all about and the part that laboratories play within it; Career Assistance: informing career plans; creating professional connections for the future; Fellowship Experience: positive/negative influences during the fellowship. These results suggest that the fellowship program provided fellows the opportunity to increase their laboratory-related professional skills/knowledge and develop an appreciation for laboratory interaction within the “big picture” of public health. Thus, fellows may be better prepared for, and better understand the importance of, a career in the laboratory science profession, which could impact laboratory workforce entry and retention numbers.

Lactate Results in Samples Stored at 25°C Versus 4°C

Victoria B. Moore, B.S., Darryl Touchet, B.S., Jason Frazier, B.S., Brian Blades, B.S., Tera Webb, MS, Janelle M. Chiasera, PhD, The University of Alabama at Birmingham, Birmingham, AL

Lactate levels have long been used to identify patients with severe hypoperfusion and, over the years, has evolved as a marker of perfusion- and nonperfusion-related disease states. More recently, literature on the importance of lactate levels has focused on its role in diagnosing, determining the severity of, and playing a role in the management of patients with sepsis. As a result, we have experienced an increase in the number of lactate tests ordered annually. Lactate levels can be rapidly and easily obtained; however, sample handling requires that samples be kept on ice if not analyzed within 15-30 minutes. Our lab has experienced increased barcode degradation due to samples being submerged in an ice bath and this has caused delays in testing and operational inefficiencies. The purpose of this study was to determine if samples collected for lactate can be stored at 25°C and how long the samples would

remain viable for lactate measurement compared to those stored at 4°C. Two fluoride/oxalate vacutainer tubes of blood were collected from 22 subjects. One sample was collected and stored immediately on ice and the other was kept at room temperature. Each sample was analyzed for lactate at baseline, one hour after collection, two hours after collection, and three hours after collection. The tubes labeled as ice were stored at 4°C between measurements and the tubes labeled as room temperature were stored at 25°C. The average lactate values for samples stored at 4°C and 25°C were 1.8 mEq/L at all times. There was no significant difference between samples stored at 4°C and 25°C at all time intervals with concentrations staying at 1.8 mEq/L up to 3 hours for both samples. We conclude that samples for lactate may be stored at 25°C and the results will remain stable over a period of three hours.

Oral Presentation Abstracts

Differences in Opinion on Direct Access and Direct to Consumer Testing

Brandy D Gunsolus, MS, MLS(ASCP)^{CM}, Rutgers University, Newark, NJ

The purpose of this study was to investigate the opinions of different healthcare professionals from different settings regarding direct access testing (DAT) and direct to consumer testing (DTC) as well as the opinions of non-healthcare professionals considered potential consumers. A total of 39 individuals consented to an interview regarding direct access testing including ten physicians spanning five specialties, six laboratory professionals, seven nurses, two medical office managers, and eleven individuals that were not employed in the medical field. Interviews were conducted either in person or via social media platforms. Of the ten physicians interviewed, none of them were in support of unlimited DAT although half were support of DAT with a limited testing menu. All other physicians were adamantly against any DAT. All ten physicians responded against all DTC genetic testing. Within the non-physician medical professionals, three were in favor of unlimited DAT and the other ten agree with DAT with a limited test menu. Of the eleven non-medical

individuals interviewed one was against all DAT, one was in favor of DAT with a limited test menu, and all of the remaining nine wished for unlimited DAT. Of the non-physician medical professionals, three were in favor of DTC genetic testing full access, three nurses were in favor of limited access, and the remaining thirteen were against. Only one non-medical professional was against any access of genetic tests and the other ten non-medical professional were in favor of complete access to all genetic tests available. Open responses indicated that medical professionals were more likely to be concerned about liability regarding both DAT and DTC testing and accuracy of testing, whereas non-medical professionals cited their right to know their medical information. As more DAT and DTC is made available, this investigation concludes that public safety and physician liability issues should be addressed.

