**B-328**

**Point of care measurement of creatinine and eGFR in the emergency department**

A. Ivanov, T. Tammert-Müürsepp, K. Nõmm. Tartu University Hospitals, Tartu, Estonia

**Background:** Incidence of chronic kidney disease (CKD) around the world is reported to be between 8.5-15.6%. Identifying patients with CKD prior to a diagnostic radiological imaging with nephrotoxic contrast agents will reduce a risk of contrast-induced acute kidney injury (CI-AKI). **Aim:** To compare POCT-creatinine and eGFR with central laboratory and assess the impact of POCT-creatinine and eGFR testing with immediate feedback to the clinician on the risk of developing CI-AKI. **Methods:** The study was performed during three month period using samples obtained from the Emergency Department of Tartu University Hospital. Creatinine was measured prior to the diagnostic radiological imaging with LIS-connected handheld POCT-creatinine meter (Stat Sensor, Nova Biomedical, MA, USA). eGFR was automatically calculated by LIS after connecting the Stat Sensor Creatinine meter to the docking station. At the same time venous blood was collected and tested on Cobas 6000 analyzer (Roche Diagnostics, Switzerland) utilizing a creatinine enzymatic method. The IDMS-traceable abbreviated Modification of Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation was used to estimate and report eGFR. **Results:** We have compared the results of 214 patients for creatinine measurement ranged from 16 μmol/L to 610 μmol/L (eGFR from 6 to 207 ml/min/1.73m²). We used three partitions of eGFR results according to stages 3-5 of chronic kidney disease (<30, 30-60, >60) and evaluated the statistical parameters for each interval. The linear regression analysis demonstrated a slope of 0.79 for creatinine and 0.88/0.72/0.87 for eGFR<30/ eGFR 30-60/eGFR >60. POCT-creatinine had the mean bias 0.02 μmol/L or 1.6% for creatinine and 0.57/1.13/2.86 ml/min/1.73m² or 5.3/1.7/4.4% for eGFR compared with laboratory method. The results demonstrated that POCT and laboratory methods had no significant bias for creatinine (p=0.989), for eGFR <30 (p=0.687) and for eGFR 30-60 (p=0.313). The significant bias was for eGFR >60 (p=0.002). The 90th percentile of laboratory turnaround time for creatinine/eGFR is 69 min, the time to result of Stat Sensor Creatinine meter is 30 sec. **Conclusion:** The data demonstrates that Stat Sensor Creatinine meter is an effective tool for rapid assessment and identification of CI-AKI risk of CKD patients, improve the general workflow while preserving the patient’s quality of life.

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**B-329**

**From Paper to Plastic: Re-innovating Ultra Low-cost Electricity-Free Point-of-Care Blood Centrifuge for Resource Challenged Clinical Chemistry Laboratory**

A. Gautam, B. Subedi, A. Kumar, N. Koirala. Dr. Koirala Research Institute for Biotechnology and Biodiversity, Kathmandu, Nepal

**Background:** We are witnessing a great paradigm shift from central laboratory-based diagnosis to point-of-care based diagnosis. Currently used centrifuges are heavy, large, expensive and impractical for field clinics, which may have no electricity access. A hand-powered, ultra low-cost, portable centrifuge has long been required in a Point of Care settings. However, if carried out incorrectly, capillary blood sampling can cause inaccurate test results, pain and tissue damage. In addition, the small volumes involved and the variability in sample quality based on puncture site and technique make capillary sampling particularly susceptible to errors during the pre-analytical phase. **Methods:** This method comparison study using samples collected via capillary puncture was performed at one external Point of Care (POC) setting in combination with one internal laboratory setting, located at IL, which simulates a POC setting by use of POC operators. A minimum of 120 native capillary samples were collected per analyte. **Results:** Good correlation between GEM Premier 5000 and GEM Premier 4000 was observed for all analytes tested. All slopes were between 0.9 and 1.1 and r > 0.950 (see table 1). In addition, bias at the medical decision levels (MDL’s) was within the total allowable error (TEa) for all analytes tested. **Conclusion:** The data illustrates excellent analytical performance with a clinical sample type that is known to have challenging pre-analytical characteristics. Based on the results obtained in this study, native capillary performance on the GEM Premier 5000 is substantially equivalent to the GEM Premier 4000.

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**Table 1: Method Comparison results for GEM Premier 5000 vs. GEM Premier 4000**

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Slope</th>
<th>Intercept</th>
<th>r</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH</td>
<td>0.935</td>
<td>0.494</td>
<td>0.975</td>
</tr>
<tr>
<td>pO₂ (mmHg)</td>
<td>1.008</td>
<td>2.545</td>
<td>0.996</td>
</tr>
<tr>
<td>pCO₂ (mmHg)</td>
<td>1.000</td>
<td>1.000</td>
<td>0.980</td>
</tr>
<tr>
<td>Na⁺(mmol/L)</td>
<td>1.015</td>
<td>-1.750</td>
<td>0.981</td>
</tr>
<tr>
<td>K⁺(mmol/L)</td>
<td>1.000</td>
<td>0.100</td>
<td>0.995</td>
</tr>
<tr>
<td>Ca²⁺(mmol/L)</td>
<td>1.050</td>
<td>-0.016</td>
<td>0.998</td>
</tr>
<tr>
<td>Cl⁻(mmol/L)</td>
<td>1.000</td>
<td>-1.000</td>
<td>0.995</td>
</tr>
<tr>
<td>Glu(mg/dL)</td>
<td>0.966</td>
<td>4.775</td>
<td>0.997</td>
</tr>
<tr>
<td>Lac(mmol/L)</td>
<td>1.000</td>
<td>0.000</td>
<td>0.995</td>
</tr>
<tr>
<td>Hct(%)</td>
<td>1.003</td>
<td>-0.407</td>
<td>0.987</td>
</tr>
<tr>
<td>dHb(μL)</td>
<td>1.028</td>
<td>-0.470</td>
<td>0.994</td>
</tr>
<tr>
<td>O₂Hb(%)</td>
<td>1.000</td>
<td>0.802</td>
<td>0.997</td>
</tr>
<tr>
<td>COHb(%)</td>
<td>0.988</td>
<td>-0.269</td>
<td>0.999</td>
</tr>
<tr>
<td>Methb(%)</td>
<td>1.000</td>
<td>-0.100</td>
<td>0.998</td>
</tr>
</tbody>
</table>

---

**Conclusion**

Re-purposing of a simple toy has resulted in a novel point-of-care electricity-free blood centrifusing device for remote clinical laboratory. This device can act as promising alternative to electric centrifuges for point-of-care field diagnosis. Additionally the device and methodology provides a practical alternative when the serum or plasma is required for point-of-care field testing or analysis by diagnostic kits and device (e.g. testing for a number of diseases conditions).
Comparison of the time required for manual and semi-automated Urinalysis and Pregnancy testing with associated EMR manual entry errors.

R. Kalariya, P. Mann, G. Díaz, J. Utahia, M. Benbrook, K. Avandasaleh, J. R. Petersen. University of Texas Medical Branch, Galveston, TX

Background: Urinalysis (UA) is commonly used for the evaluation of proteinuria, glucose, urinary tract infection, and pregnancy (hCG/UGT) in Ob/Gyn patients. In our Ob/Gyn clinics we perform >50,000 UA tests/year (>94% being performed manually). The same clinic manually perform ~30,000 UPT/year. Studies have indicated that this subjective evaluation is only moderately accurate compared with the evaluation of urine using automated instrumentation. In addition to the result being subjective it also requires significant time to perform and document results in the patient’s chart (EMR).

With the availability of semi-automated POCT instruments (in our case Siemens ClinicStatus Connect) capable of performing and transmitting to the EMR both UA and UPT results it is possible to reduce preanalytical (bar code reader), analytic (instrumental, result reading), and postanalytical (transmission to the EMR) errors. The objective of this study is to determine the potential time savings associated with using the ClinicStatus instrument-read solutions for routine urinalysis dipstick and UPT vs. manual testing and to determine the transcription error rate for manual entry of results in the EMR.

Methods: Data was collected prospectively in 5 Ob/Gyn clinics, 2 of which currently have ClinicStatus Connect instruments that are not connected to the EMR. The IRB approved study specifics are: 1) Conduct a time study in Ob/Gyn clinics comparing workflow of UA and UPT associated with manual read vs. ClinicStatus. Total test time includes the time required to document the results in the EMR (test time + EMR entry time). 2) Review the results from UA and UPT results manually entered in the EMR to identify transcription error rates associated with manual entry. Total tests resulted were used to calculate error rate (i.e. Chem 7 tests)

Results: The difference of test time and total test time to perform for a Chem 6-10 UA (N=67) was significant (p<0.01) for the ClinicStatus (0.77 min; p<0.001 and 0.64 min; p<0.002, respectively) while the difference in test time for the Chem 2 (N=30) manual read was significantly less (0.09 min; p=0.005) but not for the total test time (0.08; p=0.33). For the UPT the ClinicStatus has a 5 min test time to report a negative result thus the test time was significantly greater (1.45 min; p<0.001), however, the total test time was the same (0.61 min; p=0.059). Preliminary results for the clinic studied found a transcription error rate of 0.3-1.7% for individual UA results (N=3350 individual test results). No transcription errors were seen for UPT. Although unanticipated but perhaps not unexpected, we also found that ~8% the UA results and ~12% UPT results were not documented in our EMR.

