

ASCLS Annual Meeting 2017: Official Abstracts of Submitted Papers, Case Studies and Posters

San Diego, CA

The following abstracts have been accepted for presentation at the 2017 American Society for Clinical Laboratory Science (ASCLS) Annual Meeting and Clinical Laboratory Exposition to be held July 31 through August 3 in San Diego, CA. 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 1 and 2, 9:30am-5:00pm at the San Diego Convention Center in the Sails Pavilion. Authors will be present on Wednesday, August 2 from 10:30am to Noon to discuss their work and answer questions.

ORAL RESEARCH PRESENTATIONS

Monday, August 1st at 10:00am in room Gallery 2 at the Omni San Diego Hotel

Poster Presentation Abstracts

Effective Incorporation of Performance Standards in Quality Control Systems

Selom Agboyi, Shashi Mehta, Rutgers, The State University of New Jersey, Newark, NJ

A statistically designed quality control (QC) method can effectively detect errors in the analytical system while minimizing false rejection. While most laboratories use standard statistical QC processes, with or without Westgard multi-rules to evaluate quality, few incorporate performance standards in their QC systems. Setting quality goals allows the laboratory to determine the sigma value of each test. The sigma metric guides the selection of optimal QC

rules specific to the quality level achieved by each analyte.

The aim of the study is to emphasize the role of performance standards in quality control systems. The analytical performance of 5 analytes (AST, sodium, magnesium, glucose, and creatinine) were used as examples.

Internal quality control data from May 2016 to November 2016 was used to assess the method performance of the 5 analytes included in the study. The calculated performance characteristics include cumulative mean and SD, mean bias, analytical system total error, sigma metric, and critical systematic error.

The study demonstrated that 4 analytes (AST, creatinine, glucose, magnesium) out of 5 performed above 6 sigma metric. Sodium recorded a poor performance with a sigma value less than 3. It was determined that a single rule, 1_{3s} was sufficient to control AST, creatinine, glucose, and magnesium, while more stringent QC rules $1_{3s}/2_{2s}/R_{4s}/4_{1s}/8_x$ need to be adopted for sodium.

Our study demonstrates that setting quality goals is essential to improve quality monitoring systems. Laboratories can statistically evaluate the size of analytical error and determine if the probability of producing clinically misleading patient results or unacceptable proficiency tests is greater than 5%.

Submandibular Zygomycosis

Sean Ahrens, BS, MLS(ASCP)^{CM}, Deborah Josko, PhD, SM(ASCP), Rutgers University: School of Health Professions, Newark, NJ, Thomas Kirn, MD, PhD, New Brunswick, NJ

The *Zygomycetes* are a class of fungi that have been associated with rhino-facial infections in both healthy and immunocompromised patients. Risk factors associated with rhinofacial zygomycosis include: diabetes mellitus, neutropenia, and the use of broad

spectrum antibiotics or immunosuppressive agents. This case study follows an immunocompromised 27 year old male with a history of astrocytoma, Ewing's sarcoma, and Acute Lymphocytic Leukemia (ALL). Patient presented to the ED with diffuse muscle pain, left neck swelling and fever after a relapse of ALL. In addition he was neutropenic and thrombocytopenic (platelet count of 18,000 μ L). A submandibular mass was observed on physical examination and later identified to be an abscess anterior to the left submandibular gland. Prior to surgical removal of the abscess the patient was transfused with platelets and advised of risk factors which included bleeding, infection, recurrence and need of post-operative intubation. Culture results of the abscess revealed a rapidly growing white, fluffy fungus that became darker with age. Microscopic results showed rhizoids aligned with the base of the sporangiophores. These results were consistent with a fungal identification of *Rhizopus*. *Rhizopus* is a ubiquitous organism that can be found in soil, decaying matter, and on bread products. Although the cause of acquisition of the organism was unknown, the infection was most likely due to the patient's severe immunosuppressive state. Prompt identification and treatment of these infections are critical as angioinvasive species of *Rhizopus* have been described in the literature. Treatment includes surgical intervention and antifungal medications. The prognosis for cutaneous infections are generally good when treated promptly.

