Wednesday, August 2, 2017

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

Point-of-Care Testing

B-272

Analytical and clinical accuracy of blood glucose testing by point of care glucose meters when using ISO 15197 and Thailand's national guidelines

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Background: Glucose meters play an important role in the management of diabetes mellitus (DM) patients. Analytical and clinical performance of blood glucose testing deserves to be evaluated before using it in hospital settings. The objectives of this study were to evaluate the analytical performance of commonly used glucose meters and to evaluate the clinical performance.

Methods: Analytical performance including precision, recovery, common interferences, and comparison were carried out. One hundred capillary and venous blood samples obtained from 60 diabetes patients and 40 healthy adults were used in comparison studies. Whole blood samples were measured for glucose by glucose meters and a YSI reference analyzer, while plasma samples were measured for glucose by a Cobas c111 analyzer. All data obtained from the comparative studies was evaluated by using the international guidelines for blood glucose testing, and also Thailand's national guidelines for point of care testing. The clinical performance of blood glucose testing was evaluated by Park Error Grid analysis.

Results: The coefficients of variation of blood glucose testing by glucose meters were less than 8% and recoveries ranged from 95 to 105%. We found that hemoglobin and triglyceride can interfere with one of the glucose meter. However, blood glucose levels obtained from four of the glucose meters were compatible with the reference analyzers published in ISO 15197 and CLSI (> 95%). All five glucose meters were in conformance with Thailand's national guidelines for point of care testing by correlation coefficient > 0.975 (r^2> 0.95), Bland-Altman plot > 95% and clinical performance with biases felt within zone A and B >99% of error grid plots.

Conclusion: Four of the five glucose meters tested showed good analytical accuracy, all five glucose meters showed good clinical accuracy.

B-273

Application of a Monte Carlo simulation model to estimate clinical risk associated with the analytic performance of point of care INR devices

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BACKGROUND: In 2016 FDA proposed performance expectations for POCT INR devices in response to a post market risk analysis of serious clinical and patient self-monitoring adverse events: 95% of all INR results should fall within ±0.4 for INR <2; ± 20% for INR ≥2 to 3.5; ± 20% for INR ≥3.5 to 4.5 and ± 25% for INR ≥4.5. OBJECTIVE: To estimate the clinical risk of warfarin dosing error as a consequence of POCT INR assay inaccuracy and imprecision at FDA performance goals. METHOD: INR values (n= 53, 535) were obtained from community adult patients in the Saskatoon Health Region (SHR). Monte Carlo simulation models were used to assess the influence of analytical bias and imprecision on INR values by evaluating the fraction of warfarin-dose-categories according to the SHR algorithm that were unchanged or changed by ≥1, ≥2 or ≥3 dose categories. RESULTS: Simulations used a bias of ±0.4 to ±0.8 combined with 3% imprecision and predicted that 45% to 75% of results would have ≥1 category warfarin dosing error, and 1% to 18% of results would have ≥2 category errors. If INR imprecision was increased to 10%, then the model predicted that 45% to 75% of results continue with ≥1 category warfarin dose error but the fraction with ≥2 category error would increase to 2% to 24%. CONCLUSIONS: Simulation models demonstrated the extent of one category and two category treatment errors for POCT INR assays is highly dependent on method bias and only partially affected by method imprecision ≤10%.

B-275

Utility and accuracy of transcutaneous bilirubin as a screening test to identify the need for serum bilirubin assessment in neonates in Nepal

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Background: Neonatal hyperbilirubinemia is very common and most of the times just a benign problem in neonates. But with high levels of serum bilirubin, there remains a possibility of development of kernicterus which could be devastating. Severity and decision for management are usually based on serum bilirubin (TsB) which requires blood sampling. However, transcutaneous bilirubin (TcB) measurement is a noninvasive point-of-care alternative to TsB, which can be very helpful in the resource constrained setting such as Nepal. This study aimed at evaluating the accuracy of the TcB measurement when compared to TsB and developing a cut-off point of TcB level with desirable sensitivity and specificity values for various clinically relevant TSB levels. **Methods:**

This was a hospital based prospective study done in neonates admitted in NICU of College of Medical Sciences Teaching Hospital, Bharatpur, Nepal. A total of 127 neonates were enrolled in the study from October 2015 to April 2016. TcB was measured using Drager Jaundice Meter JM-103 in the neonates in whom jaundice was suspected by visual assessment following the guidelines mentioned in the information leaflet. A TsB was also sent within 30 minutes of measuring the TcB. The agreement between the two measurement methods was analyzed by Pearson's correlation followed by Bland-Altman analysis. Receiver Operating Characteristic (ROC) curves were plotted for TcB at various clinically relevant cut-off points of TsB that were set at 13, 15 and 17 mg/dl. A p value of less than 0.05 was considered statistically significant. **Results:** Out of the total cases, 81 were male (63.8%) and the rest 46 were female (36.2%). The median post natal age was 56 hours, ranging from 4- 480 hours. The median birth weight was 2560 g (1570 g- 4300 g). The two measurements had high degree of correlation (Pearson's r= 0.872, P <0.01). The Bland Altman error distribution plot shows a tendency of TcB to underestimate TsB throughout the range of measurement with the mean difference of 2.03 ± 1.66 mg/dl, with an uncertainty of 3.31 mg/dl. The cut off value of TcB at 10.15 mg/dl suggested that the TsB is >13 mg/dl with the sensitivity of 96.1% and specificity of 80%. The cut off value of TcB at 11.75 mg/dl suggested that the TSB is >15 with sensitivity of 93.9 % and specificity of 68.9 %. Similarly, the cut off value of 13.65 mg/dl suggested the TSB value of >17mg/dl with the sensitivity of 93.9% and 73.1% specificity. **Conclusion:**

The accuracy of the TcB measurement is excellent overall and offers a sensitive screening alternative to identify the need for blood sampling for serum bilirubin level. The JM-103 jaundice meter offers painless, accurate point-of-care bilirubin determinations, with advantages such as high level of parent and staff acceptance, easy portability and cost-effectiveness. Furthermore, it can be very helpful in monitoring of the bilirubin level once the treatment has been initiated, to avoid frequent needle-pricks to the neonates.

B-276

Simulation Models to Rule-Out Acute Myocardial Infarction with Two Point of Care Testing Devices and a High-Sensitivity Cardiac Troponin T Method

M. E. Lyon[1], P. A. Kavsak[2], A. Worster[2], A. W. Lyon[3]. *[1]Royal University Hospital, Saskatoon, SK, Canada, [2]McMaster University, Hamilton, ON, Canada, [3]St. Paul's Hospital, Saskatoon, SK, Canada*

Background: Few studies have assessed the utility of Point of care (POC) cardiac troponin methods to rule-in or rule-out acute myocardial infarction (MI). These studies are difficult to conduct due to lack of method standardization, variation among patients, low incidence of non-STEMI AMI and high cost per test. To overcome study limitations, simulations were used to evaluate the diagnostic performance of the Radiometer AQT90 and Roche h232 cardiac troponin T (cTnT) POC methods and the Roche Elecsys high-sensitivity cardiac troponin T method (hs-cTnT) using an emergency department (ED) patient database expanded to n=10,000 in a finite mixture model. **Objective**: To estimate and compare clinical sensitivity and specificity, positive and negative predictive values (PPV, NPV) for the Radiometer AQT90 and Roche h232 cTnT POC methods with hs-cTnT using simulated data at diagnostic thresholds. **Methods:** Finite mixture analysis of the 0 hr data obtained from the ROMI trial (n=1137 Optimal Troponin Cut Offs for acute coronary syndrome (ACS) by Roche hs-cTnT) enabled derivation of a simulation data set (n=10,000) troponin test results. Regression equations were used to convert hs-cTnT test results into simulated AQT90 and h232 cTnT results. Clinical sensitivity, specificity, PPV and NPV were

calculated using the simulated hs-cTnT, AQT90 and h232 data for MI diagnosis using the limit of detection for the assays. **Results:** For the Radiometer AQT90 cTnT at 10 ng/L: sensitivity 98.4%, specificity 29.2%, PPV 15.6% and NPV 99.3%. For the Roche h232 cTnT at 50 ng/L: sensitivity 55.6%, specificity 91.6%, PPV 46.7% and NPV 94%. For the Roche hs-cTnT at 5 ng/L: sensitivity 99.1%, specificity 20.3%, PPV 14.1% and NPV 99.4%. **Conclusions:** Only the Roche hs-cTnT in this simulated data-set achieved both sensitivity and NPV values above 99% similar to the published study (Clin Chem 2017;63:403-414). The Radiometer AQT90 cTnT assay approaches these estimates, suggesting a prospective study is required to determine if the AQT90 cTnT assay can be used to rule-out MI at presentation in an all comer emergency department chest pain population.

B-277

Point of care measurement of blood beta-hydroxybutyrate in children with drug-resistant epilepsy

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Background: Incidence of childhood epilepsy in Estonia is 80:100.000 (0-19 years). Up to 70% of patients have their seizures controlled with anti-epileptic drugs. For some children who continue to have seizures, the ketogenic diet (KD) may help to reduce the number and severity of seizures. The KD is a special high-fat, low-carbohydrate diet that helps to control seizures. It is prescribed by a physician and carefully monitored by a KD team. Clinical guidelines advocate the measurement of ketones for the management of KD. A ketone urine nitroprusside test measures only one of the ketones - acetone while a ketone blood test measures the main ketone- beta-hydroxybutyrate (BHB) which accounts for 75% of ketone bodies in blood. POCT BHB and glucose meter Stat Strip (Nova Biomedical, Waltham, MAS, USA) was used for the measurement. **Aim:** To compare ketone measurement in urine and blood of these patients and to describe the impact of the ketone measurements on patient management with the KD.Methods: Case histories were retrospectively reviewed for all of the patients who are treated with KD in the Pediatric Clinic of Tartu University Hospital during years 2011-2016. Epilepsy course, etiology, and outcome as well as laboratory data (ketone, glucose, pH and BE) were collected and analyzed. During 2016, four children with drug-resistant epilepsy were treated with the KD. In two of them ketones were measured from urine (group1, before POCT BHB) and in two of them from blood (group2). Ketones, glucose, pH and BE measurements was performed regularly 1-2 times per day (and more frequently when the child's condition deteriorated) during one week.**Results:** 1. Mean glucose concentration, pH and BE of the patients' group 1 were significant lower than group 2: 2.76, 7.34, and -8.51 vs. 3.35, 7.38, and -5.71, respectively. 2. We compared the mean, minimum, and maximum values of glucose, pH and BE with reference ranges. 90% of values from group 1 were outside the reference range (except max value of pH 7.39: reference range is 7.35-7.45). From group 2 only 40% of values (mean and min of BE and min of pH) were outside the reference range. **Conclusion:** Measuring blood ketones gives more reliable data about the patient's condition and the level of ketosis thus allowing a better management of patients treated with KD.

B-278

Increasing the Limit of Detection and Performance of Rapid Immunological Tests

K. Whiting. *BBI Solutions, Cardiff, United Kingdom*

Background: Lateral flow immunoassay (LFI) rapid tests are accessible and low-cost diagnostic solutions for many POC applications, fulfilling many of the World Health Organisation's ASSURED characteristics. BBI have identified a market demand for increased performance of tests in terms of assay limit of detection, sensitivity, specificity and time to result. In direct response, they have developed a proprietary signal enhancement technology, Morffi™ that increases the test signal intensity (compared to traditional methods), improves the limit of assay detection and the time to result. This improvement could facilitate quicker diagnosis times for conditions requiring urgent treatment such as cardio metabolic or infectious diseases. The improved limit of detection can also expand the applicability of LFI to compete with more traditional lab based tests. **Methods:** BBI uses an in-house developed BNP-32 LFI as a model system for the assessment of new technologies. The assay combines BBI's colloidal gold label with commercially available antibodies and test materials. 40nm colloidal gold was passively conjugated to an anti-BNP antibody under predetermined optimal conditions. Following antibody immobilisation on the particle, unconjugated sites were blocked with an excess of either a BSA control or BBI's patent-pending Morffi technology. The conjugates were then normalised to the same optical density in buffer . The assay strips were tested against a range of BNP antigen concentrations (n=5). Test strips were read at 15 minutes using a CAMAG TLC Scanner 3 at 520 nm. The limit of detection (LoD) for the BNP-32 assay was then determined for each blocking technology, based on double the standard error (SE) above and below the mean signal for each concentration.

Results: Improved sensitivity The use of the novel technology results in a significant improvement in the LoD compared to the BSA-blocked control. The LoD achieved using Morffi was 0.08 ng/ml, compared to 0.8 ng/ml for the BSA-blocked control, representing a 10-fold increase in the limit of detection. The use of Morffi technology leads to a significant increase in signal intensity at all antigen concentrations compared to the BSA-blocked control. This can be attributed to more efficient binding of the detector conjugate to the antigen-capture antibody complex.

Conclusion: The results presented demonstrate the feasibility of the Morffi signal enhancement technology, offering a clear improvement in signal intensity over the BSA blocked control for the BNP-32 assay system. This difference was visually discernible at high antigen concentrations, and provided a 10-fold enhancement in the limit of detection. Due to the improved signal intensity the time to result is also improved with an up to four times faster rate to result. To-date more than 30 conjugates have been evaluated and have shown to be stable and robust. BBI has used this technology to enhance the sensitivity of a number of other model assay systems and are continuing to work on the applicability of the technology with other detector labels as well as with different assay formats.

A published whitepaper: Enhanced performance of a lateral flow assay, supports this abstract and provides further data.

B-279

Prevalence and factors associated with diabetes mellitus in patients with tuberculosis

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Background: Tuberculosis and diabetes mellitus are both global health burdens. Prevalence of both diseases continues to rise in developing countries. Some studies have shown diabetes increases the risk for tuberculosis. The relationship between the two diseases has not been fully investigated in Kenya.

Methods: This was a cross-sectional descriptive study involving adult patients diagnosed with tuberculosis attending outpatient clinics in two referral hospitals in Kenya. Informed consent was obtained from all participants. Demographic information was then recorded from each participant after which HbA1c was determined in venous blood using the CLOVER A1c™ Analyzer System. The main outcome variables were age, gender, HbA1c value, type of diabetes and HIV status.

Results: A total of 124 patients with tuberculosis were enrolled in the study. Most study participants were female (55.6%); most were aged 18yrs to 40yrs (72.5%); most had pulmonary tuberculosis (69.4%); most were HIV negative (83.1%). Thirteen patients (10.5%) had diabetes mellitus and 32 (25.8%) had impaired glucose tolerance. Majority of the patients with diabetes had pulmonary tuberculosis (8.1%). The mean HbA1c in patients with pulmonary tuberculosis was significantly higher than in those with extra pulmonary tuberculosis (6.9% vs 6.1%; p-value 0.017).

