# Wednesday, July 29, 2015

Poster Session: 9:30 AM - 5:00 PM

Point-of-Care Testing

## B-225

### Evaluation of GEM4000® whole blood bilirubin as a screening tool for neonatal hyperbilirubinemia

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Background: Whole blood bilirubin is proposed as an alternative method for neonatal hyperbilirubinemia screening. It provides fast results with small sample volume and can measure co-oximetry and other tests.

Objectives: The objectives of the study were to compare whole blood bilirubin results on the GEM4000® (Instrumentation Laboratory) against plasma bilirubin results on the Vitros 5600® (Ortho Diagnostics), and to examine whether measurement is impacted by various pre-analytical, analytical or clinical factors.

Methods: 440 consecutive samples obtained from newborn babies in both outpatient clinics and postpartum wards, who had bilirubin testing as per usual care, were included. The inclusion criteria were babies who were less than 14 days postnatal age and their samples had sufficient volume for both the whole blood and plasma bilirubin analyses. Bilirubin was measured on specimens in the central laboratory, first on the whole blood using the GEM4000®, and then on the Vitros 5600® using plasma obtained from the remaining blood. Statistics were performed with SPSS, R, and Stata software.

Results: 378 samples (87.5%) with both whole blood bilirubin and co-oximetry results were included in the analysis. 62 (12.5%) were excluded because of an incalculable instrument error for either bilirubin or co-oximetry on the GEM4000®. The demographic data of the babies were: Mean gestational age, 38.8 weeks; Mean birth weight, 3274.2 grams; Postnatal age, 48 hours; Male:female ratio, 52:48; Delivery, 60% vaginal, 40% C-section. Passing-Bablok regression of GEM4000® versus Vitros 5600® results revealed a negative bias at low levels of bilirubin and a positive bias at higher levels (y=1.438x - 63.14). The Bland-Altman plots found an overall negative bias with a mean difference of -2.23 mmol/L (95% CI: -86.99 to 82.52 mmol/L). Stata-multivariate regression revealed that the degree of hemolysis (H index) and the hemoglobin level accounted for approximately 86% of the observed variation between the results on the different methods. Applying the Bhutani nomogram 40th percentile (95th percentile) to categorize risks, the results by the GEM4000®, in comparison to the Vitros 5600®, exhibited a false positive rate of 20% (63%) and false negative rate of 23% (37%).

Conclusions: An imperfect correlation was observed between whole blood bilirubin measured on the GEM4000® and plasma bilirubin on the Vitros 5600®. The major contributors to the differences were specimen hemolysis and the accuracy of total hemoglobin by GEM4000®, the latter of which affects the calculation of plasma-equivalent bilirubin. Additionally, the lack of standardization of total bilirubin calibration between the two instruments, particularly in newborn specimens, may account for some of the disagreement in results. The present work does not support the application of whole blood bilirubin measured on the GEM4000® for neonatal hyperbilirubinemia screening.

## B-226

### Using Point-of-Care Glucose Meters in the Critically Ill: Assessing Meter Performance in the Clinical Context

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**Background:** Point of care (POC) glucose meters are widely used in hospitals to aid in monitoring blood glucose levels. Recent publication of FDA draft guidelines, setting stringent accuracy requirements for manufacturers of POC glucose meters to be used in hospitals, has again raised concerns of off-label use, particularly in "critically ill" patients.

**Methods:** In order to evaluate the accuracy of results obtained from meters in our institution by our end-users, we matched six months of POC glucose results using the Precision *Xceeed* Pro Blood Glucose POC system (Abbott Diabetes Care Ltd., Alameda, CA) with central laboratory glucose data that was obtained by either the Roche Cobas Modular P Gluco-quant Glucose/Hexokinase (Roche Diagnostics, Indianapolis, IN) or the RAPIDLab 1265 Blood Gas (Siemens AG, Munich, Germany). In an effort to reduce the likelihood of changes in blood glucose concentrations due to clinical interventions occurring between POC and lab glucose samples, we minimized the difference between the collection times and restricted our analysis to samples collected no more than 10 minutes apart. We evaluated the correlation between the POC and lab glucose pairs using Thiel-Sen linear regression analysis and interpreted the differences in a clinical context using the Clarke Error Grid (CEG). We also evaluated the performance in the critically ill, based on location (non-ICU vs. ICU) and other relevant laboratory results (sodium, bicarbonate, lactate, hematocrit, $pO_2$) collected within 24 hours of the POC/lab glucose pair. Finally, as a quality assessment of each individual glucose meter in use at our institution, we also prepared CEGs by serial number for those meters with at least ten POC/lab glucose pairs.

**Results:** Our final dataset comprised 860 records, obtained from 41 unique hospital locations, 97 unique glucose meters, and 452 unique patients. From an analytical perspective, the agreement within the POC/lab glucose pairs was far from ideal, where the correlation of the POC glucose results to the laboratory concentrations was described by the equation: $y=0.93x+15.27$, and $r^2=0.65$. However, when analyzed with the CEG, the overwhelming majority (802/860, 93.3%) of these discrepancies were found to be clinically insignificant. No relationship was found between severity of illness and degree of discrepancy, by non-ICU or ICU location ($p>0.5$) nor abnormalities in the additional laboratory results obtained ($p>0.1$). Finally, no significant biases were observed for any particular meter and all displayed a predominance of POC/lab glucose pairs that fell within Clarke zones A and B.

**Conclusions:** Evaluating POC glucose meter performance in a clinical context, rather than in a strictly analytical manner, offers a more robust determination of the accuracy necessary to effectively manage hospitalized patients, especially in the absence of "tight glycemic control" protocols. Our data suggests that the meters used in our institution are performing well, allowing for the advantages of real-time blood glucose monitoring and outweighing the limited instances of potential clinical errors. Another interesting aspect of this performance evaluation is that it provides a mechanism for ongoing quality assurance and would identify specific meters that may not be performing optimally.

## B-227

### Glucose Connectivity Meter Evaluation in Intensive Care Unit

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Background: The CLSI POCT12-A3 guideline states that a) 95% of meter measurement results should be within 0,67 mmol/L for glucose <5,55 mmol/L and within 12,5% for glucose ≥5,55 mmol/L and b) 99% of values should fall within 0,86 mmol/L for glucose <4,2 mmol/L and within 20% for glucose ≥4,2 mmol/L comparing with laboratory.

We assessed the performance of a point-of-care (POC) glucose meter by using the spreadsheet program is designed for estimating the bias between two methods using patient samples.

Methods: The study was performed over a three week period using samples obtained from the intensive care unit of Tartu University Hospital. Method correlation was performed by analyzing 120 whole blood specimens on the Stat Strip glucose connectivity meter (Nova Biomedical) compared to ABL blood gas analyzer (Radiometer). Sample collection was performed by arterial Disposable Pressure Transducer Kits and Safeset Closed Blood Sampling/Conservation System (Philips). Mean glucose concentration was 7,31 mmol/L (range 3,8-26 mmol/L).

Results: The imprecision for glucose meter of the 3 levels was 6,1/3,4/5,4 %(mean values: 3,3/6,4/16,1 mmol/L) and for ABL was 3,7/1,1/1,1% (mean values: 1,6/5,6/14,1 mmol/L).

The linear regression analysis demonstrated a slope 0,99, intercept -0,38 and $R^2$ -0,988. The glucose meter had the lowest mean biases (-0,151 mmol/L) compared with laboratory method (ABL) ($p<0,001$). Mean relative difference was 5,93 %.

114 (95%) of glucose meter results was within 12,5% and 11 of them (glucose value <5,55 mmol/L) was within ±0,67 mmol/L. Furthermore, 120 (100%) of glucose meter results was within 20%.

Conclusion: Stat Strip glucose connectivity meter met POCT 12-A3 performance criteria and demonstrated a close correlation to the laboratory method.

## B-228

### Development of a Novel, Lab-on-Cartridge based Point-of-Care Device for the Measurement of Clinical Diagnostics Tests

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**Background**:

Point-of-care testing for common clinical diagnostics tests (immunoassays, clinical biochemistry, electrolytes/blood gases & coagulation) requires multiple dedicated instruments that are often unreliable, expensive and need frequent maintenance. It is not possible for small labs & clinics in developing countries to afford the instrument infrastructure needed to provide healthcare diagnostics. In order to provide healthcare diagnostics to ALL at affordable costs, there is a need for a device that can do all common diagnostic tests reliably and is low in cost (device and consumable cost).

We have developed the world's first portable lab-on-cartridge based point-of-care device (**QDx InstaLab**) for quantitative measurement of all common diagnostics tests typically used in lab. **QDx InstaLab** incorporates an innovative, high performance, inexpensive microfluidic cartridge for rapid quantitative measurement of diagnostic tests in whole blood /plasma/serum samples. Our proposed methodology utilizes a novel, patented nanomaterial based plastic electrochemical biosensor /immunosensor that uses chronoamperometry / differential pulse voltammetry technique to provide a sensitive and accurate result in ~3 min for clinical biochemistry tests and in ~10 min for immunoassays. The device is simple, easy-to-use and reliable as the measurements are carried out at a constant temperature of 37°C. The **QDx InstaLab** is capable of performing a single test or multiplexed tests from a fingerpick with 10 microliters of whole blood sample per parameter.

**Methods**:

We evaluated the **QDx InstaLab** using patient samples for linearity, precision, interference and cartridge stability for all the clinical biochemistry profiles such as metabolite profile (glucose, lactate), kidney profile (urea, creatinine), diabetic profile (HbA1c, Hb), lipid profile (total cholesterol, triglycerides), electrolyte profile (Na/K/Cl), liver profile (ALT, AST, bilirubin) and coagulation profile (PT-INR). Interference study was done against hematocrit variation of 30% to 60% and with ascorbic acid at 3 mg/dL at two different analyte concentrations with samples run in triplicate. Accelerated stability testing was done at 2-8°C and at 45°C for 2 weeks for the assays during which linearity samples were run on 0, 4, 7, 14 days respectively.

**Results**:

Data analysis indicates that the assays have a CV < 3%, with $R^2 > 0.95$, interference bias of < 10% and the cartridges are stable up to 9 months at 2-25°C storage temperature based on preliminary extrapolated data.

**Conclusion**:

The developed technology platform for **QDx InstaLab** is reliable and meets all the performance specifications of a lab. Hence, it can be easily adapted for low cost, sensitive and rapid measurement of common diagnostics tests in low resource settings such as in urban, semi-urban and rural areas in the developing countries.

## B-229

### A comparison of values on point-of-care instruments in patients with EBOV

E. L. Ryan[1], N. A. Brammer[2], R. Powers[2], K. Jenkins[2], C. Evans[2], J. C. Ritchie[1]. *[1]Emory University School of Medicine, Atlanta, GA, [2]Emory University Hospital, Atlanta, GA*

**Background:**The ongoing epidemic of Ebola Zaire (EBOV) in West Africa has mandated a handful of patients with the disease being treated in western medical facilities. Four patients with confirmed EBOV were admitted to the specialized isolation unit at Emory University between August and October 2014. All laboratory values were generated within the dedicated isolation laboratory. Anecdotal differences between instrumentation were noted.

**Methods:**Sodium, potassium, chloride, glucose, hemoglobin, and hematocrit were measured on more than one instruments in our laboratory. The electrolytes (Na, K, Cl) and glucose were measured via Chemistry analyzer (Abaxis Piccolo Xpress [ABAXIS, Inc, Union City, CA]) and Blood-gas analyzer (GEM Premier 4000 [Werfen, Barcelona, Spain], while hemoglobin and hematocrit on Blood-gas analyzer (GEM Premier 4000 [Werfen, Barcelona, Spain] and Hematology analyzer (pocH 100i [Sysmex Corporation, Kobe, Japan]). All instruments went through verification studies prior to patient testing and met expectations. Samples for the blood gas analyzer and chemistry analyzers were lithium heparin while those for the hematology analyzer potassium EDTA.

**Results:**Results from paired samples (drawn at the same time) across all 4 patients were looked at along with the reported indices for each sample, where appropriate. There were 44 paired results for the chemistry values (Na, K, Cl, and glucose) and 38 for hemoglobin and hematocrit. Overall there was no significant bias between instruments for any of the analytes. However, when looking at hemolysis there were differences in bias for potassium and glucose. The bias among hemolyzed samples (H≥1+) was 0.37±0.07 while it was 0.16±0.05 among non-hemolyzed samples(p=0.0155). The trend was reversed for glucose with hemolyzed samples having a bias of 4.7 ±1.1 and 8.7 ±0.8 with non hemolyzed values. Both of these trends continued to be significant when accounting for those samples that were arterial rather than venous. Chloride showed no bias and Sodium showed a bias among lipemic samples although it was no longer significant when accounting for arterial sampling. Hemoglobin and Hematocrit showed no bias between instruments.

**Conclusion:**When using values from point-of-care instruments to inform clinical decision making precision and accuracy of the methods used should be taken into consideration. The usual performance characteristics of test results may be different. The laboratory professional must be aware of these issues and communicate with the clinical team to ensure interpretation of test results is appropriate.

## B-230

### Assessment of Interference from Hemolysis, Lipemia and Icterus on the Abaxis Piccolo Liver Panel Plus Reagent Disc

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Background: Interference due to hemolysis, lipemia or icterus in samples tested at the point-of-care can be problematic, especially in critically ill patients who tend to produce samples containing these endogenous interferents. Although manufacturers provide data on interference effects, these claims are often too vague to be of use. Other aspects of interference effects often not considered include the number and permutations of different analyte and interferent concentrations that are investigated when performing interference studies. In an attempt to more accurately assess the effect of endogenous interferences on the Piccolo Xpress analyzer (Abaxis, Inc., Union City, CA), we conducted a comprehensive study on interference effects from hemolysis, lipemia and icterus.

Methods: We evaluated interference on analytes included in the liver panel plus reagent disc: total protein, albumin, alanine aminotransferase (ALT), aspartate aminotransferase (AST), gamma glutamyltransferase (GGT), alkaline phosphatase (ALP), amylase (AMY), and total bilirubin. We prepared two separate plasma pools obtained from remainder patient samples. One pool contained increased activity (3-5 times the upper limit of normal) of enzyme activities while the other pool contained normal enzyme activities. We purchased an interference test kit containing plasma hemoglobin, bilirubin and triglycerides of human origin (Sun Diagnostics, LLC., New Gloucester, ME). We divided each plasma pool containing either normal or abnormal enzyme activities into two equal aliquots. To one aliquot we added hemoglobin, triglyceride or bilirubin interferent solution to produce interferent concentrations of approximately 600 mg/dL, 1700 mg/dL and 15 mg/dL, respectively. We added an equal volume of saline to the other aliquot of plasma to produce a pool with negligible interferent. Next, we created five intermediate pools by making admixtures of the low and high interferent pools. Thus, for each interferent, we created seven aliquots containing interferent across a broad range of concentrations, and testing both normal and increased enzyme activities. Each of the aliquots was measured in quadruplicate. Interference affects were considered to be clinically significant on the basis of expected within-lot precision based on quality control data. If the measured analyte value differed by more than +/- 2.8 standard deviations of the expected quality control imprecision, the interference effect was considered to be significant.

Results: Icterus had no effect on any of the analytes evaluated. Hemolysis demonstrated interference with measurement of total bilirubin, with a decrease of approximately 0.5 mg/dL in measured concentrations at plasma hemoglobin concentrations of 600 mg/dL. AST, when present at normal activity, was affected when plasma hemoglobin concentrations exceeded 600 mg/dL. Lipemia affected ALT, although the effect was less pronounced when ALT was present at high activities. Total protein showed a decrease of up to 50% when triglycerides were greater than 1500 mg/dL and total bilirubin showed significantly decreased measured concentrations when triglycerides were greater than 1000 mg/dL.

Conclusions: The Piccolo Xpress has very good specificity when endogenous interferents are present, even at very high concentrations of interferent. Use of the

Piccolo in critically ill patients who tend to produce samples with a higher likelihood of endogenous interferents is warranted.

## B-231

### Clinical evaluation of mobiLab, a smartphone-enabled microfluidic NAAT platform for Chlamydia trachomatis screening

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Chlamydia trachomatis is the most common notifiable disease in the United States with over 2.8 million diagnosed cases and direct medical cost estimated at $516.7 million in 2008 [1]. Affordable and highly sensitive point-of-care diagnostics has the potential to reduce the social and economic costs associated with Chlamydia infections. We report the development of a low-cost mobile nucleic acid analysis platform (mobiLab) utilizing a smartphone-enabled microfluidic device for streamlined analysis of biological samples. By using magnetic particles as a mobile solid phase for DNA capture and transport, fluidic processing is simplified to particle translocation on a robust and scalable cartridge. Process integration facilitated by Bluetooth-enabled microcontrollers enables full control of the instrument by the user with a smartphone application.

The mobiLab platform consists of three discrete units: a droplet microfluidic cartridge, a battery-powered instrument for droplet manipulation and amplification, and a smartphone for user interface, data acquisition and processing. The microfluidic cartridge design utilizes open-surface magnetofluidic manipulation [2] which enables bioassays requiring multiple buffer exchanges to be performed without complex instruments. Each cartridge costs less than $2 using off-the-shelf components at retail price, which is an order of magnitude cheaper than $9.98/test for a subsidized Cepheid GeneXpert cartridge [3]. The instrument utilizes a microcontroller which controls the rotary bead manipulator, thermal incubation and Bluetooth-based communication with the smartphone application. Each assay consumes approximately 10% of the battery capacity, allowing up to 10 assays to be performed consecutively without access to a power outlet.

We designed a single-stream loop-mediated isothermal amplification (LAMP) assay to operate in tandem with the mobiLab platform. In this assay, polyhistidine-coated magnetic particles capture DNA targets from sample lysate via electrostatic interaction. The affinity between particles and nucleic acids is maintained at acidic pH, which is reversed when particles enter LAMP buffer. The basic pH of LAMP mixture is compatible with the elution conditions for nucleic acids, enabling seamless integration between DNA extraction and amplification. We tested the single-stream assay using plasmid targets and were able to capture and amplify $10^3$ copies of gene targets. Specificity of the assay for Chlamydia trachomatis was tested, and the absence of cross-reactivity with human or other bacterial genomic DNA was verified.