The β -lactamase Resistome within Bacteria Recovered from Long-Term Acute Care Hospital Patients in Chicago

Nicholas M. Moore, MS, MLS(ASCP)^{CM}, Rush University Medical Center, Chicago, Illinois

Long-term acute care hospital (LTACH) patients have high levels of colonization with multidrug resistant organisms (MDRO), including *Klebsiella pneumoniae* carbapenemase (KPC)-producing *Enterobacteriaceae*. The diversity of the β -lactamase resistome remains largely uncharacterized. In this study, surveillance cultures consisting of five anatomic skin sites and rectal swabs were collected from 62 patients. Organisms were identified and susceptibility testing was performed using the MicroScan WalkAway 96 Plus System (Siemens, Tarrytown, NY). Isolates were tested for *bla*_{KPC} by real-time PCR. 216 *bla*_{KPC}-positive isolates were tested to identify other β -lactamases using the OpGen Acuitas Resistome test. 194 (89.8%) of organisms recovered were *K. pneumoniae* and 119 (61.3%) of *K. pneumoniae* were identified as multilocus sequence type-258 (ST258) by real-time PCR. Using the results from the β -lactamase testing performed, we constructed a resistome profile for each organism. 20 different resistome profiles were reported for all organisms identified, with 3

predominating among *K. pneumoniae*. Resistome type 2 was significantly associated with ST258 [OR=3.344, 95% CI (1.813-6.170), $p<.001$], which included SHV and TEM wild-type β -lactamases. Those that were resistome type 4 were less likely to be ST258 [OR=.150, 95% CI (.053-.426), $p<.001$]. Resistome type 4 included CTX-M extended spectrum β -lactamases as well as SHV and TEM wild-type β -lactamases. Other β -lactamases identified included chromosomal and plasmid-mediated AmpC β -lactamases and oxacillinases. One patient isolate had a unique class A extended spectrum- β -lactamase, *bla*_{VEB-1}, which is less frequently identified. In conclusion, *bla*_{KPC} remains highly prevalent among LTACH patients in Chicago, and *K. pneumoniae* remains the dominant organism isolated. These patients, however, have been found to possess antibiotic resistance genes other than *bla*_{KPC}. The epidemiologic importance of these β -lactamases is still unclear.

The Role of the Clinical Laboratory in Identifying Adverse Effects Related to Energy Drinks

Maria Teresa Aguirre, MS, MT(ASCP), University of Texas Rio Grande Valley, Edinburg, Texas

Objective: The purpose of this study was to provide insight into energy drinks and their consumption in the US, their active ingredients, their effects on certain populations, and how certain laboratory tests help in the identification of possible toxicity or adverse effects related to over-consumption or adverse reaction. Description of Method: Literature review in preparation for an on-campus survey to be conducted 2016-2017 regarding energy drink use. This survey includes age, sex, marital status, family, jobs, and full-time or part-time student status. It also includes frequency of use and use in combination with alcohol. Literature includes published articles on toxicity and death due to overuse or adverse effects and data published by the National Health and Nutrition Examination Survey (NHANES) 2007-2010 of 19,142 participants and their consumption of caffeine. It also includes data from the Drug Abuse Warning Network, a public health surveillance system, which lists the number of emergency room visits related to energy drink use in the U.S. from 2007 to 2011, among other articles.

Results: The active ingredient in energy drinks is caffeine. Energy drinks contain, on an average, 242 mg of caffeine per serving. The World Health Organization (WHO) describes normal caffeine intake as ≤ 400 mg/day in an adult. Caffeine can have both beneficial effects and adverse effects on individuals, depending on different factors such as tolerance and the amount consumed. The profile of an individual presenting themselves to the emergency room due to possible toxicity or adverse effect due to energy drinks includes primarily males <25 years, athletes, shift workers, those with undiagnosed or poorly controlled mental health disorders such as depression and bi-polar disorders, those with a history of familial mental health disorders, those with a history of seizures, heart problems, and other possible physical or mental predispositions that precipitate an adverse reaction to excessive caffeine intake (>400 mg/day). Laboratory tests which would provide the best indication of caffeine toxicity would be a Complete Blood Count, a drug and alcohol test, total CK (creatinine kinase), urinalysis, glucose, serum pregnancy, thyroid, arterial blood gas and kidney function tests, serum theophylline (a bronchodilator). A test for caffeine is not recommended as this is usually done at a reference lab with 2-5 day turnaround time. Conclusion: There are many different brands of energy drinks on the market at present, and many misconceptions about the benefits they provide. This study provides factual information regarding their use and benefits or adverse effects. It also provides those in the medical field such as clinical lab scientists and clinicians with information on detecting and diagnosing toxicity or adverse reactions due to energy drink use.