Conclusion: As anticipated the ClinicStatus UA system was more efficient than the manual process. Manual UPT testing was faster than the ClinicStatus although the total test time was the same. Once connected to the EMR the ClinicStatus will eliminate the transcription errors and lack of documentation of some test results. Partial study funding was received from Siemens.

B-333

Precision and Total Error of the Afinion HbA1c Dx Test with Fingerstick Samples

W. D. Arnold1, K. Kupfer1, M. Hvidsten Swensen1, H. E. Buys2, M. Davis3, L. L. H. Van Gerwen1, R. C. San George1, J. Collins1, *Univ of Minnesota, St. Paul, MN, 1Zepha Life Technology, St. Paul, MN

Background: Since the significant discovery of cardiac natriuretic peptide hormones, a great deal of research has identified 2 peptides derived from pro-B-type natriuretic peptide (proBNP), namely BNP and N-terminal-proBNP (NT-proBNP), as valuable plasma biomarkers for indication of heart failure (HF) and other cardiac diseases. Many *in vitro* diagnostic kits of BNP/NT-proBNP for assessing HF 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 NT-proBNP, which revealed advantages of high sensitivity and specificity, 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 immunosensor process is set up based on sandwich-type format. NT-proBNP capture antibodies (Abs) were printed and immobilized on different sensors one 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 diluting NT-proBNP analytes to desired concentrations in assay buffer was loaded into sample entry well which was prefilled with bait-labeled NT-proBNP 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* detection of human NT-proBNP 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 analytical ranges of 15-20000 pg/mL for NT-proBNP, and its detection limits is around 10 pg/mL.

Conclusions: The Afinion HbA1c Dx test is precise across its measurement range when using fingerstick whole blood samples. The total error estimates are well below the current NGSP requirements of ±3% total allowable error across the assay range. The Afinion HbA1c Dx test is not FDA cleared for sale in the U.S. *"Under FDA review for pre-market notification*

B-333

Giant Magnetoresistive Based Handheld System for Rapid Detection of Human NT-proBNP

W. Wang1, T. Klein2, J. Collins1, *University of Minnesota, St. Paul, MN, Zepha life technology, St. Paul, MN

Background: Since the significant discovery of cardiac natriuretic peptide hormones, a great deal of research has identified 2 peptides derived from pro-B-type natriuretic peptide (proBNP), namely BNP and N-terminal-proBNP (NT-proBNP), as valuable plasma biomarkers for indication of heart failure (HF) and other cardiac diseases. Many *in vitro* diagnostic kits of BNP/NT-proBNP for assessing HF 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 NT-proBNP, which revealed advantages of high sensitivity and specificity, 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 immunosensor process is set up based on sandwich-type format. NT-proBNP capture antibodies (Abs) were printed and immobilized on different sensors one 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 diluting NT-proBNP analytes to desired concentrations in assay buffer was loaded into sample entry well which was prefilled with bait-labeled NT-proBNP 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* detection of human NT-proBNP 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 analytical ranges of 15-20000 pg/mL for NT-proBNP, and its detection limits is around 10 pg/mL.

Conclusions: The Afinion HbA1c Dx test is precise across its measurement range when using fingerstick whole blood samples. The total error estimates are well below the current NGSP requirements of ±3% total allowable error across the assay range. The Afinion HbA1c Dx test is not FDA cleared for sale in the U.S. *"Under FDA review for pre-market notification*
Point-of-Care Testing

sensitively and specifically detect human NT-proBNP. Not only the assay time has been shortened, but also simple and automatic assay operation has been accomplished. Hence, we believe it can be further integrated and developed for POCT diagnostics.

B-334

High sensitivity cTnI capability demonstrated on the Minicare Point of Care Platform


Background: Cardiac Troponin (cTn) has been accepted as the biomarker of choice for detection of acute myocardial injury (AMI). Advances in assay technology have led to high sensitive (HS) cTn assays that have a profound impact on clinical practice, supporting clinical decision making based on results at presentation and 1 hour after admission. Next to the time between measurements, workflow plays an important role in the turn-around time. Currently, HS-cTn tests are only available on central lab-systems and the associated logistics to get a sample to the lab and the result reported back to the physician significantly impacts the time to a disposition decision. Point-of-care (POC) assays have the potential to drastically shorten this turn-around time, especially when combined with a first measurement in an ambulance setting. This enables more rapid decision making. Here we evaluate an improved version of the current Philips Minicare cTn assay under development, which has the potential to combine the benefits of HS cTn protocols with a POC workflow.

Objective: Evaluate the capability of the Minicare HS-cTn assay under development to meet the criterion1 for HS of having a 10% CV < 99th percentile.

Methods: The evaluation is based on the Clinical Laboratory Standards Institute (CLSI) guidelines. Li-heparin whole blood and Li-heparin plasma samples were used to establish Limit of Quantitation (LoQ) and to perform a method comparison study between Minicare and Abbott Architect high-sensitivity troponin I (n=426).

Results: With an assay time of less than 10 minutes, the 10% CV LoQ was established at <10 ng/L. The method comparison between Minicare and Abbott Architect high-sensitivity troponin I resulted in a Pearson correlation coefficient of 0.92. The Passing-Bablok regression demonstrated a slope of 1.59, so expressed in Architect units, the 10% CV LoQ on Minicare would be <7 ng/L. For the Abbott Architect high-sensitivity troponin I assay the 99th percentile has been established at 34 ng/mL (male) and 16 ng/mL (female). This would lead to a 10% CV LoQ for the Minicare HS-cTn assay well below the 99th percentile.

Conclusions: With demonstrated HS cTnI capability on the Minicare platform, we show the potential to support a 0.1 h sampling protocol, with the speed of a POC workflow. This enables rapid and safe rule-out of patients with suspected AMI in the ED.


B-335

Comparative evaluation of urine dipsticks with regard to urinary leukocyte screening

G. Rheinheimer, J. Boone, J. Fox, J. Stradinger. Siemens Healthineers, Elkhart, IN

Background: Urinary tract infections (UTI) are responsible for over 8.1 million office visits per year.1 Screening with urine dipsticks is a quick and cost-effective method for initial patient evaluation that can prevent unnecessary testing. One screening method involves testing for leukocyte esterase, the product of leukocytes in infection. The objective of this study is to compare the Siemens Multistix® 10SG reagent strips/CARDIAC POC Troponin T assay with contrived solutions and confirming findings in native specimens.

Methods: The study consists of two parts. The first consists of testing urine strips in duplicate with contrived samples containing known quantities of leukocyte esterase. The second assessment involves visual and instrumental testing of 62 clinical urine specimens spanning the reporting range of the urine leukocyte dipsticks, in an attempt to confirm the findings of the contrived study.

Results: The Siemens and CLARITY tests matched the expected results of the contrived leukocyte esterase solutions without issue. The YD DIAGNOSTICS and TECO DIAGNOSTICS tests exhibited negative bias with the moderate/+ solution.

Analysis of clinical sample results showed overall visual assessment agreement versus the Multistix® 10 SG Reagent Strips at 85.4% with the CLARITY strips, 48.3% with the YD DIAGNOSTICS strips, and 24.1% with the TECO DIAGNOSTICS strips. Compared to the CLINITEST Status® Urine Chemistry Analyzer, the CLARITY device exhibited 57.8% overall agreement and the YD OPTIMA device exhibited 12.9% overall agreement.

Conclusion: Clinical outcomes are highly dependent on the results of initial diagnostic screening in the Point of Care environment, as they determine the preemptive course of action or confirmatory tests required for expeditious treatment. This study demonstrates that significant negative bias exists when comparing several urine tests versus the Multistix®10 SG Reagent Strips, and that this bias will translate to the point of care environment.

Footnotes

https://www.nichd.nih.gov/health/topics/urinaryconditioninfo/affected

B-336

Performance evaluation of the point of care cardiac troponin T assay

K. Hong, Y. Kim, T. Jeong. College of Medicine, Ewha Womans University, Seoul, Korea, Republic of

Background: The cobs h232 POC system (Roche Diagnostics) is a point-of-care testing device for troponin T assay. Herein, we aim to evaluate the analytical performance of the CARDIAC POC Troponin T assay (Roche Diagnostics) on the cobs h232 POC system.