The mobiLab platform was validated by testing Chlamydia trachomatis infection from patient-collected vaginal swab samples. Volunteers enrolled in an internet-based Chlamydia screening program, where two sets of swabs were self-collected and mailed back to our lab [4]. One set of swabs was analyzed using the gold standard Gen-Probe AC2 CT assay, while the second set was tested using the mobiLab platform. The two results were in agreement for 20 out of 20 samples after 30-minute incubation, demonstrating that the droplet assay performance is comparable to the gold standard for the samples tested. To our knowledge, this abstract presents the first smartphone-based NAAT platform that integrates sample preparation, amplification and data processing.

[1]Owusu-Edusei,K *et al*. *Sex Transm Dis*. 40(13),(2013).

[2]Zhang,Y et al. *Adv Mater*. 25,2903-2908(2013).

[3]Finddiagnostics.org,. Price for Xpert MTB/RIF and FIND country list. (2013).at (http://www.finddiagnostics.org/about/what_we_do/successes/find-negotiated-prices/xpert_mtb_rif.html)

[4]Gaydos,CA *et al*. *Int J STD AIDS*. 24(9):736-744(2013).

## B-232

### Viscoelastic Coagulation Monitoring: Current use of TEG, ROTEM, and Sonoclot

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Objective: Viscoelastic hemostasis assays (VHAs) including thromboelastogram (TEG), rotational elastometry (ROTEM) or sonoclot are FDA cleared tests that are used to assist in the administration of blood and transfusion products. These assays have the potential of altering the practice of transfusion medicine and management of blood utilization in critical and surgical care settings by improving long-term patient outcomes in time-sensitive fields such as trauma. The goal of this study was to survey members of the National Academy of Clinical Biochemistry (NACB) to estimate: How many hospitals in the United States are using the three VHA assays; what hospital areas are using information from these tests; the type of personnel performing VHAs and how the information is delivered to caregivers..

Design and Methods: An on-line survey was conducted among all members of the AACC/NACB. Data were reported as descriptive statistics

Results: Respondents from 51 institutions, having bed size from 50 to 1500 participated in the survey. 67% of these hospitals used either TEG or ROTEM. Use of Sonoclot was not reported by any of the responding institutions. 65% of those using VHAs were able to view results in real time, while the testing was being conducted. 65% of TEG/ROTEM testing was found to be performed exclusively by laboratory technologists. Additionally only 39% of TEG users and 13% of ROTEM survey respondents used the device in a trauma center clinical environment.

Conclusion: This survey of AACC/NACB members showed that VHAs are currently used in a variety of hospitals. VHA testing at most centers was available for decision making in real time. Use of VHAs for patient management is now part of transfusion guideline algorithms, and it is likely that use of TEG/ROTEM in time sensitive areas such as trauma will increase.

| Viscoelastic coagulation assays in hospital areas | |
|---|---|
| Hospital Area | % Responding institutions (n=31) |
| Cardiac Surgery | 65% (20/31) |
| Emergency Room | 23% (7/31) |
| Hepatic Surgery | 48% (15/31) |
| Intensive Care Unit | 35% (11/31) |
| Liver Transplantation | Liver Transplantation61% (19/31) |
| Obstetrics | 19% (6/31) |
| General Surgery | 29% (9/31) |
| Trauma | 42% (13/31) |

## B-233

### Differences between concurrent central laboratory and point-of-care glucose measurements: a comparison between distributions from critical care units and non-critical care units using the Roche Accu-chek Inform II analyzer

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**Background**: The Centers for Medicare and Medicaid Services (CMS) recently issued a notice to state survey directors to identify use of waived blood glucose monitoring systems (BGMS) in critically ill patients as non-compliant unless the system has been specifically cleared for such use. Consequently, many hospitals are investigating how best to define critically ill patients, and documenting analytical performance characteristics of BGMS within this population. One option is to define critically ill patients by location within critical care units. Our objective was to evaluate differences between point-of-care glucose meter measurements (POCT) and concurrent central laboratory glucose measurements (LAB), specifically to compare distributions of such differences between patients in critical care (CC) vs. those in non-critical care (N-CC) units.

**Methods**: Retrospective POCT data (capillary, Roche Accu-chek Inform II) and LAB data (serum, Roche Cobas) were obtained for a one-month interval (November 2014). LAB and POCT measurements were defined as concurrent if recorded times-of-collection were within 15 min of each other. Among 38,489 POCT measurements and 23,549 LAB measurements, 1221 measurement pairs were concurrent. These data were divided according to location from among 23 CC locations (500 pairs, 41% of total) and 58 N-CC locations (721 pairs, 59% of total) for comparison.

**Results**: Correlations of results between POCT and LAB were very similar for CC and N-CC. Results within ±30 mg/dL showed overall 1:1 numerical correspondence: for C (88.4% of results), POCT(CC) = 0.991 LAB (r2 = 0.962); for N-CC (88.6% of results), POCT(N-CC) = 1.00 LAB (r2 = 0.976). Differences (D) between POCT and LAB within ±30 mg/dL were normally distributed: for CC, D = -0.53 ±11.5 mg/dL; for N-CC, D = 1.84 ±12.2 mg/dL. Whereas means of these distributions were numerically distinct ($p<0.01$), they were indistinct from a clinical perspective. For D >30 mg/dL, LAB>POCT (A) outnumbered LAB<POCT (B) for both CC and N-CC: for CC, A/B = 2.05 (A+B = 11.6% of total results); for N-CC, A/B = 1.16 (A+B = 11.4% of total results). Such outliers are known historically to include circumstances of interventions

between reportedly concurrent POCT and LAB draws, but such circumstances cannot be discerned from retrospective data. Review of ICD-9 diagnoses associated with each CC and N-CC patient showed that CC and N-CC were distinct populations with respect to critical illness. Within CC, 28% of diagnoses were unique to CC (i.e., not represented within N-CC); within N-CC, 54% of diagnoses were unique to N-CC (i.e., not represented within CC). Unique diagnoses among CC were, expectedly, of far greater acuity/morbidity than those among N-CC.

**Conclusions**: Distributions of POCT vs. LAB glucose measurements for CC and N-CC units were essentially equivalent. To the extent that critical illness can adversely affect POCT, it is unlikely, based on review of diagnoses, that such circumstances should occur with equal prevalence in both CC and N-CC populations. Our interpretation of comparison data is that use of the Roche Accu-chek Inform II glucose meter for capillary POCT in CC (non-waived) is analytically equivalent to its predicate use for capillary POCT in N-CC (waived).

## B-234

### Performance Characterization of a Liver Function Panel on the Abaxis Piccolo Xpress

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**Objectives:** Laboratories that choose a point of care approach for liver function testing in patients undergoing evaluation for Ebola virus disease (EVD) have few options to choose from. The primary objective of this study was to conduct a performance characterization of a CLIA-waived liver function panel on the Abaxis Piccolo® Xpress chemistry analyzer. Secondary objectives were to evaluate multiple specimen types, characterize whole blood specimen stability, and validate disposable exact transfer pipettes. Our final objective was to assess instrument airflow from a biosafety perspective.

**Methods:** An instrument validation, including imprecision, linearity, comparison to Roche Cobas c502 and c702 methods, reference interval verification, and specimen type evaluation was conducted using the Liver Panel Plus reagent discs, which included albumin (ALB), alanine aminotransferase (ALT), alkaline phosphatase (ALP), amylase (AMY), aspartate aminotransferase (AST), gamma glutamyl transferase (GGT), total bilirubin (TBIL), and total protein (TP) assays.

**Results:** The Piccolo Xpress demonstrated excellent imprecision with total CV's less than 6% over ten days of testing. All assays were linear over suitable analytic ranges. Method comparison studies showed good correlation for all assays though notable biases were seen for ALP (average bias, -18.6%), AMY (average bias, -29.1%), and TBIL (constant bias, approx. +0.3 mg/dL). Pre-programmed reference intervals were verified except for the ALP (male and female) and ALT (female) assays, which had greater than ten percent of results below the programmed ranges. Results for sample types (PST whole blood- uncentrifuged, PST plasma-

centrifuged and SST serum) when compared to lithium heparin whole blood were overall quite consistent. It was noted, however, that AST trended lower in PST whole blood (-11.6 ± 14.8%; p=0.062), PST plasma (-14.8 ± 17.7%; p=0.048), and serum (-15.9 ± 17.4%; p<0.025). GGT results in serum were significantly higher (33.0 ± 37.2%; p <0.001) and TP results were significantly lower (-4.9 ± 1.7%; p <0.001) in serum. Whole blood stability results showed no clinically or statistically significant differences over five hours of ambient storage. Results using disposable exact transfer pipettes were comparable to results using a standard fixed volume pipette. Airflow studies suggested that, in the context of EVD protocols, instrument placement in a biosafety level (BSL) 2 cabinet or greater is justified.

**Conclusion:** Given its analytical performance and ease of operation, the Piccolo Xpress was transferred to a BSL 2 cabinet in our BSL 3 suite for use in our hospital's diagnostic protocol for providing liver function testing in patients undergoing evaluation for EVD.

## B-235

### Diagnostic Utility of Leucocytes Esterase and Nitrites in Detecting Urinary Tract Infection in Tertiary Care Hospital

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Background: Urinary tract infections are very common illness in outpatient setting. Urinalysis and microscopy is one of the most requested test in those type of patient's population. The diagnostic accuracy of in dipstick's leucocytes esterase and nitrite in this population has been evaluated in comparison to urine culture. Our objective is to reduce unnecessary urine culture.

Methods: A total of hundred consecutive urine samples from outpatients were evaluated. Each sample underwent testing using urinalysis and urine culture. Each matched pair of urinalysis and urine culture was considered as the unit of measurement. We evaluated the diagnostic performance and calculated the sensitivity, specificity, negative predictive value, positive predictive value and overall accuracy.

Results: Of 100 patients, 73 (73%) were female. The presence of bacterial growth was confirmed in 83% of the samples. There were fifteen different types of bacteria were identified. *Escherichia coli* (35%) were the major bacteria detected followed by *Klebsiella pneumonia* (21%) and *Streptococcus agalactiae* (8.4%). Using Leucocytes Esterase as marker had sensitivity and specificity of 55.4% and 64.7% respectively with overall accuracy of 57%. The presence of nitrites on dipstick had high specificity (100%) but very poor sensitivity (8.4%) with overall accuracy of 24%. The positive and negative predictive values were 88.5% and 22.9% respectively for Leucocyte Esterase and 100% and18.3% for nitrites respectively.

Conclusion: The study concludes that combined Leucocyte esterase-nitrite dipstick test is not sufficiently sensitive and specific to be used for routine screening of bacteriuria in replace of laboratory culture, though it has an excellent indicators for infection and may be more cost effective in low resource settings.

## B-236

### Hemoglobin A1c Screening using ADx100 Dried Blood Spot Collection Cards on the Trinity Primus Affinity Ultra2 Analyzer

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**Introduction:** The use of the Dried Blood Spot (DBS) card as a screening method for various endogenous compounds is not a new concept in laboratory medicine; it has been used for a number of years in various capacities for numerous tests. Blood spotted onto DBS cards has been found to be a suitable collection medium for direct to consumer testing for a number of assays. Compared to traditional venipuncture, the DBS sample can be collected by non-phlebotomists in non-clinical settings; the cards are relatively inexpensive and can be stored and transported more conveniently. The goal of this study was to create a simple extraction and testing method for Glycated Hemoglobin testing ($HbA_{1c}$) that could be easily integrated with the current DBS test offerings employed in our laboratory, optimized on existing instrument platforms and provide a quality screening result comparable to the whole blood plasma methods.

**Methods:** In our study, 148 previously tested patient samples spanning the clinically diagnostic range were analyzed over 19 separate runs. No distinction was made as to the clinical diagnosis, gender, race or the age of the patient. The DBS samples were tested against fresh, previously run EDTA whole blood samples and the data analyzed using Microsoft Excel and Data Innovations EP Evaluator. Advance Dx100 Technology (ADx) cards were selected as a result of their ability to separate the cellular material from the serum component of whole blood in a cellulose matrix; this property creates a region of concentrated cellular material well suited for testing the A1c component. The cards were inoculated with 4 to 5 drops of peripheral blood (approximately 200 µL) collected from a finger stick and a ¼ inch (6.4 mm) punch is taken from the inoculation area of the card. The punched spot is added to 1.5 ml of a hemolysing reagent, vortexed and incubated at room temperature for 30 - 60 minutes. Following the incubation the residual paper punch is removed from the lysate reagent and the samples are loaded onto the Trinity Primus Affinity Ultra2 Analyzer and analyzed using boronate affinity chromatography.

**Results:** In order to determine the Glycohemoglobin A1c results from the ADx100 DBS card a correlation calculation had to be extrapolated as no true 1:1 relationship exists to correlate whole blood A1c results from recovered dried blood spot cards. Our final calculation provided us with a >90% correlation across the analytical range

(3.2% - 28.7%). Linearity studies performed from pooled patient materials provided us with a slope of 0.991 and an observed error of 5.7%. Inter- and intra-assay precision data showed that we could reproduce results: CV% = 2.0% - 5.7%. In our final correlation studies, whole blood EDTA samples were compared to the corresponding DBS A1c samples (n=108) and demonstrated a correlation coefficient of 0.9182 with a slope of 0.9490 and a negative bias of -0.20.

**Conclusion:** Preliminary validation studies have demonstrated that it is possible to quantify Glycohemoglobin A1c from DBS specimens for the purposes of screening patients.

## B-237

### Patient identification errors in 20 point-of-care blood gas analyzers

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**Background:** At La Paz University Hospital, there is a Point-of-Care Testing (POCT) project including 20 blood gas analyzers. Various components comprise the functional organization of the connectivity system: Analyzers, a data manager system (DMS), and laboratory information system (LIS) / hospital information system (HIS). Briefly, after a sample measurement, a trained operator identifies the patient with the medical record number (MRN) using barcodes. Then, patient demographics are transferred by DMS/LIS/HIS and an accession number (AN) is created by the LIS. The AN is added to the patient results and the record is sent to the LIS. The identification (ID) procedures must be correctly implemented and followed because errors put patient safety at risk.

The aim of this study was to evaluate the type and frequency of patient identification errors in the point-of-care network.

**Material and Methods:** The measurements performed on all POCT analyzers (ABL90/ABL80; Radiometer Aps) over 4 months were evaluated with DMS Radiance (Radiometer Aps) and LIS LabTrak (Intersystems). We assessed the type and rate of incidents related to patient ID errors.

**Results:**

| Setting (Number of analyzers) | Samples (n) | No patient ID (%) | Patient ID with operator number (%) | Patient ID with patient name (%) | Patient ID with unknown number (%) | Total errors (%) |
|---|---|---|---|---|---|---|
| Delivery room (3) | 3.724 | 11.7 | 2.0 | 0.5 | 2.0 | 16.1 |
| Pediatric intensive care unit (1) | 3.090 | 2.4 | 0.2 | 0.6 | 1.3 | 4.5 |
| Pediatric reanimation unit (1) | 2.252 | 2.6 | 0.2 | 0.1 | 0.7 | 3.6 |
| Pediatric hemodynamics unit (1) | 212 | 5.7 | 0.5 | 0.0 | 0.0 | 6.1 |
| Neonatal intensive care unit (3) | 5.955 | 6.4 | 0.6 | 7.1 | 3.1 | 17.3 |
| Coronary intensive care unit (1) | 913 | 9.7 | 0.2 | 0.3 | 0.4 | 10.7 |
| Reanimation unit (3) | 7.492 | 4.2 | 0.2 | 0.1 | 1.3 | 5.8 |
| Intensive care unit (1) | 3.850 | 3.6 | 0.8 | 2.1 | 0.2 | 6.6 |
| Burn unit (1) | 1.793 | 3.5 | 0.4 | 0.2 | 1.1 | 5.1 |
| Surgical suites (3) | 1.199 | 3.6 | 2.0 | 0.0 | 0.7 | 6.3 |
| Pulmonology offices (2) | 649 | 0.6 | 0.0 | 0.0 | 3.9 | 4.5 |
| **Total (20)** | 31.129 | 5.2 | 0.7 | 1.8 | 1.5 | 9.2 |

**Conclusions:** The samples with "no patient ID" (5.2%) could not be measured due to clots, air bubbles or insufficient sample volume. The other 3 types of errors (4%) included the use of a patient ID different from the correct MRN. These results were not transferred to the patient electronic medical record, with a possible impact on patient care. Moreover, if a patient ID with an erroneous MRN is used, the blood gas results could be assigned to another patient medical record. It is important to evaluate and monitor the type and frequency of these errors in each setting. Due to the high incidence observed and despite having an adequate identification procedure, specific training for POCT operators is critical to ensuring correct patient identification.

## B-238

### Evaluation of a POC Glucose Meter for High Complexity Testing in the ICU and NICU for Critically Ill Patients at Centura Health Network of Hospitals

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**Background:** Several Point-Of-Care (POC) glucose meters state "not for use with critically ill" in the package insert. Using these meters to monitor the effectiveness of diabetes control in critically ill patients is considered off-label high complexity testing according to Centers for Medicaid and Medicare Services (CMS). The American Diabetes Association (ADA) recommends monitoring of blood glucose levels in these patients in order to avoid hypo and hyperglycemic events which has been shown to reduce mortality and improves outcomes. Measurement with a POC device allows for rapid assessment with results available at the bedside in 20 seconds, leading to faster intervention than with main lab methods. Centura Health has defined critically ill as all patients in the Intensive Care Units (ICU) and Neonatal Intensive Care Units (NICU). In order to determine if this meter can be used as a high complexity test system for critically ill patients in the ICU and NICU we followed CLSI guidelines for evaluation of a high complexity test, and additionally wanted to evaluate the diagnostic sensitivity and specificity of the meter for this patient population.

**Objective:** The objective of this study was to calculate the diagnostic sensitivity and specificity of the POC glucose meter for critically ill patients in the ICU and NICU.

