ASCLS 2008 Annual Meeting: Official Abstracts of Submitted Papers, Case Studies, and Posters

WASHINGTON DC

The following abstracts have been accepted for presentation at the 2008 American Society for Clinical Laboratory Science (ASCLS) Annual Meeting and Clinical Laboratory Exposition to be held July 29 through August 2, 2008 in Washington DC. The preliminary meeting program was published in the Spring 2008 issue of *Clinical Laboratory Science*. Abstracts are reviewed by appropriate representatives of the ASCLS Abstract 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. Room assignments will be listed in the final program.

ORAL RESEARCH AND CASE STUDY PRESENTATIONS

Friday, August 1, 2008, 9:00 a.m.-10:30 a.m. and 4:00 p.m.-5:30 p.m. at the Capital Hilton Hotel.

POSTER PRESENTATIONS

Tuesday and Wednesday, July 29 and 30, 2008, 10:00 a.m.-4:30 p.m.; Thursday, July 30, 9:30 a.m.-noon at the Washington DC Convention Center. *Authors will be present on Wednesday, July 30, 2008 from 12:30 p.m.-1:30 p.m. to discuss their posters.*

ORAL RESEARCH ABSTRACTS

Assessing Shortness of Breath Using BNP Levels in Adults

Eileen Carreiro-Lewandowski MS CLS(NCA), *University of Massachusetts Dartmouth, North Dartmouth MA*

Distinguishing the underlying cause of dyspnea remains challenging for general practitioners in those patients without a prior history of either pulmonary or cardiac disease. The purpose of this study was to determine if B-type natriuretic peptide (BNP) levels could be used to assist in identifying whether the shortness of breath might be cardiac related. The clinical utility of natriuretic peptides during emergency room visits in assessing congestive heart failure is widely accepted, however, its use by family practitioners to determine appropriate treatment and follow-up in patients experiencing unexplained dyspnea, remains unclear. During a 12-week interval, twenty-three patients, ages 58-84 years, whose primary complaint was weakness and shortness of breath, were referred for follow-up blood work, including a BNP level (Triage, Biosite™). Patients were divided into two diagnostic groups, either cardiac or "other" based on the final diagnosis, relative to the underlying cause of the dyspnea. The mean BNP value for the cardiac group was significantly higher than that for the "other" population ($p < 0.0001$). In the cardiac group the mean was 249(63-666)pg/mL, while the "other " group's mean was 20(8-44)pg/mL. This small sample size provides limited information. However, it can be concluded that further evaluation is needed to determine the clinical utility of BNP testing when assessing patients with dyspnea in the primary care setting.

Consumer Satisfaction to Laboratory Test Interpretation by the ASCLS Response Team

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The objective of this study was to assess consumer satisfaction to responses to laboratory test interpretations as provided by the ASCLS Consumer Response Team. Additional information studied included demographics, whether a response to the question was received, and the respective discipline related to the question. Research in the area of consumer satisfaction with health-related websites is quite rare. A computerized questionnaire was sent to 339 participants who had sent questions concerning their laboratory results to the ASCLS consumer website in May 2007. A total of 99 completed questionnaires (29.3%) provided usable data for analysis. Consumer satisfaction, measured by 11 satisfaction statements, with laboratory interpretations provided by the ASCLS Response Team averaged 4.06 on a scale 1 = Strongly disagree to 5 = Strongly agree. Overall satisfaction of the website itself was 4.24 on the scale 1 = Poor to 5 = Excellent. The majority of respondents were female (71.1%) and ranged in age (71.7%) from 36 years to 64 years. Seventy-five percent of respondents reported they had received an answer to their laboratory test question. The most frequent disciplines for questions received were in chemistry, immunology, and

hematology respectively. This study indicates consumers of the ASCLS website (www.ascls.org) were very satisfied with the clinical laboratory scientist volunteers' responses. The ASCLS Consumer Response Team model is contributing to the advancement of healthcare by providing this important service to the public.