Treatment of Type 2 Diabetes with *Kalanchoe pinnata* Preparation

Lizette E Rios, MS, Jean Sparks, PhD, Felix Omoruyi, PhD, Texas A&M University, Corpus Christi, TX

Type 2 Diabetes (T2D) accounts for approximately 90% of all diabetes globally according to the World Health Organization. Currently there is no cure for the disease. In this study, we evaluated the potential

role of aqueous *Kalanchoe pinnata* preparation in the treatment of T2D using animal models of the disease. Initially, six rats were fed a normal diet, while 24 rats were fed a high fat diet (HFD) for 21 days. Diabetes was induced in eighteen of the rats fed HFD by a low dose of streptozotocin administration on day 14 and diabetes was confirmed on day 21. Animals were then divided into five groups as follows: non-diabetic group; non-diabetic control group fed HFD; diabetic group; diabetic plus *K. pinnata*; diabetic plus metformin. Animals were euthanized by decapitation after treatment for 28 days and blood was collected for assays. Treatment with *K. pinnata* reduced fasting blood glucose by 29% compared to 40% reduction in the group treated with metformin. There was a significant ($P < 0.05$) increase in alanine amino transferase (ALT) activity in the *K. pinnata* treated group. We also noted significant ($P < 0.05$) increases in HDL levels and in alkaline phosphatase (ALP) activity in the groups treated with *K. pinnata* or metformin compared to the diabetic control. Metformin administration significantly increased triglyceride levels compared to the group administered *K. pinnata*. Similarly, uric acid levels were significantly elevated in the group treated with *K. pinnata* compared to the metformin group. Overall, *K. pinnata* administration lowered blood glucose and increased HDL levels, which may be beneficial in the management of T2D. However, traditional use of *K. pinnata* in the management of the disease should be done with caution due to the observed increases in uric acid levels, ALT and ALP activities, which may be indicative of organ damage.

Epigenetic and Gene Expression Analysis of Host Susceptibility Genes for *Chlamydia trachomatis* Infection

Katie M. Bennett, Ph.D., MB(ASCP)^{CM}, NRCC-CC, Christopher Burns, Danielle Dailey, Jorge Chavez, Cliff Jou, Andrew Smith, Vanessa Torres, Texas Tech University Health Sciences Center, Molecular Pathology Program, Dept. Laboratory Sciences and Primary Care, Lubbock, TX

Chlamydia trachomatis is a common sexually transmitted infection that can cause pelvic inflammatory disease, ectopic pregnancy, and tubal

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infertility. There are many differences between patients in the persistence and progression of infection, believed to be influenced by the genetics of the host. The goal of this study is to examine the genetic and epigenetic characteristics of host susceptibility genes for *C. trachomatis* infection. Human gene products such as protein disulfide isomerases have been shown to play a role in the intracellular *C. trachomatis* life cycle. Our previous studies show a correlation between host polymorphisms in the isomerase *PDIA2* and *C. trachomatis* infection. In the current study, an epigenetic profile of *PDIA2* was examined in HeLa human cervical epithelial cells. DNA methylation was quantified for two CpG islands in the *PDIA2* gene using pyrosequencing. The methylation profile for HeLa *PDIA2* differed significantly from the control (fully methylated DNA) for 4 out of 10 loci ($p < 0.05$), with an average percent methylation of 47% ($\pm 10.8\%$). Lowered methylation may indicate that *PDIA2* is transcriptional active, so we examined

gene expression of *PDIA2* and a related isomerase family member, *P4HB*. Reverse-transcriptase qPCR was performed to quantify relative mRNA expression of the isomerase genes in HeLa cells. *PDIA2* showed detectable but very low mRNA expression in HeLa, while in contrast, *P4HB* exhibited extremely high relative expression (5E+4-fold higher as compared to *PDIA2*). After treatment with 0.5 μ g of *Chlamydial* lipopolysaccharide (LPS) for 48 hours, the expression of *PDIA2* was significantly ($p < 0.01$) decreased from untreated control to 0.609-fold (0.52-0.71). In contrast, *P4HB* expression was significantly ($p < 0.01$) increased from untreated control to 3.78-fold (3.50-4.09). These results provide evidence that these host genes may be transcriptionally regulated by exposure to *C. trachomatis*. Future studies include epigenetic characterization of *P4HB* and *PDIA2* in *C. trachomatis*-positive patient specimens.