Risk Management and Quality Control in Mass Spectrometry

Zoe C. Brooks, ART, AWEsome Numbers Inc.' Sudbury, ON, Canada' John Hopkins, BSc(Hons)' Clinical Mass Spectrometry Consulting Ltd, George Sweeney, MLS(ASCP)^{CM}, M.O.R.E. Quality Consultant

LC/MS offers many advantages over other techniques in terms of specificity, accuracy and precision, but existing quality control processes are challenged to effectively monitor the analytical performance against healthcare objectives and risks. "Risk [is the] combination of the probability of occurrence of harm and the severity of that harm" (ISO/IEC Guide 51). We examined patient and QC sirolimus results from 2016 from a hospital/reference laboratory. We

calculated the probability of risk from the sigma or z-value based on the monthly mean and SD of the QC sample relative to the package insert midpoint and a TEa limit of $\pm 15\%$. We created scatter plots of the full year's patient results below 50, plus 3 QC samples with package insert means of 3.6, 10.8 and 17 ng/L. Because of daily calibration, we saw no obvious multi-day or multi-week shifts as seen in the biochemistry data previously examined. We examined histograms of monthly patient data. In the month of September, 16% of reported results were above 21, twice as many as the overall average of 8%. The month of December reported only 2% of results > 21 , just $\frac{1}{4}$ the oval average and only $\frac{1}{8}$ as many as September. We considered these clinically significant changes creating unacceptable patient risk. In September, the sigma value of was below the acceptable risk criteria of 2 sigma. In December, sigma passed at 2.2. We used software to simulate a shift to the acceptable risk criteria of 2 sigma. The existing QC chart limits of $\pm 15\%$ failed to flag this failure. Software designed a mathematically-optimiZed QC strategy based a Margin for Error (the number of SD the mean can shift before risk becomes unacceptable) that was effective to detect unacceptable risk in one day. We believe that this process of "Mathematically-OptimiZed Risk Evaluation" will improve analytical compliance and reduce patient risk and costs.

The Significance of the Laboratory in the Work Up and Monitoring of Seemingly Independent Illnesses That In Fact Were Interrelated

Demetra Castillo, M.Ad.Ed, MLS(ASCP)^{CM}, Carolina College of Health Sciences, Charlotte, NC

This is a case involving a 39 year old female who has a history of type 2B von Willebrand Disease, endometriosis, epilepsy, and iron deficiency anemia. While seemingly independent conditions, the pathophysiology of these conditions are actually interrelated. This was discovered through the laboratory tests conducted as part of the diagnosis for each condition and also along with the careful monitoring for each condition. The laboratory was crucial in their diagnosis but also in the monitoring and treatment of her illnesses. The initial diagnosis of von Willebrand Disease was confirmed with a platelet count, aPTT, vWF antigen, vWF activity through

RIPA, and multimer analysis and was monitored quarterly with the platelet count and aPTT. Her endometriosis, a condition not normally confirmed in the laboratory, was monitored using prolactin levels, which interestingly has also been used as a biomarker for epileptic seizures. Her gynecologist, with the assistance of a medical laboratory scientist, monitored her monthly, approximately 5-7 days after the cessation of menstruation to determine her prolactin levels, which coincided with her ovulation. This was her period of highest risk of developing endometriomas in her ovaries, and incidently was also the period where she wasn't at risk for developing seizures. Her results were consistently elevated (PRL: 24.5 +/- 2.5 ng/ml). Her highest frequency of seizures occurred approximately 5 days before the onset of her menstruation and was also monitored by prolactin levels. Prolactin levels were drawn before and during a seizure, showing consistent results (PRL (before seizure): 14.5 +/- 1.5 ng/ml and (after seizure): 29.6 +/- 1.6 ng/ml). Her iron deficiency anemia was confirmed with iron studies and monitored using ferritin levels and was also measured quarterly especially around her menstrual cycle. Despite her bleeding disorder, her ferritin remained stable for the entirety of the 6 month monitoring period.

The Education Gap in Clinical Microbiology

Ryan Cordner, PhD, Celeste Dunn, Mary F. Davis, PhD, Brigham Young University, Provo, UT

The objective of this study is to establish the differences that exist between clinical microbiology coursework in university based MLS and MLT programs, and the actual testing that takes place in clinical laboratories. The gap that exists between the university and hospital settings is often a concern for educators and for hospital staff who train students. A survey was sent to all of the MLS/MLT programs in the state of Utah. Another survey was sent to the hospitals in Utah. The survey results revealed several differences between university programs and clinical laboratories, including the fact that 100% of the MLS/MLT programs use biochemical tubes and CAMP plates, while only 5% of hospital respondents reported the use of any biochemical tubes and 9% the use of CAMP plates. Despite these differences, only 55% of hospital respondents considered the clinical

microbiology coursework insufficient to prepare students to work the microbiology bench, with most citing the need for longer exposure on a hospital bench for proficiency, suggesting that clinical microbiology coursework still provides an important scientific foundation for students. Increased focus on current methodologies and exposure to true clinical specimens may help to better prepare students for work in the clinical laboratory.