Determining the Usefulness of the Modified Hemoglobin Solubility Test in Diagnosing Infants with Homozygous Sickle Cell Anemia

Tim R Randolph MS CLS(NCA), *Major Burger, Saint Louis University, St. Louis MO*

The purpose of this study was to determine if absorbance readings of filtrates from the modified hemoglobin solubility test (MHST) correlates with HbS levels in samples simulating the gamma to beta switch in infants. The MHST was developed in our laboratory to provide a simple, inexpensive, and rapid method of sickle cell diagnosis in developing countries where electrophoresis and HPLC are not available. HbSS samples were obtained from Saint Louis University Hospital and Cardinal Glennon Children's Hospital along with sickle cell negative cord blood samples from the Pediatric Research Institute. The cord blood samples (HbF + HbA) were mixed with the HbSS samples (HbS + HbF) in 10% increments creating increasing HbF+A and decreasing HbS level. A MHST was performed on these samples trapping the HbS precipitate in the filter leaving HbF+A in the filtrate. Absorbance readings of the filtrate were correlated with the HbF+A levels as determined by hemoglobin electrophoresis. We hypothesize that filtrate absorbance readings will correlate to HbA+F levels which are inversely proportional to HbS levels. A Pearson's Rho was used to correlate absorbance of filtrates to HbF+A levels. The r-value for the correlation of expected HbA+F% (based on the dilution) to mean absorbance was 0.978 while the r-value for the actual HbA+F% (based on electrophoresis results) to the mean absorbance was 0.951. Absorbance readings of MHST filtrates correlate strongly with the expected and actual HbA+F levels. Further studies are needed to determine if HbS estimates from MHST absorbance readings can predict sickle cell zygosity in infants.

Insulin Syringe Validation Study

Camille B Williams MT (ASCP) BB, *Rosemary Sheehan RN BSN CDE, Faulkner Hospital Laboratory, Boston MA*

This study was initiated to address nursing concerns regarding syringe dead air space and correct delivery of insulin doses less than 30 units. Patients managed by tight glycemic control protocols often receive corrective insulin doses of 10 units or less and accuracy is paramount to successful treatment. Prior to this study a 100-unit safe syringe product with a visible dead air space at the 2-unit mark was in use. The question arose whether to draw to a 4-unit mark to actually dispense two units. The manufacturer cited ISO 7886-1:1993 as their standard of performance, noting a residual 0.02ml dead air space. This is the equivalent of two units of insulin. This study compared the current 100-unit syringe to a competitor's 100-unit and 30-unit syringes utilizing a spectrophotometric laboratory pipette calibration protocol at 4-unit and 20-unit test points. The working hypothesis was that the smaller volume pipette, or in this case syringe, would yield more accurate results. At the 4-unit test point, the 30-unit syringe outperformed the 100-unit product currently in use. At a 20-unit test point, the competitor's 100-unit syringe outperformed the 100-unit syringe currently in use. Better performance was determined by comparing standard deviation and CV. Based upon this study (N=17) a change was made in both the vendor and syringe purchased for insulin use. This study may be expanded in the future to include a larger sample for statistical analysis and may include low dose insulin pens to support best practice diabetes care in a hospital setting.

Reduction of Bak Protein Level by Human Papillomavirus 16 (HPV16) in Laryngeal Cancer

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HPV16 E6 and E7 oncoproteins cause a number of cancers including laryngeal cancer. Previously, we found the level of pro-apoptotic Bak was significantly reduced in laryngeal cancer tissue samples with HPV16. Here, we employed two laryngeal cancer cell lines, UMSCC12 and UMSCC11A, to study how E6 and E7 affected the Bak expression. The cells were transfected with the E6 and E7. The expression of Bak and the stability of Bak protein were determined by a specific Bak antibody. Compared with controls, both types of laryngeal cells transfected with E6 showed a reduction of Bak protein. The expression of Bak was significantly elevated in the cells without E6 and E7 when the cells were treated with apoptotic stimuli, TNFa plus CHX. Following the Bak increase, a significant number of the cells became apoptotic. In contrast, Bak did not decrease in the cells with E6 and E7, and thus these cells resisted TNFa/CHX treatment. Further

study found that E6 and E7 facilitated protein degradation of Bak, suggesting that E6 and E7 shortened the half-life of Bak protein. E6 and E7 did not alter the level of Bak through interaction with the promoter of Bak, as the luciferase assay showed that E6 and E7 did not change the Bak promoter activity. The finding suggests that the Bak degradation by E6 and E7 may be through a mechanism other than by interfering with its promoter. In conclusion, E6 and E7 render laryngeal cancer resistant to apoptosis possibly via a mechanism of decreasing Bak protein.

CASE STUDY ABSTRACTS

Building Success in the Laboratory with Innovative Design

Judith Darr MS MT(ASCP)DLM, *PinnacleHealth System, Harrisburg, PA; Karen K Mortland MArch MT(ASCP), Mortland Planning & Design, Inc., Chicora PA*

The PinnacleHealth Laboratories were struggling to meet the goals of productivity, staff efficiency, turnaround time of test results, and cost per test. Mergers had resulted in a laboratory that was split between two campuses. The two laboratories necessitated constant transportation of staff and materials and created a duplication of services and instrumentation. In addition, an increase in testing from outreach and internal expansion, an increasing absentee rate among an aging workforce, anticipated retirements, and the shortage of available, trained technologists to replace retirees all pointed to a likely erosion in the quality and efficiency of laboratory services.