Methods: The repeatability and within-laboratory imprecision of the CARDIAC POC Troponin T assay were evaluated by using the Roche CARDIAC POC Troponin T assay on the cobs h232 POC system. The data were collected and transferred electronically to the CLSI document EP9-A3. Since the concentration of troponin T of Level 1 control solution was less than the lower limit of quantification (e.g., 40 ng/L) on the cobs h232 POC system, only Level 2 control solution was used. In addition, repeatability was determined by running n=10 replicates per patient sample. Linearity of the CARDIAC POC Troponin T assay was determined using five levels of patient samples according to CLSI document EP6-A. The method comparison between Eclays Troponin T high sensitive (TriT- hs) assay on the cobs e411 analyzer and CARDIAC POC Troponin T assay on the cobs h232 POC system was performed based on the CLSI document EP9-A3.

Results: The repeatability (%CV) and within-laboratory imprecision (%CV) of Level 2 control solution (mean troponin T, 441.6 ng/L) was 8.5% and 8.6%, respectively. The repeatability of patient samples was 7.5% at 88.7 ng/L and 7.2% at 454.6 ng/L. Linear range of the CARDIAC POC Troponin T assay was confirmed between 54.0 ng/L and 1347.7 ng/L. Compared with the high sensitive troponin T assay, the linear correlation equation (correlation coefficient) was $y=0.988x + 20.8$ ($r = 0.988$).

Conclusion: Our data suggest that the CARDIAC POC Troponin T assay could be useful in cases where the POC troponin T testing is required.

B-337

Polynomial Regression Analysis Techniques to Evaluate Variables. A Practical Example with Internal Proficiency Data Comparing AccuChek® Inform II with cobas® and i-STAT® methods.

V. M. Genta1, E. Drumm1, M. Kiger1, F. Alfere1, S. Shumate2, A. Schoen1, E. Drumm2, B. Boston1, L. Wyer1, S. Shumate2, Y. Shen1, Sentara Virginia Beach General Hospital, Virginia Beach, VA, Sentara Healthcare, Norfolk, VA

Background: In the Sentara Hospitals system the performance of AccuChek® Inform II glucose meters is monitored with both cobas® and i-STAT® methods. We report the results of the analysis of data obtained in a four year continuous internal proficiency testing program, with polynomial multivariate regression analysis techniques.

Methods: AccuChek Inform II (Roche Diagnostics), i-STAT cartridges (Chem8 and CG5®; Abbott Diagnostics), cobas c501, c311 (Roche Diagnostics). Patient specimens, with different levels of glucose were assayed in parallel on the i-STAT. i-STAT results were compared to the Cobas¬ h232 POC system using both cobas® and i-STAT® methods. The data were collected and transferred electronically to Miniatab® (version 17, MiniTab Inc.) statistical software and analyzed with regression analysis statistical techniques. Results: Since the three glucose methods display an increase in variance for increasing values of glucose the orthogonal regression model ($y=3.7+0.96x$) was compared with the weighted least squares model ($y=4.7+0.95x$). Clearly the two models showed very similar estimates of the regression parameters which would not affect either quality assurance or clinical applications. The weighted polynomial regression model was used to compare location, year, and reference method. The ANOVA table showed that there were no statistically significant differences between the regression lines for facility ($P=0.68$), year ($P=0.96$) and reference method ($P=0.22$). Stepwise regression (x to enter=0.15, x to remove=0.25), identified as...
Method comparison and bias estimation at clinical decision levels for creatinine and urea measurements with ABL90 Flex Plus blood gas analyzer and Dimension Vista

C. Pirrago, I. Tomoiu, P. Oliver, P. Fernandez-Calle, A. Buno. Hospital Universitario La Paz, Madrid, Spain

Background: Creatinine and urea are relevant parameters to monitor renal function. The ABL90 Flex Plus blood gas analyzer has recently incorporated a new electrode-based biosensor cassette capable of measuring these parameters with the same sample volume and measuring time. The availability of these parameters as POCT in clinical settings such as emergency department or critical care units could be very useful in order to make clinical decisions faster and reducing waiting times. The aim of this study was to estimate bias at clinical decision levels in order to establish if creatinine and urea measurements are interchangeable between the ABL90 Flex Plus and a central laboratory method (Dimension Vista). Material and methods: ABL90 Flex Plus (Radiometer®) and Dimension Vista (Siemens Healthineers®), as a comparative method, were used for the study. According to Clinical and Laboratory Standards Institute (CLSI) protocol EP09-A2-IR, 40 whole blood heparinized samples were analysed by duplicate. Linear regression and comparability at clinical decision levels between both analyzers were calculated. The allowable bias was established according to desirable Total Error (dTE) based on biological variation criteria. Statistical analysis was performed with Analyse-it® software.

Results: The estimated bias was lower than the allowable bias at different clinical decision levels. Therefore, creatinine and urea patient results are interchangeable between ABL90 Flex Plus and Dimension Vista. This ensures no impact on patient care when using alternatively both analyzers.

### Results

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Pearson correlation (CI 95%)</th>
<th>Bilateral significance level</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH</td>
<td>0.986 (0.965-0.993)</td>
<td>0.000</td>
</tr>
<tr>
<td>Partial pressure of CO2</td>
<td>0.984 (0.993-0.991)</td>
<td>0.000</td>
</tr>
<tr>
<td>Partial pressure of O2</td>
<td>0.995 (0.979-0.998)</td>
<td>0.000</td>
</tr>
<tr>
<td>Ion sodium</td>
<td>0.887 (0.393-0.960)</td>
<td>0.000</td>
</tr>
<tr>
<td>Ion potassium</td>
<td>0.989 (0.975-0.994)</td>
<td>0.000</td>
</tr>
<tr>
<td>Ion chloride</td>
<td>0.945 (0.909-0.967)</td>
<td>0.000</td>
</tr>
<tr>
<td>Ionic calcium</td>
<td>0.824 (0.712-0.892)</td>
<td>0.000</td>
</tr>
<tr>
<td>Glucose</td>
<td>0.984 (0.947-0.993)</td>
<td>0.000</td>
</tr>
<tr>
<td>Lactate</td>
<td>0.985 (0.973-0.991)</td>
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</tr>
<tr>
<td>Hemoglobin</td>
<td>0.916 (0.824-0.953)</td>
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</tr>
<tr>
<td>Oxygen saturation</td>
<td>0.959 (0.893-0.980)</td>
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<tr>
<td>Total CO2</td>
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<td>0.000</td>
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<tr>
<td>Bicarbonate</td>
<td>0.984 (0.974-0.990)</td>
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</tr>
<tr>
<td>Hematocrit</td>
<td>0.956 (0.923-0.975)</td>
<td>0.000</td>
</tr>
</tbody>
</table>

### Conclusion

- Both teams, GEM PREMIER 4000 (WERFEN GROUP) and EPOC (ALERE), present very significant correlations (p < 0.0005) for all the parameters studied. Therefore, both gasometers are interchangeable methods and therefore, the results can be interchangeable. Given that the EPOC team is a small equipment that can be easily transferred by the medical team, it has many advantages such as: Handling and transport of the minimum sample. Determination in the place of assistance of the patient. Reduction of time for decision making. Rapid stratification of patients.
and one lactate meter compared with the Radiometer ABL837 lactate method. Meter to meter variation was assessed using venous cord blood specimens (n=40) and one strip lot number compared with the Radiometer ABL837 lactate method. Results: Imprecision (CV) was dependent upon both specimen type and lactate concentration. CV was greater with arterial specimens (11-13%) than venous specimens (4.8-6.1%) or Nova QC materials (1.9-8.3%). CV also increased with decreasing lactate concentration. The following regression equations describe the relationship between: a) Individual lactate strip lots and the assigned lactate linearity material concentration = 0.974x + 0.161 (strip 1) R² = 0.998; y = 0.999x + 0.122 (strip 2) R² = 0.998; y = 0.989x + 0.055 (strip 3) R² = 0.998 b) Patient correlations and individual lactate strip lots = 0.791x - 0.145 (strip 1) R² = 0.975; y = 0.796x - 0.158 (strip 2) R² = 0.973; y = 0.819x - 0.187 (strip 3) R² = 0.984 c) Venous cord blood correlations and individual lactate meters = 0.876x - 0.114 (meter 1) R² = 0.941; y = 0.925x + 0.330 (meter 2) R² = 0.932; y = 0.859x + 0.122 (meter 3) R² = 0.920 Conclusions: Strip lot and meter variation detected with the NovaStatstrip® lactate meter were clinically insignificant. Specimen type was found to influence method CV.

B-341

Hyperglycemia from Eating Preserved Sweet Plums?

L. Lam, J. Lee, S. Lim. Ng Teng Fong General Hospital, Singapore, Singapore

Background: On 27th May 2017, a Point-of-care testing (POCT) glucose result of 33.1 mmol/L was observed in a ward diabetic patient. The test was repeated with a result of 9.3 mmol/L. On 28th May 2017, a POCT glucose result of 33.1 mmol/L was observed in the same patient. The test was repeated with a result of 9.8 mmol/L. We suspected the elevated POCT glucose results could be due to pre-analytical factors. On both occasions, we found out that the patient was eating preserved sweet plums 1-2 hours before the blood test. We designed a study to replicate the clinical scenario to validate our suspicion of possible finger contamination with food containing sugar resulting in a false high glucose.