Validation of an Allelic Discrimination Assay for Drug Metabolism

Hatoon Dablouk, **Erica Hendrix, PhD, MB(ASCP)^{CM}**, Chanel Nwokey, MLS(ASCP)^{CM}, Texas Tech University Health Sciences Center, Lubbock, TX

The goal of this project is to validate a series of genotyping assays in order to investigate drug metabolism genes that may also be associated with trigger points and myofascial pain. We hypothesized that the allelic discrimination assay would be more advantageous for genotyping the candidate genes as an alternative to sequencing, which is currently the gold standard. Genotyping studies were performed using a sample size of 19 subjects. Subject DNA were previously isolated and de-identified prior to assignment. Genotyping was performed using TaqMan allelic discrimination assays (Applied Biosystems) on the StepOne real-time PCR instrument. To confirm the genotype determined, a percentage of the samples were analyzed by Sanger sequencing. The GenoTyper app was used for comparison to StepOne software for genotyping. We were able to obtain 100 % accuracy when comparing the allelic discrimination assay to the sequencing method. 100% reliability was obtained within assay for both SNPs with 100% reliability for the CYP2C9 SNP and 88% reliability for the CYP1A2 SNP between assays. We established our LOD at 10ng/μL of DNA. We could not confidently validate the assay due to the software's inability to automatically call the genotype without manual assistance from the use of the multi-component plot. Hence, we were led to seek an alternative software to predict the genotype without manual interference. In conclusion, we have determined that the allelic discrimination assay validation had not been fully successful due to the

software's inability to accurately call genotypes. For future studies, we recommend the use of the GenoTyper (GT) app for accurately identifying the genotype due to its advanced algorithm. Further validation is necessary for this new algorithm before adopting this method.

Development of a High Resolution Melt Curve Assay to Detect Sickle Cell Disease

Connie R. Maza, B.S., Yvonne N. Umeh, MLS(ASCP)^{CM}, Ericka C. Hendrix, PhD, MB(ASCP)^{CM}, Texas Tech University Health Sciences Center, Lubbock, TX

Sickle cell disease is a disorder that results in a point mutation which changes glutamic acid to valine and is responsible for sickle shaped red blood cells. At the nucleotide level adenine is replaced by thymine which is known as a class IV mutation. Class IV mutations are very difficult to detect; therefore, the proper instrumentation and software is needed to capture this mutation. The purpose of this research is to design a high resolution melt curve assay (HRM) on the Qiagen Rotor-Gene instrument for the detection of sickle cell disease (SCD). We determined the optimal primers and cycling conditions for a reliable and accurate HRM SCD assay. By detecting slight differences in melting temperatures this assay is able to differentiate between the various SCD genotypes; wild-type (AA), heterozygous (AT), and homozygous mutant (TT). We were able to obtain a 92.8% accuracy rate and a 94.4% precision rate, as well as a 90% concordance rate when compared to sequencing. Future studies should include more positive samples with sickle cell disease, as we only had known positives from a DNA bank. The Rotor-gene HRM SCD lab developed assay, once validated, could be a cost effective and quick molecular diagnostic assay to detect sickle cell disease.

Phytochemical Effects on Bacterial Biofilm

Rita M. Heuertz, PhD, MT(ASCP), Saint Louis University, St. Louis, MO

The purpose of this study was to identify effects of different phytochemicals on biofilm formed by *Staphylococcus aureus* and *Pseudomonas aeruginosa*.

The organisms were selected for assessment since each one is prevalent in hospital settings, is difficult to treat, forms biofilms on solid surfaces (such as catheters and medical implants) and behaves differently in community (as a biofilm) than it does planktonically (as a single entity). Interestingly, little has been published on effects of phytochemicals on biofilm formation even though a plethora of reports on antibacterial actions of many plant-derived compounds are present in the literature. Bacterial biofilm is important for study since it is associated with antibiotic resistance, bacterial evasion of the immune host response and predilection for medical implant and chronic infections. In this age of ever-increasing antimicrobial resistance and medical device interventional medicine, bacterial biofilms pose a major threat to healthcare. For this reason, alternative therapeutics need to be considered, such as plant-derived compounds. This research focused on assessment of phytochemicals with reported antibacterial properties, many of which remain undefined. Results of select phytochemicals (such as cinnamaldehyde, curcumin, neem) gave evidence of inhibition of biofilm formation in a statistically significant manner. Preliminary studies focused on determination of phytochemical effect on biofilm and identification of means by which antibiofilm action occurred. It was determined that phytochemicals hold great potential as antibiofilm alternatives to antibiotics due to their effectiveness, low toxicity and minimal cost. Continued studies are needed to further define antibiofilm effects and mechanisms of action relevant to major human pathogens that are biofilm producers, *S. aureus* and *P. aeruginosa*.