A needs assessment process conducted by management identified six initiatives to be addressed: consolidation; reduce the clerical workforce; improve workflow; design a new laboratory that was ergonomically sensitive and aesthetically pleasing to staff; and enhance employee and patient safety.

PinnacleHealth teamed with Mortland Planning and Design to create a new laboratory to address management's goals. After two years of intense interactive teamwork between hospital and laboratory management, architect, designer, and construction team, the new laboratory was opened.

The results were not only pleasing to the staff but also resulted in efficiencies beyond expectations. Productivity increased greater than 12%, as it increased from 98% to 110%. Staffing was reduced through attrition by 12 clerical and support FTEs. Turnaround times decreased by over 15% as the turnaround time from receipt to result for the basic metabolic panel decreased by 5.5 minutes. This was all combined with a six percent reduction in cost per test.

Partial D in a Surgical Patient

Elizabeth E Correiro MAT CLS (NCA), *University of Massachusetts-Dartmouth, North Dartmouth MA and Faulkner Hospital, Boston MA; Dolores Marmol MT (ASCP), Gaetano DeMartino MA MT (ASCP)BB, Susan D Bezanson MT (ASCP) SBB, Theresa Gorey, MT (ASCP) SBB, Faulkner Hospital, Boston MA*

A sixty-eight-year-old female presented at Faulkner Hospital for a pre-operative visit. The patient was scheduled for orthopedic surgery that required two units of red cells to be cross-matched and available during surgery. Historical records (Brigham and Women's Hospital) indicated her to be group B, D-positive, antibody negative, and hematocrit of 35.8/L. The ABO and Rh were confirmed, but the antibody screen was now reactive. Initial panel results indicated the presence of an anti-D. Both the auto control and direct antiglobulin test were negative. The patient had no history of Rh immune globulin injections and had never been pregnant. The patient had previously received one unit of B positive liquid red cells in 2006 with no adverse affects. Further pre-transfusion testing identified the patient as positive for red cell antigens D, C, e (probable R1r' genotype) and empirical evidence indicated that the patient had a partial D phenotype. Upon evaluation of the patient's phenotype, autocontrol, and strength of reactivity with D positive panel cells, the patient was not thought to have an anti-LW. One unit of B, D-negative red cells was successfully transfused post-operatively and the patient was discharged two days after surgery.

POSTER PRESENTATION ABSTRACTS

Antibody Responses to the Simultaneous Administration of Four Bioterrorism Vaccines in Rhesus Monkeys

Barbara A MacKenzie, *Raymond E Biagini, Jerome P Smith, Deborah L Sammons, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, Cincinnati OH; Robert G Ulrich, Garry L Morefield, US Army Medical Research Institute of Infectious Diseases, Frederick MD*

The purpose of this study was to determine the efficacy of the anthrax (PA), botulinum neurotoxin A (BotA), plague (Yersinia pestis, Yp), and staphylococcal enterotoxin B (SEB) vaccines when they were administered simultaneously to Rhesus monkeys (24 vaccinated and six controls) intradermally. Sera were collected 1 week prior to and 4, 8, and 12 weeks

post primary vaccination. Anti-vaccine specific IgG levels were measured using a multiplexed liquid suspension array assay (performed in duplicate). The inter-assay coefficients of variation (CV) were <20% while the intra-assay CVs were <10%. At 13 weeks post-vaccination, treated animals' anti-PA IgG levels were (mean + standard deviation [range]; median fluorescence intensity [MFI]): 2766 + 418 (1877-3436), anti-BotA, 2764 + 286 (2137-3296), anti-Yp, 2471 + 803 (1272-3718) and anti-SEB, 2938 + 345 (2302-3727). Control animals' (13 weeks, MFI) anti-PA IgG levels were 3 + 1 (2-5), anti-BotA, 2 + 2 (1-6), anti-Yp, 1 + 1 (0-1) and anti-SEB,14 + 22 (2-59). Increases in anti-toxin IgG levels in vaccinated animals (compared to controls) ranged from 164-fold (anti-SEB) to 1272-fold (anti-Yp). These data indicate that simultaneous administration of bioterrorism vaccines appears to be an effective method to elevate specific-anti-vaccine IgG levels to multiple agents simultaneously.