Methods: A non-diabetic subject was recruited for the study. POCT glucose was performed for the subject after handling preserved sweet plum, followed by no cleaning with alcohol swab, cleaning the fingertip with alcohol swab once and swabbing 3 times. POCT glucose was analyzed using Roche Accuchek Inform II glucometer.

Results: POCT glucose results before and after handling preserved sweet plums (with no cleaning with alcohol swab) were 5.2 and 19.1 mmol/L respectively. POCT glucose was 8.4 mmol/L after cleaning fingertip with alcohol swab once. When the fingertip was cleaned thoroughly with 3 times swabbing with alcohol swab, the POCT glucose was 5.2 mmol/L.

Conclusion: Inadequate cleaning of fingertip with alcohol swab prior to POCT glucose testing in patients who handled food containing sugar could produce falsely elevated blood glucose result.

B-342

Principles and Practice of Point-of-care Environmental Stress Testing: Static and Dynamic Robustness of a WBC-Differential Instrument and its Role in Detecting Highly Infectious Diseases

A. Zadran, I. Ventura Curiel, L. Zadran, G. Kost. UC Davis, Davis, CA

Background: Point-of-care (POC) instruments that perform rapid diagnoses at or near patient sites must withstand environmental stresses (ES). Changes in white blood cell and differential (WBC-DIFF) counts determined by optical scanning can help identify communicable infections in epidemics of highly infectious diseases like Ebola. This project enables rapid and accurate detection of critical infections to help prevent outbreaks. Our goals were to evaluate the environmental robustness of a POC hematologic instrument (HemoCue, Sweden) that determines WBC-DIFF in capillary whole blood to and to establish the principles and practice of this new POC field.

Methods: We investigated the simultaneous environmental robustness of the instrument and its reagents. Whole-blood capillary samples were obtained from consented human volunteers (IRB 298372-10). The instrument (FDA investigational in the US) reports total white blood cell count (WBC) and a five-part differential (neutrophils, lymphocytes, monocytes, eosinophils, and basophils). For dynamic temperature, humidity was held constant to eliminate that confounding variable, while for humidity perturbations, temperature was held within the manufactures acceptable range. Whole-blood measurements were performed in hot and cold environments using Tenny ES chambers to establish dynamic low and high temperatures from 18-30 °C (manufacturer’s specifications) versus room temperature control. ES chambers simulated high and low static and dynamic humidity conditions less than and greater than 90% RH, the manufacture specified upper limit. The results were compiled and significance was determined using Student’s t-test for paired differences. ANOVA was performed on serial clusters of paired differences.

Results: Month-long storage of reagents at static high temperatures (~50°C) and static and dynamic humidity (25% to ~90% RH) did not affect paired differences significantly (P>0.05) However, results indicate that dynamic high temperature (>30°C) impairs WBC-DIFF measurements. In addition, humidity exceeding manufacturer specifications (~90% RH) affects WBC-DIFF system (instrument and reagents) reliability, accuracy, and performance. We optimized an ES module comprising written instructions, protocols, and specifications for national POC policy and guidelines, which will be particularly useful in limited-resource settings and conditions associated with temperature, humidity, dust, and other physical challenges.

Conclusions: Our research protocol uniquely evaluated both instruments and reagents simultaneously during temperature and humidity stress, in order to consistently and realistically simulate conditions encountered in community hospitals, primary care sites, patient homes, and field settings during crises, such as disasters and pandemics. We conclude that this WBC-Diff instrument and future POC devices: a) must be evaluated for environmental limits, b) can perform well within objectively defined temperature and humidity brackets, and c) should be designed to withstand ES in limited-resource settings. We used these results and well-defined protocols [see Louie RF et al., Global Point of Care, AACC Press-Elsevier, 2015, pp. 293-306] to establish unique principles and practice module for environmental stress testing of instruments and reagents. Robustness is needed to improve diagnosis and evidence-based decision making in regions of risk at points of need, including screening in primary contact sites. Additionally, national point-of-care policy and guidelines with the ES module would help assure the quality of diagnostic performance and enhance standards of care worldwide.

B-343

Presespin and N-terminal pro-B-type Natriuretic Peptide Improve Outcome Prediction of Patients admitted with Sepsis to the Emergency Department

E. Spanuth1, B. Ivandic2, J. Wilhelmi3, R. Thomae4, K. Werdan1. 1DiaReassuring GmbH, Heidelberg, Germany, 2Department of Medicine III, University Hospital Heidelberg, Heidelberg, Germany, 3University Clinics Halle (Saale), Department of Medicine III, Martin-Luther-University Halle-Wittenberg, Halle, Germany, 4Mitsubishi Chemical GmbH, Düsseldorf, Germany

Background: Assessment of disease severity of sepsis at the time of initial presentation is crucial as the mortality of severe sepsis or septic shock is 30 to 60%, whereas the mortality of sepsis without organ failure remains below 10%. It has been reported that implementation of early goal directed therapy into the treatment of severe sepsis and septic shock in the emergency department (ED) may reduce mortality. This underscores the necessity to adequately identify patients with a high risk of poor outcome in the ED as early as possible. The point-of-care (POC) test PATHFAST Presespin has been shown to provide early prognostication in sepsis. N-terminal pro-B-type natriuretic peptide (NT-proBNP) may provide information about cardiovascular organ failure which occurs commonly in severe sepsis and septic shock.

Objectives: We thought to evaluate presespin (PSEP) in combination with NT-proBNP to assess disease severity and outcome prediction in patients with sepsis directly after admission to the ED.

Methods: PSEP and NT-proBNP concentrations were measured in plasma samples which were drawn from 106 patients with sepsis according to sepsis-1 definition at the time of admission to the ED. PSEP and NT-proBNP were determined using PATHFAST Presespin (LSI Medience corporation, Tokyo) and Elecsys NT-proBNP (Roche Diagnostics). PCT, CRP and creatinine were measured using routine clinical chemistry methods in the central laboratory. Primary endpoint was death within 30 days. The combined endpoint “major adverse events” (MAE) consisted of at least either the primary or at least one of the secondary endpoints intensive care, mechanical ventilation or dialysis.

Results: 15 patients died and 26 patients exhibited MAEs during 30 day follow up. The number of non-survivors was 3 (4.4%) and 13 (34.2%) in patients with sepsis (n=68) and severe sepsis or septic shock (n=38), respectively. MAEs occurred in 6 (8.8%) and 26 (52.6%) patients with sepsis and severe sepsis or septic shock. Median values of NT-proBNP and PSEP in Sepsis were 193 and 693 ng/L and in severe sepsis or septic shock. Median values of NT-proBNP and PSEP in Sepsis were 193 and 693 ng/L compared to 555 and 1407 ng/L (p<0.0001) in severe sepsis or septic shock. ROC analysis revealed AUC values of NT-proBNP and PSEP of 0.714 / 0.715 and 0.707 / 0.737 for risk prediction of MAE and death, respectively. The logistic regression of simultaneous assessment of NT-proBNP and PSEP revealed elevated AUC values of 0.736 and 0.745 for risk prediction of MAE and death, respectively.

70th AACC Annual Scientific Meeting Abstracts, 2018 S243
Conclusion: NT-proBNP and PSEP demonstrated strong relationship with disease severity and outcome in patients with sepsis admitted to the ED. The simultaneous assessment of NT-proBNP and PSEP provided higher risk prediction of MAE and death than both markers alone. The PATHFAST POC system allows early determination of PSEP and NT-proBNP in parallel from whole blood within 17 min directly in the ED and may improve the management of sepsis.

B-344

Automatic Mixing as a Patient Blood Management Tool

G. Wennecke, Radiometer Medical Aps, Brønshoej, Denmark

Objective: The aim of the studies were to show how automatic mixing of an arterial blood gas (ABG) syringe (safePICO, Radiometer Medical) ensures comparability of hemoglobin results obtained on theABL90 FLEX blood gas analyzer at the Point of Care, with a laboratory hematologist analyzer (XN-series, Sysmex). Patient blood management is a focus area with the purpose to follow the highest standards in blood conservation. This also includes collection of the lowest possible blood volume with the highest possible sample quality.

Methodology: Heparinized venous blood was split into two ABG syringes; A), A 1 mL ABG syringe with no automatic mixing capacity B). A 1.5 mL ABG syringe containing a mixing ball for automatic mixing. The two syringes were initially mixed and stored equally, and the syringes were handled by one laboratory person only. An EDTA sample was simultaneously drawn and measured on the Sysmex.

Results:

Data was collected at five US sites and pooled. A regression analysis and bias plots were performed comparing hemoglobin measured in each of the two syringes measured on the blood gas analyzer to the hematologist analyzer.