Field Evaluation of Onsite Monitors for Surface Contamination by 5-fluorouracil

Jerome Smith, PhD, Deborah Sammons, BS, Shirley Robertson, Barbara MacKenzie, BS, John Snawder, PhD, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, Cincinnati, OH

Healthcare workers may be exposed to antineoplastic drugs from surface contamination resulting from the preparation and administration of such drugs. Despite efforts to change work practices to prevent contamination, worker exposure may still occur.

Currently drug surface contamination is evaluated with surface wiping and analysis with laboratory analytical techniques. Techniques such as liquid chromatography-mass spectrometry (LC-MS) are accurate but expensive and results are obtained after a long delay during which exposure can continue to occur. In order to reduce contamination, the National Institute for Occupational Safety and Health (NIOSH) has developed monitors that are capable of assessing contamination on site in near real-time. These monitors use surface wiping and lateral flow immunoassay for evaluation of contamination. The monitors have been successfully evaluated in the laboratory to assess the sensitivity of detection on contaminated surfaces. NIOSH, in collaboration with a medical equipment supplier, is evaluating the monitors in the field to assess their ability to detect contamination in healthcare facilities. In this evaluation the levels of contamination measured with the monitors is compared to levels measured with LC-MS. In this poster we present the results for monitors for 5-fluorouracil (5-FU). While the laboratory evaluation indicated that 0.1 ng/cm² could be detected on a surface, the field data indicated this level would result in a slight positive bias. To account for this bias, receiver operating characteristic (ROC) curves were developed for the data which indicated that a lower limit between 0.1 to 0.2 ng/cm² would result in a more acceptable level of false positives while retaining positive samples. The data indicate that the monitors will be useful in identifying contamination by 5-FU since the monitors detected contamination in many areas. These monitors will enable users to take immediate action if needed, to reduce exposure to this Hazardous drug.

Comparison of Test Results for IHC, FISH and NGS when Screening for Molecular Markers

Adam Janssen, MS, MB(ASCP)^{CM}

Thuy Nguyen, MS, MB(ASCP)^{CM}, Miriam Block, MD, Hany Magharyous, MD, Jason Christiansen, PhD, Jennifer Lamoureux, PhD, MT(ASCP), Ignyta, Inc., San Diego, CA

A consequence of personalized medicine is that as the number of potential therapies that target uncommon molecular variant markers grows, clinical testing is faced with the challenge of accurately stratifying

patients for therapy. An example of these rare alterations are gene rearrangements, such as those found in the NTRK, ROS1 and ALK genes. This effort can be confounded by the fact that in small patient populations (e.g., for targeted kinase inhibitor therapies) the prevalence in a patient population can be as little as ~1-10%. Rare patient populations like this make the development of testing platforms challenging due the limited availability of materials. A number of testing methods can be employed by a laboratory depending on their volume and cost. Immunohistochemistry (IHC) is both high throughput and cost efficient, but is not specific to rearrangements. Fluorescence in situ hybridization (FISH), while currently the most common diagnostic detection of gene rearrangements, does not provide information regarding the gene fusion partner, while Next Generation Sequencing (NGS) is expensive and labor intensive.

We have compared the clinical testing results from a combination of FISH and IHC testing to NGS testing. These results were generated from a subset of patients prospectively enrolled in a phase 1 clinical trial of the targeted therapy, entrectinib (n=23). Entrectinib targets tumors who harbor gene rearrangements in NTRK, ROS1 and ALK. The outcome results demonstrate that testing by RNA based NGS testing is more predictive of patient response (ORR=66.7%) than FISH/IHC alone (38.5%). These results provide important information as the detection of gene rearrangements moves from the clinical trial setting to routine practice.

Severe Factor VII Deficiency in a Newborn

Wendy C. Lumm, MHS, MLS(ASCP)^{CM} MB(ASCP)^{CM}, Gloria Sloan, MT(ASCP), Mary Jonah MT(ASCP)SH, Natasha Savage, MD, Augusta University and AUMC, Augusta, GA

Factor VII deficiency is classified as a RBD, rare bleeding disorder. It is however the most common of all RBDs and is more prevalent than Hemophilia C. It is an autosomal recessive disease. Factor VII deficiency is unlike hemophilia or other bleeding disorders in that genotype does not predict bleeding severity phenotype in patients.