**Methods:** A total of 80 NICU and 379 ICU patients were included in the study. Glucose was measured on both the POC glucose meter and the chemistry lab analyzer within 5 minutes. Each data pair was then tagged as True Positive (TP), True Negative (TN), False Positive (FP) and False Negative (FN) for hypo and hyperglycemia. Hypoglycemia was defined as a lab value of <40mg/dL and <70mg/dL for NICU and ICU respectively. Normoglycemia was defined as any lab value between 71-180 mg/dL, and hyperglycemia was defined as any lab glucose >180 mg/dL for ICU patients (no instances of hyperglycemia from the NICU were observed). From this, diagnostic sensitivity, specificity, PPV and NPV were calculated using standard formulas. Data pairs were then plotted using EP Evaluator® for Two Instrument Method Comparison to determine the percentage of results that met CLSI guidelines for values <75mg/dL and >75mg/dL.

**Results:** Diagnostic sensitivity and specificity of POC glucose measurements for NICU patients were 97% and 89% respectively for hypoglycemic events within 24 hours of birth (PPV=87%), (NPV=98%). Sensitivity and specificity of POC glucose measurements for ICU patients were 93% and 97% respectively for hypoglycemic events (PPV=97%),(NPV=95%), and 97% and 96% respectively for hyperglycemic events (PPV=95%),(NPV=98%). Two method comparison studies showed that 98% of values across the AMR were within a TEa of 15mg/dL for values <75mg/dL and 20% for values >75mg/dL.

**Conclusions:** Blood glucose measured by the POC glucose meter has an acceptable diagnostic sensitivity and specificity for critically ill patients at Centura Health facilities. This information in addition to separate studies for accuracy, precision, reportable range, reference range, analytical sensitivity and analytical specificity show that it can continue to be used in ICU and NICU for monitoring the effectiveness of diabetes control programs at Centura Health facilities.

## B-239

### Accellix Automated Flow Cytometry

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**Background:**

Medical flow cytometry (FC) provides diagnostic answers by detecting the presence and concentration of cell populations, and/or by measuring concentrations of cell surface markers expressed on cells. Currently, FC is limited to high complexity labs by time consuming pre-analytical steps, requiring highly trained technologists. Inter-instrument and inter-operator variability limit broad acceptance of IVD FC. Finally, interpretation of FC results requires highly trained professionals typically available only during business hours. The Accellix compact table top multicolor flow cytometer automates the 3 step process required for population identification and/or cell surface marker measurement. Sample preparation and reading are performed in a dedicated disposable cartridge. Analytical data processing utilizing proprietary algorithms provides answers directly to the user.

**Methods:**

Accellix Cartridge - This disposable cartridge-based platform provides 24/7 availability in a moderate complexity lab - ultimately CLIA waved setting - by implementing sample preparation using three reagent blisters. With different reagents in the blisters the same cartridge structure can be used for multiple applications. The 3 Accellix CD64 cartridge blisters contain staining cocktail of conjugated monoclonal antibodies, lysis buffer, and reference beads respectively. Once sample processing is complete, the sample flows through a dedicated reading channel where data is acquired.

Applications implemented on Accellix:

•Sepsis diagnosis and monitoring based on upregulated CD64 expression on neutrophils.

•HIV monitoring based on determining T cell subsets: proportion of T helper cells (CD4) to cytotoxic T cells (CD8) compared with total T cells (CD3).

•Population analysis of cells: differentiating T cells, B cells, NK cells and monocytes based on cell surface marker expression.

•Measuring sepsis induced immunosuppression via HLA-DR expression on circulating monocytes.

**Results:**

In a demonstration of cell surface marker quantitation a comparison study of 53 blood samples showed a correlation coefficient of 0.91 for Accellix determined neutrophil CD64 compared to those determined using a FACS. In a study to identify lymphocyte subsets a comparison study of 5 samples (run in triplicates) showed a correlation coefficient of 0.99 for Accellix determined T cell differentiation based on CD4/CD8 ratio, and correlation coefficients of 0.94 and 0.99 for lymphocyte population analysis to determine B cells (CD19/CD45) and NK cells (CD56/CD3-/CD45) compared to FACS.

**Conclusions:**

These initial studies show that the cartridge-based Accellix system can determine the presence and concentration of cell populations as well as determine the concentration of cell surface markers. Thus, implementation of a wide range of fully automatic IVD assays with results in 30 minutes or less is possible using Accellix.

## B-240

### Analytical Validation of Point-of-Care Emergency Tests on the PATHFAST System in Comparison with Automated Laboratory Analyzers

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**Background:**

The PATHFAST system consists of an automated analyzer that uses single cartridges containing reagents for quantitative measurement in whole blood (WB), serum and heparinized, citrated or EDTA plasma. The turn-around-time (TAT) lies within 16 min. We evaluated the determination of the 6 emergency parameters cardiac troponin I (cTnI), high sensitivity C-reactive protein (hsCRP), myoglobin (Myo), CK-MB, NT-proBNP, and D-Dimer in comparison with Roche E 170 and cobas Integra 800.

**Methods:**

Intra- and inter-assay imprecision were evaluated using BioRadLiquicheK Cardiac Markers Control, patient plasma and WB samples. Linearity, analytical and functional sensitivity, limit of blank (LoB) were determined by using predefined samples and zero calibrators. The method comparison with Roche E 170 and cobas Integra 800 was performed using patient samples with marker concentrations comprising the whole measurement range.

**Results:**

Coefficients of variation (CVs) of intra- and inter-assay imprecision ranged between 3.3% and 8.0%. All assays showed recovery between 90% and 110% and complete linearity across the total range. The LoB was determined by measurement of 10 replicates of the zero calibrator and of the lowest non-zero calibrator in parallel. Sample matrix evaluation was performed using WB and plasma samples. All assays showed high comparability between WB, serum, heparinized, citrated plasma or EDTA plasma. The results method comparison with Roche E 170 and cobas Integra 800 are displayed in the table.

**Conclusion:**

Method comparison revealed high concordance of the PATFAST system with the Roche E 170 and cobas Intregra 800 analyzer. POC testing on the PATHFAST analyzer allows measurement of whole blood samples within 16 min after blood drawing in the point-of-care setting providing comparable results with the central laboratory.

PATHFAST imprecision data and results of method comparison

| | WB samples Mean (n=20) | Intra-assay CV (%) | Inter-assay CV (%) | Comparison | Intercept | Slope | r |
|---|---|---|---|---|---|---|---|
| CKMB (µg/L) | 2.51 | 6.2 | 8.2 | E-170 | -1.278 | 0.9221 | 0.988 |
| cTnI (µg/L) | 0.19 | 6.1 | 5.6 | E-170*) | | | |
| D-Dimer(µg/L) | 0.69 | 4.8 | 5.5 | Integra | 0.3133 | 1.005 | 0.977 |
| hsCRP(mg/L) | 0.63 | 6.4 | 6.6 | Integra | 0.0334 | 0.883 | 0.998 |
| NTproBNP(ng/L) | 411 | 4.0 | 6.9 | E-170 | 196.3 | 1.265 | 0.967 |
| Myoglobin(µg/L) | 37.7 | 5.6 | 6.1 | Integra | -1.037 | 1.050 | 0.991 |

*) Overall agreement at 99th% cut-off 77% and at 0.264 µg/L 97%

## B-241

### Analytical Performance of the Abaxis Piccolo Xpress Point of Care Analyzer in Whole Blood, Serum, and Plasma

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Background: The Abaxis Piccolo Xpress is a portable bench top analyzer that performs multiple simultaneous assays with a single-use reagent disc. The analyzer is designed to accept whole blood, serum, or heparinized plasma, which is directly added to the plastic reagent disc. The analyzer is able to report a total of 31 separate analytes, including lipids, electrolytes, liver function tests, renal function tests, and general chemistry assays. There has been much interest in these devices due to a recent Ebola outbreak, with many hospitals establishing policies restricting clinical laboratory testing on confirmed or suspected Ebola patients to point-of-care testing. Despite much interest in this device, there have been limited comprehensive studies published in the literature that have critically examined the analytical performance of this device in all three matrices. The primary objective of this study was to examine the analytical performance of 14 comprehensive metabolic panel (CMP) analytes on the Abaxis Piccolo Xpress point-of-care analyzer in serum, plasma, and whole blood. Methods: Precision was evaluated by running two levels of control material. Linearity was evaluated using material provided by the manufacturer and the College of American Pathologists (CAP) linearity surveys. Accuracy was evaluated by comparing the results from 60 patient specimens on the Piccolo with the Ortho Vitros 5600 analyzer. The method comparison was performed on all three specimen types intended for use on the Piccolo; serum, heparinized plasma, and whole blood. Results: High precision was noted for all the analytes with the exception of TCO2, which had a CV of almost 16%. Linearity was found to span the clinically useful range for all analytes. The method comparison demonstrated significant proportional bias (slope <0.85 or >1.15), poor correlation(R2 < 0.85), or both, for sodium, ALT, albumin, total protein, and total CO2 in all matrices. Furthermore, significant proportional biases and or poor correlations were noted for calcium, total bilirubin, and urea nitrogen in whole blood and plasma. Conclusion: The Piccolo Xpress allows for the delivery of CMP results in a footprint small enough to be stored in a biological safety cabinet, while providing satisfactory performance for the majority of analytes.

## B-242

### Combination of the Mortality in Emergency Department Sepsis (MEDS) Score with PATHFAST Presepsin Improves Outcome Prediction of Sepsis

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**Background:** Assessment of disease severity at presentation could be helpful in the management of patient with sepsis. The POC test PATHFAST Presepsin has been shown to provide powerful prognostication. We thought to evaluate PATHFAST Presepsin (PSEP) for outcome prediction in combination with the MEDS score.

**Methods:** 121 septic patients were included. MEDS score, PSEP and procalcitonin (PCT) were determined at admission to the ED. Primary endpoint was death. The

combined endpoint (MAE) consisted of the primary or at least one of the secondary endpoints ICU, mechanical ventilation or dialysis. **Results:** 21 patients died and 34 patients exhibited MAEs during 30 day follow up. The number of decedents and patients with MAEs were 2 (3.2%) / 5 (8.1%), 8 (21.6%) / 15 (40.5%) and 11 (50,0%) / 14 (63.6%) in patients with sepsis (n=62), severe sepsis (n=37) and septic shock (=22), respectively. Median values of MEDS score and PSEP in sepsis (n=62) were 8 and 738 ng/L compared to 11 and 1407 ng/L ($p<0.0001$) in severe sepsis or septic shock (n=59). 30-day mortality was 17.4 %, ranging from 0 % in the 1st to 43.3 % in the 4th quartile of PSEP concentration. ROC analysis revealed AUC values for MEDS score and PSEP of 0.851 and 0.810, respectively, compared to 0.549 of PCT. The combination MEDS+PSEP revealed an AUC value of 0.909.

**Conclusion**: MEDS score and PSEP demonstrated strong relationship with disease severity and outcome in patient with sepsis in the ED. The combination of MEDS score and PSEP provided a higher predictive value than both markers alone. The PATHFAST system allows early determination of PSEP from whole blood in the ED in addition to MEDS score and may improve the management of sepsis.

| Results of ROC analysis | | | | | |
|---|---|---|---|---|---|
| | | AUC | SENS (%) | SPEC (%) | Cutoff |
| MEDS | Death | 0.851 | 81.0 | 85.0 | >12 |
| | MAE | 0.806 | 82.4 | 65.1 | >9 |
| | | | | | |
| PSEP | Death | 0.810 | 81.0 | 70.0 | >1179 ng/L |
| | MAE | 0.736 | 97.1 | 39.5 | >608 ng/L |
| | | | | | |
| MEDS+PSEP | Death | 0.909 | 95.2 | 83.8 | >0.122 |
| | MAE | 0.860 | 97.1 | 60.5 | >0.041 |

## B-243

### Development of a new rapid assay for quantitative measurement of H-FABP in whole blood and plasma.

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**Introduction:** H-FABP (Heart-type Fatty Acid Binding Protein), a member of the FABP group, is present in the cytoplasm of cardiac muscle cells and leaks rapidly into blood circulation after suffering a myocardial injury. Therefore, H-FABP is used for diagnosis of acute myocardial infarction. We have developed a new rapid and quantitative assay kit for H-FABP that works on the principle of lateral flow immunochromatography. The test requires only 10 minutes and 120μL of whole blood or plasma. After application of the sample onto the ready-to-use cartridge-type reagent, immunoreactions and test report will automatically be performed by our easy-to-use immuochromato-reader "Rapidpia™ (SEKISUI MEDICAL Co., LTD.)".

**Principle:** The test strip housed in the cartridge contains two monoclonal antibodies which react with H-FABP. One of the antibodies is labeled with colloidal gold and the other coats the detection zone membrane. While flowing on the test strip, the labeled antibody forms a complex with the H-FABP. Following the separation of the red blood cells, the labeled H-FABP in the plasma react with the antibody coated membrane and form a reddish line while passing through the detection zone. The intensity of the line increases depend on the concentration of the H-FABP. Rapidpia™ measures, and converts the signal intensity to a quantitative report.

**Performance:** The lower detection limit for H-FABP was 2.0 ng/mL, and upper quantitation limit was 160 ng/mL. No prozone effect was observed in H-FABP samples of concentrations from 160 through 2,300 ng/mL. The within-run C.V. (n=5) at 7.2 ng/mL, 37.8 ng/mL, and 108 ng/mL was 5.7%, 3.8%, and 6.7%, respectively. The between-run C.V. (n=5) at 7.7 ng/mL, 38.8 ng/mL and 119 ng/mL was 2.5%, 1.3% and 2.3%, respectively. Comparison of our assay kit with an approved IVD reagent, the principle of which is latex-enhanced immunoturbidimetry, yielded a correlation coefficient of 0.993 and an equation of Y (present method) = 0.99X + 0.00 (n = 88 heparinized plasma samples). Furthermore, a high correlation was also observed in the comparison of heparinized plasma and whole blood (R : 0.996 ; Y = 1.01x - 0.60).

**Conclusion:** This newly developed assay kit is accurate, precise and easy to use for the measurement of H-FABP in whole blood and plasma. We believe that this assay kit will be a useful tool in emergencies.

## B-244

### Point of Care Testing Expansion in Public Health; One County's Experience

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**Background:**

The Marion Co. Public Health Department Laboratory increased the quality and quantity of point of care (POCT) in health department clinics in 5 years. This mirrors a national trend to decentralize clinical testing, which has the potential to improve healthcare delivery, and public health in particular1. Decentralized testing along with improved connectivity of information and more robust testing devices also supports a greater responsiveness to emergency response essential for public health. 2

**Methods:**

We made the improvements through continuous quality improvement projects, Lean management practices and without increased staffing. Over 18-24 months, and through the Clinical Manager and Quality Manager staff turnover we implemented CLSI standards and put in to place CMS suggestions3 to assure the accuracy and reliability of POCT (waived) testing through implementation of structured staff training and competency assessment. Successes with this approach and expansion of the WIC and Refugee/Foreign Born (RFB) programs resulted in increased need for the expanded lab support of POCT.

**Results:**

The number of WIC sites grew from 12 to 13, and the RFB programs began to offer POCT, including HIV screening, urinalysis and urine pregnancy tests. Substance Use Outreach Services department also began rapid HIV screening. Only the School-Based Clinic sites contracted from 4 to 1 sites in the same time. Overall the number of non-lab personnel using POCT rose in the past 3 years from 77 to 122, and the test count increased from 1 to 4, increasing the number and complexity of training and competency assessment materials needed for that training. By 2014 a large shift had occurred, nearly a quarter (23%) of the results from waived tests were produced outside the lab by staff who were trained and had competency assessed by the lab QA program. Improvement continues. In 2014 we created the Laboratory Support Division, managed by the QA Manager to better serve not only POCT, but also in-lab testing QA.

**Conclusion:**

The Lab working together with clinical departments has been able to make great strides in improving the amount and quality of clinical testing that occurs near the public health client. This allows rapid clinical decision-making in a single patient visit, minimizing the impact of losing patients to follow-up while waiting for test results to be returned; a particular problem in economic challenge areas. This POCT-QI program has empowered more health department employees to gain competency in POCT. This in turn results in improving Analytical/Assessment Skills and Public Health Sciences Skills across the health department.

**References:**

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## B-245

### Performance of Estapor® Microspheres and Hi-Flow™ Plus Membranes in a Lateral Flow Assay for Human Chorionic Gonadotropin (hCG)

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**Background:**

Available in a range of sizes, latex microspheres are versatile detector particles which can, depending on their composition, be detected by colorimetry, fluorometry, or paramagnetism, and with functional chemistries be covalently attached to antibodies and other molecules.

In lateral flow assays particles must move through a porous membrane. Since particle size and membrane flow rate will impact particle mobility, assay manufacturers must optimise these parameters to achieve their desired assay sensitivity.

In this study, we examine the relationship between microsphere size, membrane flow rate, and assay sensitivity, using Estapor® carboxyl-modified dyed microspheres and Hi-Flow™ Plus membranes.

**Methods:**

Lateral flow test strips for the detection of hCG were assembled using blue Estapor carboxyl-modified microspheres with diameters ranging from 0.185 to 0.478µm, and Hi-Flow Plus lateral flow membranes with flow rates ranging from 75s/4cm to 180s/4cm. Microspheres were conjugated to anti-hCG antibodies using a two-step EDC/Sulfo-NHS covalent coupling procedure and resuspended to a concentration of 1% (w/v) in 50mM Tris (pH. 8.0), 0.5% casein. For conjugate pad application, conjugates were diluted to 0.065% (w/v) in 50mM Tris (pH 8.0) containing 0.5% casein, 2.5% trehalose, 10% sucrose, and 0.5% polyvinylpyrrolidone. A 1µL microsphere suspension was applied to each pad (0.5 x 30 cm), yielding 10.8µg of microspheres per test. Hi-Flow Plus membranes were striped with ß-hCG antibody at a concentration of 1mg/mL in 50mM MES (pH 6.0) and goat anti-mouse IgG, as a control antibody, at 1mg/mL in Milli-Q® water.

**Results:**

After assembly, test strips were run with hCG samples of known concentration and test line signal intensities evaluated colorimetrically. Microspheres of 0.185µm produced weakest signals regardless of the membrane's flow rate. Microspheres of intermediate diameters produced comparable signals. While microspheres of 0.478µm diameter produced the most intense signals, they also exhibited nonspecific binding as evidenced by measureable test line signals with hCG-negative controls.

To eliminate nonspecific binding, modifications to the conjugation procedure were investigated. Reducing the amount of ethanolamine by 50% and changing the blocking agent from 0.5% (w/v) casein to 1% (w/v) fish skin gelatin were most effective.