<table>
<thead>
<tr>
<th>Syringe</th>
<th>n</th>
<th>Slope</th>
<th>Intercept (g/dL)</th>
<th>Correlation coefficient r²</th>
<th>Mean difference to Sysmex (g/dL)</th>
<th>Confidence interval (g/dL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>99</td>
<td>0.79</td>
<td>3.6</td>
<td>0.515</td>
<td>-0.89</td>
<td>-0.5 to -1.3</td>
</tr>
<tr>
<td>B</td>
<td>99</td>
<td>1.02</td>
<td>-0.1</td>
<td>0.986</td>
<td>-0.22</td>
<td>-0.2 to -0.3</td>
</tr>
</tbody>
</table>

Conclusion: Using syringe B with automatic mixing at the Point of Care results in a significant better correlation of hemoglobin with the laboratory analyzer. Automatic mixing ensures a homogenous sample and accurate hemoglobin results. Accurate hemoglobin results are essential also when the focus is on patient blood management, i.e. collecting the lowest possible blood volume with the highest possible sample quality in the conservation of patient blood.

B-345

Performance evaluation of the Point of Care Minicare BNP assay

A. van Reenen,1, M. Berger,1 E. Moreau,2 D. Kemper,2 L. van Lippen,2 J. Vissers1, F. de Theije1, V. Semjonovs1, E. Michielens1, J. Maiert1,2 Philips, Eindhoven, Netherlands,1 Future Diagnostics Solutions, Wijchen, Netherlands,1 Diagnostiek Voor U, Eindhoven, Netherlands,1 Medical University of Innsbruck, Innsbruck, Austria

Background: B-type natriuretic peptide (BNP) is increased under conditions of myocardial pressure or volume overload, primarily in patients with heart failure. It is therefore considered to be a useful marker of myocardial function. International guidelines1 recommend its use for the exclusion of heart failure in patients with dyspnea. Point-of-care (POC) systems for BNP can replace laboratory systems to support the routine evaluation of patients presenting to an emergency department (ED) with acute dyspnea and may accelerate the throughput and disposition of at-risk patients in the ED. The Minicare BNP test (currently under development) is a rapid POC in-vitro diagnostic test for the measurement of BNP in low volumes (30 µL) of human EDTA whole blood, EDTA plasma and capillary blood.

Objective: To assess the performance characteristics of the Minicare BNP assay under development.

Methods: Analytical performance of the Minicare BNP assay was evaluated following applicable CLSI guidelines. Studies were performed at the Department of Internal Medicine III — Cardiology and Angiology (Innsbruck), Diagnostiek Voor U (Eindhoven), Future Diagnostics Solutions (Wijchen) and at Philips (Eindhoven) using human whole blood, plasma and capillary blood specimens.

Results: Limit of Blank (LoB) and Limit of Detection (LoD) were determined in EDTA plasma to be 3.3 ng/L, and 5.8 ng/L respectively. The Limit of Quantitation (LoQ) at 20% CV was <10 ng/L for both EDTA whole blood and EDTA plasma. Total imprecision was found to be between 6.7% and 9.7% at BNP testing concentrations of 93 - 3984 ng/L. The sample type comparison study was done on capillary whole blood, venous EDTA whole blood and EDTA plasma samples (n=150) and resulted in a Pearson correlation coefficient (r) of 0.98-0.99 and a Passing-Bablok slope between 1.03 and 1.09. The normal value study on 158 healthy subjects showed a median BNP concentration of 16 ng/L. 99% of values (158/159 for whole blood and 156/158 for plasma) were below the generally recommended cut-off of 100 ng/L for the exclusion of acute heart failure, with no significant influence of sample type. Method comparison studies against a core laboratory assay (Siemens ADVIA Centaur BNP), demonstrated a Passing-Bablok slope of 1.06-1.08 and a Pearson correlation coefficient (r) of 0.92-0.93 (n=187). The percentage of agreement using the cut-off value of 100 ng/L was 92%.

Conclusion: The Minicare BNP assay is a fast and easy-to-use test which is intended for the near-patient setting. The test requires only a drop of blood that can be obtained by capillary draw or from venipuncture. The Minicare BNP assay under development is a robust and accurate assay as demonstrated by its high analytical sensitivity, low imprecision and high correlation to an established core lab assay. Capillary blood samples can be used on Minicare BNP and deliver results which are highly comparable to venous blood measurements.

1 Task Force for the Diagnosis and Treatment of Acute and Chronic Heart Failure 2012 of the European Society of Cardiology. ESC guidelines for the diagnosis and treatment of acute and chronic heart failure 2012, Eur. Heart J. 33 (2012) 1787-1847.

B-346

Evaluation of “Rapidchip® fFN,” a new rapid quantitative measurement of fetal fibronectin to predict preterm labor

E. Hamada1, M. Morita2, M.Maekawa1,1 Department of Laboratory Medicine, Hamamatsu University School of Medicine, Hamamatsu, Japan, 2Research & Development Division, Sekisui Medical Co., Ltd., Ryugasaki, Japan

Background: Testing for fetal fibronectin (fFN) is used to predict preterm labor in pregnant women between 22 weeks and 35 weeks of gestation. A rapid and quantitative point-of-care (POC) test kit for fFN (“Rapidchip® fFN; Sekisui Medical Co., Japan) was recently developed that is based on the principle of lateral flow immunochromatography. We evaluated the analytical performance of a system consisting of this new Rapidchip® fFN assay and a RapidPia® POC testing instrument (Sekisui Medical Co., Japan).

Methods: The immunochromatography test strip in the cassette housing contains two monoclonal antibodies that react with fFN. Colloidal gold-labeled antibody coats the conjugate pad and the other antibody coats the detection zone of the membrane. The labeled antibody forms a complex with fFN that reacts with the antibody coating the membrane to form a red line at the detection zone. The intensity of the red line depends on the concentration of fFN. This assay system measures the signal intensity and converts it to quantitative and qualitative values based on a cut-off of 50 ng/mL. All patients underwent serial vaginal sampling for fFN measurement from 22 to 32 weeks of gestation by collection of cervicovaginal secretions during speculum examination. We compared the performance of this fFN assay with that of ELISA by using 81 samples of cervicovaginal secretions.

Results: The lower limit of detection of the assay was 25 ng/mL, while the upper limit of quantification was 500 ng/mL. No prozone effect was observed in samples with fFN concentrations from 250 to 6475 ng/mL. At fFN concentrations of 75 ng/mL, 175 ng/mL, and 352 ng/mL, the within-run CV (n = 5) was 6.2%, 3.5%, and 2.2%, respectively. Compared to ELISA, the sensitivity of the fFN assay was 91.7% (11/12) and its specificity was 97.1% (67/69), with an overall agreement rate of 96.33% (78/81). The performance of this new fFN assay system was equivalent to that of ELISA, and only 3 out of 81 samples showed discrepant results compared with the gold standard assay.

Conclusion: This new fFN assay based on immunochromatography provided results in only 10 minutes, allowing rapid diagnosis and management of patients with a high risk of preterm labor. The results of this study suggest that the fFN assay system is not only a useful diagnostic tool for inpatient perinatal care, but also for reducing the risk of preterm labor and predicting premature delivery in the outpatient setting.
Evaluation of the precision performance on the GEM® Premier™ 5000 at CHR Citadelle (Belgium)


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, all-in-one PAK to provide quantitative measurements of pH, pCO2, PO2, sodium, potassium, chloride, ionized calcium, glucose, lactate, hematocrit, total bilirubin and CO-Oximetry parameters. These measurements aid in the diagnosis of a patient’s acid/base status, electrolyte and metabolite balance and oxygen delivery capacity. The system precision performance of the GEM Premier 5000 was evaluated at the CHR Citadelle Hospital compared against three Critical Care analyzers from different manufacturers: the GEM Premier 4000 (Instrumentation Laboratory), ABL® 90 (Radiometer) and the RapidPoint® 405 (Siemens). The evaluation was conducted by clinical personnel at CHR Citadelle Hospital. Three (3) levels of external, traditional-ampule based quality control (QC) material was used in the evaluation (RNA Medical QC). QC material was run for six (6) days, two (2) runs per day and three (3) replicates per run (36 samples). First samples were run as soon as the system was available after cartridge installation to evaluate the performance of the system at this critical time. Total SD was calculated for each tested analyte. Results were compared against a selected criteria derived by CLIA recommendations. Results are summarized in Table 1. Most of the precision results were within the recommended criteria. However, pCO2 for RapidPoint 405 and Glucose and Lactate for the ABL 90 showed results outside the criteria. The source of the observed imprecision and possible implications in analytical performance will be discussed in this poster.

Conclusion: The results obtained during the verification process demonstrate that the GEM Premier 5000 system offers optimal performance for point-of-care or laboratory testing with consistent performance from the start of the cartridge use-life.