Severe bleeders with Factor VII deficiency are usually detected in the first 6 months of life. We report here a

Factor VII deficient patient diagnosed at day 5 by the Prothrombin Time (PT) assay. His first symptom was difficulty nursing and the physician ordered gentamicin IV in case of meningitis. The child's first blood work revealed only slightly low creatinine and BUN. A frenulotomy (tongue clip) was performed to correct feeding issues. The next day the nurse noticed bleeding underneath the tongue; she applied pressure to stop the bleeding. She also noted swelling in the left groin and occipital area of the skull. The physician stopped the IV and ordered PT/INR, and aPTT. PT was prolonged at 53 seconds. The newborn was transferred to AUMC on day 5. Lab tests revealed normal platelet function, a Factor VII level of 1% normal range is 50-150%. The child was given NovoSeven[®] RT regularly, but at 3 months, the child was spitting up blood, at four months, his left arm was swollen and he was transfused with O negative blood. At 5 months, the infant was vomiting daily and underwent surgery because of intracranial bleeding. During surgery, the patient was transfused with O negative blood and given NovoSeven[®] RT. The patient was discharged 9 days later and receives NovoSeven[®] injections twice a week.

Validation of Vysis LSI ALK and ROS1 Break Apart FISH Probes

Wendy C. Lumm, MHS, MLS(ASCP)^{CM}, MB(ASCP)^{CM}, Barbara Kraj, PhD, MLS(ASCP)^{CM}, MB(ASCP)^{CM}, Lester Pretlow, PhD, Augusta University and AUMC, Augusta, GA

The purpose of this study was to validate two probes used in the detection of two rearrangements found in Non-Small Cell Lung Cancer (NSCLC). Conducted at the cytogenetics lab at Augusta University Medical Center, the validations were a requirement of the American College of Medical Genetics (ACMG) which states that every assay must be validated before implementation. The two probes, manufactured by Abbott Molecular Inc. of Des Plaines, Illinois as part of a FISH kit, detected the ROS1 and ALK rearrangements of NSCLC patients and were a companion diagnostic to crizotinib (trade name Xalkori, Pfizer). The prevalence of Anaplastic Lymphoma Kinase (ALK) gene rearrangements was 2-5% and the prevalence of ROS1 gene rearrangements, was 1-3% in NSCLC. For validations, the sensitivity

and specificity of each probe agreed with the manufacturer's published performance standards. The data represented enumerations from 25 nuclei as opposed to 50 nuclei per patient slide enumerated by each cytogeneticist at AUMC. The data from the two AUMC cytogeneticists were comparable to Abbott Molecular's data. The sensitivity and specificity for the ALK probe was 96.4% and 98.4% respectively and for ROS1 99.4% and 100% as documented by the cytogeneticists in the AUMC cytogenetics lab. The investigator's sensitivity and specificity data were 100% and 98.8% for ALK rearrangements and 100% and 100% for ROS1 rearrangements. All technologists' data were concordant with Clariant Inc.'s data. The Abbott Molecular Vysis ALK and ROS1 probes had high specificity and high sensitivity for the detection of NSCLC rearrangements.

A Prospective Study of Patients Diagnosed with Sarcoidosis: Nutrition, Health Assessment and Environmental Exposures

Louis B. Caruana, PhD, MT(ASCP), Gerald D. Redwine, PhD, MT(ASCP), Sheridan Limmer, BSCLS candidate (senior), Rodney E. Rohde, PhD, SV^{CM}, SM^{CM}, MB(ASCP)^{CM}, Christopher Russian*, Ph.D., RRT-NPS, RPSGT, Texas State University, CLS Program & *Respiratory Care Department, San Marcos, TX

Sarcoidosis is a systemic granulomatous disease of unknown cause that primarily affects the lungs, but may affect any organ and tissue. This purpose of this study (IRB approved) was to determine factors which contribute to a diagnosis / etiology cause of sarcoidosis. A prospective survey was used that included 121 questions covering nutrition, health history, environmental exposures, lifestyle, and demographic information. The survey collected data on both external and internal risk factors that might predispose to sarcoidosis for 801 individuals diagnosed with the disease. The group consisted of 654 females and 143 male subjects with a median age of 49 years (range 14 to 76). Participants for the study were recruited by posting a short web-based survey on 31 Sarcoidosis Support Groups on the social network Facebook. Subjects in the study were placed into sub diagnostic classifications of acute sarcoidosis (AS), chronic sarcoidosis with limited dissemination

(CSLD), chronic sarcoidosis with full dissemination (CSFD) and chronic sarcoidosis with neurosarcoidosis (CSN). Among the parameters of the study found to be statistically significant were exposure to ciprofloxacin across all groups with AS reported the least exposure. A similar exposure pattern to copper and iron was observed and for alcohol and tobacco usage. Of the infectious diseases, only a diagnosis of Candidiasis was found to be statistically significant across the subgroups.