Optimized 0.478-µm microspheres were re-evaluated on Hi-Flow Plus 75 (HF075), Hi-Flow Plus 135 (HF135), and Hi-Flow Plus 180 (HF180) membranes. The signal intensity on HF075 was reduced at all concentrations. On HF135 and HF180, reduced signal intensities were observed at concentrations below 1600mIU hCG/mL. Above that, the optimized and standard microspheres produced similar signal intensities. No signals were detected with hCG-negative controls.

**Conclusion:**

By pairing microspheres of varying diameters with membranes of varying flow rates, we show quantitatively that microspheres of 0.478µm diameter produced the highest signals. Microspheres with diameters of 0.228, 0.413, and 0.422µm produced intermediate signal intensities that were similar across membranes. Microspheres with a diameter of 0.185 µm produced the lowest signals. False positives with negative controls observed on test strips run with 0.478µm microspheres were eliminated through conjugation optimization. Thus, using hCG detection as a model system, we have demonstrated the efficacy of Estapor microspheres in lateral flow test strips manufactured on Hi-Flow Plus membranes.

## B-246

### Comparison of Nova StatStrip Xpress and Roche Advantage glucose meters for use during hyperbaric oxygen treatment

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**Background:**

Blood glucose testing is commonly performed in a hyperbaric chamber (HBC) for patients undergoing hyperbaric oxygen treatment (HBOT). The Roche Advantage glucose meter, a device evaluated for use during HBOT, is no longer being manufactured. We compared Roche Advantage (Roche Diagnostics, Indianapolis IN) and Nova StatStrip Xpress (Nova Biomedical, Waltham MA) for use during HBOT.

**Methods:**

Accuracy evaluation was performed outside HBC using residual lithium heparin whole blood samples (n=47) on the Advantage, Xpress, and Radiometer ABL825 (Radiometer Medical ApS, Bronshøj, Denmark). Immediately following analysis, samples were centrifuged and plasma glucose measured using a Roche cobas c501. Advantage and Xpress glucose results were compared to the average of ABL825 and c501 values (reference).

Accuracy under 2 atmospheres (ATA) of pressure in HBC was assessed by dosing both meters with specimens (n=49) that had glucose measured on Radiometer ABL90 blood gas analyzer (reference method outside of HBC). Within 15 minutes of analysis on ABL90, syringes were transported to HBC where samples, test strips, and meters equilibrated at 2 ATA for up to 15 minutes prior to testing. Additionally, 25 samples were tested in duplicate on Xpress under 3 ATA and compared to ABL90 performed outside HBC. Glucose meter results were compared to reference glucose by calculation of median (interquartile range, IQR) bias and comparison of number of outlier results obtained in HBC.

**Results:**

Outside HBC, median (IQR) bias between Xpress and reference glucose among the 47 samples (range 12-525 mg/dL) was -1- (-6 to 3) mg/dL; compared to median (IQR) bias of 6 (1 to 16) mg/dL for Advantage ($p < 0.0001$). 44 of 47 Xpress results and 37 of 47 Advantage results fell within current CLSI POCT12-A3 accuracy guidelines.

Among the 49 samples (range 25-456 mg/dL) tested under 2 ATA in HBC, median (IQR) bias on Xpress was -12 (-23 to -6) mg/dL, compared to median (IQR) bias on Advantage of -25 (-42 to -9) mg/dL ($p=0.0232$). Median bias on both devices was impacted by several outliers. 8 of 49 Xpress and 23 of 49 Advantage results differed from reference result by more than 20 mg/dL (for Radiometer glucose < 100 mg/dL) or 20% (for Radiometer glucose ≥ 100 mg/dL).

When 25 lithium heparin whole blood samples were analyzed in duplicate on Xpress under 3 ATA in HBC, median (IQR) bias was -3 (-10 to 1) mg/dL, with only 2 of 50 measurements resulting in an outlier.

**Conclusion:**

Nova StatStrip Xpress is a suitable replacement for Roche Advantage for measuring whole blood glucose during HBOT. Xpress had better accuracy outside HBC and produced fewer outliers under 2 ATA inside HBC. It is unclear whether glucose meter outliers observed under 2 or 3 ATA were due to pre-analytical effects on the lithium heparin whole blood samples or whether outliers may occur when capillary whole blood is analyzed during HBOT.

## B-248

### Using urine dipstick as a presumptive result for urinary tract infection.

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**Background:**

Urine dipstick (UD) point of care (POCT) is a quick and inexpensive alternative to urine screening that reduces the time of patients in emergency department (ED). The aim of this study is to evaluate the sensitivity and specificity of two specific parameters in UD compared to the urine sediment and urine culture.

**Methods:**

We performed retrospectively from January to March 2014, 2261 patients who performed concomitantly the three tests: Urine dipstick in ED was performed in Uryxxon 300 (Macherey Nagel®), the sediment in iQ Sprint (IRIS®) and urine culture performed in chromogenic CPS culture media (Biomerieux®). For positive culture when applicable, identification and sensitivity were obtained through Vitek 2 (Biomerieux®).

**Results:**

When was compared UD (nitrite and esterase) with urine culture it was observed a sensitivity of 45% and a specificity of 99%. When another parameter was included such a presence of proteins the sensitivity increased to 73%. On the other hand when compared the quantification of leukocytes in the sediment and urine culture we observed a sensitivity of 93% and a specificity of 75%.

**Conclusion:**

We conclude that the UD nitrite and esterase has high negative predictive value for urinary tract infection when compared to urine culture. Thus, when these parameters are negatives in UD it almost excludes the possibility of urinary tract infection according urine culture. However there is a lack of sensitivity that could possibly be improved using an additional parameter, as positive protein. The sensitivity of positive protein, nitrite and esterase increase 28% the sensitivity of the test compared with positives nitrite and esterase only. As an alternative for resources management the use of UD to exclude urinary tract infection could be useful in emergency department once 68,9% (1552/2261) of the patients will have nitrite and esterase negative of the total.

## B-249

### How Much Training is Required on the epoc® Blood Analysis System to Produce Clinically Accurate & Reproducible Results in a Point-of-Care Setting?

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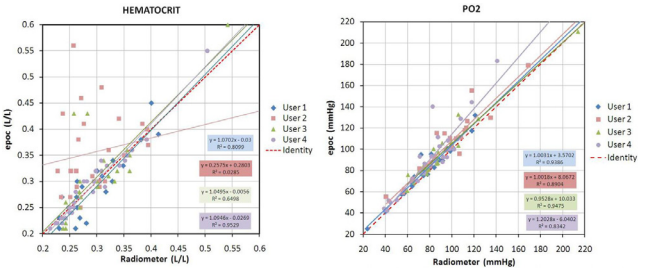
**Introduction:** To reduce Emergency Department visits Alberta Health Services is introducing a new Emergency Medical Services (EMS) program which brings diverse medical services, including point-of-care testing, to continuing care facilities. The suitability of the Alere epoc® blood analysis system was studied to determine whether non-laboratory staff with minimal training could produce clinically accurate & precise results.

**Methods:** The evaluation was performed last year at University of Alberta Hospital. Two EMS workers and two nurse practitioners performed all testing after having received 2.5 hours of epoc® training. Precision was estimated by analyzing either hematology or chemistry quality control material in duplicate each day at two (hematocrit) or three levels (pH, $pCO_2$, $pO_2$, sodium, potassium, ionized calcium, glucose, lactate). Each staff member ran 25 patient samples on the epoc® using a Radiometer ABL825 as the comparative device. Each patient sample was first run on the Radiometer; leftover sample was then analyzed on the epoc®. Acceptability criteria for bias and imprecision were based on CLIA '88, biological variation, or other resources.

**Results:** Initial analysis of the complete data set revealed acceptable performance for pH, $pCO_2$, potassium, glucose, and lactate. The performance of $pO_2$, sodium, ionized calcium, and hematocrit was more variable. The figure shows a user-dependent variation in accuracy for hematocrit and $pO_2$; similar user-dependent variation was identified for sodium and ionized calcium. Exclusion of just one user's results yielded acceptable overall performance for all analytes.

**Conclusion:** Our results suggest that the 2.5 hour epoc® training program is sufficient for many non-laboratory users to generate clinically accurate & reproducible test results. However, our results also indicate that select users require additional training. Point-of-care programs should design training sessions carefully in order to identify such individuals and to provide them with additional support as necessary.




## B-250

### Development of Multiplex Rapid POC Test for Current, Persistent, and Recurring Syphilis Infections Based on the Simultaneous Detection of Treponemal and non-Treponemal Antibodies in Human Blood Specimens

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**Background:**Syphilis, caused by Treponema pallidum, is an STD with serious consequences if left untreated. Despite availability of diagnostic tests and effective treatment, it remains a global health problem. Correct diagnosis requires clinical evidence combined with results of serological tests for antibodies against: nTP (cardiolipin) and TP antigens. These two serological tests are complementary, and widely used for screening and confirmation of syphilis. There is an unmet need for a solution that combines the two in a POC test that can be performed while a patient waits. MedMira's Multiplo Rapid TP/nTP Antibody Test (Multiplo) is a manually performed, visually interpreted assay that can be completed in three minutes and provides screening and confirmatory results based on the presence of nTP and TP antibodies.

**Methods:**Preclinical studies were undertaken by testing commercially obtained specimens with Multiplo (per manufacturer's instructions). Multiplo contains two test zones; a TP zone and an nTP capture antigens zone, and a control zone. The TP test zone contains optimized TP recombinant antigen. The nTP test zone contains a proprietary cardiolipin-based antigen. Antibodies from patient specimens, if present, are captured through their respective immobilized antigens, and are subsequently visualized in the distinct test zones through binding to protein A gold conjugate. Two syphilis mixed titer panels (n=23) and a dilution panel were tested to assess sensitivity. Specificity was assessed using 22 plasma and 42 whole blood specimens. Interference/cross-reactivity was assessed using a set of 95 specimens collected from individuals with unrelated conditions. Results in each test zone was recorded and compared to available reference results.

**Results:**Within performance panels, there was 100% concordance between Multiplo and reference assays for both TP and nTP antibodies. Serial dilutions of three highly positive (both TP and nTP antibodies) specimens into negative specimens illustrated reactive results for TP and nTP in all dilutions tested (1/2 to 1/8) confirming the high sensitivity of this assay. Specificity was evaluated for the TP portion by testing a set of 22 specimens certified as non-reactive for HIV, HBV, HCV, and TP antibodies by FDA approved assays and an additional 42 whole blood samples. 100% specificity of Multiplo TP was observed. Interference/cross reactivity was evaluated using a 95 member panel. nTP results were positive in 34 of the 95 specimens, reporting a variety of disease states. At the time, reference nTP results were not available for the 95 specimens. Observed Multiplo nTP results are likely biologically false positives. More significantly, there was no interference observed in the TP test zone of Multiplo in this panel.

**Conclusion:**Multiplo, built on MedMira's Rapid Vertical Flow (RVF) technology, has been designed to meet the ASSURED criteria established by the WHO. Sensitivity and specificity of the TP portion Multiplo TP/nTP were both calculated to be 100%. Normal state specimens showed approximately 5% nTP biological false positives compared to 36% for the diseased state specimens. Additional studies will be conducted to further assess performance in a larger scale trial.

## B-251

### Diagnosis of Clostridium difficile diaherra using the Xpert C. difficile PCR assay for detection in fecal specimens as a point of care test in a tertiary care hospital in São Paulo, Brazil.

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**Background:**

Toxin-producing *Clostridium difficile* is the most common cause of health-care-associated diarrhea. *C. difficile* infection (CDI) diagnosis is defined by positive laboratory test detecting toxigenic *C. difficile* in the stool (toxins A and B). In the last years, the epidemic strain of *C. difficile* producing a third toxin called the binary toxin, referred to either NAP1, BI, or 027, has been associated with several outbreaks. Although culture followed by toxin detection remains the gold standard for diagnosis of CDI, alternative tests has been used in clinical practice, including detection of *C. difficile* toxins in stool samples by enzyme immunoassays (EIAs), and real-time PCR assays, with variations in sensitivities and specificity.

**Methods:**

From July 2014 to January 2015, a total of 63 stool samples from 63 patients attending a private hospital in São Paulo, Brazil, with CID suspected were tested by Clostridium toxin by Xpert *C. difficile* assay, and 34 out of 63 samples were also tested by EIA for detection of the GDH antigen. Xpert *C. difficile* PCR assay detects the toxin B gene (*tcd*B), the binary toxin gene (*cdt*), and the *tcd*C gene deletion at nt 117.

**Results:**

A total of 63 stool samples from 63 patients were studied; 13 samples were Xpert *C. difficille* assay positive and 1 sample was also positive for toxigenic *C. difficile* 027-NAP1-BI. A total of 34 fecal specimens were tested by both methods PCR and Immunoassay; only 2 out of 13 positive samples by Xpert C. difficile were positive by immunoassay. The turnaround time for Gen Xpert C. difficile assay was less than two hours.

**Conclusion:**

Xpert *C. difficile* assay had a higher sensitivity for screening toxigenic *C. difficile* in fecal specimens compared to EIA. The rapid diagnosis based on Xpert permits a faster result since the clinical suspicion of CDI and laboratory investigation, which is important to appropriate management of the patients infection control practices. In

addition, the detection of NAP1-B1 is important to epidemiological surveillance and adequate healthcare policies.

## B-252

### Evaluation of Bias of Glucose Measurement Among Multiple Analytical Systems in Various Specimen Types

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**Background:**

Glucose measurement is one of the most frequently ordered tests in clinical settings. Multiple methods are available for point-of-care (POC) and central laboratory glucose testing using plasma, serum, or whole blood (WB) specimens. However, bias may exist among various systems when various specimen types are used. The objective of this study is to determine the bias in glucose measurements among POCT devices, critical care analyzers, and central clinical chemistry laboratory analyzers when different specimens are used.

**Methods:**

Abbott FreeStyle glucose meter is based on the glucose dehydrogenase-nicotinamide adenine dinucleotide method (GDH-NAD reaction), while Abbott i-STAT, Radiometer ABL800 FLEX analyzer, and Beckman Coulter UniCel®DxC 800 analyzers measure glucose amperometrically by oxidation of glucose using glucose oxidase. Venous whole blood (VWB) samples (n=26) collected in lithium heparin (LH) tubes were analyzed for glucose by Radiometer, FreeStyle and i-STAT in duplicates. Then, these WB samples were spun down and the plasma was measured for glucose by Beckman Coulter UniCel®DxC800 in duplicates immediately. Arterial whole blood (AWB) samples (n=25) in LH syringes were used to analyze glucose by Radiometer, FreeStyle and i-STAT. The overall average percent bias was calculated between i-STAT-DxC, FreeStyle-DxC and Radiometer-DxC for VWB vs plasma comparison employing DxC as a reference. For VWB vs VWB and for AWB vs AWB, average percent bias was calculated between i-STAT and Radiometer, FreeStyle and Radiometer using Radiometer as a reference, also FreeStyle and i-STAT was compared using i-STAT as a reference.

**Results:**

For the VWB vs plasma comparison, -12% and -4% biases were observed between FreeStyle and DxC and between i-STAT and DxC, respectively, whereas no significant bias (-0.1%) was observed between Radiometer and DxC. For VWB vs VWB in LH tubes, -4% and -12% biases were observed between i-STAT and Radiometer and between FreeStyle and Radiometer, respectively, and a -8% bias was observed between FreeStyle and iSTAT. For AWB vs AWB from LH syringes -3% and -3% biases were observed between i-STAT and Radiometer and between FreeStyle and Radiometer, respectively, and no significant bias (-0.2%) was observed between FreeStyle and iSTAT.

**Conclusion:**

Overall for VWB vs plasma comparison, FreeStyle shows the most significant negative bias (-12%). FreeStyle also has significant negative bias in VWB when compared to Radiometer (-12%) and i-STAT (-8%). However, in AWB, the negative bias of FreeStyle decreases to an insignificant level when compared to radiometer (-3%) and i-STAT (-0.2%). It is unclear why FreeStyle demonstrates different bias in venous and arterial blood samples. However, since the oxygen content in venous blood is much lower than that in arterial blood, the difference in the oxygen content between arterial and venous blood might play a role in the better correlation in arterial samples. Further studies are to be conducted to determine the underlying factors contributing to this difference in bias of glucose measurement by FreeStyle meters between arterial and venous blood samples.

## B-253

### Glucometer performance in critically ill patients: a correlation of the Roche Accu-chek Inform II vs the Roche Accu-chek Inform I, Abbott i-STAT and Beckman Coulter AU 680

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**Background:** Historically, the Food and Drug Administration(FDA) evaluated glucometers used in hospitals and at home by patients by the same methods and standards. Since over-the-counter "home use" glucometers are classified as waived testing, hospitals have used these meters for convenient, rapid bedside glucose testing. However, it has become increasing clear that these two settings are different, with critically ill hospitalized patients having physiological derangements that could potentially affect glucometer performance. The FDA's draft guidelines call into question the waived status of glucometers currently in use at many hospitals and deems hospital blood glucose testing as "off label" use, which would nullify the glucometer's waived status, categorize it as "high complexity" testing, and subject glucometers to much more stringent testing personnel, competency, and validation requirements. Also recommended is that manufacturers label their glucometers with a statement regarding use in critically ill patients, which would make it very difficult to perform rapid bedside glucose monitoring in hospital intensive care units, operating rooms, emergency rooms, and ambulances.

**Methods:** We defined "critically ill" as the patient population in intensive care or critical care units. Samples were collected over a 3½ month period at four hospitals. Glucose measurements were performed on the Roche Accu-chek Inform I, Roche Accu-chek Inform II, Abbott i-STAT, and Beckman Coulter AU680.