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Evaluation of Whole Blood Basic Metabolic Panel Assay with ED Samples

C. Xu1, Z. Bellio1, P. Stack2, B. Kilburn3, K. Schulz2, S. Love2. 1Instrumentation Laboratory, Bedford, MA, 2Hennepin County Medical Center, Minneapolis, MN, 3Department of Laboratory Medicine & Pathology, Hennepin County Medical Center, and University of Minnesota, Minneapolis, MN.

Background: A Basic Metabolic Panel (BMP) is one of the most commonly ordered blood tests that provides Emergency Department (ED) physicians with a quick assessment of a patient’s electrolyte and fluid balance, blood glucose level and kidney function. A whole blood (WB) BMP cartridge based on electrolychemist creatinine, blood urea nitrogen (BUN), and total CO2 (iCO2) assays for the GEM Premier analyzer (Instrumentation Laboratory) is currently in development. This is an addition to the electrolytes and metabolites currently offered on the GEM Premier analyzers. The goal of this clinical evaluation is to compare the WB analytical performance of the GEM Premier BMP cartridge in a point-of-care (POC) setting to the established reference methods for ED samples.

Methods: Random heparinized WB samples were obtained from the ED at HCMC and evaluated by POC staffs. The WB samples were analyzed on the GEM Premier analyzer (IL) with four BMP cartridges over the course of eight weeks. As reference methods, the WB samples were then assayed on a standard GEM Premier 4000 analyzer (IL) for Na+, K+, Ca++, Cl-, glucose, lactate, pH, pCO2, and hematocrit. The plasma portions were assayed on the Cobas 6000 analyzer (Roche Diagnostics) for creatinine, BUN, and iCO2. Some of the native samples (<10% per analyte) were adjusted to expand the measured ranges.

Results: The WB creatinine, BUN and iCO2 results from GEM Premier BMP cartridges correlated well with those obtained from plasma samples on the Cobas analyzer across the ranges of the tested samples, the same was true for the correlation of rest of the analytes to GEM Premier 4000 (results summarized in Table 1). Conclusion: Strong correlations were observed between the GEM Premier BMP and the reference methods. GEM Premier BMP cartridge can provide reliable results with quick turnaround time in POC environments like the ED.

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**Table 1. Method Correlation Results for the GEM Premier WB Assays vs. References**

Roche Cobas 6000 or GEM Premier 4000 by Passing-Bablok or Deming Regression Analysis

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Slope</th>
<th>Intercept</th>
<th>r</th>
<th>N</th>
<th>Sample Range</th>
<th>MDL1 (Bias)</th>
<th>MDL2 (Bias)</th>
<th>MDL3 (Bias)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BUN</td>
<td>1.04</td>
<td>0.85</td>
<td>0.999</td>
<td>114</td>
<td>3.5 - 107.5 mg/dL</td>
<td>6.0 (1.09)</td>
<td>26.0 (7.3%)</td>
<td>50.0 (5.7%)</td>
</tr>
<tr>
<td>Crea</td>
<td>1.05</td>
<td>0.034</td>
<td>0.999</td>
<td>115</td>
<td>0.375 - 13.63 mg/dL</td>
<td>0.6 (0.06)</td>
<td>1.6 (0.11)</td>
<td>6.0 (5.2%)</td>
</tr>
<tr>
<td>dCO2</td>
<td>0.90</td>
<td>1.87</td>
<td>0.983</td>
<td>111</td>
<td>6.4 - 42.3 mmol/L</td>
<td>6.0 (1.28)</td>
<td>20.0 (-0.5%)</td>
<td>33.0 (-4.2%)</td>
</tr>
<tr>
<td>Na</td>
<td>1.01</td>
<td>-1.89</td>
<td>0.987</td>
<td>127</td>
<td>109 - 169 mmol/L</td>
<td>115 (-3.3)</td>
<td>135 (-0.1)</td>
<td>150 (0.1)</td>
</tr>
<tr>
<td>K</td>
<td>1.00</td>
<td>0.00</td>
<td>0.999</td>
<td>132</td>
<td>0.6 - 16.2 mmol/L</td>
<td>3.0 (0.0)</td>
<td>5.8 (0.0)</td>
<td>7.5 (0.0%)</td>
</tr>
<tr>
<td>CI</td>
<td>1.00</td>
<td>-2.00</td>
<td>0.996</td>
<td>129</td>
<td>40 - 147 mmol/L</td>
<td>90 (-2.2%)</td>
<td>112 (-1.8%)</td>
<td>n/a</td>
</tr>
<tr>
<td>Ca</td>
<td>1.05</td>
<td>0.01</td>
<td>0.999</td>
<td>128</td>
<td>0.21 - 4.47 mmol/L</td>
<td>0.37 (0.01)</td>
<td>0.82 (0.05)</td>
<td>1.58 (0.05%)</td>
</tr>
<tr>
<td>Hct</td>
<td>1.04</td>
<td>-0.55</td>
<td>0.995</td>
<td>123</td>
<td>15 - 65 %</td>
<td>21 (0.3)</td>
<td>33 (0.8)</td>
<td>55 (1.7)</td>
</tr>
<tr>
<td>Glu</td>
<td>1.05</td>
<td>-0.01</td>
<td>1.000</td>
<td>126</td>
<td>5 - 679 mg/dL</td>
<td>45 (-3.3)</td>
<td>80 (-1.7%)</td>
<td>180 (1.7%)</td>
</tr>
<tr>
<td>Lac</td>
<td>1.00</td>
<td>0.00</td>
<td>1.000</td>
<td>131</td>
<td>0.4 - 20.0 mg/dL</td>
<td>2.00 (0.0)</td>
<td>5.0 (0.0%)</td>
<td>n/a</td>
</tr>
<tr>
<td>pH</td>
<td>0.99</td>
<td>0.11</td>
<td>0.992</td>
<td>120</td>
<td>6.81 - 7.53</td>
<td>7.30 (0.003)</td>
<td>7.35 (0.002)</td>
<td>7.45 (0.001)</td>
</tr>
<tr>
<td>pCO2</td>
<td>1.00</td>
<td>0.00</td>
<td>0.990</td>
<td>120</td>
<td>21 - 65 mmHg</td>
<td>35 (0.0)</td>
<td>50 (0.0)</td>
<td>70 (0.0%)</td>
</tr>
</tbody>
</table>
Evaluation of the performance of albumin-to-creatinine ratio with automated urinalysis

H. Ning, Chang-Gung Memorial Hospital, Tao-Yan Guan-Shan, Taiwan

Background: Taiwan has the highest end-stage renal disease prevalence among all countries and the costs on maintenance dialysis imposes a great financial burden on National Health Insurance. As a marker of kidney damage, albumin creatinine ratio (ACR) is recommended by National kidney Foundation (NKF) for detecting early stage of chronic kidney disease. Routine urinalysis provide an opportunity for early detection microalbuminuria. Herein, we evaluated the accuracy of semi-quantitative chemical methods from SIEMENS NOVAS PRO12 dipstick for ACR.

Methods: We collected 1029 random urine samples underwent urinaly-tic tests from outpatient department. Urinary protein, microalbumin and creatinine were measured by SIEMENS Novus with PRO12 dipsticks, a semi-quantitative test. The urinary ACR was also calculated. The reference method was turbidimetric immunoassay (AutoK mic Mini Albumin kit, WAKO) performed by Hitachi LST008, an automatic quantitative assay. Within 2 hours, the accuracy of PRO12 dipsticks for ACR was assessed by percentage of agreement with the value measured by quantitative assay, and the sensitivity, specificity, positive and negative predictive values for microalbuminuria were calculated.

Results: The percentage of exact agreement in ACR was 81.9% between PRO12 dipsticks and quantitative assay. The percentage of agreement within one level between two methods was 99.5%. When ACR > 30 mg/g as defined as positive results, the sensitivity, specificity, positive and negative predictive values for microalbuminuria were 87.2%, 91.6%, 91.5%, and 87.3%, respectively. Among 1029 cases, there were 778 cases with negative results of urinary protein analyzed by conventional dipsticks. However, 149 of 778 (19.2%) cases were positive for ACR measured by PRO12 dipsticks. Moreover, 111 out of 149 (74.5%) cases were confirmed positive ACR by quantitative assay.

Conclusion: Early-stage of kidney disease is usually asymptomatic which requires routine urinalysis for detection. Urinary ACR measured by SIEMENS Novus with PRO12 dipsticks was shown to be a reliable test for screening of microalbuminuria.