Characterizing Phospholipase D1 Activity in *Candida albicans* Isolates from Different Host Sites

April L Harkins PhD MT(ASCP), *Department of Clinical Laboratory Science, Marquette University, Milwaukee WI; Danielle Miskulin, Erik Munson PhD, Wheaton Franciscan Laboratory, Wawautosa WI*

With the advent of immunosuppressive therapies, the use of broad-spectrum antibiotics and organ transplants, *Candida albicans* has emerged as a clinically important opportunistic pathogen. *C. albicans* is characterized as a dimorphic fungus with the ability to switch from yeast to hyphal phase. This transition in many dimorphic fungi has been shown to be an important virulence factor. Previous reports have shown that the enzyme phospholipase D1 (PLD1) and its hydrolysis of phosphatidylcholine (PC) to phosphatidic acid (PA) play a role in the morphogenic change. The purpose of this study was to compare PLD1 activity during hyphal induction (germ tube formation) of *C. albicans* strains taken from multiple host sites of infection. The different strains were subjected to a temperature shift and exposed to fetal bovine serum to induce hyphal production. Protein extracts were prepared at multiple time points and PLD1 assays were performed with analysis of PA production by means of thin layer chromatography. The results revealed PLD1 activity varied significantly between *C. albicans* strains. PLD1 activity increased significantly during hyphal induction in the strains isolated from genitourinary, blood, and peritoneal fluid compared to dialysis fluid and respiratory sites. The differences of the *C. albicans* PLD1 activity from the multiple host sites may help to discern if one or more virulence factors are important for invasion of certain environments. More studies on the role of lipids and lipid modifying enzymes in *C. albicans* will aid in the understanding of the signaling programs leading to virulence essential to the infectious agent.

The Chromogenic Factor X Assay May Substitute for the Prothrombin Time for Monitoring Oral Anticoagulant Therapy

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In 1997, Moll and Ortel concluded the international normalized ratio (INR) is invalid for some patients with lupus anticoagulants (LA) and the chromogenic factor X (CFX) assay correlated well with INR. They established an oral anticoagulant therapeutic (OAT) range of 22%-40% for CFX, which, because it employs no phospholipid, is unaffected by LA. Our investigation compares INR to the DiaPharma® CFX method using a Stago STA-R Evolution® analyzer. We assayed 30 normals and 309 sub-therapeutic (INR <2.0), therapeutic (INR 2.0-3.0) and super-therapeutic (INR >3.0) in a random sampling of oral anticoagulation clinic patients. Normals generated a CFX range of 72-132%, mean 96%. The OAT patient INR and CFX ranges were 0.92-12.76 and 9%-131%, respectively. Regression revealed an inverse relationship with R = 0.964, p <0.0001. The sub-therapeutic arm generated a CFX range of 32%-132%, mean 53%; therapeutic range 18%-48%, mean 28%; super-therapeutic range 9%-46%, mean 21%. Sensitivity and specificity crossed at 35.5%, equivalent to an INR >2.0. The CFX clinical sensitivity and specificity for INR > 2.0 were 91.7% and 91.9%, respectively and the area under the receiver-operating characteristic curve was 0.984. Our data support the Moll and Ortel study, suggesting the CFX may be effectively employed to monitor OAT in an anticoagulation clinic population.

Comparison of Lipids Performed on Cholestech LDX vs Roche Modular (PE)

Janice Frerichs MT (ASCP), *Thomas Longley MT (ASCP), University of Iowa, Iowa City IA; Khaldee Lindsey Davenport MT (ASCP), Veterans Affairs Medical Center (VAMC), Iowa City IA.*

The purpose of this study was to compare total cholesterol and HDL cholesterol values by two different methods. The systems we used for the comparison were the Cholestech

LDX, which is used in a mobile clinic setting, and the Roche Modular PE, located in a hospital laboratory. Review of the literature reported that finger stick capillary cholesterol levels are consistently higher than serum levels by as much as seven percent. Thirty-six samples used for the comparison study were collected in heparinized tubes by venipuncture with the patients' fasting states noted. Samples were centrifuged and plasma was removed for testing. The set-up menu on the Cholestech was changed to the serum/plasma mode. Samples were run side-by-side on the Cholestech and Roche Modular PE. The numbers generated by the Roche PE served as the "gold standard" since they were performed on a standardized laboratory instrument with coefficients of variation <3.0%. Data analysis using the paired t-test showed the total cholesterol on the Cholestech has a positive bias vs. the Modular (p<0.5). Correlation between the two instruments was 0.95 for total cholesterol and 0.80 for HDL. The average bias for total cholesterol was nine percent and three percent for HDL respectively. The investigators concluded this study fell within the National Cholesterol Education method comparison guidelines for total error. Although there will be additional variability when using capillary blood, we will continue to use our current referral criteria in the mobile clinic.