**Results:** Samples from 34 patients, of which 21 were female and 13 were male, ranging in age from 36 hours to 89 years, were obtained. Due to available blood volume limitations on newborn and pediatric patients, results on all four instruments were available for 23 patients, three instruments for 8 patients, and two instruments for 2 patients. Mean blood glucose concentration ranged from 61mg/dL to 307mg/dL. When data was available for all four instruments, the linear regression line was (Inform II) = (0.8677)*(i-STAT) + (-0.0996)*(Beckman AU) + (0.2165)*(Inform I) +(-1.6299), with an $R^2$ of 0.9900 and a standard error of 6.009. Looking at the Inform I, i-STAT, and AU680 vs the Inform II individually, the slopes were 0.9634, 1.0329, 1.0143, the intercepts were -0.8815, -3.4617, -1.5020, and the standard errors were 8.48, 7.26, 6.46, respectively. The $R^2$ values were all greater than 0.9. The paired t-test (two-tailed) were less than t critical for the i-STAT and AU680, with p-values of 0.64 and 0.80, respectively, while that of the Inform I was larger than t critical, with a p-value of 0.001.

**Conclusion:** The t-test difference between the Inform I and Inform II was somewhat surprising; however, the Inform II was developed because of issues with interferences and to improve accuracy of test results. Limitations of this study include the small sample size and issues with not having enough specimen for testing to be performed on all four instruments. For both pediatric and adult, a larger sampling of different kinds of critically ill patients would have been preferable, as would additional hypo- and hyperglycemic specimens. However, the Accu-chek

Inform II, despite having the limitation regarding use in critically ill patients, performed relatively similarly to the Inform I, i-STAT, and AU680.

## B-254

### Comparison of the Abaxis Piccolo Xpress to core-laboratory automated chemistry analyzers

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Background:

The Abaxis piccolo Xpress is a small disc-based centrifugal analyzer designed to separate plasma from whole blood, and test plasma for acute-care clinical chemistry panels. Its compact size, minimal volume requirements (0.1 mL) and high test yield make it appealing for small laboratories, point of care applications, and use inside biological safety cabinets. As little published data exists on its performance, we sought to compare it to two popular core-laboratory random access chemistry analyzers.

Methods:

A minimum of forty anticoagulated whole blood specimens were sampled each from core laboratories at the University of Alberta Hospital (Edmonton, Alberta, Canada) and Alberta Children's Hospital (Calgary, Alberta, Canada). Specimens were split and immediately tested on the Piccolo Xpress , the Beckman UniCel 800 (Edmonton) and the Roche Cobas 6000 (Calgary) for the comprehensive metabolic panel (Na, K, Cl, Ca2+, CO2, glucose, creatinine, urea, total protein, albumin, ALT, AST, ALP, total bilirubin). Proportional bias (slope), constant bias (intercept), coefficient of determination (R2) and Syx as a proportion of the mean were calculated for each comparison using linear regression. Total error of each Piccolo assay was determined based on stated precision claims and bias versus main analyzers, and contrasted to allowable error set by the College of American Pathologists.

Results:

The Piccolo Xpress proportionally underestimated results in 80% of tests versus main analyzers (up to 37% difference), but 85% had constant overestimations that tended to resolve many of these differences. Most R2 values were above 0.80, suggesting that each analyzer ranked specimen results similarly for most tests. Total error remained below allowable error for most tests. However in comparisons with the Roche Cobas and the Beckman Unicel, the R2 for Sodium was 0.57 (slope = 0.84, intercept = 22) and 0.63 (slope = 0.67, intercept = 50) respectively. Allowable error was exceeded for both comparisons, and was exceeded for creatinine in comparison to the Beckman UniCel, and Syx as a % of the mean was 19% in comparison to the Roche Cobas.

Conclusions:

The Piccolo Xpress does not yield identical results as core-laboratory chemistry analyzers for several important clinical chemistry tests. While correction factors may be applied to harmonize results with core-lab analyzer tests, this should only be done if correlations between tests are high. Further, it may not be necessary to drop individual tests that exceed allowable error thresholds. Poorly performing tests may instead be re-purposed for semi-quantitative or qualitative testing in different clinical scenarios. For highly correlated Piccolo tests which differ from core laboratory results by clinically important proportional or constant differences, we encourage Abaxis to allow the user to set correction factors within the Piccolo software interface.

## B-255

### Clinical evaluation of point-of-care assay for urinary NGAL & TIMP-2 as early biomarker of acute kidney injury in ICU patients

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Introduction: Acute kidney injury (AKI) is a major public health problem affecting millions worldwide that deserves more awareness [1]. AKI is associated to poor outcomes, including decreased survival, increased progression to chronic kidney disease (CKD), as well as higher susceptibility to other complication such as bacterial infection [2]. Using the RIFLE for AKI definition, a study [3] examined 325,395 ICU patients and determined 22% developed AKI with a mortality rate of 10%. Recent publications [4] have shown that biomarker neutrophil gelatinase-associated lipocalin (NGAL) is an early predictor of AKI in emergency department and ICU patients. In contrast, tissue inhibitor of metalloproteinases-2 (TIMP-2) [5,6] in urine has been tested in subsets of ICU patients, such as those who underwent cardiac surgery, or with complication in respiratory or cardiovascular system. In this study, we investigated a general ICU population by evaluating the performance of urinary NGAL, TIMP-2 individually, and in combination of the two biomarkers.

Methods: In 43 ICU patients at a AAA hospital in China, we measured the concentration of both biomarkers using immunoassay point-of-care testing at the following time points after ICU admission: 0, 2, 4, 8, 12, 24 hour. Patient serum creatinine level was monitored daily after ICU admission. AKI was defined by applying the Kidney Disease: Improving Global Outcomes (KDIGO) classification.

Results: Out of the 42 patients, 28 individuals experienced AKI based on the KDIGO definition. NGAL, TIMP-2, and combined markers demonstrated modest AUC of 0.64, 0.68 and 0.66, respectively. When we examined those who enrolled into ICU within 24 hours from emergency department (n=31), the AUC of NGAL, TIMP-2, and NGAL x TIMP-2 were improved to 0.83, 0.77, and 0.86, respectively. Analysis of other parameters, including sensitivity, specificity, positive and negative predictive values from both biomarkers were equivalent to published data on NGAL and TIMP-2 [4,5].

Conclusion: In addition to identifying AKI in subgroup of ICU patients, this study illustrated that TIMP-2, similar to NGAL, also have strong predictive value of AKI in the general ICU patients who enrolled into ICU within 24 hour from emergency department. The data also supports future exploration of the clinical utility of NGAL and TIMP-2 in patients at risk for AKI in the emergency department using point-of-care testing.

## B-256

### Validation of a hand-held point of care device for lactate in adult and pediatric patients: analytical and clinical considerations for use in the pre-clinical setting

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Background: Sepsis and trauma are leading causes of mortality in adults and children in the US and worldwide. Delayed diagnosis and treatment are associated with significant mortality and there is a need for prognostic biomarkers in early disease. Advanced stages of these conditions are characterized by poor organ perfusion and elevated lactate. The pre-hospital use of lactate by emergency medical systems (EMS) could enhance the process of triaging patients in need of specialized care and decrease morbidity. The availability of handheld devices for lactate measurement makes such studies feasible but analytical validation is needed in the context of the intended use. Objective: We aimed to evaluate the analytical performance of the StatStrip Lactate Xpress Hospital Meter (Nova Biomedical, NJ) in samples from critically ill adults and children. Methods: This study used residual heparinized arterial and venous whole blood samples from critically ill adults (n=50) and children (n=50) to compare the test method to the Radiometer ABL 800 (Radiometer, Denmark), which was used as the reference method in two independent hospitals. Statistical analyses consisted of linear regression and difference plots. The bias observed was evaluated in the context of risk stratification and impact in serial measurements. Results: The ranges of concentrations in the ABL800 were 1.0-17.5 and 0.6-18.5 mmol/L in the adult and pediatric populations, respectively. Linear regression analysis between the StatStrip and the ABL800 resulted in slopes of 0.806 in adult and 0.718 in pediatric samples. The mean bias ± SD (% bias) between methods was −0.6 ± 0.7 (18.1%) in adult and -0.6 ± 1.1 (21.1%) in pediatric samples. For both populations, the StatStrip Lactate Xpress method demonstrated a negative bias, proportional with increasing lactate concentrations. Lactate underestimation in the StatStrip Lactate Xpress method was most dramatic >5 mmol/L. There were some discrepancies between methods when samples were classified into 3 risk categories defined using evidence-based cut-offs for sepsis and/or trauma as follows: low (≤2.0 mmol/L), intermediate (2.1 - 3.9 mmol/L) and high (≥4 mmol/L). One pediatric and three adult samples classified as intermediate risk by Radiometer were classified as low risk by the Nova meter. Three adult samples classified as high risk by Radiometer were classified as intermediate risk by the Nova meter. At lactate concentrations ≥4 mmol/L, results between the methods were 10% to 55% different. Conclusions: For concentrations ≤5 mmol/L, which comprise the cut-offs for medical decisions in sepsis and trauma, the StatStrip Lactate Xpress Hospital meter showed a slight low bias but overall acceptable comparability with the ABL800. The negative bias above >5mmol/L was >20% in the test method. The discrepant risk classification observed in our study suggests that pre-hospital stratification models must be derived from data generated using the field method. Since the two methods studied demonstrated intrinsic bias, measurements of patient samples across these methods to determine lactate clearance will be misleading. The meter evaluated here is not currently approved by the US Food and Drug Administration, but its compact size and ease of use warrants evaluation for lactate measurement by EMS in the pre-hospital setting.

## B-257

### Demonstration of a Urine Dipstick Control in a Revolutionary Single-Use Pouch with Extended Room Temperature Stability Ideal for Point-Of-Care Testing (POCT).

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**Background:** Since refrigeration is not always available near the site of patient care, many point-of-care test (POCT) devices are designed to be stored and operated at room temperature (RT). Quality control materials that are used to verify the performance of the POCT devices would ideally also have extended RT stability. Urinalysis using multi-analyte dipsticks is one of the most commonly performed POCT. These dipsticks contain reagent pads to assay analytes such as bilirubin, blood, creatinine, glucose, hCG, ketones, leukocytes, microalbumin, nitrite, pH, protein, specific gravity, and urobilinogen in a urine sample. They are typically stored at RT and require testing with control materials to verify performance. An ideal quality control material would therefore have extended RT stability, allow for full dipstick immersion, and be packaged in a single-use design that minimizes contamination risk.

**Objective:** To formulate a two level urine dipstick control in a single-use thermoplastic pouch with RT stability of at least 90 days.

**Methods:** Two levels of a simulated urine control were formulated using proprietary stabilizers and excipients. Level 1 was formulated to test as negative/normal while Level 2 formulated to test as abnormal/elevated for bilirubin, blood, creatinine, glucose, hCG, ketones, leukocytes, microalbumin, nitrite, pH, protein, specific gravity, and urobilinogen. Using a custom form-fill-seal machine, 1.5 mL was dispensed into single-use thermoplastic polymer pouches. RT stability was evaluated by maintaining pouches at 25ºC for up to 60, 90, and 120 days while real-time stability will be followed for up to 3 years at 2-8ºC. SG Roche Chemstrip® 10MD, Siemens Multistix® 10SG, McKesson 10SG, and Henry Schein Urispec® 11-way dipsticks were used to evaluate bilirubin, blood, glucose, ketones, leukocytes, nitrite, pH, protein, specific gravity and urobilinogen. Siemens Clinitek® Microalbumin 2 dipsticks were used to evaluate creatinine and microalbumin. Quidel QuickVue® cartridges were used to evaluate hCG. All tests were performed in triplicate.

**Results:** All tests performed on Level 1 maintained the appropriate negative/normal level for every analyte and every test method for up to 120 days at 25ºC and up to 600 days at 2-8ºC. All tests performed on Level 2 maintained the appropriate abnormal/elevated level for every analyte and every test method for up to 120 days at 25ºC and up to 600 days at 2-8ºC, with only one exception of the Urispec dipsticks failing to detect ketones only after 120 days at 25ºC.

**Conclusion:** The RT stability of at least 90 days for all analytes across several urine dipsticks exceeds the RT stability of all other urine controls formulated with native ketones on the market. The pouch design allows the user to visually verify that the dipstick is fully immersed into the control solution. The single-use feature minimizes the risk of contamination while the slim pouch design minimizes the volume required for testing. Lastly, the elongated rigid pouch design allows for a full dipstick immersion which directly simulates the dipping method utilized on patient samples. All of these features make the new Quantimetrix urinalysis dipstick control in the revolutionary single-use pouch the ideal companion for urinalysis POCT.

## B-258

### Lactate, procalcitonin, white blood cell, neutrophil and immature granulocyte count as biomarkers of sepsis, and severe sepsis or septic shock

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**Background:** We compared lactate, procalcitonin, white blood cell (WBC), neutrophil, and immature granulocyte (IG) count for the prediction of sepsis, and severe sepsis or septic shock in patients presenting to the Emergency Department (ED) with suspicion of sepsis.

**Methods:** We prospectively enrolled 501 patients presenting to the ED at St Marys Hospital (Rochester, MN) with suspected sepsis who had a sepsis panel (includes lactate, WBC and neutrophil count) ordered. WBC, neutrophil, and IG were measured on a Sysmex XT-2000i analyzer (Sysmex America) and lactate was measured by i-STAT (Abbott Diagnostics). Procalcitonin was later measured (Brahms Kryptor; Thermo Scientific) using frozen (-70C) EDTA plasma from the initial sepsis panel sample. Patients were classified as having sepsis if within 24 hours (of sepsis panel) they had 2 or more of the following: WBC>12 or <4, respiratory rate >20 (two consecutive measurements) or pCO2<32 mmHg, temperature>38C or <36C, or heart rate>90 (two consecutive measurements); ***and*** either a positive sterile site culture or suspected site of infection noted in ICU transfer or discharge records. Severe sepsis was defined as sepsis ***and*** development of blood lactate >4mmol/L or increased creatinine >0.5mg/dL within 5 days of sepsis panel. Septic shock was defined as severe sepsis ***and*** systolic blood pressure <90mmHg despite 30mL/kg fluid resuscitation. Univariate ROC sensitivity analysis was performed to determine the odds ratio (OR) and AUC for prediction of sepsis (no sepsis vs. any sepsis), and prediction of severe sepsis or septic shock (no sepsis or sepsis vs. severe sepsis or septic shock). Recursive partitioning and multivariable ROC analyses were used to determine whether a multi-marker strategy provided benefit over any single biomarker.

**Results:** There were 267 patients without sepsis, 199 patients with sepsis, and 35 patients with severe sepsis or septic shock. Lactate had the highest OR (1.44, 95$^{th}$% CI 1.20-1.73) for sepsis prediction; while WBC, neutrophil number and percent (neutrophil/WBC) had OR >1.00 ($p<0.05$) by univariate ROC analysis. IG number and percent (IG/WBC) and procalcitonin had OR that did not differ from 1.00 ($p>0.26$). Lactate, WBC, and neutrophil number/percent did not differ significantly in AUC (0.59-0.69), or optimal cut-off sensitivity (55-63%) or specificity (57-63%) for prediction of sepsis. Multi-marker models could improve either sensitivity or specificity of sepsis prediction (but not both) compared to any single biomarker. Initial lactate was the best biomarker for predicting severe sepsis or septic shock, with an odds ratio (95$^{th}$% CI) of 3.07(2.29-4.11) and AUC 0.88(0.81-0.96). At the optimal cut-off (1.9 mmol/L), lactate had a sensitivity 82.9(67.3-91.9)% and specificity 81.4(77.6-84.7)% for severe sepsis or septic shock. Multi-marker models did not improve the AUC, sensitivity, or specificity for prediction of severe sepsis or septic shock over lactate alone. In a subset of patients (n=182) who had positive sterile site cultures, lactate remained the best predictor of severe sepsis or septic shock.

**Conclusion:** Lactate was the best biomarker for prediction of severe sepsis or septic shock in patients presenting to the ED. Lactate, WBC, and neutrophil (count and percent) all had some value in predicting sepsis.

## B-259

### Comparison of Cardiac Troponin Specificity between the Stratus CS Acute Care Diagnostic System and the VITROS 5600 Integrated System

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**Background:** This study compared the clinical specificity for troponin I of the Stratus® CS Acute Care™ Diagnostic System from Siemens Healthcare Diagnostics and the Ortho Clinical Diagnostics VITROS® 5600 Integrated System used in emergency departments. Given troponin's high myocardial specificity and sensitivity, it is recognized as the preferred biochemical marker for myocardial damage. The results of cardiac troponin testing serve as guidance for intervention; cardiac troponin l measurements can be used as an aid in diagnosis of acute myocardial infarction (AMI) and in risk stratification of patients with acute coronary syndrome (ACS).

**Method:** A comparison study was conducted at the Community Hospital of the Monterey Peninsula comparing the VITROS 5600 system to the Stratus CS system. Random specimens with results on the VITROS 5600 system that fell specifically within the clinical decision window for observation or further work-up (between 0 and 0.10 ng/mL) were immediately run in parallel on the Stratus CS system and the values compared. A "positive" result is defined as one above the manufacturer's 99th percentile upper reference limit (URL) (0.034 ng/mL for the VITROS 5600 system and 0.07 ng/mL for the Stratus CS system), whereas "negative" is below the URL. A random chart review was performed on a subset of discrepant results (over 50%, selected randomly) by a pathologist to assess for further work-up, prolongation of hospital stay, and the presence or absence of acute myocardial infarction.

**Results:** 12 specimens were excluded from comparison because they were high and obviously positive for acute MI. 34 of 47 (72%) and 5 of 47 (11%) of the remaining specimens were positive on the VITROS 5600 and Stratus CS instruments, respectively. All specimens positive on the Stratus CS system were also positive on the VITROS 5600 system. Thus, 29 of 34 results (85%) were discrepant (all positive on the VITROS 5600 system and negative on the Stratus CS system). Review of the charts on 16 of the 29 discrepant results showed further work-up and prolonged hospital stays but no evidence of acute myocardial infarction in any of the cases (false-positive results).

**Conclusions:** The findings suggest a significantly higher rate of false-positive results with the VITROS 5600 system and support the argument that the Stratus CS instrument has a higher positive predictive value and specificity than the VITROS 5600 system, which may eliminate additional costly follow-up studies and time in the hospital. The higher specificity does not appear to come at the cost of lower sensitivity.