Conclusion: The overall prevalence of diabetes mellitus was 10.5 % and that of impaired glucose tolerance was 25.8%. This is higher than the national estimated diabetes prevalence of 3.3% and is suggestive of an association between diabetes mellitus and tuberculosis. Routine screening of patients with tuberculosis for diabetes mellitus is recommended to increase early detection and management.

B-280

A Novel Multiplexed Lab-on-Cartridge based POC Device for the Measurement of Common Clinical Diagnostic Tests

A. Singh, H. Singh, V. MATHUR. *Diasys Diagnostics India PVT. LTD, Mumbai, India*

Background:

Measurement of routine clinical biochemistry tests is common in labs worldwide for screening of illness or diseases. Most of the clinical tests require multiple instrumentation devices that perform multiple tests using cartridges for treating an illness. The costs required to maintain such cartridge based POC/Lab instrumentation is high and this limits the use of the device to only highly specialized personnel and sophisticated labs. 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 universal device/cartridge that is affordable, reliable, easy-to-use, requires very low sample volume and is maintenance-free and can do multiple tests at the same time.

DiaSys India has developed a world's first, patent pending, versatile electrochemical multiplexed biosensor based lab-on-cartridge device that is capable of performing a 1, 4, 8, or 16 tests simultaneously (QDxInstaLab CC). QDxInstaLab CC incorporates an innovative, high performance, inexpensive microfluidic cartridge for rapid quantitative measurement of diagnostic tests in whole blood/plasma/serum & QC samples. Our proposed methodology utilizes a novel, patented nanomaterial based plastic electrochemical biosensor that uses chronoamperometry to provide a sensitive and accurate result in <3 min for ALL the common clinical biochemistry tests. For the first time in a POC cartridge based device, we have built-in an Onboard QC sensor and a Hematocrit correction sensor to ensure the reliability of the results. The QDxInstaLab CC is capable of performing an eight clinical chemistry multiplexed tests from a fingerpick with just 30 microliters of whole blood sample.

Methods:

We have evaluated the multiplexed QDxInstaLab CC cartridge using samples for linearity, precision, interference and cartridge stability for all the clinical biochemistry profiles such as metabolite profile (glucose, lactate), kidney profile (urea, creatinine), haematology profile(Hb), lipid profile (total cholesterol, triglycerides), liver profile (ALT, AST, bilirubin). Method comparison was done against Repsons®910, a mid-size lab based clinical chemistry analyser. Precision study was done using modified CLSI guidelines with N = 10 samples. Interference study was done against haematocrit 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 37°C for 4 weeks for the assays during which linearity samples were run on 0, 4, 7, 14, 21, 28 days respectively.

Results:Data analysis indicates that the assays have a CV < 5%, with R^2 > 0.95, interference bias of < 10% and the cartridges are stable up to 12 months at 2-8°C storage temperature based on preliminary extrapolated data.

Conclusion:

The developed technology platform for multiplexed cartridge for QDxInstaLab CC is reliable and meets all the performance specifications of the lab. Hence, it can be easily adapted for low cost, sensitive and rapid measurement of common diagnostics tests in urban, semi-urban and rural areas in the developing countries and also can be used as a general POCT system for worldwide applications.

B-281

Point of Care Testing (POCT) Five-Years Performance Review Evidenced Connectivity is Essential for the Establishment and Appraisal of an Effective Quality Management (QM) System for the Best of Patient Care

V. Lo. *Hong Kong Sanatorium & Hospital, Apleichau, Hong Kong*

Backgrounds: Our hospital adopted Nova glucometer (Nova) (Nova Biomedical Corporation, U.S.A.) for Point of Care Glucose Testing. Two proprietary systems, BioViewer and NovaNet, enabled connectivity. Bioviewer captured daily internal quality control data of 65 operating Nova devices for laboratory monitoring and troubleshooting; blocking Nova for analysis when satisfactory internal quality control performance was NOT available within 24-hours. NovaNet enabled laboratory to activate lot number of reagent and internal quality control, upload clinically relevant internal quality control range after performance verification and in-house establishment respectively. This study evidenced the criticalness of connectivity for the establishment and appraisal of an effective Quality Management system for the best of service quality and patient care.

Methods: In 2011 laboratory adopted ISO-22870 standard to establish Quality Management System, of which the effectiveness was appraised in a five-years performance review according to five quantifiable quality indicators. (1) Royal College of Pathologist Australasian Quality Assurance Program Key Performance Indicator (KPI) score, (2) sigma-metric by (TEa-bias)/CVa , TEa was total error analytical, CVa was analytical coefficient of variation of period collected low and high internal quality control imprecision, (3) analytical goal by CVa/CVi, CVi was intra-individual biological variation, (4) daily internal quality control repeat status was interpreted as repeat frequency and reason of repeat, and (5) external quality assurance sample analysis failure rate.

Results: Three biannual KPI scores indicated good performance. Sigma-metric mean of low and high internal quality control were 5.9 and 7.8 corresponded to error rate of 0.00050% and <0.00034% respectively. Analytical goal was achieved satisfactorily. External quality assurance sample analysis failure rate declined from 10.0% to 0.9% in January 2015 and kept persistently low at <1.0% till January 2017. Daily internal quality control repeat status identified two deficiencies of (1) sample application technique and (2) sample verification compliance before analysis owning to lacking focus in the training program.

Conclusion: Connectivity and data integration enabled laboratory to establish a well-designed Quality Management system. and conduct a periodic effectiveness appraisal scientifically to identify areas for improvement, aimed to achieve excellent service quality for the best of patient care.

B-283

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** on Accellix**:**

- Sepsis diagnosis and monitoring based on upregulated CD64 expression on neutrophils.
- Measuring sepsis induced immunosuppression via HLA-DR expression on circulating monocytes.
- CD34+ for stem cell numeration for hematopoietic (bone marrow) transplantation
- Measuring activated platelets using CD41 and Annexin V for real time blood coagulation activity
- Cell characterization:
  - 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.

Results and Conclusions: 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. A similar study showed a correlation coefficient of 0.97 for Accellix HLA-DR compared to using a FACS. In a study to identify lymphocyte subsets a comparison study showed a correlation coefficient of 0.99 for Accellix determined T cell differentiation based on CD3/CD45 ratio compared to FACS. 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-285

Point of Care (POC) International Normalized Ratio (INR) Anti-Coagulation Testing: Human Factors, Quality Patient Care and Error Reduction

D. J. Augustin, L. K. Beyer, S. M. Woolley. *Mayo Clinic, Rochester, MN*

Background: Point of Care (POC) International Normalized Ratio (INR) is used to monitor anticoagulation therapy in the outpatient anticoagulation clinic. We used human factor analysis of the testing process to reduce patient identification errors. **Methods:** Human factors analysis revealed multiple potential sources of error when entering patient identification information into the Roche CoaguChek® XS

Plus (Roche Diagnostics, Indianapolis IN). These included failure to follow patient identification procedure, manual entry of medical record number (MRN), and instrument limitations including no backlighting on visual display, small font size, and inability to use dashes when entering MRN. After investigation, the manual MRN entry process was determined to be the most error prone part of the identification process. The process was modified from manual MRN entry using a barcode label on the CoaguChek XS Plus, to scanning of a patient identification card using a device with a barcode scanner (CoaguChek XS Pro). We measured patient identification errors for a 6 month period before implementing the CoaguChek XS Pro, and two six month periods after implementation of the patient identification card and barcode scanning.

Results: Sixty-seven errors were observed in a 6 month period in 2014 using the CoaguChek XS Plus. Of those 67, 33 errors were incorrect entries, 32 errors were incomplete entry and 2 were due to transposed numbers. With the introduction of the barcode scanner on the CoaguChek XS Pro, patient identification errors were dramatically reduced to 3 errors during a six month period in 2015, and 2 errors during a six month period in 2016. This represents a 97% error reduction rate.**Conclusion:** Introduction of the barcode scanner on the CoaguChek XS Pro dramatically reduced patient identification errors in the anticoagulation clinic. The additional XS Plus and Pro limitations: no backlighting on visual display, small font size, and inability to use dashes when entering the MRN (e. g. 1-234-567 versus 1234567) were passed onto the manufacturer for consideration in future versions.

B-286

Low pO_2 Contributes to Potential Error in Oxygen Saturation Calculations Using a Point of Care Assay

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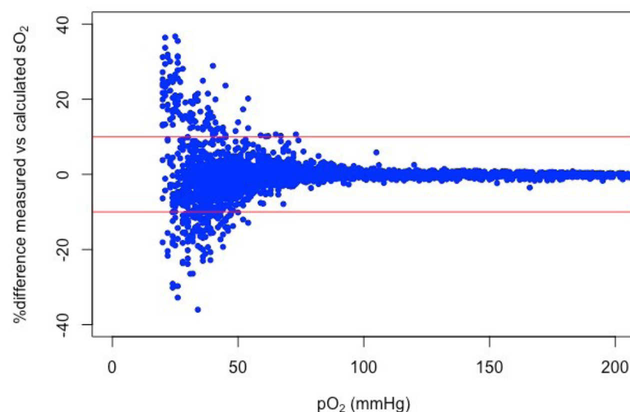
Background: Oxygen saturation (sO_2) is an indicator of respiratory status, monitored during in-patient and out-patient clinical settings and surgical procedures. The present study addressed the accuracy of calculated sO_2 using point of care (POC) testing compared to measured values on a blood gas analyzer.

Methods: 3323 sO_2 values were measured in 1180 patients using a CO-oximeter (ABL 800 Flex blood gas analyzer) and using the measured parameters we subsequently calculated the expected sO_2 values using an indirect POC method (Abbott iSTAT). Cases in which calculated sO_2 differed from measured sO_2 by greater than or equal to 10% were classified as discrepant and analyzed.

Results: Approximately 60% of patients were male. Venous, arterial, and cord blood samples comprised 79%, 15%, and 6% of measured samples. Of the 3323 comparisons performed, 260 (8%) showed discrepancies (+/- ≥ 10%) between measured and calculated sO_2 values. Calculated values that were more than 10% higher or, alternatively, more than 10% lower than measured values occurred with approximately equal frequency. Notably, 94% of discrepant measurements (245 of 260) occurred when pO_2 was less than 50 mmHg. The distributions of measured pH and bicarbonate were shifted to lower values in discrepant cases. The frequency of pH ≤ 7.4 and bicarbonate ≤ 25 mEq/L were 16% and 3% higher in discrepant vs. non-discrepant cases.

Conclusions: We demonstrate that calculated sO_2 values from a POC assay are expected to be clinically discrepant in 8% of cases, the majority of which occur when pO_2 is <50 mmHg. In settings where inaccuracies in sO_2 calculations may have significant consequences on patient care, direct measurements of sO_2 by CO-oximetry should be used.



B-287

Clinical Significance of Accurate Total Hemoglobin Measurements in the Perioperative Setting

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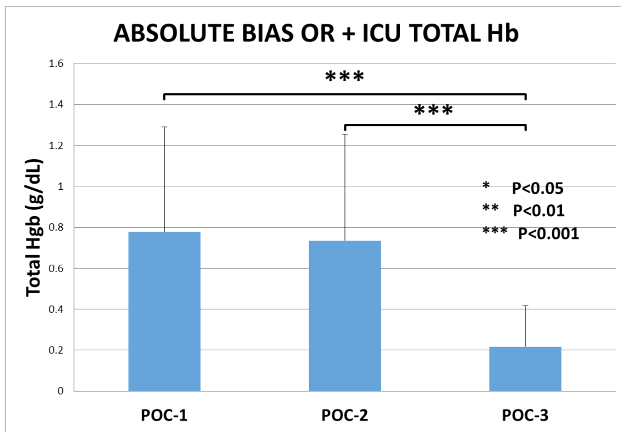
Background: Intensive care unit (ICU) and operating room (OR) patients frequently require transfusions from pathologic and iatrogenic blood loss. Some point-of-care (POC) devices employ conductance-based techniques to determine total hemoglobin (tHb), indirectly calculated through hematocrit measurements, which may be susceptible to hemodilution effects. Conversely, optical sensors are considered more accurate by measuring tHb spectrophotometrically. Inaccurate determination of tHb may result in inappropriate blood product utilization. *The objective of this study is to evaluate the accuracy and clinical significance of POC conductance-based versus optical-based tHb in ICU and OR settings.*

Methods: Performance of three POC analyzers (POC-1, -2, and -3) was compared against central laboratory hematology analyzer for burn, surgical ICU, and OR patients. POC-1 and -2 were conductance-based; POC-3 was optical-based. Venous, arterial, or mixed-venous (≥1.0mL) remnant whole-blood specimens obtained from adults (age≥18 yrs.), assayed for tHb, and compared to central laboratory. Administered packed red blood cell (PRBC) units and transfusion events were recorded. Mean (SD) biases (POC minus reference) were compared with paired t-Tests. PRBC units were estimated from institutional recommended thresholds (≤7g/dL non-cardio; ≤8g/dL cardio patients). Cost was calculated by price/PRBC unit alone.

Results: Fifty patients (72 samples total) were enrolled. Mean (SD) bias for burn, surgical ICU, and OR populations summarized in Figure-1. POC-1 and -2 exhibited higher mean biases than POC-3 (P<0.001). POC-3 results correlated closer to central laboratory platform; mean (SD) bias=0.2 (0.20) g/dL. Potential bias outcome: 27 unnecessary transfusions (6 missed) with POC-1, 18 (9 missed) with POC-2; 3 missed with POC-3. Point-of-care-1 use would have cost $6,075 and POC-2 $4,050 ($225/PRBC).

Conclusion: Conductance-based system bias may result in inappropriate transfusions. Spectrophotometric methods may enable appropriate utilization of blood products. Analytical biases for POC-1 and -2 differ, compared to central laboratory and POC-3. Studies are needed to determine when conductance-based measurements become unreliable, as in cases of hemodilution.



B-288

i-STAT Alinity: The Use of Human Factors Engineering and Usability Engineering in the Design of a Next Generation Point of Care Instrument

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Objective: To demonstrate that the design of the i-STAT Alinity instrument is safe and effective and meets the needs of end users by using human factors engineering and usability engineering.

Background: The next generation i-STAT instrument, the i-STAT Alinity, is a handheld, *in vitro* diagnostic analytical device designed to run i-STAT cartridges. The system is designed for use with-patient care, by trained healthcare professionals and is for prescription use only. Human factors are defined as the application of knowledge about human capabilities and limitations. Usability is defined as the characteristics of the user interface that establishes effectiveness, efficiency, ease of use and user satisfaction. The i-STAT Alinity instrument is certified to the American National Standard ANSI/AAMI/IEC62366-1:2005 *Medical devices - Part 1: Application of usability engineering to medical devices* and has shown to meet the requirements of the Quality System regulation (21 CFR 820.30) where the need for human factors is implied.