Point-of-Care Testing

Performance evaluation of AQT90 FLEX procalcitonin assay

H. Chiu, J. Lee, S. Kee, S. Kim, M. Shin, S. Suh. Chonnam National University Hwasun Hospital, Hwasun, Korea, Republic of

Background: Early diagnosis and differential diagnosis of sepsis using appropriate blood markers is very important for lowering the mortality rate and reducing the unnecessary use of antimicrobial agents through appropriate antibiotic treatment in sepsis patients. The AQT90 FLEX procalcitonin (PCT) assay (Radimetrics, Australia) is easy-to-use and point-of-care testing analyzer that can be used in an emergency room or an intensive care unit where rapid diagnosis and differential diagnosis are required. The aim of this study was to assess the analytical performance of this new AQT90 FLEX PCT assay and to compare it with the previously used Cobas e602 Elecsys BRAHMS PCT (Roche, Switzerland). In addition, we assessed the correlation of PCT results among different specimen types. Methods: We evaluated the analytical performance of AQT90 FLEX PCT including precision, linearity and correlation with the Cobas e602 Elecsys BRAHMS PCT in accordance with CLSI EP 15-A, EP 6-A, and EP 9-A2. Additionally, the PCT levels in EDTA whole blood, EDTA plasma, and serum samples obtained from the same individuals were compared to evaluate the matrix influence. Results: The AQT90 FLEX PCT assay showed good linearity (linearity range, 0.17-88.8 ng/mL, R² > 0.99). The within-run and total coefficients of variations were within 5% for low and high level quality control materials (3.0% and 4.7%, 1.7% and 1.8%, respectively). The carryover rate was 0.03%. In the methodology study using EDTA plasma sample, the Pearson’s correlation coefficient (r) was 0.9995 (95% CI, 0.9988 to 0.9999), but the PCT value on AQT90 FLEX PCT was about 22% higher than that on the Cobas e602 Elecsys BRAHMS PCT, on average. In the correlation study between EDTA whole blood and plasma on AQT90 FLEX analyzer, Pearson’s correlation coefficient (r) was 0.99 (95% CI, 0.99 to 1.00). The PCT levels in EDTA whole blood were, on average, about 6% higher than those in EDTA plasma. Conclusion: The AQT90 FLEX PCT assay showed suitable analytical performance with respect to precision, linearity and carryover rate. The PCT value in EDTA whole blood showed higher than that in EDTA plasma, on average. In conclusion, the AQT90 FLEX PCT assay provided reliable and precise PCT results, and can be used to diagnose sepsis rapidly not only as point of care testing but also in clinical laboratory, through application of appropriate cut-off level according to different sample types.

Accuracy and Reproducibility Evaluation of ADAMS HA-8180V using HbA1c Quality Targets Model (QTM)

K. Pomasi, R. Shankar, D. Takahashi, N. Thuramallila. Arkay USA, Edina, MN

Background: HbA1c, a key parameter in diabetes management, is now being recommended for diagnosis and screening. Hence, the laboratory quality management should focus on both accuracy and reproducibility of the chosen HbA1c device. To aid with this, the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) developed a model that is based on the concept of total error which includes both bias (related to accuracy) and imprecision (related to reproducibility). The model grades the performance in five categories: fail, pass, in bronze, pass in silver, and pass in gold [Weykamp C, Little RJ, Sacks DB.
et al, Clin Chem 61:5, 752-759 (2015)]. The ARKRAY ADAMS A1c HA-8180V was recently cleared by FDA. The device measures HbA1c (IFCC mmol/mol and NGSP%) in human whole blood and hemolysate samples using ion exchange high performance liquid chromatography (HPLC). The purpose of this study was to evaluate the accuracy and reproducibility of ADAMS HA-8180V using the HbA1c QTM.

**Methods:** A precision study was performed per CLSI EP05-A3 Evaluation of Precision Performance of Quantitative Measurement Methods. EDTA whole blood samples from four donors at HbA1c concentrations of ~5.0%, ~6.5%, ~8.0%, and ~12.0% were utilized in the study. Whole blood and hemolysate samples were run in duplicate in two runs per instrument per day for 20 days using three HA-8180V analyzers.

**Results:** This pilot study showed that the ADAMS A1c HA-8180V system results for all samples fell in the “pass in gold” (Fig. 1) range of the HbA1c QTM plot.

**Conclusion:** The ADAMS A1c HA-8180V system is a robust, safe, and accurate method for routine HbA1c measurement in laboratories. Further studies evaluating its performance across different laboratories in the US is required.

Figure 1: Bias vs. Imprecision of the HA-8180V performance on the QTM at the measured patient values.

**B-354**

**A novel tool to relate glucose meter performance to clinical outcome: The Insulin Dose Error Assessment (IDEA) Grid**

**M. E. Lyon**1, O. A. S. Lyon2, N. K. Tran3, J. A. DuBois4, A. W. Lyon1. 1Saskatchewan Health Authority, Saskatoon, SK, Canada, 2ALOL Biomedical Inc, Saskatoon, SK, Canada, 3UC Davis, Sacramento, CA, 4Nova Biomedical Inc, Waltham, MA

**Background:** The Clarke grid, Parkes error grids and Surveillance error grid were developed from expert opinion to assess the clinical accuracy of glucose meters. In the past decade there have been technological advances in the analytical performance of glucose meters and numerous insulin-dose protocols developed for local hospitalized and community patients. To relate accuracy of glucose tests and clinical use of insulin, an error grid could express glucose error in units of the ‘size of error of insulin dose’ administered, customized for the local insulin protocol for a specific patient group.

**Objective:** To develop a grid to display the relationship between glucose error and the associated error in insulin dose, using an individual institutional insulin protocol.

**Methods:** To develop a grid to display the relationship between glucose error and the associated error in insulin dose, using an individual institutional insulin protocol.

**Results:** Figure 1. IDEA error grid analysis: Patient correlation data (n = 199) measured by reference and test glucose methods are plotted on the error grid and a histogram represents the frequency of insulin dose errors. A precision study was performed per CLSI EP05-A3 differences between reference and test methods on the risk of insulin dosing error was simulated using a published insulin dosing protocol (Karon et al., 2010). Data are displayed on a grid of reference glucose and meter glucose values with increasing color intensity applied as the size of clinical error in units of insulin dose errors increases. To evaluate a glucose meter, paired glucose data for the reference and test methods are plotted on the error grid and a histogram represents the frequency of insulin dose errors.

**Conclusion:** The IDEA grid is a useful tool that describes differences in glucose measurement in terms of insulin dosing error. This grid is capable of being individualized to an insulin dosing protocol to enable objective assessment of clinical risk attributed to analytic glucose meter error.
**Evaluation of health outcomes after the implementation of rotational thromboelastometry in patients undergoing cardiac surgery.**

I. RODRIGUEZ MARTIN, C. Sánchez Mora, F. Sánchez Jiménez, C. González Rodríguez, V. Sánchez Margalet. UNIVERSIDAD DE SEVILLA, SEVILLA, Spain

**Background:** Viscoelastic tests (rotational thromboelastometry, ROTEM®), together with the implementation of a specific algorithm for coagulation management in cardiac surgery, can enable perioperative coagulopathy to be better controlled. **Methods:** Retrospective cohort study evaluating patients who underwent cardiac surgery with cardiopulmonary bypass. The incidence of allogeneic blood transfusions and clinical postoperative complications were analyzed before and after ROTEM® implementation. **Results:** Following viscoelastic testing and the implementation of a specific algorithm for coagulation management, the incidence of any allogeneic blood transfusion decreased (41.4% vs 31.9%, p=0.026) during the perioperative period. In the group monitored with ROTEM®, decreased incidence of transfusion was observed for packed red blood cells (31.3% vs 19.8%, p=0.002), frozen fresh plasma (9.8% vs 3.8%, p=0.008), prothrombin complex concentrate administration (0.9% vs 0.3%, p=0.599) and activated recombiant factor VII (0.3% vs 0.0%, p=0.603). Increased incidence was observed for platelet transfusion (4.8% vs 6.8%, p=0.530) and fibrinogen concentrate (0.9% vs 3.5%, p=0.066), tranexamic acid (0.0% vs 0.6%, p=0.370) and prothrombin administration (0.6% vs 0.9%, p=0.908). Similar results were observed in the postoperative period, but with a decreased incidence of platelet transfusion (4.8% vs 3.8%, p=0.813). In addition, statistically significant reductions were detected in the incidence of postoperative bleeding (9.5% vs 5.3%, p=0.037), surgical reexploration (6.0% vs 2.9%, p=0.035), and length of Intensive Care Unit (ICU) stay (6.0 days vs 5.3 days, p=0.026). **Conclusion:** The monitoring of hemostasis by ROTEM® in cardiac surgery, was associated with decreased incidence of allogeneic blood transfusion, clinical hematologic postoperative complications and lengths of ICU stay.