*Tracker artifact #A91DX-POC-150325-GC1-4A00*

## B-260

### Icon Norma Hematology analyzer compared with Sysmex XE-2100; a preliminary evaluation

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Background. Complete Blood Count (CBC) in POCT in the past was less success compared to chemistry or gas analysis, since the marketed analysers were time consumers showed less effective performance and yielded results less comparable to those provided by the analyzers used in main laboratory. Now a new generation hematology analyzer (based on volumetric impedance and microfluidics) is available: the aim of the study was to compare the analytical performance of the new hematology analyzer Icon to the XE-2100 Sysmex analyzers used in our laboratories.

Methods. We measured Red Blood Cells (RBC), Hemoglobin (Hb), Hematocrit (Ht), White Blood Cells (WBC), Platelets (PLT), Mean Cell Hemoglobin (MCH) Mean Cell Hemoglobin Concentration (MCHC) and Mean Cell Volume (MCV) in 105 consecutive samples received by Ravenna Laboratory. The analyses were carried out within one hour using Icon analyzer (Norma, Untertullnerbach, Austria) and XE-2100 (Sysmex, Kobe, Japan). Results were evaluated using Medcalc software (Ostende, Belgium).

Results. Comparison data yielded the following results: 1) RBC: Bland-Altman plot: Mean Difference %: XE-2100-ICON= 0.0 (+1.96=6.6;-6.6); Passing-Bablok regression analysis: ICON= 0.186+0.950 XE-2100; t-test: 0.936 (p=0.351); Wilcoxon test: p = 0.920; correlation coefficient r: 0.9915 (95% confidence interval = 0.9875-0.9942); 2) Hb: Bland-Altman plot: Mean Difference %: XE-2100-ICON= -0.7 (+1.96=6.2;-7.6); Passing-Bablok regression analysis: ICON= -0.368+1.040 XE-2100; t-test: -2.253 (p=0.0264); Wilcoxon test: p = 0.064; correlation coefficient r: 0.9821 (95% confidence interval = 0.9737-0.9878); 3) Ht: Bland-Altman plot: Mean Difference %: XE-2100-ICON = 0.6 (+1.96=8.1;-6.9); Passing-Bablok regression analysis: ICON=1.64+0.945 XE-2100; t-test: 1.995 (p=0.0487); Wilcoxon test: p = 0.068; correlation coefficient r: 0.9789 (95% confidence interval = 0.9691-0.9856); 4) MCH: Bland-Altman plot: Mean Difference %: XE-2100-ICON= 0.7 (+1.96 = 9.1;-7.8); Passing-Bablok regression analysis: ICON= 0.057+0.833 XE-2100; t-test: 2.163 (p=0.033); Wilcoxon test: p = 0.253; correlation coefficient r: 0.9717 (95% confidence interval = 0.9585-0.9807); 5) PLT: Bland-Altman plot: Mean Difference %: XE-2100-ICON=4.0 (+1.96 = 75.5;-83.4); Passing-Bablok regression analysis: ICON= 7,514+0.943 XE2100; t-test: 0.309 (p= 0.757); Wilcoxon test: p = 0.703; correlation coefficient r: 0.9919 (95% confidence interval 0.9881-0.9945); 6) WBC: for values >600 Bland-Altman plot: Mean Difference % XE-2100-ICON= 6.1 (+1.96 = 20.3;-32.6); Passing-Bablok regression analysis: ICON= 0.1614+0.9853 XE-2100; t-test: -2.456 (p=0.0163); Wilcoxon test: p = 0.0371; correlation coefficient r: 0.9899 (95% confidence interval 0.9841-0.9935).

Conclusions. The Icon analyzer not only yields results consistent with those obtained with XE-2100 particularly in RBC, Hb, Ht, PLT (for values > 20,000) counting, but also presents several features very important in a POCT environment such as extremely compact dimension (263 X 206 X 313 mm); limited weight (9.7 kg), high throughput (60 tests/hour), a two mode (open and close vial) functionality requiring respectively 9.8 and 15 uL sample volume, a totally touch screen interface with the operator production of histograms for WBC, RBC and PLT, all the reagents (diluent, lysant, etc) pack a single kit. The Icon is simple and practical to operate, very user friendly for nurses and Medical Doctors and demonstrated particularly suitable for POCT.

## B-261

### Evaluation of Whole Blood Basic Metabolic Panel Assay with Clinical Samples

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BACKGROUND: A Basic Metabolic Panel (BMP) is one of the most commonly ordered blood tests and it provides physicians with a quick assessment of patient electrolyte and fluid balance, blood sugar level and kidney function. A BMP cartridge based on electrochemical enzymatic creatinine and urea sensors for the GEM Premier analyzer (Instrumentation Laboratory) is currently in development. This is an addition to the electrolytes and metabolites currently offered on the GEM Premier analyzers. The goal of this clinical evaluation is to compare the whole blood (WB) analytical performance of GEM Premier BMP cartridge to the established reference methods.

METHODS: A total of 327 random samples were obtained from various sources (Emergency Department, Radiology, Critical Care Unit, Intensive Care Unit, Cardiothoracic and Outpatient). Both the heparinized WB and the plasma samples were analyzed on the GEM Premier analyzer (IL) with three BMP cartridges over the course of eight weeks. As reference methods, the WB samples were then assayed on a standard GEM Premier 4000 analyzer (IL) for Na+, K+, Ca++, Cl-, glucose, lactate, and hematocrit, the plasma was assayed on the ARCHITECT c8000 analyzer (Abbott Laboratory) for creatinine, BUN, and tCO2. A large portion of the patient samples were tested against the ARCHETECT as the focus was to evaluate the new assays under development.

RESULTS: The WB creatinine, BUN and tCO2 results from GEM Premier BMP cartridge compared well with those obtained from plasma on the reference analyzer across the ranges of the tested samples. Noticeable intercepts of Na+ and Cl- were due to the narrow ranges of samples tested. The correlation of the GEM Premier BMP cartridge vs. references is summarized in Table 1.

CONCLUSIONS: Good correlations were observed between the GEM Premier BMP cartridge and the reference methods. It can provide reliable WB BMP information with quick turnaround time in Point of Care environments.

Table 1. Correlation of the GEM BMP vs. References (a) ARCHITECT (N=665), (b) GEM 4000 (N=121)

| Analyte | Slope | Intercept | R^2 | Sample Range |
|---|---|---|---|---|
| tCO2 (a) | 0.8622 | 3.1333 | 0.920 | 8-36 mmol/L |
| Crea (a) | 0.9349 | 0.0806 | 0.937 | 0.28-10.32 mg/dL |
| BUN (a) | 0.9024 | 1.4482 | 0.989 | 4-125 mg/dL |
| Na+ (b) | 1.1145 | -15.961 | 0.935 | 128-150 mmol/L |
| K+ (b) | 0.9499 | 0.1763 | 0.984 | 2.7-5.9 mmol/L |
| Cl- (b) | 0.8347 | 17.752 | 0.941 | 94-119 mmol/L |
| Ca++ (b) | 0.894 | 0.0497 | 0.963 | 0.85-1.31 mmol/L |
| Hct (b) | 1.0431 | -0.1532 | 0.985 | 15-56 % |
| Glu (b) | 0.9673 | 1.3615 | 0.996 | 9-219 mg/dL |
| Lac (b) | 1.0312 | -0.1512 | 0.995 | 0.6-14.4 mmol/L |

## B-262

### Performance Evaluation Of Roche Cobas b 221 Point Of Care Blood Gas Analyzers Used In Intensive Care Units

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**Background:**Blood gas analyzers are important in assessing and monitoring critically ill patients. It is vital for the purpose of patient care to assure that all analyzers installed in the same unit give comparable results. Recently, 6 point of care Roche cobas b 221 blood gas analyzers were installed in neonatal , pediatric and adult intensive care units(ICU).The objective of this study was to evaluate the performance of these analyzers in measuring blood gases and whole blood electrolytes in the ICU setup.

**Methods:**A total of 60 blood gas samples were evaluated in this study for method comparison for analyzers that were installed in the same units,using heparinized arterial and capillary blood that were collected from adult, pediatric and neonatal ICU patients .Twenty samples were analyzed at each site immediately upon collection. Correlation for blood gases [pH, partial pressure of carbon dioxide(pC02), partial pressure of oxygen (pO2) and whole blood electrolytes [sodium(Na+), potassium(K+), chloride (Cl-),and ionized calcium(Ca2+)] were calculated for each machine. Regression analysis was used for the validation and the allowable systematic error.Precision study was done on quality control solutions at three different level concentrations for each test and coefficients of variation(CVs) were calculated. Linearity was done using 5 different concentrations spanning the analytical range for each test.

**Results**:All% CVs were consistent with those claimed by the manufacturer for all tests at all three concentration levels.% CVs of level 1 for pH, pC02, p02,Na+; K+,Cl-, and ionized Ca2 were less than or equal to 0.08, 2.72, 8.20,0.93,0.95,1.96,0.98 ,level 2 were less than or equal to 0.06,1.74, 5.38, 0.55,0.53,0.97,1.20,and level 3 were less than or equal to 0.07,2.74,4.51, 0.53,0.74,0.87,1.43 respectively .pH,pC02, pO2,Na+; K+, Cl- and ionized Ca2 were linear over a measured range of 6.87-7.70,12-126 mmHg,24-457 mmHg,90 -173 mmol/L ,2.0-8.8mmol/L,68-131 mmol/L,and 0.42-2.59 mmol/L, respectively. All analyzers located in the same unit showed satisfactory correlation between the results for all tests, the correlation coefficients were ≥0.975 for all tests.

**Conclusion:**Overall performance of cobas b 221 system was acceptable,it provided reliable results for all tests in all ICUs.

## B-263

### Harmonization Verification of three Platforms for Assaying Patient Blood Glucose. A Practical Example Using Polynomial Regression Analysis.

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***Background:*** In our hospital patient blod glucose is assayed with three different platforms, namely cobas c-501®, the laboratory method (LM), i-STAT® cartridges and ACCU-CHEK® *Inform*II, the point of care (POCT) methods. Evaluation of the performance of the two POCT methods versus that of the LM gives important information to the physicians regarding the harmonization and interchangeability of

the results for patient care. We employed polynomial regression analysis to evaluate bias, linearity, and equality of the regression lines. M***ethods:*** Patient specimens were collected by venipuncture in green top test tubes (Becton-Dickinson) and analyzed with the three methods in parallel and within 15 minutes. The observations were transferred to Minitab® (version 16, Minitab Inc.) statistical software.Since previous experience had shown increase in variance for increasing values of blood glucose as determined with the three platforms, the values obtained with the POCT methods (dependent variables) were regressed against those obtained with the LM (independent variables) using a weighted polynomial regression model with coded variables (1 for ACCU-CHEK® *Inform* II, 2 for i-STAT®). ***Results*:** The weighted polynomial regression equation was: POCT= 1.7 + 0.98 LM + 0.87 POCT coded. The t-test for the beta of POCT methods showed that it was not statistically significantly different from zero (P=0.42). This indicated that there were no statistically significant differences between the regression lines of the two POCT methods. The analysis of the standardized deleted residuals (SDR) showed that they were quasi-normally distributed, that there were six potential outliers (SDR >|3|) and no statistically significant autocorreletion. The leverage and the Cook's distance did not show influential observations. For glucose blood values exceeding 450 mg/dL there was a curvilinear relationship.This was confirmed by the pure error test with data subsetting (P<0.001) and visually supported by the locally weighted scatterplot smoother(lowess) model. The plot of the differences between the POCT methods and the laboratory method showed that for values greater than 60 mg/dL the relative differences were within ±20% for ACCU-CHEK® *Inform*II and within ±10% for i-STAT; for values less than 60 mg/dL 85% (23/27) of the absolute differences were within ± 6 mg/dL. ***Conclusions*:** These results indicated that , for monitoring patient blood glucose,values obtained with the POCT methods within the interval 60-450 mg/dL may be used interchangeably with those obtained with the laboratory method and that values exceeding this interval should be confirmed with the laboratory method. This study also clearly showed that the availability of appropriate statistical software, such as Minitab®, using a multivariable weighted regression model supported by numerical and graphic diagnostic techniques, allowed the direct comparison of two POCT methods with a reference laboratory method.

## B-264

### Evaluation of Liver Function Tests on Piccolo Xpress Chemistry Analyzer

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**Background:** Point of care testing (POCT) provides fast turnaround time of test results and easy use of assays for diagnosis and monitoring. We evaluated the analytical performance of the Abaxis Piccolo Xpress point of care chemistry analyzer using the Liver Panel Plus discs (provided by Abaxis) for our pediatric patient population.

**Methods:** Evaluations were performed on alanine aminotransferase (ALT), albumin (ALB), alkaline phosphatase (ALP), amylase, aspartate aminotransferase (AST), Gamma glutamyltransferase (GGT), total bilirubin (TBIL) and total protein (TP) assays. Intra- and inter-assay precision studies were conducted using two levels of quality control materials as ten replicates. Linearity studies were performed using commercially available verification samples at three concentration levels as five replicates. Comparison studies were carried out on twenty samples using Piccolo Xpress chemistry analyzer and Vitros 5600 analyzer. Interference from hemolysis, lipemia and icterus were performed using nine different patient pool sera. Severe lipemic sample pools were treated with LipoClear to remove lipemia interference.

**Results:** The percent coefficient of variations (%CV) were less than 5% for intra- and inter-assay precision on all measured assays except TBIL which had %CV of 7.8% and 5.3% at low QC level for intra- and inter-assay precision, respectively. Results of linearity studies showed that all results were linear and accurate within the allowable total error. Results of comparison studies showed that ALP and TBIL did not have significant bias. Among others ALB, ALT, AST and TP had small but significant bias while AMY and GGT had significant bias (>10%) which could be due to differences in methodologies. None of the analytes were affected by hemolysis (p>0.05) up to interferent concentrations of 300 mg/dL. All eight analytes were not affected by icteric interference at concentrations of 7.5 mg/dL and 15 mg/dL. Five analytes (ALB, AMY, GGT, TBIL and TP) were not affected from mild, moderate and severe lipemia. AST and ALT was not affected by mild lipemia while both analytes were affected by moderate lipemia. ALT was the only analyte which was affected from mild lipemia. Treatment with LipoClear abrogated lipemic interference for all analytes except TP.

**Conclusions:** The analytical performance of the Abaxis Piccolo Xpress chemistry analyzer was acceptable for precision, linearity and interference from common substances. The good performance and capability of analysis for eight analytes using only 100 µL whole blood sample make the analyzer a good alternative for bedside analysis in infectious patients in the pediatric setting, as well as in remote areas.

## B-265

### Telehealth and Glucose Monitoring in Nursing Homes and Patient's Residence

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Fifteen years ago we proposed point-of-care (POCT) glucose monitoring away from the hospital environment, employing the PC and Internet for data transmission (Clin Chem

2000; 46(6): Suppl, p47, Abstract 22). Our efforts were a failure due to the lack of technical support at both ends, especially since physician offices were not wired at that time for an electronic health record (EHR). In the area of medical technology, the recent buzz words are Telehealth and Cloud (T&C). In simple terms, T & C is a replacement of expensive and bulky computer hardware with software applications that run on less expensive special computers and also meet cloud computing requirements. Realizing the need for increased self-management of diabetes, we have written a software app for this purpose using generic hardware (smart phones, androids, tablets, glucometer, etc.) and supplies (e.g., test strips). We have reduced patient identification errors by restricting the use of a glucometer to one person. If more than one person is using the same glucometer (e.g. nursing homes) the name and date of birth of the patient should appear on the screen for proper identification. For each user, under his or her name and date of birth, the latest prescription medications for diabetic control are also listed.

We have also introduced the concept of an upper limit of glucose (>160 mg/dL) and lower limit of glucose (<60 mg/dL) to modulate the dosage. Another feature of quality control is the repeat assay in case of glucose values > 160 mg/dL or < 60 mg/dL. The repeat assay must provide glucose results within ± 5 mg/dL. The glucose results are transmitted by a disconnected mechanism (e.g. WiFi) to the user's cell phone. The patient's glucose data is stored in a "Private" cloud using a de-identified mechanism to protect patient's identity. The patient's results are transmitted in real time basis into the EHR at the physician office. All abnormal results, e.g. > 160 mg/dL and < 60 mg/dL are flagged for the review of the physician. A weekly graph of the glucose values for the past 30 days is also provided to the physician for his or her review. Finally we envisage, as for any other medical device and procedure, a proper training of the user.

## B-266

### Accuracy assessment of three different cartridge lots of the LABGEO PT Hemoglobin A1c Test using reference materials

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**Background:** Since the point-of-care (POC) hemoglobin A1c (HbA1c) testing plays an important role for monitoring glycemic control and determining treatment strategies in patient with diabetes mellitus, both accurate measurement of HbA1c and minimal reagent lot-to-lot variability are essential for POC HbA1c assay. In this study, the accuracy of three different cartridge lots of the Samsung LABGEO PT HbA1c test (Samsung Electronics, South Korea) was investigated to determine whether the result of the LABGEO PT HbA1c test can be used for follow-up and screening of diabetes patients.

**Methods:** The Samsung LABGEO PT10 device and three different lots of LABGEO PT HbA1c test cartridge were used. A total of 7 levels of reference materials, 3 levels of certified reference materials and 4 levels of in-house reference materials, were measured using each cartridges in duplicate manner for three days. The bias (measured value minus reference value), within-laboratory precision, and total error were calculated, and medical-decision point analysis was performed.

**Results:** The mean bias was 0.23 for lot number 1, 0.11 for lot number 2 and0.06 for lot number 3. The mean percent bias was 3.3% (range, 0.7% to 5.0%) for lot number 1, 1.5% The correlation coefficient of lot number 1, 2 and 3 was 0.989, 0.987 and 0.977, respectively. The mean absolute bias (%), coefficient of variation (%) and total error (%) of each cartridge were 3.3%, 2.5% and 8.1%, respectively, for lot number 1; 1.9%, 2.6% and 7.1%, respectively, for lot number 2; and 2.7%, 2.8% and 8.1%, respectively, for lot number 3. The predicted value (95% confidence interval) of each cartridge at 6.5% of HbA1c was 6.74 (6.66-6.83) for lot number 1, 6.60 (6.51-6.70) for lot number 2, and 6.51 (6.39 -6.63) for lot number 3.

**Conclusions:** The performance of the LABGEO PT HbA1c Test showed within ±6.0% of bias, with less than 3.0% of imprecision and 9.0% of total error. In addition,

the lot-to-lot variability of the LABGEO PT HbA1c Test was negligible. Therefore we thought that the LABGEO PT HbA1c Test could be used for monitoring of diabetic patients, and for diabetes screening with a false positive result in the doctor's office.