Methods: To assess the human factors and usability of the i-STAT Alinity instrument, studies were performed that focused on the users, the use environment and the device/user interface. More than eight formative studies were performed with 7 - 12 end users to assess the usability of the instrument. These studies included an evaluation of the shape, weight and balance of the instrument, usability of the display and touch screen as well as the patient test flow, and the customization manager (AlinIQ CWi). With information from the formative studies, the design of the instrument was adapted to meet the needs of the user. A final summative study was performed. This study used 24 healthcare professionals that represented the intended users of the instrument and included the testing of patient blood samples, the reviewing and printing of patient test results, and the running of a quality test of the handheld instrument. Testing consisted of one-on-one sessions in a simulated hospital environment where participants completed a series of tasks targeted at evaluating the ease of use and overall usability of the instrument.

Results: The summative study assessed behavioral and qualitative data. During the running of a patient test no use errors were found 92% to 100% of the time and operational difficulty was noted on 0% to 13% of the tasks. Correct review of results was achieved 96% to 100% of the time with operational difficulty noted on 0% to 21% of the tasks. Proper quality testing of the handheld instrument was achieved 100% of the time with operational difficulties noted on 0% to 21% of the tasks. None of these findings had implications on the effectiveness for user or patient safety and did not require additional risk mitigation. Potential root causes were identified and the residual risk to both patients and users was determined to be minimal.

Conclusion: These studies demonstrate that the i-STAT Alinity instrument was designed for usability and meets all of the expectations of a safe and effective device that is easy to use with very high user satisfaction.

These studies were funded by Abbott Laboratories.

B-289

Analytical Evaluation of Pleural Fluid pH Measurement on the GEM Premier 5000 Analyzer

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Pleural effusions are an abnormal accumulation of fluid in the pleural space between tissue that lines the lungs and chest cavity. A thoracentesis can be performed to remove the excess exudative fluid and pH is measured for an indication as to the cause of the pleural effusion. Depending on the pH of the pleural fluid, therapeutic decisions can be made.

Pleural fluid with pH levels less than 7.30 are considered to be potentially malignant effusions. Conditions that can result in a low pleural fluid pH are tuberculous pleuritic, esophageal rupture, lupus pleuritic, or purulent pleuritic. The American College of Chest Physicians recommends the use of blood gas analyzers for the measurement of pleural pH. Thus, to meet clinical best practices, the GEM Premier® 5000 (Instrumentation Laboratory, Bedford, MA) was evaluated for performance in measuring pleural pH. Preliminary testing indicate that the GEM Premier® 5000 pH sensor technology has the ability to precisely measure pleural fluid. Samples run under the proposed pleural pH custom sample type denotes that, within the pH range of 7.00-7.50, GEM Premier® 5000 has greater than 95% confidence that pleural fluid pH results are within total allowable error. In-house testing consisted of manipulating pooled pleural fluid with an acid or base, as well as tonometry, in order to span the desired pH range for pleural fluid. Clinical testing was performed at three different hospitals, using clinical samples collected from patients with a variety of pleural effusion presentations. Both in-house and clinical samples were analyzed on the GEM Premier® 5000 and the Radiometer® ABL835 FLEX (Radiometer Medical, Denmark). Method comparison results for samples are shown in Table 1.

Table 1: GEM Premier® 5000 Pleural Fluid pH Method Comparison Results

Pleural pH Decision Level	GEM Premier® 5000 vs. Radiometer® ABL835 FLEX Bias	Total Allowable Error	Pass/Fail
7.20	0.006	±0.04	Pass
7.30	0.001	±0.04	Pass
7.45	-0.007	±0.04	Pass

A full analytical evaluation and clinical evaluation is planned to establish claims and validate the process by which pleural fluid pH results could be reported.

B-290

Clinical Evaluation of the Next Generation i-STAT Alinity Point of Care Instrument using tests for Glucose, and Hematocrit

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Objective: To assess multi-day and whole blood precision of the new i-STAT Alinity instrument, and compare patient results to those from the i-STAT 1 Wireless instrument for glucose and hematocrit. **Background:** The i-STAT Alinity is the latest in Abbott Point of Care's line of *in vitro* diagnostic instruments for with-patient testing. It includes advanced connectivity and quality control features, and measures specific analytes in whole blood using i-STAT cartridge-based technology. A study was conducted at 3 clinical sites using prospectively collected and leftover de-identified venous and arterial whole blood specimens. **Methods:** Multi-day precision was assessed by testing multiple levels of calibration verification materials. Each level was tested once daily for 5 days on 5 Alinity instruments. Whole blood with abnormal low, normal, and abnormal high levels of analyte were tested 3 times each on 7 i-STAT Alinity instruments to assess whole blood precision. Glucose and hematocrit method comparisons were also performed using venous and whole blood specimens tested in duplicate. **Results:** Results are summarized in Table 1. Slope, correlation coefficient, Estimated and Estimated Percent Bias were calculated using Passing-Bablok Regression on the first replicate of the i-STAT Alinity System and i-STAT 1 Wireless System results. For Bias Estimates, the following medical decision levels were used: 45 (L1), 120 (L2), and 180 (L3) mg/dL for glucose, and 33, 53, 56, and 70% packed cell volume (PCV) for hematocrit.

Table 1

	Glu (mg/dL)	Hct (%PCV)
Multi-day Precision (Total SD, per site)	**Site 1:** 0.48-4.74 **Site 2:** 0.53-4.2 **Site 3:** 0.44-4.76	**Site 1:** 0.33-0.52 **Site 2:** 0.35-0.49 **Site 3:** 0.44-0.55
Whole Blood Precision (Total SD, per site)	**Site 1:** 0.22-7.46 **Site 2:** 0.51-2.81 **Site 3:** 0.46-3.56	**Site 1:** 0.48-0.51 **Site 2:** 0.30-0.52 **Site 3:** 0.22-0.50
Method Comp. Range (Alinity)	25-668	18-70
N	188	229
Slope (95% CI)	1.000 (1.000, 1.000)	1.000 (1.000, 1.000)
Intercept (95% CI)	1.000 (1.000, 1.000)	0.000 (1.000, 1.000)
Correlation Coefficient r (95% CI)	1.000 (1.000, 1.000)	0.980 (0.975, 0.985)
Estimated Bias	1.00, all levels	0.00, all levels
Estimated Percent Bias	L1: 2.2% L2: 0.83% L3: 0.56%	0.00, all levels

Conclusions: Glucose and hematocrit testing on the i-STAT Alinity instrument demonstrated acceptable multi-day and whole blood precision. Method comparisons correlated well with whole blood specimens. Overall, the clinical evaluation of the i-STAT Alinity System with the glucose and hematocrit test demonstrated equivalent performance to the i-STAT 1 Wireless System in a point of care setting.

The study was funded by Abbott Laboratories.

B-291

Evaluation of the Next Generation i-STAT Point-of-Care Instrument (i-STAT Alinity) for Chemistry/Electrolyte, Hematology and Blood Gas Tests

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Objective: The i-STAT® Alinity instrument was designed to provide laboratory quality results in minutes at the patient's bedside. The purpose of these studies was to assess the analytical performance of the i-STAT Alinity system with the following tests: Chemistry/Electrolyte (including sodium, glucose, potassium, blood urea nitrogen, chloride, creatinine, lactate, ionized calcium), Hematology (hematocrit) and Blood Gases (including partial pressure oxygen, partial pressure carbon dioxide, total carbon dioxide and pH).

Background: The i-STAT Alinity system represents the latest innovation in with-patient testing. The system uses the same i-STAT cartridges as the i-STAT 1 wireless system while offering enhanced functionality and ergonomics.

Method: The analytical performance of the i-STAT Alinity instrument for Chemistry/Electrolyte, Hematology and Blood Gas tests was demonstrated through testing of multi-day precision, linearity, analyte recovery, limit of quantitation (LoQ) and interference from potential substances. Tests were also completed to evaluate total precision in blood and correlation to the currently marketed i-STAT 1 wireless instrument.

Results: Acceptance criteria were met for all tests performed. The within-laboratory (total) precision ranged from 0.26% – 10.29% for Chemistry (excluding creatinine level <0.1mg/dL), 0.60% – 4.53% for Hematology (Hematocrit) and 0.03% – 8.52% for Blood Gas tests. Linearity across the reportable range was demonstrated for each test. The % recovery for samples within the reportable range varied from 96.0% to 108.5% for Chemistry tests, 100.1% – 102.8% for the Hematocrit test and 96.6% to 106.9% for Blood Gas tests. Many new potentially interfering substances were tested and for most tests, there were no new interferences found. All interferences will be labelled accordingly. Correlation between the i-STAT Alinity system and the i-STAT 1 wireless system was demonstrated through a weighted Deming regression slope within the range of 0.98 – 1.02 and a correlation coefficient (r) range of 0.99 – 1.00 for all tests.

Conclusion: These studies demonstrate that the next generation i-STAT Alinity instrument provides comparable results to the currently marketed i-STAT 1 wireless instrument.

These studies were funded by Abbott Laboratories.

*Pending review with FDA.

Not all products are available in all regions.

Contact your Abbott representative for availability in specific markets.

B-292

Performance Evaluation of Critical Analytes in Capillary Blood Using The epoc Point of Care System

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Background: Close monitoring of blood gases and other critical analytes on point-of-care (POC) devices is crucial during pre-hospital or inter-hospital transfer of patients. Capillary blood is a preferred sample type in transport, due to its better reflection of the arterial oxygen supply status than venous blood, and the convenience of sampling. Limited data are available on the performance of POC devices using capillary blood for critical tests during transport. The objective of this study was to evaluate the performance of capillary blood testing on the epoc Point Of Care Blood Analysis System (Alere Inc).

Method: Institutional Research Board waiver of consent approval was obtained before study initiation at Texas Children's Hospital (TCH). Eleven tests contained in the single-use, self- calibrated epoc BGEM Test Card were evaluated for reference range concordance and correlation with predicate analyzers. The minimum volume requirement for epoc system is 92µl, and results are available in approximately 30 seconds. Capillary blood, obtained from 20 apparently healthy volunteers between 18 and 65 years was tested on the epoc system to assess the concordance to reference ranges used locally at TCH. In addition, 10 whole blood samples were used for method correlation of epoc in the capillary mode. For method correlation of Na^+, K^+, Cl^-, ionized Ca^{2+}, glucose, lactate, hematocrit, hemoglobin, pO_2, pCO_2, and pH, fresh venous blood samples were collected in heparinized vacutainer tubes and were tested on GEM Premier 4000 (Instrumentation Laboratory, a minimum volume of 150µl) and on the epoc system under capillary mode. For method correlation of creatinine, freshly collected venous blood samples were centrifuged within an hour from the collection and were tested on the Vitros 5600 Integrated System (Ortho-Clinical Diagnostics, a minimum volume of 41µl) and the epoc system under capillary mode. Distribution of results from healthy individuals was examined for reference range concordance after excluding outliers based on individual health conditions, fasting states (for fasting glucose) or genders (for gender-specific reference ranges). Correlation of epoc with Vitros 5600 and GEM 4000 was assessed with Deming Regression.

Results: In capillary blood, concordance of greater than 85% to the local TCH reference ranges was obtained for all assays except pO_2 and Cl^-. The test result distribution of pH, pCO_2, hematocrit, hemoglobin, creatinine, Na^+, and K^+ showed good concordance to the TCH reference ranges (≥90%). Ca^{2+}, glucose, and lactate showed between 85% and 90% concordance. Deming regression correlation coefficients for all the comparisons were above 0.65 except for Ca^{2+}. For method correlation in the epoc capillary mode, excellent correlation (>0.90) between instruments was observed for K^+, glucose, lactate, and creatinine.

Conclusion: Our results, in consensus with previous findings, suggest that majority of the analytes available on the epoc system have comparable results to other chemistry analyzers. In addition, this study has shown an excellent concordance of measured analytes in capillary blood for the following analytes: Na^+, K^+, glucose, lactate, creatinine, hematocrit, hemoglobin, pH, and pCO_2, enabling the use of such critical tests in pediatric transport.

B-293

New microscopic counter system ADAMII for enumerating CD3+/CD4+ T-Cells.

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Background: $CD4^+$ T-cell counts are used to monitor the immune status of HIV-infected patients. Laboratory monitoring of HIV-infected patients receiving antiretroviral treatment (ART) is currently done by measuring CD4 cells. World Health Organization (WHO) guidelines recommend that people with HIV to start ART when their CD4 counts fall below 350 CD4 cells/mm^3. The CD4 count is very important to know when to start ART and for the evaluation of treatment efficacy. Flow cytometric analysis is used as the standard method for enumerating, but it is difficult to utilize it because of the complicated procedure and the use of expensive equipment in developing countries. In recent years, the flow cytometry analyzers has been developing to miniaturize and to be portable alternative devices, which can save on the cost of reagents consumed in a single test and can be manipulated with minimal training. We have developed a image based cell counter ADAMII™ CD4 system

that is cost-effective, easy to use, and maintenance-free. **Methods:** ADAMII™ is a bench top fluorescent cell counting analyzer that can be used in hospitals and research laboratories. The obtained images are processed by an image analysis software integrated in the system. All procedures are automatic once the stained sample is loaded into the disposable assay slide. We have evaluated ADAMII™ and Alere Pima, using the FACSCalibur as a reference method. Since there is limited number of HIV / AIDS patients in Korea, it was practically difficult to receive infected blood periodically. Thus, we have demonstrated the performance of the device by artificially controlling the concentration of leukocyte after collecting the blood samples of the normal person through the recruitment of subjects. We evaluated the new image based cell counter ADAMII™ CD4 system (including the reagents and software) against the predicate system FACSCalibur™ (Tritest™ CD3/CD4/CD45 reagent with Trucount™ tubes) for the determination of absolute count of CD4+ cells to assess the performance characteristics. Statistical analyses, such as the bland-altman, correlation, linear regression and accuracy determination, were performed. **Results:** The numbers of $CD4^+$ cells obtained with the ADAMII™ are highly correlated with the FACSCalibur (R^2>0.9837, n=81, bias=-13.5 cell/uL) and PIMA (R^2>0.9867, n=81, bias=-14.75 cell/uL). Linearity of $CD4^+$ cell counts was confirmed over a range of dilutions (4-1015.85 cells/uL of sample). Linear regression analysis was performed at a low count range, 4-228.18 cells/µL (R^2 = 0.997) and normal range, 4-1015.85 cells/µL (R^2 = 0.9968). For the reproducibility test, samples were diluted to an expected concentration. ADAMII™ had a CV of 11.15%, 9.32%, 6.69%, 5.63%, 3.16% at 20 cells/µL, 100 cells/µL, 230 cells/µL, 430 cells/µL, 1100 cells/µL, respectively, and CV's were below 20%. **Conclusion:** The $CD4^+$ counts obtained by ADAMII™ CD4 analyzer showed a good correlation and low bias to the reference method and PIMA CD4 analyzer. The ADAMII™ CD4 analyzer gave CD4+ counts comparable to the reference methods for all CD4 ranges. Furthermore, our data show an excellent correlation with the current standard method. We expect the new image-based cell counter ADAMII™ will be a clinical application by replacing flow cytometry analyzer.