A Comparison of Total, Free, and % Free Prostate Specific Antigen for the Serodiagnosis of Prostate Cancer in African-American and Caucasian-American Males

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There were 234,460 new cases and 27,350 deaths due to prostate cancer in the USA during 2006, making it the leading non-skin cancer in males. Serum levels of prostate specific antigen (PSA) have been used to screen for prostate cancer. Genetic biases have not been described but Fowler and others reported higher %Free PSA ratios in African-American males. The objectives of this study were to: a) compare a manual assay (Diagnostic Automation, Inc) with an automated assay (Beckman Access, Inc) for PSA and Free PSA, and b) compare total PSA and %Free PSA results in African-American males with Caucasian-American males. It was hypothesized that there would be a racial bias for PSA (t-test, p<0.05) and that the diagnostic sensitivities of the manual test would be superior to those of the automated one. Analytical parameters were good for both assays (assay precision [%CV <10%], assay linearity [R-squared >0.99], assay sensitivity [analytical sensitivity <0.008 ng/mL]). Sera from 402 healthy adult males (334 Caucasian-Americans, 68 African-Americans) were assayed for Total, Free, and %Free PSA and the results compared. Using the t-test, there was no significant difference (p>0.05) between the results. Sera from 974 patients (155 prostate cancer, 819 non-prostate cancer) were assayed for Total PSA and Free PSA and the predictive values calculated. Diagnostic sensitivities ranged from 75% (Beckman) to 98% (Diagnostic Automation) for %Free PSA and from 10% (Diagnostic Automation) to 18% (Beckman) for Total PSA. Both hypotheses were rejected.

Evaluation of CHROMagar MRSA for the Direct Detection of Methicillin Resistant *Staphylococcus aureus* from Surveillance Cultures

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The purpose of this study was to determine if CHROMagar MRSA is as accurate and cost-effective in detecting MRSA as other established methods. If so, its use would speed up and simplify the screening process for MRSA from surveillance specimens. A total of 47 nares specimens were collected over a six-week period: 22 from ICU patients, 12 from ICU RNs, and 13 from laboratory phlebotomists. The recovery of MRSA on CHROMagar MRSA was compared to that from TSA agar. Isolates identified as *S. aureus* on TSA were tested for oxacillin susceptibility using four different methodologies. Thirteen *S. aureus* isolates were recovered: 11(85%) were oxacillin (methicillin) susceptible and 2(15%) were oxacillin resistant. One MRSA isolate was recovered from an ICU patient and one from a hospital employee. The specificity of the CHROMagar MRSA was determined to be 100% at 24 hours (45/45) and 95.7% (45/47) after 48 hours of incubation. Time to MRSA detection/identification was 16 hours-24 hours for the CHROMagar MRSA and the PBP2' latex tests. The other test methodologies—oxacillin screen agar, cefoxitin disk and MicroScan—all required 40 hours-48 hours before identification of MRSA was complete. Although the CHROMagar MRSA plate has a high initial cost, additional media and/or further testing to confirm results are rarely needed, making the expense compare favorably to other methodologies. The results indicate that CHROMagar MRSA is indeed an accurate and cost-effective method of detecting MRSA in surveillance specimens.

Quality Control and Assurance in Physician Office Laboratories in Fayette County, Kentucky

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The purpose of this study was to determine the level of quality control and quality assurance performed in physician office laboratories (POLs). Waived testing, performed by POLs, is not closely regulated and minimal regulations state that the laboratory need only follow manufacturers' guidelines. Two Office of the Inspector General reports and one CDC Morbidity and Mortality Report show that POLs are testing without a Clinical Laboratory Improvement Amendment (CLIA) certification, testing beyond their certification, or are not following good laboratory practices. Surveys were mailed to 60 physician offices in Fayette County, Kentucky. Twenty-five offices responded (42%) however, 8 of the 25 (32%) stated that they did not perform laboratory testing. Of the 16 (27%) who responded that they performed laboratory testing, 2 (12.5%) stated that they did not have a CLIA certification. Four of the sixteen respondents (25%) stated that they performed neither continuing education nor maintained a quality assurance program. Urinanalysis was the most frequently performed test (15 of 16) and had the least amount of quality control since 4 of 16 (25%) stated that they did not perform any type of quality control. Quality control was performed on a given schedule (once daily, weekly, monthly, or with a new lot number) for all other analytes, although there was one response per test that did not perform any quality control. In conclusion, significant strides have been made regarding performance of quality control materials in POLs, however, quality assurance procedures leave room for improvement.