## B-268

### Roche Accu-Check® Inform II Blood Glucose Meter Reduces Maltose Interference and Risk to Patient Safety

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**Background:** Roche Accu-Check® Inform II blood glucose test strips were developed to replace Comfort Curve strips previously reported to give falsely elevated glucose levels in patients treated with maltose-containing or maltose-producing therapies e.g. some immunoglobulin preparations or peritoneal dialysis solution containing icodextrin. Strip chemistries susceptible to maltose interference can be misinterpreted and risk inappropriate insulin dosing and subsequent consequences of hypoglycemia. Inform II uses a variant of quinoprotein glucose dehydrogenase (Mut. Q-GDH enzyme) to eliminate maltose interference.

**Objective:** Verify that Inform II does not suffer interference from maltose up to 360 mg/mL and confirm assay performance compared to UniCel DxC800 (Beckman Coulter) analyzer used in our laboratory.

**Methods:** Clinical studies showed that plasma maltose concentration of up to 600 mg/dL could be expected in some individuals. We used plasma (lithium heparin) at low (46 mg/mL), medium (145 mg/mL), and high (243 and 364 mg/mL) glucose concentrations. To 1 mL of each sample, maltose powder was added to obtain the final concentrations of 280, 630, 990 mg/dL of maltose. Glucose concentrations were measured with Inform I & Inform II meters and Beckman DxC800, which is not subject to maltose interference.

**Results:** The difference in glucose concentrations between maltose-containing and maltose-free samples in patient specimens measured by the Beckman DxC800 glucose oxidase, Inform I, and Inform II methods are summarized below:

| Initial Glucose concentrations with Inform I, Inform II, and DxC800, mg/dL | Maltose added, mg/dL | Glucose with DxC800, mg/dL | Glucose with Inform I, mg/dL | Glucose with Inform II, mg/dL | Δ Glucose with DxC800, mg/dL | Δ Glucose with Inform I, mg/dL | Δ Glucose with Inform II, mg/dL |
|---|---|---|---|---|---|---|---|
| Patient A (44, 51, 46) | A + 280 | 44 | 143 | 56 | 2 (5%) | 99 (69%) | 5 (9%) |
| | A + 630 | 43 | 268 | 71 | 3 | 224 | 20 |
| | A + 990 | 44 | 431 | 80 | 2 | 387 | 29 |
| Patient B (147, 159, 145) | B + 280 | 149 | 263 | 163 | 4 (3%) | 116 (44%) | 4 (2%) |
| | B + 630 | 149 | 388 | 174 | 4 | 241 | 15 |
| | B + 990 | 150 | 529 | 182 | 5 | 382 | 23 |
| Patient C (219, 227, 243) | C + 280 | 250 | 349 | 218 | 7 (3%) | 130 (37%) | 9 (4%) |
| | C + 630 | 255 | 516 | 233 | 12 | 297 | 6 |
| | C + 990 | 252 | qns | 253 | 9 | qns | 26 |
| Patient D (359, 417, 364) | D + 280 | 367 | 469 | 423 | 3 (1%) | 110 (23%) | 6 (1%) |
| | D + 630 | 371 | qns | 432 | 7 | qns | 15 |
| | D + 990 | 370 | qns | 441 | 6 | qns | 24 |

**Conclusions:** No clinically significant interference by maltose up to 360 mg/mL was found with Inform II strips, confirming the manufacturers' claim. Maltose > 360 mg/mL increased glucose readings on Inform II, but the increase likely will not change the clinical decision to control blood glucose levels in these patients.

Recovery of glucose after spiking was consistent with CLSI EP7-A2 (< +/-10 mg/mL at glucose <100 mg/mL and < +/-10 % at glucose >100 mg/mL).

## B-269

### A point-of-care experience with GeneXpert MTB/RIF assay performance in detecting Mycobacterium tuberculosis and rifampicin resistance.

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**Background:**

Tuberculosis (TB) remains a major threat to public health, exacerbated by the emergence of multiple drug-resistant (MDR), defined as resistance to the first line anti-TB drugs such as isoniazid and rifampicin (RIF). About 9.4 million new tuberculosis cases and 2 million TB-related deaths occur every year. Rapid TB diagnosis and drug-resistance detection is important to reduce TB-related morbidity and mortality, especially in regions where TB is endemic.

**Objective:**

To evaluate the GeneXpert MTB/ RIF assay as a rapid point-of-care diagnosis of TB in a private hospital in São Paulo, Brazil, from July 2014 to January 2015.

**Methods:**

Clinical specimens from patients suspected to have TB were analyzed by GeneXpert assay at the site hospital laboratory. The test was used in hospitalized patients as the initial test for TB diagnosis with a turnaround of two hours. The GeneXpert MTB/RIF assay (Cepheid, Sunnyvale, CA, USA) uses real-time PCR for simultaneous detection of *Mycobacterium tuberculosis* (MTB) *rpoB* gene and mutations associated with rifampicin resistance.

**Results:**

A total of 55 samples were tested, including 41 respiratory (sputum and bronchoalveolar lavage) and 14 other clinical specimens (biopsies, urine, synovial liíquido, pleural fluid, breast secretion and other). A total of 8 samples were positive - 5 respiratory, 2 bone biopsies and 1 synovial fluid specimen. Two specimens (one bronco alveolar fluid and one sputum) detected by GeneXpert were also positive by both smear microscopy and mycobacterial culture. Mutations associated with rifampicin resistance was not detect in any of the studied samples.

**Conclusion:**

GeneXpert MTB/RIF assay is more sensitive than smear microscopy and culture for detection of TB in respiratory specimens. Considering little hand-on time, easy to perform, easy to implement, point-of-care capability, the GeneXpert MTB/RIF assay is an excellent option for TB diagnosis. Rapid point-of-care diagnosis is needed to provide a better management of hospitalized TB patients and infection control procedures at the hospital setting. Investment in the TB diagnostics pipeline should remain a major priority for health care funders.

## B-270

### Comparison of Two Methods for Monitoring Compliance and Thoroughness of Glucose Meter Disinfection Practices

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**Background:**

Improper use of blood glucose test systems in healthcare environments has been linked with hepatitis B virus infection outbreaks in the United States. In 2010, the Centers for Disease Control and Prevention (CDC) released recommendations for cleaning and disinfecting glucose meters after every use if a glucose meter cannot be dedicated to a single patient; moreover, recommends periodic assessment of user compliance with disinfection practices. Previous studies have highlighted advantages and limitations in methods for monitoring disinfection practices in environmental health services; however, limited studies have compared methods for monitoring disinfections practices in point-of-care (POC) testing services. Fluorescent gel markers are used routinely to covertly monitor environmental cleaning in healthcare. With technological advances, select glucose meters can electronically capture user comments upon test result verification. The aim of this study was to compare fluorescent gel marker versus user entry of a "disinfection" comment for monitoring compliance and thoroughness of glucose meter disinfection practices within 1 institution.

**Methods:**

Study inclusion criteria included trained users of StatStrip glucose meter (Nova Biomedical, Waltham, MA) who performed routine patient testing within 7 wards at the University of North Carolina Hospital between October-November, 2014. All

users (n>400) were trained to enter a "disinfection" comment within the glucose meter upon patient result verification, with immediate device disinfection using a Super Sani-Cloth (Professional Disposables International, Inc, Orangeburg, NY). Comments entered in glucose meters were automatically transmitted to Telcor data management system (TELCOR, Inc., Lincoln, NE) upon device docking. On 12 random days within the study period, 12 glucose meters located in the 7 wards were each covertly marked with Dazo Fluorescent Marking gel (Ecolab, St. Paul, MN) in 2 places; near the test-strip port and on the "OK" button on the device surface. Following a single patient test, the glucose meters were covertly examined for presence/absence of fluorescent marker using a black-light and (non)entry of the disinfection comment using Telcor software. Glucose meters not used for patient testing or performed > one patient test during the observation were excluded; 50 observations from 36 users performing routine testing were included in analyses. The % disinfection compliance rate using fluorescent marker=(# devices with ≥1 marker removed/50)*100. Disinfection thoroughness (%) =(# devices with both fluorescent markers removed/# devices with ≥ 1 marker removed)*100. The % disinfection compliance rate using "disinfection" comment =((#"disinfection" comment entries/50)*100).

**Results:**

98% compliance with glucose meter disinfection was captured using the "disinfection" comment method. Using the fluorescent marker approach identified 64% disinfection compliance, of which, 59% demonstrated thoroughness in glucose meter disinfection practices.

**Conclusion:**

Monitoring glucose meter disinfection using user entry of a "disinfection" comment versus covert fluorescent marker observation demonstrated poor concordance in compliance rate. Reasons for the discordance remain unclear. A limitation of the "disinfection" comment method is inability to assess the thoroughness of glucose meter disinfection, whereas the fluorescent marker method demonstrated poor thoroughness in disinfection practices within our study cohort. Altogether, this study highlights the need for active monitoring of glucose meter disinfection practices to proactively minimize risk of infection transmission.

## B-271

### Determination of Analytical Performance Characteristics of the RAMP® D-dimer Test

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Background: The RAMP® D-dimer test is a quantitative immunochromatographic test for the determination of the fibrinogen degradation product (FDP) D-dimer in human EDTA anti-coagulated whole blood. D-dimer is considered to be a marker of coagulation activation and is present in the circulation as part of the normal wound healing process. It is also valuable as a diagnostic marker for Disseminated Intravascular Coagulation (DIC) and as an aid to the rule-out of Venous Thromboembolism (VTE), a spectrum of diseases that include Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE). The objective of these studies was to determine the analytical performance characteristics of the RAMP D-dimer test.

Methods: Detection limits, linearity, hook effect, repeatability, total precision, interference and cross-reactivity were determined for the RAMP D-dimer test according to methods outlined in CLSI guidelines, where applicable, using either plasma-based controls or EDTA whole blood samples.

Results: The limit of blank (LoB) and limit of detection (LoD) were determined to be 51 ng/mL FEU and 89 ng/mL FEU, respectively, using methods described in EP17-A. The 20% and 10% limits of quantitation (LoQ) were determined to be 419 ng/mL FEU and 839 ng/mL FEU, respectively, using total error estimates as described in EP17-A. Linearity was determined as per EP6-A on three lots of RAMP D-dimer tests, meeting a goal for total error of ≤ 20% from 100 to 5000 ng/mL FEU. No high dose hook effect was observed up to 250,000 ng/mL FEU.

Repeatability and total precision were determined as per EP5-A2 by testing three levels of frozen plasma control materials in duplicate, twice per day for 12 days on three lots of RAMP D-dimer tests. Repeatability and total precision CVs were 6.6 and 8.5% at 363 ng/mL FEU, 5.4 and 6.3% at 656 ng/mL FEU and 6.5 and 6.9% at 4044 ng/mL FEU, respectively. Repeatability and total precision were also determined for whole blood samples by testing three levels in triplicate, in five runs over three days on three lots of RAMP® D-dimer tests. Repeatability and total precision CVs were 19.7 and 22.6% at 174 ng/mL FEU, 10.3 and 12.3% at 465 ng/mL FEU and 7.8 and 10.0% at 2753 ng/mL FEU respectively.

As per EP7-A2, no interference was observed in the RAMP D-dimer test as the result of hemoglobin (200 mg/dL), bilirubin (conjugated 5 mg/dL, unconjugated 15 mg/dL), cholesterol and triglycerides (500 mg/dL each), gamma-globulins (60 mg/dL) or 45 common pharmaceutical compounds (3 x MRTD). No statistically significant cross-reactivity was observed with fibrinogen (1 mg/mL) or fragment E (20ug/mL); a bias of 0.009 ng/mL per unit was observed for fragment D.

Conclusion: The RAMP D-dimer test demonstrated acceptable analytical performance for the quantification of D-dimer, based on methods outlined in applicable CLSI guidelines.

## B-272

### Analytical validation of MRSA detection test through GeneXpert®.

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**Background:**

Healthcare-associated-infections affect hundreds of millions of patients worldwide every year and represent an important cause of morbidity and mortality. Methicillin-resistant *Staphylococcus aureus* (MRSA), now endemic in many healthcare facilities, is a leading cause of healthcare associated infections; patients in intensive care and surgical units are at increased risk for MRSA infections due to factors such as invasive procedures, antibiotic exposure and prolonged healthcare contact. Controlling MRSA is a primary focus of most hospital infection control programs. Currently, the standard surveillance method for detecting MRSA is culture, which is very laborious and time intensive. A rapid and more sensitive method for active surveillance of MRSA will represent a definite advantage for infection control programs.

**Objective:**

Validate the Xpert® MRSA assay (Cepheid) to identify MRSA using two comparative conventional tests: PCR and phenotypic identification by Vitek®2 (bioMérieux).

**Methods:**

Validation experiments were conducted with ten available laboratorial strains of MRSA previously detected by two conventional validated tests: phenotypic identification by Vitek®2 and an in-house real-time reaction. The GeneXpert Dx System is a polymerase chain reaction-based method for identifying *S. aureus* and methicillin resistance using an automated system. The system requires the use of single use disposable GeneXpert cartridges that hold the PCR reagents and host the PCR process. Because the cartridges are self-contained, cross-contamination between samples is eliminated. The GeneXpert MRSA assays were performed according to the manufacturer's package insert, and results were interpreted directly from the report generated by the GeneXpert instrument. In-house PCR was based on the identification of mecA gene.

**Results:**

Among 10 available laboratorial strains, the Xpert® MRSA test showed agreement of 90% (within in-house PCR and Vitek®2 results). All MRSA strains identified by Vitek®2 (5/10) were suggestive of *mec*A, in accordance with in-house PCR results. One strain fell on the validation procedure, while the laboratory partner and Vitek®2 system had a negative result to MRSA and GeneXpert had a positive result. The turnaround time of GeneXpert was faster compared with the other tests, taking 69 minutes from beginning to result.

**Conclusion:**

We found that GeneXpert Dx System had a good performance to identify MRSA compared to in-house PCR and Vitek and it was a rapid and accurate tool with a good turnaround time. The good sensibility and faster speed in delivering the final results has a potential benefit in clinical practice, permitting to reduce length of stay, unnecessary hospital admissions and antimicrobial therapy. Also, GeneXpert can optimize effectiveness of infection control programs.

## B-273

### Linearity Standards for Automated Urinalysis Systems

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**Background:** Currently urinalysis systems are not required to undergo calibration verification, reportable range, and new instrument performance validation using linearity standards. Linearity standards have long been used to perform calibration verification, reportable range, and new instrument performance validation of quantitative methods in the clinical laboratory as required by CLIA 88 regulations. Traditionally, linearity standards were not required for urinalysis because it was performed visually by operators using urine test strips. Increasingly, urinalysis is performed by automated and semi-automated instruments, but the use of linearity

standards for these devices has not yet been incorporated into standard practice. As the clinical laboratory environment becomes more regulated, requirements for linearity standards testing may be applied to urinalysis systems in the future. This study is designed to show that linearity standards can be formulated for urinalysis systems and that they can be used for calibration verification, reportable range, and new instrument performance validation of these systems. **Method:** Liquid ready to use linearity control solutions were prepared at Quantimetrix Corporation from human urine with added reagents to simulate positive human samples for each of the analytes on the Multistix® 10 SG strips; leucocytes, nitrite, urobilinogen, protein, pH, blood, specific gravity, ketones, bilirubin, and glucose. Analyte concentrations were targeted to the mid-point of each test pad on a Siemens Multistix10 SG reagent strip. Each linearity standard was tested by performing ten measurements on four different Siemens Clinitek Status® or Status Plus readers, for a total of 40 measurements per test point. Testing was performed as per the Siemens Multistix 10 SG and Siemens Status or Status Plus operating instructions. **Results:** All standard solutions met the requirements of the study 1) ≥70% of the results were on the targeted pad 2) no test results greater than 1 pad away from the targeted pad. **Conclusions:** The solutions prepared in this study produced results on the Multistix 10 SG and Clinitek Status system that effectively demonstrated calibration verification and reportable range for the test instruments. Similar linearity standard sets could be developed for other urinalysis systems in the future.

## B-274

### An RNA Aptamer that Specifically Binds to Mycolactone and Serves as a Diagnostic Tool for Buruli Ulcer

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**Background:** Buruli Ulcer Disease (BUD) is a neglected tropical disease caused by *Mycobacterium ulcerans*. It is the third most common mycobacterial disease after tuberculosis and leprosy. It is characterized by extensive destruction of skin and soft tissues with the formation of large ulcers usually on body extremities. BUD is often diagnosed late and molecular methods for confirmation are unavailable outside of major reference laboratories. Mycolactone, the virulence factor responsible for the pathology of BU is present in BUD infected human tissue. It is widely distributed within a lesion. It can also be found at every stage of the disease and thus, a useful marker for diagnosis. However, the chemical nature of mycolactone as a poor immunogenic lipid molecule has impeded efforts to produce a diagnostic based on an anti-mycolactone. With the advent of antibiotic therapy it is even more imperative for early diagnosis of BUD for effective treatment to prevent the morbid effects of the disease. Aptamers, a novel sensitive and specific class of detection molecules, has hitherto not been raised against mycolactone.

**Methods**: The ribozyme hammerhead was used as a template for aptamer selection using the systemic evolution of ligands by exponential enrichment (SELEX) process. Aptamers were selected against target mycolactone over counter-target comprised of cellular protein extract. A given round of selection began with incubating library members in the buffer alone (negative selection), then collecting the portion of the library that did not respond (i.e. cleave). Each round finished with a positive selection against mycolactone in buffer, where the non-cleaving material collected from the prior step was incubated with the target and the responsive (i.e. cleaved) material was then collected to regenerate the library for the next round. A counter-selection step was included between the negative and positive selections. Each selection round was followed by reverse transcription to generate cDNA, library amplification through PCR, and regeneration of the RNA library by transcription. After subjecting the initial library of diverse random sequences to 7 consecutive rounds of selection, the enriched library was divided into three fractions to perform the parallel assessment after which the three clones were sequenced. Bioinformatics analysis of the sequencing data identified candidate aptamers. To assess their affinity and specificity to the mycolactone, aptamers were screened using enzyme linked oligonucleotide assay (ELONA). The most promising aptamer was evaluated using samples obtained from 20 BUD patients and healthy volunteers. Cut-points were evaluated using ROC curve analysis.