B-294

Analytical verification of RAPIDPoint® 500 and multicentric comparison with reference blood gas analyzers

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Background: Assessment of blood gases, electrolytes, hemoglobin and other magnitudes is particularly important to manage critically ill patients. RAPIDPoint® 500 (Siemens Healthineers) is a new blood gas analyzer designed to meet the challenges of point-of-care settings. This study evaluates the analytical verification of RAPIDPoint® 500 and compares it with other analyzers located in different clinical laboratories.

Methods: Analytical verification of RAPIDPoint® 500 consisted of imprecision evaluation using two levels of quality control in duplicate, with two analytical series per day, during 20 days. Multicentric comparison was performed in five clinical laboratories in Spain using four blood gas analyzers:

•ABL90 FLEX (Radiometer): Hospital 1

•Cobas b 123 (Roche): Hospital 2

•RapidPoint 405 (Siemens): Hospital 3

•RapidLab 1265 (Siemens): Hospital 3, 4 and 5

Each laboratory included 100 blood samples collected in heparinized syringes and measured the following magnitudes: pH, pCO_2, pO_2, sodium, potassium, calcium and chloride in all analyzers. Hemoglobin was only measured in three systems. Statistical analysis was performed using Passing Bablok non parametric regression method.

Results: The estimated imprecision for intra- and inter-assay was lower than allowable imprecision based on desirable biological variation (Westgard QC). The best correlation between RAPIDPoint® 500 and reference blood gas analyzers was with RapidPoint 405. The comparison with RapidLab 1265 shows a systematic bias, mostly constant, whereas with Cobas b 123 and ABL90 FLEX a systematic bias mainly proportional is observed. A major constant systematic bias is observed with chloride in all comparisons. The table summarizes those arterial blood gases magnitudes, with the corresponding gas analyzer, which have a systematic bias.

Magnitude	Blood gas analyzer	Regression line	Intercept (95% CI)	Slope (95% CI)
pH	Cobas b 123	Y = -1.144 + 1.157 X	**-1.144 (-1.806 – -0.529)**	**1.157 (1.073 – 1.249)**
pCO_2	RL 1265 (Hospital 5)	Y = 2.130 + 0.965 X	**2.130 (0.510 – 3.670)**	0.965 (0.925 – 1.003)
pCO_2	RL 1265 (Hospital 4)	Y = 2.860 + 0.894 X	**2.860 (0.480 – 5.070)**	**0.894 (0.843 – 0.950)**
pO_2	ABL90 Flex	Y = -0.820 + 1.038 X	-0.820 (-1.860 – 0.130)	**1.038 (1.014 – 1.063)**
pO_2	Cobas b 123	Y = 2.620 + 0.943 X	2.620 (-0.110 – 5.170)	**0.943 (0.895 – 0.991)**
pO_2	RL 1265 (Hospital 3)	Y = -5.373 + 1.048 X	**-5.373 (-5.878 – -4.675)**	**1.048 (1.034 – 1.061)**
pO_2	RL 1265 (Hospital 5)	Y = 8.340 + 0.936 X	**8.340 (7.830 – 9.020)**	**0.936 (0.922 – 0.949)**
pO_2	RL 1265 (Hospital 4)	Y = -2.130 + 1.019 X	**-2.130 (-2.610 – -1.620)**	**1.019 (1.009 – 1.028)**
pO_2	RP 405	Y = -0.217 + 0.984 X	-0.217 (-0.659 – 0.326)	**0.984 (0.970 – 0.995)**
Hb	ABL90 Flex	Y = 1.080 + 0.947 X	**1.080 (0.760 – 1.380)**	**0.947 (0.925 – 0.973)**
Hb	RL 1265 (Hospital 3)	Y = 0.900 + 0.964 X	**0.900 (0.400 – 1.210)**	0.964 (0.941 – 1.000)
Hb	RL 1265 (Hospital 5)	Y = 0.550 + 0.981 X	**0.550 (0.300 – 0.800)**	0.981 (0.961 – 1.000)
Hb	RL 1265 (Hospital 4)	Y = 0.570 + 0.969 X	**0.570 (0.200 – 0.780)**	0.969 (0.950 – 1.000)

CI: Confidence Interval

Conclusion: The imprecision assessment fulfils the specifications based on biological variation. The bias observed in some magnitudes with other analyzers could be relevant for taking into account when different analyzers are used in the same healthcare center or a change of technology is performed.

B-295

Accuracy evaluation of five blood glucose monitoring systems (BGMS) and its influence on insulin dose errors

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Background: On July 2016, the Spanish Society of Laboratory Medicine (SEQC) and the Spanish Society of Diabetes (SED) jointly created an official consensus document on "Recommendations for the evaluation of BGMS technical performances". Despite the fact that POCT is becoming more and more relevant; especially in the diabetes field, it's not regulated by law in Spain. That's why; this document is an important and unprecedented initiative. The objective of this study is to evaluate the technical performance, accordingly the specifications defined in consensus document; of 5 BGMS widely used is Spain: Contour TS, Glucomen LX, TRUEresult, OKmeter and Lisubel ChekPlus. As a second objective we have evaluated the influence of the performance results in an insulin dosing error analyses.

Methods: 100 venous blood samples, collected with lithium heparin, where analyzed with the 5 BGMS and, after centrifugation, in the laboratory reference chemistry analyzer (Dimension EXL, Siemens Healthineers) using the hexokinase reference method. Time from sample reception to measurement in the Dimension EXL was always below 15 minutes. The study was performed with two different strip lots per BGMS. Accuracy was evaluated according the accuracy criteria defined in the specific ISO 15197:2013 for BGMS: ≥95% of results must be within either ±15 mg/dL of the analyzer result, for glucose concentrations <100 mg/dL, or ±15% for glucose ≥100 mg/dL.

Results: Contour TS was the only BGMS fulfilling the accuracy criteria for both strip lots, with 98% and 97%, while the other BGMS presented the following results: Glucomen LX 66% snd 66%, TRUEresult 84% and 80%, OKmeter 80% and 73%, Lisubel ChekPlus 68% and 64%. For each BGMS, the 99% range dose error (measured in insulin units) was the following (the broader the worst): Contour TS: -3.2 to 2.4 ; Glucomen LX: -5.5 to 5.0; TRUEresult: -9.1 to 4.8; OKMeter: -10.3 to 7.1; Lisubel ChekPlus: -13.3 to 9.2. **Conclusion:** Only Contour TS meets, for both lots, the accuracy criteria defined on ISO 15197:2013. Contour TS also presented the narrowest range for insulin dose errors, since 99% of the errors would be included within -3.2 and 2.4 insulin units. Differences in the insulin dose errors are statistically

significant (p=0.0001) between Contour TS and the other BGMS. The results of this study showed that accuracy can vary from BGMS to BGMS, with a clinical relevance on insulin dosing. It is important to evaluate BGMS before use in the hospital under routine conditions, in particular for patients under insulin therapy depending on high accurate BGMS for their insulin dosing.

B-296

Use of HemoLink™ for blood collection and analysis: Linking patients to clinical testing with accuracy and ease.

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Background:

Current blood-draw methods range from unpleasant to difficult for patients and are logistically burdensome for healthcare facilities due to the necessity of performing phlebotomy in most cases. These challenges are heightened for patients with limited mobility, chronic illnesses requiring routine monitoring, and poor venous access. While increased availability of clinical testing (whether at home or the doctor's office) is becoming increasingly relevant, there remains a lack of reliable methods for blood collection that (1) are self-performed and convenient (2) limit pre-analytical variation (e.g., hemolysis), and (3) allow utilization by automated or POC analyzers without modifying tests. Fingerstick blood draws are painful and, more importantly, are often inadequate in terms of analytical quality and blood volume.

Development and Objectives:

The Tasso HemoLink™ is a self-administered, disposable capillary blood collection device, which can be used at home or in clinic, and collects adequate volumes of blood for use with both automated and POC instruments. The HemoLink is applied to the deltoid area of the arm, activated by pressing a button to generate a vacuum across four specialized lancets, and uses simple fluidic principles to deliver blood to a detachable tube (with appropriate anticoagulant and/or gel barrier, etc.). The HemoLink addresses three main blood collection issues: (1) simplifying blood draws by removing technical expertise to prevent pre-analytical error, (2) a minimalist design to keep manufacturing costs low, and (3) simple integration of collected samples into existing laboratory workflows. Herein, we compare the HemoLink to fingerstick-lancet and venipuncture for lipid profile measurement (i.e., total cholesterol, HDL, and triglycerides) to assess blood volume yield, pain (standard FACES scale), and linear-regression correlation on 41 male/female adult patients. To further demonstrate HemoLink adaptability, venipuncture and HemoLink blood were shipped to core laboratories for lipid profile correlation.

Results:

Blood volumes >=100µL were collected on 88% of subjects. An average pain score of 1.1 was observed for HemoLink (vs. 2.2 for venipuncture and 3.6 for fingerstick), and user preference of over 70% was observed compared to either alternative.

Linear-Regression Through Origin (X-method taken as "Gold Standard"):

Roche Cobas 6000:

TC: HemoLink=0.992(Venous),

HDL: HemoLink=0.99(Venous),

Triglycerides: HemoLink=1.03(Venous).

Piccolo Xpress POC analyzer:

TC: HemoLink=0.998(Fingerstick),

HDL: HemoLink=0.996(Fingerstick),

Triglycerides: HemoLink=0.998(Fingerstick);

r^2>0.98 (all correlations).

The total error observed for all analytes was within allowable error established by the National Cholesterol Education Program (NCEP). For mainframe automated analyzers 200 µL of whole blood was sufficient for a lipid panel and achievable with the HemoLink.

Conclusion:

The HemoLink enables blood collection in environments where phlebotomy is not available, suitable, or desired. Blood is collected in easily detached tubes with appropriate anticoagulants enabling excellent correlation to venous plasma for common tests (i.e., lipid panel) on accurate large-scale analyzers or fingerstick blood on POC analyzers. Additionally, preliminary data shows that HemoLink is demonstrating good correlations for other common tests like the comprehensive metabolic panel (CMP). With such studies establishing clinical validity, the HemoLink has the potential to transform monitoring of chronic disease, as well as outpatient, emergency, and pediatric care by offering a versatile blood collection method that addresses individualized patient needs.

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Creatinine and Urea on the ABL90 FLEX PLUS Point-of-care Blood Gas Analyzer

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Background: To verify the performance of the two new parameters, creatinine and urea (BUN), on the Radiometer ABL90 FLEX PLUS blood gas analyzer studies were conducted using spiked whole blood at Radiometer Medical's laboratories in Copenhagen. The goal is to meet the analytical performance goals based on biological variation as recommended by NKDEP[i]. The goals are based upon intra- and inter-individual biological variation[ii] resulting in a minimum acceptable total error of 13.3 % for creatinine and 23.3 % for Urea[iii].

Conclusion: The above requirements for the creatinine and urea measurements were fully met for all the tested levels, covering the reportable range of the two parameters.

Method: To verify the analytical performance of creatinine and urea, the evaluation comprised an imprecision profiling according to CLSI EP05-A3.

A bias estimation was conducted by comparing spiked whole blood samples to the corresponding plasma results measured on the reference methods, for creatinine an IDMS calibrated HPLC, and for Urea by enzymatic spectrophotometry. With the precision and bias estimations a total analytical error for each parameter is calculated by: (1.96 x CV_T%) ± I Bias % I

Both parameters were also compared to two other whole blood methods according to CLSI EP09-A3; ABL837 FLEX for Creatinine and i-STAT for Urea.

Results:

Parameter	Mean value	Repeat-ability CV_R %	Reproduc-ibility CV_T %	Bias %	Total error %	n	Slope	r^2
Creatinine (µmol/L)	40	0.9	5.9	-0.2	11.6	101	0.97	0.998
	210	0.4	2.7	-3.6	8.9			
	489	0.4	3.0	-3.6	9.6			
Urea (mmol/L)	2.6	1.3	5.7	-0.7	11.9	109	1.03	0.993
	9.5	0.8	3.0	-1.0	6.9			
	27.5	0.8	4.1	-7.3	15.3			

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B-299

Analytic Evaluation of the b101 Hemoglobin A1c Point of Care Testing Method from Roche Diagnostics

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Background: Hemoglobin A1c (HbA1c) methods are used to screen and diagnose diabetes mellitus. The quality of HbA1c methods has been improved through method certification by the National Glycohemoglobin Standardization Program (NGSP), quality control and proficiency testing. Concern has been expressed that many point of care (POC) methods for HbA1c are not sufficiently accurate or precise enough for diabetes diagnosis, so new POC methods require thorough analytic evaluation. **Objective**: To evaluate the precision and accuracy of the Roche point of care b101 HbA1c method compared with the Cobas Tina-quant Gen. 3 NGSP certified method. **Methods:** b101 method precision (n=15) was assessed with three EDTA whole blood specimens at HbA1c levels at 5.3%, 7.0% and 13.4%. Patient specimens (n=47) with HbA1c levels ranging from (4.5% to 13.2%) were analyzed using the b101 method and compared with the Cobas Tina-quant Gen. 3 NGSP certified HbA1c method on a c501 analyzer. Results were evaluated using Passing Bablok regression analysis and Bland Altman method comparison. **Results:** For the b101, coefficients of variation

(precision) was determined to be 1.6% at HbA1c of 5.3%, 1.0% at HbA1c of 7.0% and 1.7% at HbA1c of 13.4%. A patient correlation study yielded the following regression equation with the 95% confidence intervals: b101-HbA1c = 0.9284 (Tina-quant-HbA1c) + 0.6741; slope 95% confidence interval (0.8995 to 0.9574); Y intercept 95% confidence interval (0.43 to 0.92). The average bias over the range of HbA1c levels examined according to Bland Altman analysis was 0.10% HbA1c with 95% confidence interval (0.012 to 0.179). **Conclusions:** The Roche Diagnostics point of care b101 HbA1c method provides excellent precision and accuracy relative to the Cobas Tina-quant Gen. 3 NGSP certified HbA1c method.