Assessment of Intake of Cinnamon Supplements on Hemoglobin A1c Levels in Pre-Diabetics

Shokrani M, Ph.D. MT(ASCP), Lukaszuk J, Ph.D., RD, LDN, Walker DA, Ph.D., McCann H, McMahon L, Kim E, Northern Illinois University, DeKalb, IL

Cinnamon often is used in attempts to lower blood sugar levels, however, previously published research suggests conflicting results of its usefulness. Many individuals who are pre-diabetic will eventually develop type 2 diabetes within 10 years. Hemoglobin A1c blood test (HbA1c) reflects average blood sugar levels in the past two to three months. Pre-diabetic individuals have HbA1c levels equal or higher than 5.7 percent. In this study, we investigated whether cinnamon supplements would affect HbA1c levels in the treatment group as compared to the control group. In addition to HbA1c levels, body mass index (BMI) and percent body fat (PBF) of subjects in the treatment and control group were determined. Participants in the treatment group (30 pre-diabetic individuals, ages 18-70 years) received two capsules of 500 mg cinnamon daily while the control group (22 pre-diabetic individuals, ages 18-70 years) did not receive any cinnamon supplements for the duration of the study. Thirty-three subjects completed the study at the end of ten weeks (20 subjects in the treatment group and 13 subjects in the control group). Due to the study's small sample size, Mann-Whitney U test for two independent groups was used and indicated that there were no statistically significant differences between the treatment and the control groups based on: HbA1c levels $U = 123.50$, $p = .810$; BMI $U = 112$, $p = .507$; and PBF $U = 119$, $p = .685$. The data in this pilot study warrant larger studies in the future to

determine the benefits of cinnamon supplements in lowering HbA1c levels in pre-diabetics.

NGS Testing Helps to Identify New Treatment Opportunities for Advanced Solid Tumor Cancers Driven by Molecular Alterations

Audrey Thacker, MPH, MLS(ASCP)^{CM}, Jessica Templer, MLS(ASCP)^{CM}, Hany Magharyous, MD, Pratik Multani, MD, Jason Christiansen, PhD, Jennifer Lamoureux, PhD, MT(ASCP), Ignyta, Inc. San Diego, CA

NTRK, *ROS1*, *ALK* and *RET* fusions have been identified as oncogenic drivers in multiple solid tumors. In general, these gene alterations are rare, but targeted therapies are being developed that may provide new therapeutic options for patients whose tumors harbor these alterations. However, in order to develop these new drugs, new methods must also be developed to efficiently and comprehensively identify appropriate patients.

Two clinical stage investigational small molecule tyrosine kinase inhibitors, entrectinib (RXDX-101) and RXDX-105, target TRK/ROS1/ALK and RET, respectively. The anti-tumor effects of entrectinib and RXDX-105 have been demonstrated in multiple preclinical models, including in cell lines and in murine patient-derived tumor models, driven by *NTRK*, *ROS1*, *ALK* or *RET* fusions. Entrectinib and RXDX-105 exerted these potent inhibitory effects, *in vitro* and *in vivo*, in cancer models driven by *NTRK*, *ROS1*, *ALK* or *RET* alterations, irrespective of their histologies.

Based upon these data, clinical trials are underway to study these two investigational agents and determine their safety and efficacy in molecularly selected patients. Patients with solid tumors containing *NTRK*, *ROS1* or *ALK* fusions are being enrolled in the ongoing STARTRK-2 trial of entrectinib (NCT02568267) and patients with RET fusions are being enrolled in the ongoing Phase1/1b RXDX-105-01 trial of RXDX-105 (NCT01877811). To date, both entrectinib and RXDX-105 have demonstrated durable RECIST responses in a high proportion of molecularly selected patients.

Utilization of Next Generation Sequencing testing for alterations in *NTRK*, *ROS1*, *ALK* and *RET* has proven to be a valuable tool in selecting patients with solid

tumor malignancies, for whom promising new treatment opportunities (such as entrectinib and RXDX-105) are being developed.