**Results:** 197007 sequences were analyzed from the positive target-exposed library. From this set of data, 6859 sequence families were constructed containing between 10 and 583 members each. Five RNA aptamers specific to mycolactone were identified, their structure predicted by the M-fold program, based on Zuker algorithm. Their dissociation constant (kd) values were in the nano-molar range. One aptamer, designated NM209D was evaluated using swab and needle aspirate samples. NM209D had sensitivity and specificity of 100% and 65.9%.

**Conclusion:** Ribozyme based RNA aptamers specifically binds to mycolactone and can serve as a diagnostic tool for early diagnosis of BUD

## B-275

### Inaccurate Point-of-Care Glucose in a Critically Ill Patient due to Norepinephrine Administration

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**Background:** In light of the recent CMS warning that use of waived blood glucose measurement systems (BGMS) on critically ill patients is "off label" and the follow-up CAP requirement for hospitals to define "critically ill" and the use of BGMS in these patients, we evaluated the possible causes of undetectable capillary point-of-care glucose (POC) in a 29 y/o African American male who was admitted in the surgical Intensive Care Unit (SICU) following a traumatic brain injury. **Method:** Capillary whole blood POC glucose was measured with the NOVA StatStrip®, now FDA-cleared for use on Intensive Care patients. The StatStrip uses an amperometric, plasma calibrated glucose oxidase method, but results are independent of sample $PO_2$. Laboratory glucose was measured in venous plasma samples on the Vitros® 5600 by the glucose oxidase method. The bias in glucose results (POC – Lab) was calculated for samples with collection times within 60 minutes of each other. Glucose bias was plotted against arterial $PO_2$ and pH, systolic blood pressure (SBP), hematocrit and platelet count, and the administration of drugs, including a neuromuscular blocker (cisatracurium), a vasoconstrictor (norepinephrine), and an antiarrhythmic (amiodarone). These graphs were evaluated visually for temporal correlation of changes in glucose bias with the listed potential factors. **Results:** Clinically significant negative bias (-25 to -134 mg/dL) occurred on hospital days 3 and 4. During this time arterial $PO_2$ ranged from 53 to 230 mmHg without correlation between $PO_2$ and glucose bias. The arterial pH was low (7.14-7.30) during the period of maximum negative bias, but pH was also low at times when there was no significant bias. SBP was very low (60-100 mmHg) throughout the hospital stay and did not correlate with glucose bias. Hematocrit and platelet count did not correlate with glucose bias. In addition, during the time when all of the discrepancies occurred, 3 different meters were used by 6 different operators. Thus, it appears unlikely that a meter or operator is responsible for the discrepancies. Of the drugs listed above, the only one for which the administration correlated with the glucose bias was norepinephrine. **Conclusion:** Norepinephrine administration accounts for the marked negative glucose bias. Norepinephrine, among other actions, functions as a peripheral vasoconstrictor to raise the blood pressure. This results in markedly reduced capillary blood flow, blood stasis in the capillaries and metabolism of the capillary glucose. Patients who are in shock or otherwise have poor peripheral circulation should not have POC glucose measured on capillary blood.

## B-276

### Discrepancies in Hematocrit and Hemoglobin Measurements by Point-of-Care (POC) Devices and Laboratory Instruments in Patients with Hemodilution

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Background:

Hematocrit (HCT) and Hemoglobin (HGB) can be measured with multiple systems based on different principles. i-STAT is one of the frequently used POC devices to measure HCT and HBG in hospital settings. For patients undergoing surgeries, HCT and HBG can be skewed due to hemodilution, if the modes for calibration and compensation of hemodilution are not selected on i-STAT. However, bias may still exist when compared with other laboratory systems, even if the right mode is selected for i-STAT. The objective of the study is to determine the accuracy of i-STAT for HCT and HGB measurements in patients undergoing surgeries when K3EDTA/CPB (Cardio Pulmonary Bypass) mode is selected by comparing i-STAT with other laboratory instruments.

Methods:

In i-STAT, HCT was measured based on conductivity of red blood cells and HGB was calculated according to HCT values. Similarly, HCT was measured by Sysmex according to voltage changes produced by cells, but HGB was measured spectrophotometrically by sodium lauryl sulfate reaction with HGB. HCT was

calculated based on HGB, which was measured by oximetry in Radiometer. The study was performed using 25 samples from patients undergoing surgeries in an operating room. HCT and HGB were analyzed in duplicate on all systems. Deming linear regression analysis was performed for HCT and HGB results for i-STAT vs Radiometer, i-STAT vs Sysmex, and Radiometer vs Sysmex.

Results:

The Deming linear regression analysis for HCT and HGB between different systems was shown below.

HCT

i-STAT (Y) vs Radiometer (X): Y = 0.84 X + 4.39 (r = 0.92); i-STAT (Y) vs Sysmex (X): Y = 0.99 X + 0.09 (r = 0.92); Radiometer (Y) vs Sysmex (X): Y = 1.14 X - 3.70 (r = 0.98).

HGB

i-STAT (Y) vs Radiometer (X): Y = 0.86 X + 1.68 (r = 0.91); i-STAT (Y) vs Sysmex (X): Y = 0.89 X + 1.29 (r = 0.90); Radiometer (Y) vs Sysmex (X): Y = 1.04 X - 0.44 (r = 0.98).

Conclusions:

i-STAT is in a better agreement with Sysmex than with Radiometer for HCT with a slope of 0.99 and 0.84, respectively. i-STAT has a similar negative bias in HGB values compared to Radiometer and Sysmex with a slope of 0.86 and 0.89, respectively. Radiometer and Sysmex compare well with each other for HGB with a slope 0.98, but Radiometer has a positive bias with a slope of 1.14 for HCT. The discrepancy in HCT and HGB results between i-STAT and other laboratory instruments still exists, even when a correct mode is selected. The bias among multiple systems is most likely due to the difference in methodology, calibration, and calculated versus directly measured parameters. Therefore, it is recommended to use a single method to trend the HCT and HGB in patients undergoing procedures that causes hemodilution.

## B-277

### Method comparison and bias estimation at clinical decision levels for lactate measurements with ABL80 and ABL90 blood gas analyzers

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**Background:** Lactate measurement provides relevant information for diagnostic and prognostic assessment of critical patients and is often used as a marker of adverse outcomes. Modern Point-of-Care Testing (POCT) constitutes a useful tool for real-time monitoring of lactate at the patient's bedside. Similarly to ABL90 blood gas analyzer, a new electrode-based biosensors cassette that incorporates lactate measurement was developed for ABL80. The aim of this study was to estimate bias at the medical decision levels in order to establish whether lactate results measured with ABL80 and ABL90 (Radiometer Medical Aps®) are interchangeable.

**Material and Methods:** Two ABL80 and one ABL90 blood gas analyzers were utilized in the study. For method comparison, ABL90 was considered as the reference measurement procedure. According to Clinical and Laboratory Standards Institute (CLSI) protocol EP09-A2-IR, 40 whole blood heparinized samples from adult patients were analyzed in replicates. Linear regression including slope and intercept calculation was used in order to estimate bias at the medical decision levels. The allowable bias was established according to desirable total error based on biological variation criteria. Statistical analysis was performed using StatisPro™ software (CLSI).

**Results:**

| | Medical decision levels (mmol/L) | Estimated bias (mmol/L) | 95% Confidence interval | Allowable bias (mmol/L) | Allowable bias (%) |
|---|---|---|---|---|---|
| ABL80 -1 vs ABL90 | 1 | 0.06 | -0.14 to 1.48 | 0.30 | 30.4 |
| | 2 | 0.31 | 0.19 to 0.43 | 0.61 | 30.4 |
| | 4 | 0.81 | 0.71 to 0.91 | 1.22 | 30.4 |
| | 6 | 1.31 | 0.89 to 1.25 | 1.82 | 30.4 |
| ABL80 - 2 vs ABL90 | 1 | 0.10 | -0.10 to 0.29 | 0.30 | 30.4 |
| | 2 | 0.29 | 0.16 to 0.43 | 0.61 | 30.4 |
| | 4 | 0.68 | 0.60 to 0.77 | 1.22 | 30.4 |
| | 6 | 1.07 | 0.89 to 1.25 | 1.82 | 30.4 |

**Conclusions:** The estimated bias for lactate measurements was lower than the allowable bias at different medical decision levels. Patient's results for lactate are interchangeable between ABL80 and ABL90 and both could be used alternatively with no impact on patient care. This could be specially useful at institutions with POCT projects were both analyzers are installed.

## B-278

### Pre-analytical Implications of Sample Mixing

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Pre-analytical errors make up the vast majority laboratory errors resulting in questionable patient results. (Bonini *et al.,* 2002) Questionable results can result in improper medical intervention or suspicion of analyzer performance. One of the common forms of pre-analytical errors is improper or inadequate sample mixing prior to sampling. Inadequate sample mixing will yield erroneous hematocrit and total hemoglobin patient results and improper mixing may cause hemolysis adversely affecting a patients electrolyte results, mainly potassium.

Common forms of sample mixing include the Rock and Roll method, 8-3 Axis method, and vortex shaking. In order to assess the effects of each of the above methods, preliminary testing was conducted in order to quantify which type of sample mixing, or lack thereof, would cause a clinical significant shift in potassium (±0.25 mmol/L), hematocrit (2%), and/or total hemoglobin (0.35 g/dL). Each one of these methods of mixing, as well as no mixing, was evaluated using GEM Premier® 4000 blood gas analyzers (Instrumentation Laboratory, Bedford, MA). Each of the four methods was evaluated using a 3 cc syringe filled to the final graduation with adult whole blood and allowed to sit on bench for >30 minutes, the results are summarized in Table 1. Per this study, a two sample t-test ($\alpha$=0.05) on the correlation between the mean bias of each method when compared to initial concentrations. In this experiment, no sample mixing had a clinically significant shift in both hematocrit and total hemoglobin results (Table 1).

**Table 1: Summary of the Effectivity of Various Sample Mixing Methods on Method Bias**

| Analyte | No Sample Mixing | Rock and Roll Mixing | Vortex Shaking | 8-3 Axis Mixing |
|---|---|---|---|---|
| $K^+$ | 0.02<br>p = 0.551 | 0.00<br>p = 1.000 | 0.03<br>p = 0.263 | 0.00<br>p = 1.000 |
| Hct | **6.00**<br>p = 0.000 | -0.33<br>p = 0.343 | -0.17<br>p = 0.667 | 0.83<br>p = 0.070 |
| tHb | **1.57**<br>p = 0.000 | -0.10<br>p = 0.403 | -0.02<br>p = 0.895 | 0.03<br>p = 0.652 |

Based on the results, we recommend the Rock and Roll, or 8-3 axis, methods of sample mixing when considering potassium, hematocrit, and/or total hemoglobin as indicators of either inadequate or improper sample mixing.

## B-279

### Comparison of the Alere i to the BD Veritor in the rapid detection of Influenza A and B viruses

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Background:The use of point-of care-testing (POCT) in patient management decisions is becoming increasingly more common. This trend requires POCT devices to generate accurate and reliable test results and makes the comparison of available testing devices a necessity when deciding which testing platform to adopt. Our goal is to evaluate the diagnostic performance of two commercially available rapid Influenza A+B virus POCT devices, the Alere™ i Instrument (isothermal nucleic acid amplification, Alere, Inc., Scarborough, ME) and the BD Veritor™ System (chromatographic immunoassay, BD Diagnostics, Sparks, MD).

Methods:This ongoing, prospective, multi-site study is a comparison to determine how well each of these testing devices detects Influenza A+B in symptomatic adult patients. A swab is collected from each nostril of symptomatic patients visiting outpatient clinics during the 2014-2015 Influenza season. The Veritor™ is performed onsite in real time, while the additional swab is stored frozen and transported to the central laboratory to be batch-tested using the Alere™ i. Discordant results between the Alere™ i and Veritor™ are resolved using the Simplexa™ Flu A/B and RSV Direct real-time reverse transcription polymerase chain reaction (RT-PCR) assay (Focus Diagnostics, Cypress, CA).

Results:Preliminary results have revealed that there is 85.7% agreement between the Alere™ i and the BD Veritor™ in the detection of Influenza A, while the detection of Influenza B showed 100% agreement between the two assays.

In the case of the discordant result between the two assays, the Simplexa™ assay was used to determine that the result obtained from the Alere™ i was correct and that the Veritor™ result was a false negative.

Conclusion:While the preliminary data suggest that the two assays showed similar performance in the detection of Influenza B, the Alere™ i may be more sensitive in its detection of Influenza A as compared to the BD Veritor™.

| Agreement between the Alere™ i and the BD Veritor™ | | | |
|---|---|---|---|
| Categories | Alere™ i | BD Veritor™ | % Agreement |
| Influenza A | 7 | 6 | 85.7 |
| Influenza B | 3 | 3 | 100.0 |
| Negative | 13 | 14 | 92.9 |
| Total | 23 | 23 | |

## B-280

### Evaluation of Siemens Immulite and CLINITEST hCG Assays for Recognition of hCG Variants in Urine

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**Background:** The Siemens IMMULITE® 2000 HCG assay has been well-documented in current literature for its excellent specificity to multiple hCG variants in urine. The Siemens CLINITEST® hCG pregnancy test is a qualitative, analyzer-read assay performed on the CLINITEK Status®+ analyzer which is most commonly utilized in point-of-care (POC) sites such as emergency departments, clinics, and physician offices. Siemens R&D and/or Support groups are often asked for data indicating how well our CLINITEST hCG assay is able to identify variant forms of hCG. We were also interested to find a respected laboratory-based test to use as a reference assay in the resolution of suspected discrepant results received in POC clinical settings. The objective of the study was to address both of these needs.

**Methods:** Although it has been known for a long time that human chorionic gonadotropin (hCG) exists in several different molecular forms throughout pregnancy, in blood and urine, until recently these hCG variants have not been available to evaluate their impact on immunoassay performance. Utilizing WHO hCG variants reference materials (5th IS hCG, intact hCG, hCGn, hCGα, hCGß, hCGßn and hCGßcf) and externally sourced variants (hCG-h, hCG-hn, hCG-hnct and asialo hCG), we evaluated the Siemens IMMULITE 2000 assay and CLINITEST hCG assay for reactivity and variant concordance.

All 11 hCG variant stock solutions and dilutions were prepared using an hCG negative urine pool and stored at ≤ -20°C. Frozen samples were utilized during testing at two Siemens sites participating in the study. Prior to testing on all immunoassay platforms, samples were thawed and mixed thoroughly and run in quadruplicate.

**Results:** The data was compiled and analyzed yielding two major observations: 1) neither assay recognized the hCGα variant; 2) both assays recognized hCGßcf. The first observation on the negative recognition of the hCGα subunit was expected as the hCGα subunit is shared by other protein hormones (LH, FSH and TSH) and is not specific to hCG. The second observation is important as assay developed for serum or plasma detection do not typically detect hCGßcf as serum and plasma do not contain hCGßcf.

**Conclusions:** In this hCG variant research study, the IMMULITE 2000 hCG and CLINITEST hCG assays recognized all of the variants tested with the exception of hCGα which was expected. Based on the similar hCG variant recognition profiles observed, the IMMULITE hCG assay was selected as the laboratory reference assay to assist in the resolution of suspected discrepant results received in the POC clinical settings. Having POC and laboratory-based assays with similar hCG variant recognition profiles also allows for stronger concordance across different testing sites in a Siemens end-to-end solution.

## B-281

### High Sensitivity Assays for Cardiovascular Risk Stratification using a Comprehensive Bioelectronic POC System

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Background

Novel applications for a comprehensive bioelectronic platform are described, which demonstrate high-sensitivity levels for hs -Troponin I, hs -Troponin T and hs -CRP. The eDx platform is designed for multiple Point-of-Care (POC) diagnostic applications, including protein, DNA and small molecule detections. An application for high-sensitivity testing for primary care in routine clinical practice has recently emerged from multiple cardiovascular KOLs. At least 5 recent randomized clinical trials (RCT) support that elevation of basal levels of Troponin in asymptomatic individuals, represents occult disease and can be used as a risk stratification tool. Patients considered at low or intermediate risk could be reclassified and receive therapy of known benefit, like Statins and ACE inhibitors in addition to other behavioral modifications. Observational data for a Statin RCTs shows cholesterol reduction associated with a lowering of cTn that predicts outcomes. Ohmx presents herein data for high-sensitivity Troponin I and T as well as hs-CRP as part of their menu for a comprehensive POC platform offered for routine clinical practice.

Methods

Assays have been developed based on bioassay procedures where a mediator substrate specifically reacts with nanolayers on micro-electrodes. An adaptable redox nanolayer technology is presented that demonstrates quantitative, ultra-sensitive, precise and accurate measurement of numerous clinical analytes in various sample matrices (e.g. whole blood, urine, semen, prostatic fluid, saliva etc). Electrochemical signal processing techniques produce a self calibrating signal allowing for a rapid, fully quantitative dose response over a broad, 1000-fold range of analyte concentration. The eDx automated system is fully developed as a programmable automated system for sample to results for all assays. Clinical data presented here for hsTnT, hsTnI and hsCRP use both whole blood and serum clinical samples.

Results

Using dilution series in analyte-free serum, all assays developed to date demonstrate a dose response that spans the analytes' clinical relevant range (hsTnT, hsTnI and hsCRP). Results for the high sensitivity hs-Troponin I, hs-Troponin T and hs-CRP tests are presented. The automated test is presented with a TAT for hsCRP of 10 minutes. The Ohmx test LOD for hs-TnI is 0.8 ng/L , hs-TnT is 1 ng/L and hsCRP is 1 pg/mL. Correlations by Passing-Bablok regression yielded correlations with predicate devices with R2 values from 0.9 to 0.95. The CV% at the 99th percentile for Troponin I (estimated at 10 ng/L) is 6.3%.

Conclusions

An alpha system, utilizing a versatile bioelectronic platform, is presented with validated tests for various clinical targets that is amenable to a high sensitivity applications, including hs-TnI, hs-TnT and hs CRP for use as cardiovascular risk stratification tests in routine clinical practice.