B-300

GEM Premier 5000 Clinical Evaluation at CHR Citadelle (Belgium)

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Background: The GEM Premier 5000 is a new critical care analyzer for providing rapid analysis of whole blood samples at the point of care or in a central laboratory. This analyzer contains a single multi-use cartridge PAK to provide quantitative measurements of pH, pCO2, pO2, sodium, potassium, chloride, ionized calcium, glucose, lactate, hematocrit, total bilirubin and CO-Oximetry (tHb, O2Hb, COHb, MetHb, HHb , sO2) parameters. These measurements (and derived parameters) aid in the diagnosis of a patient's acid/base status, electrolyte and metabolite balance and oxygen delivery capacity. Clinical performance of the GEM Premier 5000 was evaluated at the CHR Citadelle Hospital. The analytical performance of the GEM Premier 5000 was compared, under clinical environment, against three Critical Care analyzers from different manufacturers: the GEM Premier 4000 (Instrumentation Laboratory), ABL 90 (Radiometer) and the RapidPoint 405 (Siemens).

Whole Blood Method Comparison: De-identified whole blood samples from different clinical locations at CHR Citadelle Hospital were analyzed for method comparison on the GEM Premier 5000 analyzer where the GEM Premier 4000, the Radiometer ABL 90 and the Siemens RapidPoint 405 were used as reference. Method comparison and regression analysis was performed for each reference analyzer according to Clinical Laboratory Standards Institute (CLSI) EP09-A3.

Results: Regression results (Slope, intercept and regression coefficients) were summarized in table 1 below. For the analytes where a regression evaluation was not possible due to the limited sample range acquired during the study, the mean bias and 95% confident interval was calculated.

Table 1: GEM Premier 5000 Method Comparison regression results versus listed reference analyzers

Analyte Slope	GEM Premier 4000			Radiometer ABL 90			Siemens RapidPoint 405		
	Slope	Intercept	R	Slope	Intercept	R	Slope	Intercept	R
pH	0.979	0.159	0.979	1.060	-0.445	0.983	1.039	-0.273	0.965
PCO2 (mmHg)	1.000	2.000	0.978	1.053	0.000	0.977	0.909	5.545	0.951
PO2 (mmHg)	0.991	5.319	0.999	0.998	4.233	0.998	0.932	2.737	0.994
Sodium (mmol/L)	1.014	-1.506	0.982	0.911	9.938	0.977	0.964	4.678	0.943
Potassium (mmol/L)	1.000	0.100	0.995	1.125	-0.362	0.994	1.111	-0.367	0.995
Calcium (mmol/L)	1.059	-0.058	0.979	1.000	0.010	0.986	Results not provided		
Chloride (mmol/L)	1.000	0.000	0.990	0.909	11.000	0.973	1.000	2.000	0.982
Glucose (mg/dL)	1.036	1.643	0.997	1.060	-3.280	0.994	1.021	0.297	0.995
Lactate (mmol/L)	1.000	0.000	0.995	1.000	-0.100	0.991	Results not provided		
tHb, g/dL	1.035	-0.096	0.998	1.013	0.022	0.993			
O2Hb (%)	1.001	0.617	0.999	0.951	5.896	0.998			
HHb (%)	1.003	-0.907	0.999	0.964	-1.8	0.998			
sO2 (%)	1.003	0.626	0.999	0.962	5.559	0.998			

Conclusion: The GEM Premier 5000 systems demonstrate good performance against other Critical Care analyzers selected in this evaluation. Methodology differences between analyzers is attributed to the subtle differences observed between analyzers for some analytes.

B-301

Evaluation of a point of care for measurement of plasma free hemoglobin in patients receiving ECMO

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Background:

Hemolysis is common in extracorporeal circuits membrane oxygenation (ECMO) as evident by the elevated PFHb level. Values of PFHb greater than 50 mg/dL checked 24-hour post ECMO implantation are considered a useful tool to predict mortality[1]. There are many methods available for the determination of plasma free hemoglobin (PFHb) in the diagnosis of various hemolytic disorders, like *Cyanomethemoglobin* using *Drabkin's* reagent or *Benzidine*[2], both extremely laborious for routine use in hospital fast response laboratories and with restrictions related to environmental and labor legislation because of its carcinogenicity. This current study evaluated the usefulness of a Point of Care (POC) photometer for the quantitative screening of low levels PFHb (microhemolysis).

Methods:

20 consecutive samples of blood were collected of patients with different ages whom Received ECMO at an Intensive Care Unit, using collection materials and tubes from Vacuette Greiner Bio-One®. According to the manufacturer's recommendations the splitted serum samples and quality controls were analyzed with the HemoCue® *Plasma/Low Hb System* (Sweden), which principle is based on a modified azidemethemoglobin reaction.

Results:

The results obtained were statistically evaluated for correlation Pearson (p up to 0.05) and by the t-test Student (t of 0.67) paired using Microsoft Excel spreadsheet.

Conclusion:

The spectrophotometric microcuvette based technology method is a simple and rapid technique for determination of PFHb. It is linear from 0 to 3000 mg/dl with a measuring range that was shown to be adequate according to the proposal of routine checking of PFHb 24-hours after ECMO initiation is sensitive for early identification ant treatment of the cause of hemolysis[1].

B-302

Evaluation of Whole Blood BUN, Creatinine and tCO_2 Assays *vs.* Roche Cobas Chemistry Analyzer with Clinical Samples

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Background: Blood urea nitrogen (BUN), creatinine and tCO_2 are part of the basic metabolic panel, one of the most commonly ordered blood tests, which provides physicians with a quick assessment of patient electrolyte and fluid balance, blood glucose level and kidney function. A new cartridge that enables fast, accurate and reliable measurements of BUN, creatinine and tCO_2 using electrochemical sensing technologies for the GEM Premier whole blood (WB) analyzer (Instrumentation Laboratory/IL) is currently in development. This is an addition to the blood gases, electrolytes, and metabolites currently offered on the GEM analyzer. The goal of this study is to compare the analytical performance of the three new GEM WB assays to an established reference method.

Methods: A total of 695 random patient samples were obtained daily from Lahey Hospital and Medical Center (Burlington, MA). Each heparinized WB sample was assayed on up to four GEM analyzers (IL) based on the available sample volume. The plasma portion was assayed on a reference Roche Cobas c311 analyzer (Roche Diagnostics). The study was conducted over the course of four months to cover a wide range of samples and patient populations. The GEM test cartridges (N=47) were replaced on a weekly basis with minimum of 50 samples tested per cartridge.

Results: The WB BUN, creatinine, and tCO2 results from GEM analyzer compared well with those obtained from plasma on the reference analyzer across the wide ranges of the unaltered clinical samples. The cartridge-to-cartridge performance consistency is also demonstrated in this study. The results of the GEM WB assays vs. the reference method are summarized in Table 1.

Conclusion: Strong correlations were observed between the GEM WB assays and the reference method in clinical samples. These assays can provide reliable WB BUN, Creatinine and tCO2 information with quick turnaround time in Point of Care environments.

Table 1. Method Correlation Statistics for the GEM WB Assays vs. Roche Cobas Assays (N = 2522)									
Analyte	Slope	95% CI	Intercept	95% CI	R	Sample Range	MDL1 (Bias)	MDL2 (Bias)	MDL3 (Bias)
BUN	0.9750	0.971 - 0.979	0.760	0.691 - 0.824	0.997	5.1 - 126 mg/dL	6.0 (0.61)	26.0 (0.4%)	50.0 (-1.0%)
Crea	0.9678	0.960 - 0.976	0.045	0.037 - 0.053	0.994	0.2 - 13.2 mg/dL	0.6 (0.026)	1.0 (-0.007)	6.0 (-2.5%)
tCO_2	1.005	0.994 - 1.02	0.203	-0.024 - 0.438	0.962	6.6 - 34.0 mmol/L	6.0 (0.24)	20.0 (1.6%)	33.0 (1.2%)

B-305

qPCR genotyping in crude serum separated by ultralow-cost, portable and hand-powered paper centrifuge: simplification of the pre-analytic and extraction steps for a future molecular point-of-care diagnostics

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Background:

An ultralow-cost, portable and hand-powered paper centrifuge inspired by historic whirligig (or buzzer) toy was described recently. The paperfuge achieves high speeds and can be used for serum/plasma separation using only human power. Moreover, as blood coagulation releases leukocyte's genomic DNA (gDNA) to serum and blood clot continuous leakages gDNA to serum *ex-vivo*, this specimen can be used directly as template in qPCR, excepting the DNA extraction. The limitation is that incubation for 96h at room temperature is necessary for a 200 base-pairs sequence be readily detectable. This turnaround time is impractical. However, just after the coagulation, small DNA molecules are more prevalent than larger ones (1.25 ug/mL for a 65 base-pairs molecule *versus* 0.1 ug/mL for a 200 base-pairs molecule) meaning that small' sizes amplicon could be amplified earlier. Thus, the objectives of this study were: a) test if paperfuge can produce serum from capillary blood for direct use in qPCR and b) reduce the amplicon size of a molecular target and check if a reliable genotyping could be performed in crude serum separated few hours after the blood collection.

Methods:

Capillary blood was drawn from 50 volunteers (32 females), ~100ul was transferred for a 1.5mL tube and for a 200ul tube by multiple fill ups and drain out of a 50ul glass capillary. The 1.5 mL tube contained 1mL water to induce hemolysis and its content was submitted to a validated DNA extraction (Chelex method). We adapted paperfuge for 200ul tubes (instead of the original described plastic capillaries). Serum separation occurred between 4-7h after the collection and 4 minutes of spinning was necessary. The variant rs4988235 (associated with lactose tolerance in adulthood) was genotyped by ARMS-qPCR using serum or extracted DNA as template. Two reactions (executed with validated primers pairs), one specific for C allele and another specific for the T allele, were performed simultaneously by using the Maxima SYBR Green/ROX qPCR master mix (Thermo Fisher) in the StepOne qPCR System (Thermo Fisher). Amplicon (90 base-pairs) specificity was checked by melting curve analysis. The genotypes were attributed by the ΔCq between the reactions C and T: CC ($\Delta Cq<-1.5$), CT ($-1.5<\Delta Cq<1.5$), TT ($\Delta Cq>1.5$). The qPCR reactions were performed 2h after the serum separation. The agreement between the tested conditions was verified by kappa statistics.

Results:

The validated workflow reveled that 26, 21 and 3 volunteers were CC, CT and TT for the rs4988235, respectively. Identical results were observed for the qPCR performed in crude serum separated by the paperfuge (kappa = 1, perfect agreement).

Conclusion:

The paperfuge, adapted for 200ul tubes, can be use for serum separation from capillary blood and this specimen can be used as template for qPCR. Moreover, productive amplification can be obtained from serum separated 4-7h after the blood drawn if molecular target had reduced amplicon size. This study simplified the pre-analytic and extraction steps for a future molecular point-of-care diagnostics in resource-poor settings and open up opportunities for applications in science education and field ecology.

B-306

A DNA guided ultrasensitive Cardiac Troponin T testing system compared with hs-cTnT

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Background: Cardiac troponin T (cTnT) assays have been evolved to show analytical, diagnostic and prognostic improvements over the last decade. The accurate quantification of cTnT levels is crucial in the diagnosis and prognosis of acute myocardial infarction. However, the endogenous anti-streptavidin antibodies, autoantibodies, and biotin might interfere the accuracy of cTnT assays. A novel ultra-sensitive Cardiac Troponin T (*us*-cTnT) testing system, bases on the recently reported 9G technology and DNA guided detection (DAGON) method, employs DNA-DNA interactions between the immobilized oligonucleotide probes and the DNA in the DNA-capture antibody conjugate. In this study, the *us*-cTnT testing system was compared with high-sensitivity cardiac troponin T (*hs*-cTnT) using patient samples.

Methods: 200 plasma samples from individuals including men and women of different age groups were collected for this study. Analytical verification included comparison of *us*-cTnT test and the high sensitivity cardiac troponin T (Roche Elecsys TnT *hs* STAT) assay. Assessment of critical outlier data for *us*-cTnT test as compared to *hs*-cTnT assay was verified by a serial dilution test which is one of the best ways to check the interference in the immunoassay.

Results: *us*-cTnT test showed linearity in the quantification of serially diluted samples. The CV values for the detection of cTnT at the LoD and the reported 99th percentile were <10%, respectively. The concordance rate between the results of *us*-cTnT test and *hs*-cTnT test was 74.7% in the samples with the cTnT concentrations bellow 15pg/mL. The serial dilution test was performed for 17 clinical samples with the concentrations in the range of 0 - 120pg/mL. Samples at <15pg/mL were detected as 5.0, 5.0, 7.0, 9.0, 164.0, 5.0, 7.0, and 7.0pg/mL in *hs*-cTnT assay and as 9.1, 11.2, 15.0, 14.7, 8.4, 8.4, 13.9, and 7.3pg/mL in *us*-cTnT test, respectively. Samples at 15-30pg/ml were detected to contain cTnT level of 3.0pg/mL in *hs*-cTnT assay and as 15.4, 25.2, and 27.3pg/mL in *us*-cTnT test, respectively. In samples containing cTnT levels >30 pg/mL, *hs*-cTnT assay detected 3.0, 6.0, and 71.0pg/mL. However, in *us*-cTnT test the samples were found to contain 35.0, 44.1, and 40.6pg/mL of cTnT, respectively. It is important to note that *us*-cTnT test showed high degree of agreement with observed and calculated values of cTnT with the correlation coefficient of 0.9952.

Conclusion: Our results indicate the satisfactory performance of *us*-cTnT test for the detection of cTnT. The serial dilution test in this study indicate that *us*-cTnT test is a sensitive method that offers a more accurate detection of cTnT values than the conventional cTnT method, because the *us*-cTnT test employing the highly specific DNA-DNA interactions avoids the interference from the endogenous anti-streptavidin antibodies, autoantibodies, and biotin etc. Therefore, *us*-cTnT test has a very high applicability for the detection of cTnT levels in the clinical settings for regular health check-up. *us*-cTnT test can be a good asset for physicians to track cTnT level and to prevent the incidence like AMI.

Keywords: cardiac troponin, accuracy, antibodies interference

B-307

Differences in blood gas patient results between POCT and Emergency Laboratory in three intensive care units

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Background

Before the installation of a new POCT device in a clinical setting, it is important to evaluate its analytical performance and results interchangeability with laboratory. It is advisable to monitor whether this interchangeability is maintained in the long-term.