Cause and Concern for Patients with B- cell Lymphoproliferative Disorders

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

The purpose of this case study is to discuss the diagnosis of a patient who arrived to an Emergency unit and was diagnosed with Plasma Cell Leukemia which is a B-cell Lymphoproliferative neoplasm. This case study will discuss the difference between different cell line neoplasms and in this case, give a review of a patient who was diagnosed with Plasma Cell Leukemia. Included, will be a review of the different lymphocyte CD markers identified in Flow Cytometry which play a role in the diagnosis of their respective neoplasms. With the many other neoplasms having to do with the lymphocyte lineage this case study will discuss the different laboratory testing and staining processes used to differentiate particular disorders along with the many different treatment protocols. While this particular case is focused to a particular patient who was diagnosed with a Plasma Cell Neoplasm, many of the signs and symptoms to the other types of neoplasms are the same. Differentiating the many types and subtypes of neoplasms are very critical to a patient's treatment process and will be discussed into helping clinicians around the world help make the best treatment plan to improve patient's survival rate.

Oral Presentation Abstracts

Phytochemical Effect on Colorectal Cancers

Uthayashanker R. Ezekiel, PhD. MB(ASCP)^{CM}, Saint Louis University, St. Louis, MO

Colorectal cancer (CRC) is a fourth leading cause of cancer in the USA. The rate of colon cancer is dropping in people older than 50 years of age due to effective colon cancer screening programs. However, younger individuals (those < 50 years of age) are experiencing increased rates of CRC. It has been predicted that by the year 2030, the rate of CRC in the

20-34 year old age group will be increased up to 90% and 124% (colon and rectal respectively). Another concern is a recurrence of cancer that is metastatic after tumor removal. It has been reported that traditional cancer treatments, chemotherapy, and radiation, change residual epithelial cancer cells, such as those found in breast, pancreatic and colorectal cancers, into metastatic cancer. Epidemiological studies have shown that populations consuming high amounts of spices and vegetables have low incidences of CRC. An occasional exposure of colon cells to a single phytochemical may be insignificant; however, combination treatments may provide additive or synergistic effects. Combination treatments tend to be effective at low doses thereby making them potent ways to prevent colon cancer initiation and/or progression. Phytochemicals of interest are curcumin, the yellow pigment of turmeric, and silymarin, a major component of milk thistle. Silymarin has been a dietary supplement for decades and is known for its hepatoprotective effect. We have shown that curcumin and silymarin exert synergistic activity against colorectal cancer. In addition, we found curcumin reduce the expression of oncogenic protein, B cell Moloney murine leukemia virus insertion region (BMI1). The reduction of BMI1 is due to the up-regulation of Micro RNA-15a. Future studies are focused on understanding the molecular pathway of synergistic activity of curcumin and silymarin on colorectal cancers.

Inpatient Utilization of Point of Care Glucose Concomitant Testing

Anne Gaffney, MS, MLS(ASCP)^{CM}, Shashi Mehta, PhD, Rutgers University, Newark, NJ

BACKGROUND: Denver Health Medical Center, Denver, CO launched a quality initiative for appropriate utilization of point-of-care (POC) glucose testing in assessing glycemic status of patients with the intent to reduce the number of POC glucoses performed. Concomitant glucose testing, performed by laboratory and POC at the bedside by the nursing staff within a certain time frame, may be an opportunity to further reduce the number of POC glucoses performed for inpatients. A retrospective review of concomitant glucose testing was completed.

METHODS: Data was extracted from the Denver Health data warehouse to include lab ordered glucoses for the month of October 2015 and POC glucoses performed within two hours of the lab collected glucose. The concomitant POC glucose was stratified into 30, 60, and 120 minute categories. The POC glucoses performed within 30 minutes were correlated to the lab glucose results to determine concordance. A subset of results was analyzed by reviewing the patient chart to ascertain why the glucose was concomitant and if the patient was treated.

RESULTS: 9.3% of all POC glucoses are performed within one hour of collection of a lab glucose. The majority fell into a duplicate categorization (62%) with AM lab collection the reason for 25% of concomitant testing. Correlation of POC and Lab glucose collected within 30 minute time frame showed a slope of 0.961, intercept 2.2, and R value 0.98.

CONCLUSION: The risk of hypoglycemia should be carefully monitored. According to the data an opportunity exists to reduce the number of concomitant POC glucose tests at Denver Health Medical Center. The benefits include cost savings to the patient and hospital, patient contentment, and better use of staff resources.

What is That Bug in My Blood?