Our POCT network includes 27 blood gas analyzers. Six of them are located in intensive care units (1 in Adults Intensive Care Unit (ICU), 3 in the Neonatal Intensive Care Unit (NICU) and 1 in Pediatric Intensive Care Unit (PICU)). All showed results interchangeability (CLSI EP-9) with Emergency laboratory (EL) before installation. The aim was to assess the long-term interchangeability of patient results.

Material and methods

POCT and EL results from January 2015 to June 2016 were collected from laboratory information system. Paired data were established by patient and time, considering 30 minutes as the maximum difference between POCT measurement and sample reception at EL. We studied the differences in sodium, potassium, chloride,

haemoglobin and glucose measured in POCT (ABL90 Flex, Radiometer) and EL (Dimension Vista 1500, Siemens; CellDyn Sapphire, Abbott). Internal and external quality control was within allowable limits during the study period. The comparison of each measurand was performed using ANOVA, Passing-Bablok regression and Bland-Altman analysis. Results ±2SD were considered as outliers and excluded. The allowable difference criteria were based on biological variation (total allowable error; TAE).

Results:

Magni-tude	ICU (n)	r	Intercept (CI95%) Slope (CI95%)	Bland Altman (Mean%; CI95%)	TAE (%)	Outside TAE (%)
Sodium (mEq/L)	ICU (1797)	0.958	-15.66 (-18.54 to -11.80)* 1.10 (1.07 to 1.12)*	0.90* (-2.52 to 4.31)	1.1	56.5
	NICU (791)	0.918	-23.42 (-28.56 to -17.89)* 1.15 (1.11 to 1.19)*	1.87* (-1.91 to 5.65)		69.5
	PICU (2141)	0.963	-8.79 (-12.22 to -5.54)* 1.05 (1.03 to 1.08)*	1.04* (-2.75 to 4.83)		59.6
Potas-sium (mEq/L)	ICU (1766)	0.960	0.0 (0.0 to 0.0) 1.0 (1.0 to 1.0)	0.45* (-9.21 to 10.10)	8.4	4.8
	NICU (755)	0.931	-0.1 (-0.1 to -0.1)* 1.0 (1.0 to 1.0)	2.43* (-9.94 to 14.80)		16.2
	PICU (2153)	0.986	-0.1(-0.1 to -0.1)* 1.0 (1.0 to 1.0)	1.68* (-7.16 to 10.51)		6.9
Chlo-ride (mEq/L)	ICU (1163)	0.977	0.0 (0.0 to 0.0) 1.0 (1.0 to 1.0)	0.28* (-3.07 to 3.63)	2.2	14.8
	NICU (702)	0.970	-5.8 (-8.86 to -2.00)* 1.04 (1.0 to 1.07)	1.50* (-2.34 to 5.34)		33.5
	PICU (2110)	0.972	-2.0 (-2.0 to -2.0)* 1.0 (1.0 to 1.0)	1.59* (-2.05 to 5.23)		33.6
Haemo-globin (mg/dL)	ICU (1820)	0.990	-0.33 (-0.3 to -0.26)* 1.02 (1.02 to 1.03)*	0.69* (-4.96 to 6.33)	6.36	3.3
	NICU (1836)	0.988	-0.46 (-0.55 to -0.36)* 1.03 (1.02 to 1.04)*	0.61* (-8.24 to 9.46)		9.4
	PICU (2198)	0.941	-0.35 (-0.43 to -0.25)* 1.03 (1.02 to 1.04)*	-0.18 (5.90 to 11.38)		8.7
Glucose (mg/dL)	ICU (1734)	0.987	3.47 (2.00 to 4.50)* 0.99 (0.98 to 1.0)	-1.48*(-15.59 to 12.63)	5.55	24.3
	NICU (672)	0.984	4.76 (3.57 to 6.01)* 0.95 (0.93 to 0.96)*	-0.45(-18.77 to 17.87)		40.8
	PICU (2131)	0.984	1.45 (0.0 to 2.61) 0.98 (0.97 to 1.00)	0.09 (-17.60 to 17.78)		31.3

* Statistically significant differences

Sodium showed the maximum differences between POCT and EL. NICU was the clinical setting with more discrepancies observed, followed by PICU and ICU (ANOVA; p<0.001).

Conclusions

The assessment of interchangeability in the long-term is relevant. Strict analytical performance specifications might explain the large differences in sodium. Patient type and preanalytical factors could contribute to differences between ICUs. It is important to evaluate this information with POCT settings staff in order to reinforce good practices in POCT use.

B-308

Implementing Total Quality Assurance in Point-of-care Testing

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INTRODUCTION

Point-of-care testing (POCT) allows healthcare professionals to perform critical tests close to the patient, as opposed to sending samples to laboratory and waiting for the results. Since primary users of POCT are from non-laboratory backgrounds, POCT devices should be designed for ease of use, low maintenance and with comprehensive quality control for rapid detection and correction of errors. Suggested methodologies rely on understanding sources of error during each phase of the testing process. The objective of this study is to evaluate performance of a comprehensive Quality Management program called "Intelligent Quality Management 2" (iQM®2) to replace the use of traditional quality control.

METHODS

GEM® Premier 5000 analyzer (Instrumentation Laboratory, Bedford, MA, USA) performs whole-blood testing of pH, pCO_2, pO_2, Na^+, K^+, Cl^-, Ca^{++}, hematocrit, total bilirubin, total hemoglobin and fractions. The analyzer is composed of the instrument and a single, multi-use, disposable cartridge (PAK) containing all the analytical components for sample measurement and quality assurance. iQM2 is the method of control in the analyzer, based on continuous monitoring of sensor drifts by internal Process Control Solutions and analyzing response patterns during the measurement process of every sample with IntraSpect technology. Sources of error as a result of blood micro-clots, interfering substances, micro-bubbles or abnormalities in sample measurement are determined by identifying specific known patterns before, during and after every sample, followed by automatic corrective actions, as well as documentation and notification of all actions.

Data from a large number of PAKs in high-volume clinical use in several European countries were analyzed to identify errors and the outcome of corrective actions conducted by iQM2.

RESULTS

A total of 228,677 samples from 721 PAKs collected from 95 analyzers were queried with the following results:

1. Microclots

a. Affecting one or more electrochemical parameters in 0.3% of samples

b. Affecting CO-Oximetry (optical) in 0.1% of samples

c. Automated corrective action to remove clots was successful in > 95% of occurrences

d. Duration of detection, correction and verification varied from 4 to 11 minutes

2. Interference

a. Affecting electrochemical parameters in 0.1% of samples, with majority on Ca^{++} and Na^+, identified as benzalkonium contamination

b. Affecting CO-Oximetry in 1.0% of samples from excess turbidity or other sources of optical interference or sample-integrity-related interference

c. Recovery time was immediate with no lasting effect on the analytical system

3. Sample response

a. Abnormality in sensor response pattern was detected by IntraSpect in 0.6% of samples

b. Transient and sample-specific error affecting one analyte was found in the majority of cases

c. In-house studies indicate 70% of IntraSpect-flagged analytes had error exceeding CLIA analytical quality requirements

CONCLUSION

Data analysis of the GEM PAKs in actual clinical use confirmed the effectiveness of iQM2 in rapid detection of transient, sample-specific errors that could affect analytical results. This is in contrast to traditional quality control (manual or automatic) where no such errors could be detected. iQM2 can effectively help hospitals improve patient care while enhancing the efficiency of testing and reducing the total cost of care.

B-309

Assessing the adequacy of laboratory test request from POCT clinical settings

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Background

When a POCT network is installed in a healthcare system, it is relevant to determine when the magnitudes should be measured as POCT or in laboratory to avoid unnecessary sample collections, measurements or duplicate information for patient management. The POCT network developed in our third-level hospital over 18 years currently includes 27 blood gas (BG) analyzers (ABL 90 Flex, Radiometer): 3 in Emergency Laboratory (EL) and 24 in different clinical settings. Since a POCT BG analyzer is installed, all BG samples should be performed as POCT.

The aim of this study was to assess the adequacy of BG, electrolytes and glucose testing request to EL from clinical settings with POCT BG analyzers.

Material and methods

From every clinical setting, the number of POCT BG and those requested to EL were extracted from laboratory information system during 2016.

We also evaluated the number of glucose and electrolytes (sodium, potassium and chloride) performed in Dimension Vista (Siemens Heathineers) after a request to EL, having had results of these magnitudes in the POCT analyzers within the previous 45 minutes, considering all as the same sample collection.

Results

62,996 BG were performed in EL during 2016. POCT BG was 95,535 (60%).

POCT Setting	POCT BG (n)	BG request to EL n (ratio EL BG/ POCT BG)	Simultaneous EL-POCT requests Glucose n (% of total POCT BG)	Simultaneous EL-POCT requests Electrolytes n (% of Unit EL electrolytes requests)
Adults Intensive Care Unit	11,522	71 (0.006)	2,109 (18)	1,742 (15)
Burn unit	5,426	99 (0.018)	881 (16)	760 (14)
Coronary Care Unit	3,662	47 (0.013)	256 (7)	205 (6)
Post-Anesthesia Care Unit - I	8,254	55 (0.007)	2,036 (25)	2,021 (24)
Post-Anesthesia Care Unit - II	14,158	52 (0.003)	4,498 (32)	4,021 (28)
Medical Surgical Unit - I	1,903	0 (0.000)	1 (0)	2 (0)
Medical Surgical Unit - II	2,273	0 (0.000)	3 (0)	3 (0)
Medical Surgical Unit - III	567	5 (0.009)	0 (0)	3 (1)
Emergency Department	5,873	37,336 (6.360)*	2,393 (41)	2,301 (39)
Pediatric Post-Anesthesia Care Unit	7,990	41 (0.005)	1,255 (16)	1,241 (15)
Pediatric Intensive Care Unit	10,632	109 (0.010)	2,097 (20)	2,169 (20)
Neonatal Intensive Care Unit	15,405	18 (0.001)	601 (4)	598 (4)
Delivery Room	7,870	1 (0.000)	4 (0)	4 (0)
TOTAL	95,535	37,834 (0.396)	16,134 (17)	15,067 (16)

*The elevated number of BG request to EL was related to the gradual installation of the POCT through this year. Without this data, the total ratio would be 0.006.

Conclusions

After a POCT is installed, BG is rarely requested to EL. However, some magnitudes are still requested to laboratory often within an ampler request. Surgical Units and Delivery Room showed the lowest duplicate request, possibly due to the immediate clinical decision making in these areas. The locations with more duplicates were Post-Anesthesia Care Units and Pediatric ICU. These findings are relevant in order to work with POCT settings to improve rational use.

B-310

A highly sensitive Point of Care Test for GFAP - a brain biomarker in serum

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Background: Glial Fibrillary Acidic Protein (GFAP) is brain specific protein with a molecular weight of about 50 kDa which is released into blood during traumatic brain injury (TBI) and Stroke. A breakdown product of GFAP (38 kDa, GFAP-BDP) has also been detected in patients with TBI. Several ELISA kits are commercially available to quantitate GFAP in serum and most of them have very low sensitivity and require long incubation times. A highly sensitive and quantitative assay which could be used as a point-of-care diagnostic test for GFAP as a biomarker for TBI is not available.

Methods: Here we report the development of a sensitive, quantitative and highly specific lateral flow assay for measuring GFAP in human serum. The assay utilizes a high affinity monoclonal antibody against human GFAP for capture and an europium (Eu, III) labeled polystyrene nanoparticles conjugated to the $F(ab')_2$ fragment of a high affinity second monoclonal antibody against human GFAP for detection. The test strips are assembled in plastic cassettes and the assay requires 100 µL of serum sample. Calibration standards containing 0 pg/ml to 250 pg/ml of GFAP and GFAP-BDP were prepared in control human serum. One hundred microliters of the neat serum alone (0 pg/ml) and human serum containing indicated concentrations of GFAP or GFAP- BDP were applied to sample port of each cassette, followed by 50 µL of a chase buffer and allowed to stand at room temperature for 30 - 60 min. Measuring the fluorescence of Eu signal on the lateral flow membrane was performed using a Lateral Flow Fluorescence reader (Qiagen, ESEQuant LFR) and a Lateral Flow Time Resolved Fluorescence reader (Dx-Sys).

Results: The background fluorescence from the matrix and associated material (membrane and plastic) were greatly diminished in the time-resolved mode which significantly boosted the signal window as well as detection limit to below pg/ml concentration of GFAP. The assay generates a linear calibration curve from 0 pg/ml to 125 pg/ml. The assay performs equally well with the break-down product of GFAP (GFAP-BDP) as it is with intact GFAP. The sensitivity of the assay was about 15 fold higher when the signal was measured in the Time Resolved Fluorescence reader compared to the fluorescence reader from Qiagen. The assay is highly reproducible (inter assay cassette CV < 12%), sensitive with an LOQ of 0.125 pg/mL, and fast (sample application to detection <45 min).

Conclusion: A Point-of-Care, lateral flow immunodiagnostic test using Europium labeled particles and quantitation by a Time Resolved Fluorescence reader gives a very high sensitivity to measure brain biomarker - GFAP at sub-pg levels in human serum in less than 45 minutes. This rapid quantitative assay can be easily adapted to detect several other biomarkers which require high sensitivity.

B-311

Europium Based, Quantitative, Point of Care Immunoassay, Fluoro-Check for Measurement of Procalcitonin Has a High Correlation with the BRAHMS Procalcitonin

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INTRODUCTION: Procalcitonin (PCT) is a biomarker of bacterial infections and is increasingly used for early risk stratification with suspected sepsis and pneumonia. Point-of-care (POC) test is performed for early decision making, and POC for PCT is useful to diagnose bacterial infection. However, most POC devices for PCT measurement take semi-quantitative methods, and have limitations in monitoring PCT levels for evaluating the response to antibiotics. The Fluoro-Check™ PCT (Nano-Ditech Corp, NJ) is a Europium based immunoassay for the quantitative determination of PCT. In accordance with Clinical and Laboratory Standards Institute (CLSI) guidelines, within-laboratory precision of Fluoro-Check PCT is less than 15% coefficient of variation at a low, mid-, and high level. We compared Fluoro-Check PCT with Elecsys BRAHMS PCT (Roche Diagnostics, Mannheim, Germany) using clinical specimens. METHODS: The study was approved by the Institutional Review Board of Dongguk University Ilsan Hospital (2016-019) and 125 specimens, whose PCT results by Elecsys BRAHMS PCT ranged from 0.03 to 16.44 ng/mL, were included. After adding 10 uL of serum into sample well, 2 drops of developer solution were applied onto the developer well immediately. The PCT molecules in the sample bond to both biotinylated and Europium particle coupled with anti-PCT antibody at the end of the membrane. Test kits were inserted into Fluoro-Checker TRF reader,

and then PCT results were derived by analysis of fluorescence intensity, proportional to the concentration of PCT. Data from the Fluoro-Check PCT were compared with the results using cobas E601 analyzer (Roche Diagnostics) according to CLSI EP 09-A3. RESULTS: The measurable range of Fluoro-Check PCT values was 0.08 - 18.08 ng/mL and distribution was as follows : 21 samples with < 0.5 ng/mL, 33 samples with 0.5-2.0 ng/mL, 56 samples with 2.1 -10.0 ng/mL, and 15 samples with >10.0 ng/mL. Passing-Bablock regression analysis of Fluoro-Check PCT and Elecsys BRAHMS PCT showed a high correlation. Correlation coefficient was 0.921 (95% confidence interval [CI], 0.889 ~ 0.944), slope was 1.236 (95% CI, 1.181 ~ 1.299), and intercept was -0.046 (95% CI, -0.1339 ~ -0.008). CONCLUSION: Fluoro-Check, the europium-based fluorescence immunochromatographic assay, has the advantages of POC. Fluoro-Check PCT showed a high correlation with Elecsys BRAHMS PCT at the measurable range of 0.08-18.08 ng/mL. Quantitative analysis of PCT using Fluoro-Check appears useful for clinical applications to diagnose and monitor patients with bacterial infection.

B-312

Optimization of Lactate Measurements for Sepsis Guidelines Using Point of Care Testing

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Background: Sepsis is a life-threatening illness caused by an unregulated host response to infection that can lead to septic shock and death. In October 2016, CMS introduced a new core measure based on the Surviving Sepsis Campaign International Guidelines for Management of Sepsis and Septic Shock. This measure requires both a baseline and a 6-hour lactate measurement. Lactate is a marker for cellular hypoxia, and is associated with increased mortality in sepsis. Our hospital, similar to many others, requests baseline and 4-hour measurements to ensure lactate is obtained within 6 hours. The objectives in this study were to evaluate adherence to the hospital's protocol and to evaluate whether Point of Care (POC) lactates improve turnaround time (TAT).

Methods: Elevated lactate is defined as >2.0 mmol/L. We evaluated 200 pairs of lactate measurements where the baseline was >2.0 mmol/L and the second specimen was reported at 3-3.5, 3.5-4.5, and up to 6 hours. Lactate was measured by: 1) Epoc Blood Analysis System (Alere, Orlando, FL; whole blood, POC); 2) RapidLab 800 (Radiometer, Brea, CA; whole blood, sent to laboratory); or 3) Cobas 6000 (Roche, Indianapolis, IN; serum, sent to laboratory). Lactates collected <3h or >6h were excluded.

Results: 15,701 data points were evaluated from October 2016-January 2017. 200 pairs met the above criteria (Table 1). 54 pairs did not meet the hospital's guideline of lactates reported within 4 hours. Of the 54 pairs, 22 pairs were sent from units where POC lactate was available but not used, indicated by asterisk on the table.

Conclusion: Paired lactates performed non-POC fell outside of guidelines (>4.5hr). POC whole blood lactate provides immediate results that could assist in adhering to hospital sepsis guidelines and should be utilized where available.

Table 1

	ICU POC Lactate (whole blood)	ICU Lactates sent to lab (whole blood and serum)	ED Lactates sent to lab (whole blood and serum)	Other Locations Lactate sent to lab (whole blood and serum)
Average Δ Time, Paired results 3-3.5 (h)	3.14 (n=4)	3.17 (n=18)	3.25 (n=3)	3.27 (n=25)
Average Δ Time, Paired results 3.5-4.5 (h)	3.79 (n=4)	4.05 (n=29)	4.00 (n=8)	3.94 (n=55)
Average Δ Time, Paired results 4.5-6.0 (h)	n/a	*4.80 (n=17)	*4.87 (n=5)	4.89 (n=32)
Difference in collection to result time for Non POC lactate (h)	n/a	0.987	0.910	0.983

B-313

Analytical Evaluation of Blood Gas Syringes for Pneumatic Tube Systems

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Background: There are many options and considerations when choosing arterial blood gas (ABG) syringe to use. It is important to be able to fill the syringe with minimal air contamination, properly mix the sample to suspend cells, as well as the choice of heparin type and concentration. There are many commercially available devices, with different designs to optimize syringe fill, while preventing pre-analytical error. Based on review of data from customer sites, choice of ABG syringe when used in conjunction with a pneumatic tube system (PTS) must be considered.

Methods: Several types and brands of ABG syringes were evaluated using the GEM® Premier™ 4000 at Instrumentation Laboratory (Bedford, MA). Each syringe was evaluated by simulated user use to evaluate the impact of the device on blood values after simulated PTS transport. Areas of focus were: venting mechanism (cap, plunger, or both), effectiveness at purging excess air, and syringe volume on blood gas and hematology results. To simulate PTS transport, blood was tonometered to ~30 mmHg pO_2, drawn into the syringe, sampled on the GEM Premier 4000, then a slight vacuum was introduced, shaken, and sampled again. Results show that in a negative pressure state with agitation any air contamination through the venting mechanism, or trapped air, causes micro bubbles and a resulting change in patient results. Some venting mechanism combinations are more resistant to the simulated effects of PTS transport.

Conclusion: Overall, data demonstrated that vented syringes are best for preventing pre-analytical error during sample draw, where non-vented syringe components are preferred for PTS transportation. Preliminary results are shown in Table 1 for each of the six tested syringes. Each syringe type was tested 5 times. Results are expressed in the fraction averages.

Table 1: Syringe Name and Change to Hemoglobin Fractions

Syringe	O_2Hb			HHb			COHb		
	Pre	Post	Change	Pre	Post	Change	Pre	Post	Change
Pro-Vent® - Smiths Medical	37.7%	36.3%	-1.4%	60.8%	61.8%	1.0%	1.1%	1.4%	0.3%
A-Line® - Westmed	36.9%	36.6%	-0.3%	61.2%	60.8%	-0.4%	1.5%	0.8%	-0.7%
Preset™ - BD	42.7%	43.0%	0.3%	55.1%	54.1%	-0.9%	1.5%	1.0%	-0.4%
SafePICO® - Radiometer	45.5%	46.4%	0.8%	52.1%	50.1%	-2.0%	1.7%	1.1%	-0.6%
Pulsator – Smiths Medical	39.0%	47.9%	8.9%	59.3%	49.5%	-9.8%	1.3%	1.2%	-0.1%
Pulset™ - Westmed	44.0%	60.2%	16.2%	53.8%	36.2%	-17.6%	1.6%	1.7%	0.1%

A complete study of venting technique and impact to patient results is ongoing

B-314

Comparison of creatinine on the Alere epoc Blood Analysis System against multiple point-of-care and central laboratory assays

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Background: The epoc Blood Analysis System from Alere is a point-of-care (POC) instrument that measures blood gases, electrolytes, and metabolites. In Edmonton, the epoc has been used by emergency medical services since 2015 for patient assessments in continuing care facilities. Recently, Alere added creatinine and chloride to the already existing panel of 9 measured analytes. We evaluated the performance of creatinine and compared it against other assays, including central laboratory and POC, that are used in our health region.

Methods: Ethics approval for this study was obtained from our institution's ethics review board. Following informed consent, three tubes of lithium heparin blood were collected from each of 60 healthy volunteers. Creatinine was measured on two POC instruments (Alere epoc, Abbott i-STAT), and two central laboratory analyzers (Beckman Coulter DxC 800, Ortho Clinical Vitros 350). Raw creatinine results, as well as corresponding eGFR values, were compared between the epoc and the other instruments to ascertain any clinically significant differences. eGFR values were calculated using the CKD-EPI formula. Six additional patient samples with abnormally high creatinine values were also analyzed on the epoc, DxC 800 and Vitros 350 and were compared in a similar manner. Within-laboratory precision was assessed for all platforms by assaying two levels of quality control three times daily for 5 days.

Results: For healthy volunteers, raw creatinine values from the epoc showed moderate agreement with other methods (R = 0.783 to 0.886). Calculated eGFR values demonstrated 90-100% concordance between the epoc and other methods for all age groups and genders except for females of age 80 years or older. For this latter

group, the concordances were 68% (vs DxC 800), 75% (vs Vitros 350) and 82% (vs i-STAT), and mean biases were -7% (vs DxC 800), -4% (vs Vitros 350), -1% (vs iSTAT). Other analyzers demonstrated excellent concordance with each other (90-92%) for this subset of patients. For patients with abnormally high creatinine values, the epoc showed excellent correlation with other analyzers (R = 0.997 to 1.000). Concordance between calculated eGFR values was also excellent (100%). Quality control samples demonstrated coefficients of variation (CV) of 4.3% at a mean creatinine concentration of 57 mmol/L and 11.8% at mean creatinine concentration of 154 mmol/L.

Conclusion: The analytical performance of the epoc creatinine assay appears comparable to the assays on the i-STAT, DxC 800 and Vitros 350 platforms. The negative biases shown by the epoc against other analyzers were not clinically significant as they did not exceed total allowable error limits of 26.52 mmol/L or ±15% (CLIA'88) for creatinine. Despite lower concordance between the epoc and other methods for females of 80 years or older, differences in results were still within total allowable error limits. As such, the epoc appears to be a suitable POC alternative or complement to any of the other platforms examined in this study.

B-317

Design and Testing of a Novel Point-of-Care (POC) Device to Convert Whole Blood to Serum at the Bedside for Medical Diagnostics

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Whole blood is used to measure disease-diagnosing biomarkers for a wide range of molecules. Whole blood contains components that can make the measurement of these biomarkers inaccurate, leading to misdiagnosis and increased patient mortality and morbidity. While whole blood is quick and convenient for analyte detection using point-of-care (POC) devices, serum is preferred for most accurate biomarker detection. However, obtaining serum from whole blood requires extensive processing which is not feasible for POC devices and results in delays in diagnosis. What is needed is a method that can quickly coagulate whole blood so that serum can be extracted in sufficient quantities and purities that improve upon whole blood analyte detection. The objective of this study was to design an affordable system that quickly (<5 minutes) and more effectively (resulting in pure serum) converts whole Blood to Serum (B2S System). Several pro-coagulants were analyzed for their ability to induce coagulation without red blood cell (RBC) lysis. It is shown that snake venom in combination with silicon dioxide and protamine sulfate was optimal for coagulation time, firm clot formation, and serum clarity.

Methodology. Nanomaterials (NMs) were tested in the coagulation formula with snake venom, human thrombin, and protamine sulfate. Various conditions were suspended in 1 mL of whole blood and received 10mM $CaCl_2$ to counter the anti-coagulant properties of the citrated tubes used for brief blood storage. 1mL of blood was added to each condition and the blood coagulation time was measured as described below. After coagulation tubes were centrifuged at x 2000g for 10 minutes resulting in two distinct layers (serum and thrombus). Serum was removed and analyzed for RBC lyses as described below.

To quantify coagulation time standard paperclips were sanded to remove buffed layer and provide more surface area to catch the initial fibrin strand. The time at which the initial fibrin strand adhered to the paperclip was recorded as the initial coagulation time.

To investigate RBC hemolysis, serum clarity was assessed using increased absorbance of produced serum. Serum was pipetted off and seeded into a 384-well plate to measure serum purity via absorbance with a spectrophotometer. The addition of NMs facilitates the extraction of purer serum. Comparisons between conditions regarding serum purity and coagulation time using student t-tests have be done resulting in p values < .001.

In conclusion, this coagulation formula was lyophilized within the B2S prototype. The B2S system was able to draw up blood, coagulate the blood, and extrude the serum onto a strip in a time frame suitable for POC devices. Thus, the B2S system represents a novel POC device that could be adapted by existing technologies in clinical settings and improve diagnostic and therapeutic efforts for patients requiring fast and accurate blood biomarker determinations. This will improve patient care, reduce healthcare costs, and bring serum to the bedside for rapid analyte detection.

B-318

Giant Magnetoresistive Based Handheld System for Rapid Detection of Human D-dimer and C-reactive Protein

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Background: Many epidemiologic studies have indicated that D-dimer and C-reactive protein (CRP) can be used as reliable biomarkers of most cardiovascular diseases, and some *in vitro* diagnostic kits including the two biomarkers for assessing cardiovascular risk have been successfully commercialized. Biochip-based assay for biomarkers detection using giant magnetoresistive (GMR) sensors and magnetic nanoparticles (MNPs) have been developed by different research groups. However, no portable and handheld GMR biosensor system has been reported yet. In this study, a novel handheld GMR detection system with integrated microfluidics was used to detect human D-dimer and CRP, which revealed advantages of high sensitivity and specificity, multiplexity, and real-time signal readout. The developed assays have great potential for the final development of simple, rapid, automatic and cost-effective point-of-care testing (POCT).

Methods: The immunoassay process is set up based on sandwich-type format. D-dimer and CRP capture antibodies (Abs) were printed and immobilized on different sensors on one GMR chip with functional surface. Integrated with microfluidic system, the chip was assembled with plastic substrate and valves to form a test cartridge. After the cartridge was connected with the handheld detection analyzer, TBST buffer (Tris-buffered saline, 0.05% Tween 20) was pumped onto sensor surfaces to wash off unbound Abs. Then sample prepared by mixing D-dimer and CRP analytes to desired concentrations in PBST (1× PBS, 0.05% Tween 20) was loaded into sample entry well which was prefilled with biotin labeled D-dimer and CRP detection Abs. Capture Ab-analyte-detection Ab (biotin) sandwich complex was formed on sensor surface as sample solution flowed along microfluidic channel. At last streptavidin labeled MNPs (SA-MNPs) were introduced and bound onto sensor surfaces via the interaction between SA and biotin. Binding of SA-MNPs to sensor surface can be real-time recorded by the handheld analyzer. Higher detection signal reflected more MNPs binding on sensor surface.

Results: *In vitro* multiplex detection of human D-dimer and CRP using a new handheld GMR biosensor platform was well established. The assay can be completed within 20 min, which is much shorter than conventional and widely used enzyme-linked immunosorbent assays (ELISA). The novel assay provides linear analytical ranges of 0-5000 ng/mL for D-dimer and 0-500 ng/mL for CRP, and their detection limits are 8.42 ng/mL and 0.72 ng/mL respectively. D-dimer and CRP with varied concentrations were spiked into human plasma, and recoveries of 85-115% are observed for the two analytes. It is also shown that the assay is not interfered with hemoglobin, fibrinogen, human anti-mouse antibody and rheumatoid factor.

Conclusion: The developed technology platform for GMR based immunoassay is able to sensitively and specifically detect human D-dimer and CRP. Not only the assay time has been shorten, but also simple and automatic assay operation has been accomplished. Hence, we believe it can be further integrated and developed for POCT diagnostics.