Linda A. Smith, PhD, MLS(ASCP)^{CM}BB, Steven Dallas, PhD, D(ABMM), UT Health, San Antonio, TX

Babesiosis is a tick-transmitted disease that occurs frequently in the northeastern part of the United States. Infected individuals may be asymptomatic or show symptoms similar to malaria. It can also be transmitted vertically and by transfusion. Testing for infectious disease markers has contributed to the increasing safety of blood transfusions. However, some infectious diseases such as malaria and babesiosis do not have serologic methods available and assessment of transfusion transmission risk relies on responses to donor history questions. Despite these donor history questions, babesiosis remains one of the major infectious disease risks associated with transfusion because of prolonged low level parasitemia possible in donors. This case is that of a 59 year old female who presented with fever of 102°F,

anemia (hemoglobin 7.7 gm/dl), thrombocytopenia (76K/ μ L), and elevated liver enzymes. She had a history of breast cancer treatment and multiple transfusions. Examination of the peripheral blood smear demonstrated the presence of small, single and double intra-erythrocytic ring forms. Parasitemia was estimated at 6.2%. Morphology suggested either *Plasmodium falciparum* or *Babesia* sp. Initial treatment focused on malaria but patient history and subsequent testing ruled out malaria. PCR testing for *Babesia* sp. was positive. Serologic studies also demonstrated a positive titer for *B. microti*. Treatment for babesiosis was initiated with successful disappearance of organisms from circulation.

Effects of Blood Banking Advanced Technology Practice Prior to Clinical Rotations on Clinical Laboratory Science Student Outcomes

Teresa S. Nadder, PhD, MLS(ASCP)^{CM}, Virginia Commonwealth University, Richmond, VA

Introducing CLS students to automation and advanced technology before their clinical experience has been an ongoing challenge for CLS programs due to budgetary restraints. Student feedback from clinical rotations consistently address the need for increased exposure to advanced technology and automation in the student laboratory sessions to better prepare them for rotations in hospital laboratories. Previous training in the student blood banking laboratory sessions included mostly manual and some gel technology methods; the student laboratory is not equipped with solid phase testing instrumentation or cell washers. In order for students to become proficient in the discipline of transfusion medicine, it was imperative that they have working knowledge and experience operating this equipment before entering clinical rotations and the workforce. Virginia Commonwealth University's Department of Clinical Laboratory Sciences received \$77,779.00 in funding from the Commonwealth Transfusion Foundation (formerly Virginia Blood Foundation) to update the student laboratory with solid phase testing equipment and cell washers. It was anticipated that improved student performance in the clinical rotations and employer evaluations of recent graduates would be observed.

In summary, the faculty were pleased with the introduction of solid phase equipment in the student laboratory session and resulting student and clinical supervisor feedback using two cohorts of students. The results of this study strongly suggest that incorporating the advanced technology in the student laboratory sessions was valuable in preparation for the clinical rotation in Transfusion Medicine the following year and for subsequent employment in that area of the clinical laboratory. Thus, the purposes for the grant were accomplished. The need for further practice using the equipment was voiced in the survey completed by the first cohort. As a result of this feedback, students in the second cohort were given the opportunity to use solid phase testing more frequently prior to entering the clinical rotation.

Planting Your Lab Garden with Your OWN Seeds: A Novel Approach to the Laboratory Professional Shortage

Joann Rittersbach, MT(ASCP), Cynthia Wilkerson, MS, MT(MASCP), **Mark Gendron, MBA, MT(ASCP)**, Memorial Sloan Kettering Cancer Center, New York, NY

In response to a shortage of licensed Clinical Laboratory Technologists, Memorial Sloan Kettering Cancer Center (MSKCC) partnered with Marist College's Department of Medical Laboratory Sciences to train eight MSK employees in a new career as Medical Laboratory Scientists.

The program represents a cooperative effort between the college and MSK to provide a 42 credit curriculum

leading to a Bachelor of Science Degree with a major in Medical Technology. The Marist Program is accredited by the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS). The 12 month training program includes didactic lectures at MSKCC facilities, laboratory courses at the Marist facilities, and clinical rotations within MSKCC's Department of Laboratory Medicine.

Employees meeting MSK's criteria and Marist College's pre-requisite course requirements apply to the program. Applicants are screened and interviewed by a committee of administrators, managers and Laboratory Medicine faculty. Eight employees are admitted to the program annually. Tuition for the program, commuting expenses and textbooks are paid by MSKCC. The employee continues to receive their current salary with benefits during their time as a student.

Upon successful completion of the program, employees receive a second Bachelors of Science degree from Marist College and meet the requirements for the American Society for Clinical Pathology (ASCP), Medical Laboratory Scientist exam. Upon passing the ASCP MLS exam, employees apply for New York State licensure as a Clinical Laboratory Technologist. Licensed employees are offered a position in Laboratory Medicine with a two or three year commitment to the department.

The program started in the summer of 2014. The first two cohorts have completed the program, the third cohort is scheduled to graduate in August 2017 and the fourth cohort has been selected with a start date of July 2017.