B-319

A Novel One-Step One Blood Drop Beta-hCG Rapid Assay

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Background: Human chorionic gonadotropin (hCG) is a common hormone used to detect pregnancy. hCG is a glycoprotein heterodimer hormone composed of an α- and β-subunit. The α-subunit is common to luteinizing hormone (LH), follicle stimulating hormone (FSH), and thyroid stimulating hormone (TSH), while the β-subunit is unique to hCG. hCG is synthesized by trophoblastic tissue of the placenta in pregnancy making the hCG β-subunit a good predictor of pregnancy. Early detection of pregnancy is important for caregivers to avoid certain medications and procedures that could harm a fetus. Unfortunately, clinics across the country are experiencing too many false-negative results from point-of-care urine-based tests. In a March 2015 report in Clinical Chemistry, Robert N. Nerenz and Ann M. Gronowski detailed their evaluation of 11 common POC hCG urine-based devices and determined that 9 of the 11 were susceptible to false-negative results. Urine-based hCG tests are not as sensitive as blood-based tests leading to false-negative results in early pregnancy. The objective of this study is to evaluate the performance of a new blood-based hCG rapid test. **Principle:** The ADEXUSDx hCG Rapid Test ("hCG Test") was developed

using a direct sampling immunoassay technology for whole blood, plasma, serum, or capillary blood. The test requires a 35ul sample. This could be from a capillary stick or from a venous blood, plasma, or serum sample. The hCG test uses a sandwich format to detect the presence of hCG above an established reference concentration. The appearance of a purplish-red band in the test window indicates that the sample contains hCG above 10 mIU/ml. The hCG test is unique in that the sample moves directly from the patient into the device without any sample preparation, buffer application, or complex machinery required. **Performance:** A one step rapid detection of β-hCG test requires only 35μl of sample with no additional buffer. Test results can be read at 10 minutes. Using WHO hCG standard added to whole blood, the C5 concentration (5% of samples positive) was confirmed as 1.25 mIU/ml hCG and the C95 concentration (95% of samples positive) as 4.5 mIU/ml hCG, which are equivalent to approximately 2.3 mIU/ml hCG and 8.2 mIU/ml hCG, respectively, in plasma. There was no cross reactivity to the α-subunit portion of hCG as demonstrated using three other hormones. Further testing demonstrated no high-dose effect at hCG levels up to 150,000 mIU/ml. A clinical study was conducted using 84 samples above the cutoff and 476 samples below the cutoff. Results were comparable to the predicate device, Unicel® DxI 600® Access® Clinical System, with 97.6% sensitivity, 99.8% specificity, 98.8% PPV, and 99.6% NPV. **Conclusion:** The ADEXUSDx hCG Test is a true one-step rapid test with demonstrated specificity to β-hCG. It has a cut-off at 10 mIU/mL making the ADEXUSDx hCG Rapid Test a useful test for the early detection of pregnancy.

B-320

A novel one-step one drop of blood sampling HSV-2 antibody rapid test

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Background: HSV-2 infection is widespread throughout the world and is almost exclusively sexually transmitted, causing genital herpes. Genital herpes can also be caused by herpes simplex virus type 1 (HSV-1). Both HSV-1 (cold sores) and HSV-2 (genital herpes) viruses infect epithelial cells and are ubiquitous and contagious. To some extent genital herpes is attributable to HSV-1 which is not as clinically severe whereas, HSV-2 infection increases the risk of acquiring human immunodeficiency virus (HIV) infection by approximately three-fold. Neonatal herpes can also occur when an infant is exposed to HSV in the genital tract during delivery. The screening of all pregnant women and their sexual partners for HSV-2 antibodies would help to prevent primary maternal infections and neonatal infection. It would also help to identify all women at risk for recurrent HSV-2 infection as well as asymptomatic HSV-2 seropositive mothers. Immunological or molecular based tests are available to determine HSV-2 infection and are complicated to perform. A rapid one-step HSV-2 Antibody Test format is developed which detects only HSV-2 specific antibodies. The objective of the test study is to demonstrate the performance of the new one-step test.

Principle: Adexus-Dx HSV-2 Antibody test was developed using a direct sampling immunoassay technology for whole blood, plasma serum or capillary blood. Purified HSV-2 recombinant antigen has been employed for the detection of HSV-2 antibodies. 35 μl of serum/ plasma/venous blood or one drop of blood directly from the fingertip with no addition of extra buffer is required for the test. When sufficient sample volume fills the Receiving Channel, the sample flows into a dry porous test strip composed of a membrane array with colloidal gold conjugated HSV-2 specific antigen. The appearance of visible pinkish-red band at the test window region indicates that the individual sample contains HSV-2 antibody.

Performance: A one step rapid detection of HSV-2 antibody test only requires 35 μl of sample with no additional buffer. Test results can be read at 15 minutes. Testing with WHO anti-HSV-2 and anti-HSV-1 quality control serum samples confirmed that HSV-2 antibodies were recognized by the test. A clinical sample study was conducted using 102 HSV-2 positive and 109 negative samples. Results were comparable with the EIA based method for both positive and negative clinical samples. There was no cross reactivity with 30 HSV-1 positive clinical samples. Further testing of characterized 21 member anti-Herpes mixed titer performance panel showed 100% agreement with the Focus Herpes Select 2 IgG ELISA.

Conclusion: The ADEXUS-Dx HSV-2 Antibody Test is a true one-step rapid test with excellent sensitivity as well as specificity for the detection of HSV-2. It is the simplest and most suitable test to use in the detection of HSV-2 infection at the point of care or for self-testing.

B-322

Development of a Multiplexed Immunochromatographic Assay for Detection of Acute Bacterial Sinusitis

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Background: Annually, 29 million people are diagnosed with sinusitis in the U.S. and 80% receive a prescription for antibiotics. Although less than 10% of sinusitis cases are caused by bacteria, sinusitis accounts for more adult antibiotic prescriptions than any other outpatient diagnosis. Currently, there are no products available to diagnose bacterial sinusitis at the Point of Care (POC). With the looming threat of antibiotic resistance and 1 in 1000 patients suffering serious, sometimes life-threatening adverse effects due to antibiotics, physicians need better tools to diagnose and inform the clinical management of patients with sinusitis. Entvantage Diagnostics is developing the first multiplexed, Point of Care (POC) test for rapid diagnosis of bacterial sinusitis in the primary care and urgent care setting where 90% of sinusitis patients are seen. **Methods:** Mouse monoclonal antibodies were generated or licensed for each of three pathogens responsible for >90% of bacterial sinusitis; *non-typeable H. influenzae* (NTHI), *M. catarrhalis*, and *S. pneumoniae*. Antibody pairs were initially selected for the final assay prototype based on inclusivity, analytical sensitivity, analytical specificity, and interference by enzyme-linked immunosorbent assay (ELISA). Prior to licensing from the Respiratory Diseases Branch of the CDC, Anti-*S. pneumoniae* antibodies had screened positive for recognition of 90 serotypes and demonstrated minimal crossreactivity with 22 genera and 29 species of respiratory pathogens and commensals. Inclusivity: Bacterial lysates were generated using a hyperosmotic lysis buffer containing an anionic detergent, a chaotrope, and protease inhibitor and utilized as antigen by ELISA. Anti-*H. influenzae* OMP-P5 specific antibodies were selected for positive recognition of two reference strains, 5 clinical isolates, and an OMP-P5 knockout. Anti-*M. catarrhalis* CD antibodies were selected for recognition of a reference strain. Analytical Sensitivity: The target limit of detection for the final assay was $1x10^4$ CFU/ml. Antigen was diluted from $1x10^7$- $1x10^2$ CFU/ml and interrogated with the antibody pairs. Antibody pairs that met this specification were selected for additional testing. Analytical Specificity: Down-selected antibody pairs were further screened for reactivity to lysates of 12 bacterial species commonly found in the nasal cavity, including *S. aureus* and *S. epidermidis*. Those demonstrating no crossreactivity were selected for prototyping of individual lateral flow-based immunochromatographic assays. **Results:** These prototyped assays were tested in an IRB approved pilot study composed of 7 symptomatic patients, 15 healthy participants, and 22 contrived samples. Bacterial culture of endoscopically guided swab of the Middle Meatus served as the comparator method. Sensitivity for *H. influenzae*, *M. catarrhalis* and *S. pneumoniae* were 94 %, 87.5% and 90%, respectively. Specificity for *M. catarrhalis H. influenzae*, and *S. pneumoniae* were 92%, Not determined due to no true positives, and 100%, respectively. **Conclusion:** The results of this study support full validation and clinical assessment of this product. This rapid diagnostic will improve patient care by equipping health care providers with a means to quickly and accurately diagnose patients with sinusitis who otherwise would be treated empirically.We acknowledge the contribution of the Respiratory Diseases Branch, Division of Bacterial Diseases, CDC.

B-323

Microfluidic-based Point-of-Care Immunoassay for Quantitative Determination in Capillary Whole Blood

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Fast and accurate delivery of diagnostics results contributes to improving quality of healthcare. In those settings, where phlebotomists and trained laboratory staff are not readily available, the design characteristics of an immunoassay diagnostic device must be able to accommodate capillary blood samples, and pass a high bar for both ease of use and accuracy of the test result. The Claros® 1 instrument, associated with its Sangia™ microfluidic device, returns a laboratory-quality, quantitative result in approximately 10 minutes (from sample collection to result). The sample collection interface was optimized for the user to collect precisely 12uL capillary blood samples at the fingertip of the patient, before subsequent attachment to the microfluidic device. After insertion of device in the analyzer, the user may enter patient specific information and then walk away until the test result is reported. The Sangia measures analytes directly from capillary whole blood (WB), and the test is designed and calibrated to return a result matching that of conventional immunoassays performed in serum or plasma. In this contribution we present the analytical performance of the Claros 1 with

the Sangia total PSA kit, and a clinical evaluation based method comparison against an established laboratory method (Roche Cobas® and total PSA Elecsys® kit).

The limit of quantification of the PSA assay was found to be 30pg/mL (per CLSI guideline). Precision profile of the assay showed a CV=9-16% across the entire assay range (0.05-16ng/mL). Equimolarity between free-PSA and alpha-1-antichymotrypsin-PSA was demonstrated at three levels of PSA (0.3, 3 and 14 ng/mL). Following an IRB-approved protocol, a cohort of 68 men was enrolled for PSA testing in a two-arm study design: a EDTA blood tube was collected and centrifuged to obtain plasma for testing with PSA Elecsys test in a CLIA-accredited laboratory, and a fingerstick blood sample was collected for testing with PSA Sangia in the point of care. Five lots of PSA Sangia were included in the study, and some men were tested on more than one lot of PSA Sangia, yielding a total of 86 PSA determinations with both methods. The method comparison (Passing Bablok) fingerstick WB on Sangia vs. plasma on Elecsys showed excellent correlation with a slope 0.999, intercept 0.0007 ng/mL, and R^2=0.95.

The data presented demonstrates that the determination of PSA from a single drop of capillary blood using a truly point-of-care system matches closely the results from an established laboratory method. Pending completion of regulatory activities, the Claros 1 system appears to be well suited for safe and reliable use in the doctor's office.

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Comparison of three glucose meters: Accu-chek Performa-Nano, Accu-chek Active and Prestige, commercially available in Peru

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Background: The point-of-care (POC) glucose devices are routinely used for monitoring glucose levels and play a key role in the management of hyperglycemia and hypoglycemia at the patient's bedside. In addition glucometers has an important function in diabetic patients as a self-monitoring of blood glucose in a convenient manner. The purpose of this study was to evaluate the accuracy of 03 most common glucose meters: Accu-chek Performa-Nano,Roche, US (Nano);Accu-chek Active, Roche,US (Active); Prestige, Nipro,Mexico (Prestige), commercially available in Peru.

Methods: Accu-chek Performa Nano, Roche (glucose dehydrogenase/amperimetric); Accu-chek Active, Roche (glucose dehydrogenase/amperimetric) and Prestige, Nipro (glucose oxidase/amperimetric) were assessed and results compared to central laboratory method (glucose oxidase, dry chemistry), using VITROS 4600 System chemistry analyzer (Ortho Clinical Diagnostics, Inc). 80 whole blood samples from patients were prepared and divided in three groups of glucose concentration were evaluated: 20 blood samples with glucose ≤ 70 mg/dL, 40 with 70–160mg/dL and 20 with 180-500 mg/dL, were measured in duplicated with each glucometer and immediately centrifuged, the glucose plasma concentration by the routine glucose method (glucose oxidase) of the central laboratory using the VITROS 4600 System was performed. The plasma glucose values were adjusted by +/-10%. Analytical performance precision parameter of these 3 glucometers was verified using CLSI EP15-A3, with manufacturer control material (level 1-normal and level 2-high level) and was measured in quintupled during 5 days, according CLSI EP 15-A3 to estimate repeatability and intralaboratory precision. Glucose meter results were compared to reference glucose central laboratory method to estimate the bias, acceptability according ISO15197:2013 (>95% of glucose result <100mg/dL:+/-15mg/dL or >100mg/dL:+/-15%) and the Color–Coded Surveillance Error-Grid plot for each glucose meter was evaluated.

Results: The mean bias for Nano, Active and Prestige was -6.8, -7.94 and 8.93 mg/dL with r^2 values of 0.995, 0.994 and 0.979, respectively. The Accuracy using Color–Coded Surveillance Error-Grid plot, for Nano and Active, only showed 8.75 and 2.5% of the results were with slight lower degree of risk (light green/region A and B); and for Prestige, 2,5% of the results were slight higher degree of risk (yellow/region C). For Nano and Active, 100% of the glucose results met the ISO 15197:2013 requirements for glucose <100 mg/dL and 95% and 100% for glucose >100 mg/dL, respectively. The Prestige <90% of the glucose results met the ISO 15197:2013 for glucose >100 mg/dL and <100 mg/dL. Nano, had a precision of repeatability (level 1=1,4% and level 2=1,8%) and intralaboratory precision (level 1=2.8% and level 2=2,2%), for Active the precision of repeatability (level 1=2.1% and level 2=1.6%) and intralaboratory precision (level 1=3% and level 2=3%), and for Prestige, the precision of repeatability (level 1=2.6% and level 2=1.3%), and intralaboratory precision (level 1= 9.5% and level 2=3.7%), the precision was accepted according manufacturer specifications.

Conclusion: Glucose meters meet the requirements of analytical performance described by the manufacturer and showed good accuracy, correlation and clinical concordance in relation to the reference central laboratory results, but not all meet the analytical quality specifications proposed by ISO 15197:2013.