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**Evaluation of Point of Care Process Efficiency in an Emergency Department Using Abbott i-STAT**

S. Morosyak1, M. O’Hara2, V. Khangulov2, S. Kazmierczak2, A. Ahuja1. 1BD, Franklin Lakes, NJ, 2Boston Strategic Partners, Boston, MA, ’Oregon Health and Science University, Portland, OR

**Background:** Utilization of cartridge-based point of care tests (POCT) is growing. Rapid turnaround times (TAT) are especially important in the emergency department (ED) care setting. Cartridge errors and unusable results in testing can result in increased staff workload, increased reagent consumption, delayed diagnosis and adverse patient outcomes. To understand clinical and economic impact of these errors, we evaluated the frequency of occurrence of POCT errors in an ED dataset as well as estimated how these errors impact TAT. **Methods:** A retrospective analysis was conducted using de-identified records for 15,479 i-STAT cartridges run in the ED at Oregon Health & Science University between December 2015 and August 2016. Data were collected from the device middleware and EHR for three cartridge types: blood gases (CG4+), chemistry (Chem8+) and Troponin. The frequency of cartridge errors and unusable results (indicated in the data as a ***, <> or <or> code) and the effect of variables on error frequency such as operator ID and time/date of testing were evaluated for the three cartridge types. We also investigated the effect of device errors on TAT, calculated as the elapsed time from the first POCT order to the return of the first valid result from either a repeated POCT or core laboratory test. A second dataset was used to estimate Chem8+ and Troponin cartridge waste based on the difference between the number of cartridges used for patient testing (tests ordered) versus the number of reported results over a two-year period. **Results:** A total of 935 cartridge errors and unusable results (affecting 6.0% of all cartridges used for patient testing) were recorded during the study period. Of the 935 errors, 563 (3.6%) were identified as cartridge errors and 372 (2.4%) as unusable results. Across 563 cartridge errors, 156 (27.7%) were associated with error codes related to sample quality or handling issues (e.g. insufficient sample, bubbles in the sample, or over/under filling of the cartridge). Unusable results were observed for 5.7% of all Chem8+ cartridges, 2.1% of all CG4+ cartridges, and 0.6% of all Troponin cartridges. An inverse correlation was found between user experience and error rates. 5.7% of all Chem8+ cartridges, 2.1% of all CG4+ cartridges, and 0.6% of all Troponin cartridges. **Conclusion:** Device errors and incomplete test orders lead to inefficiencies in the POCT process. Although infrequent, device errors can result from multiple root causes, including poor sample quality, inappropriate sample/ device handling and device malfunction, and inversely correlate with user experience. These errors are associated with potentially increased time to definitive diagnosis that impact patient care as well as have economic impact. They lead to higher cost due to demand for additional time, resources and waste of cartridges and consumables. Incomplete test orders also contribute to cartridge waste adding to the economic impact.

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**Evaluation of the cobas h232 POCT instrument for NT-proBNP testing**

D. Gruson, A. Pouleur. Cliniques Universitaires Saint Luc, Bruxelles, Belgium

**Background:** NT-proBNP (N-terminal-pro-Brain Natriuretic Peptide) is well-established biomarker for the diagnosis and risk stratification of heart failure (HF). Nowadays, several point of care testing (POCT) are available for testing of cardiac markers and could be used in hospital settings as well as in ambulatory care. The aim of our study was to evaluate Ni-proBNP testing on the cobas h232® POCT system. **Methods:** The precision of the POCT instrument was determined with quality control materials over thirteen consecutive days. Method comparison was performed with our central laboratory Ni-proBNP assay run on cobas 8000® instrument through thirty two serum samples of patients suspected of HF. **Results:** The between-run imprecision coefficients of variation (CV) were 11% and 14% for NT-proBNP concentrations of 102 and 719 ng/mL, respectively. The median concentrations in patients' samples were 708 ng/mL (range: 22.3 to 30477) with routine assay and 655 ng/mL (60 to 9000) with POCT system. The two NT-proBNP assays were significantly correlated (r = 0.97, p<0.0001). The Passing and Bablok regression analysis showed for concentrations between 60 and 6000 ng/L a slope 1.07 (95% CI: 0.87 to 1.21), an intercept of -0.20 (95% CI: -72.2 to 42.9) and no significant deviation from linearity. The Bland and Altman Plots revealed no significant bias and a mean difference of 62.5 ng/L (95% CI: -109 to 234) between the two NT-proBNP assays. **Conclusions:** Our preliminary data showed that the performances of the cobas h232 Ni-proBNP assay could be compatible with diagnosis of HF as well as monitoring of patients with chronic HF in both hospital and ambulatory care settings.
Point-of-Care Testing

formed and documented. Most of the infections involve documentation issues.

**Conclusion:** Auditing POC sites has enabled detection of problems in real time and enabled resolution of the same in a timely manner. The audits combined with a policy containing defined ramifications for non-compliance has enabled a significant improvement in adherence to regulations and performing tests appropriately which was reflected in the latest accreditation visit (April 2017).

**B-359**

**Evaluation of a Point-of-Care Assay for Fecal Calprotectin**


**Background:** One of the most useful biomarkers to help diagnose inflammatory bowel disease (IBD) is calprotectin, a primary protein released from neutrophils during an innate immune response. Elevations of fecal calprotectin are suggestive of gastrointestinal inflammation, such as Crohn’s disease or ulcerative colitis, and may help rule out idiopathic or mechanical causes for gastrointestinal symptoms. Several clinical assays for fecal calprotectin are available; however, collection and handling of stool samples is unpleasant and patients may be resistant to testing. In response to this problem, several point-of-care (POC) kits have been produced that allow patients to collect, sample, and assay fecal specimens at the time and location of their choosing. While the advantages to the patient are obvious, the performance characteristics of such test kits are not widely reported. Therefore, our objective was to evaluate one POC kit for fecal calprotectin by comparison to 2 immunoassays performed in the clinical laboratory.

**Methods:** 120 residual stool samples were retained from specimens submitted for routine calprotectin testing using the QUANTA Lite™ ELISA (Inova Diagnostics). Specimens were stored frozen (-20°C). Calprotectin was measured using the POC QuantOn Cal kit (Immundiagnostik, Bensheim, Germany) according to package instructions. This kit utilizes a lateral flow immunochromatographic cartridge with a proprietary smart-phone app to read and quantify color change. To provide an additional comparison, calprotectin was also measured using the IDK Calprotectin ELISA (Immundiagnostik). In addition to method comparisons, precision was assessed for each assay across the measuring range. Package inserts for each stated normal calprotectin concentrations as <50 mcg/g. Cutoffs for positive inflammation were: Inova, >120 mcg/g; IDK POC, >100 mcg/g; IDK ELISA, >200 mcg/g.

In each assay, the range between normal and positive is considered indeterminate. Results: Overall qualitative concordance between the POC device and the Inova assay performed in our laboratory was 49% (Kappa = 0.27) when using normal, indeterminate, and positive categories. Using only the positive cutoff for each assay, concordance increased to 79% (Kappa = 0.41). Among results within respective analytical measuring ranges, Passing-Bablok regression was: POC = 3.24*Inova + 1.84; r = 0.274. Concordance between the POC and IDK Calprotectin assays (produced by the same company), was 61% (Kappa = 0.39) using all three ranges, and 75% (Kappa = 0.50) using only the abnormal cutoff. Passing-Bablok regression was: POC = 1.76*IDK ELISA + 1.70; r = 0.362. Precision for the POC device was calculated at 37% (64 mcg/g, n=20), 41% (166 mcg/g, n=18), and 23% (588 mcg/g, n=20). In contrast, inter-assay CVs for the IDK ELISA were 16% (12 mcg/g), 12% (75 mcg/g), and 11% (464 mcg/g). For the QUANTA Lite ELISA, inter-assay CVs were 7.6% (14.2 mcg/g), 6.0% (88.5 mcg/g), and 7.4% (525.9 mcg/g).

Conclusions: Calprotectin measurements collected by the POC device tested in this study showed only moderate qualitative and quantitative concordance with 2 laboratory immunoassays. Discrepancies between results are largely in the borderline range and may partially be attributed to the impresision of the POC device.

**B-360**

**Performance Evaluation of the Atellica UAS 800 urine particle Assay**

M. Hotta1, W. Kobayashi1, S. Matsuda1, A. Iwata1, I. Maeda1, Y. Hidaka2.

1Department of Medical Technology, Osaka University Hospital, Osaka, Japan, 2Laboratory for Clinical Investigation, Osaka University Hospital, Osaka, Japan

**Background:** Urine Microscopy testing is commonly performed in clinical laboratories to help identify kidney and urinary tract diseases. However, manual microscopy testing is known to be time-consuming, labour intensive, and most often, subjective. In this study, we evaluated the performance of the Atellica UAS 800 (UAS 800) urine particle analyzer (by Siemens).

**Method:** UAS 800 is an automated urine particle analyzer powered by high-resolution digital imaging designed to minimize the need for manual microscopy testing. It recognizes, counts and classifies particles into 11 major categories as Bacteria, Crystals, Hyaline Cast, Mucus, Non-squamous EC, Pathological Cast, RBC, Squamous EC, WBC, Sperm and WBC clumps using a reference library built based on over 110,000 particles and a dual-focusing mechanism to produce clear images. 270 freshly collected urine samples submitted to our hospital laboratory were analyzed with UAS 800 and UF-1000i (by Sysmex) .

**Results:** For RBC, the concordance rate between UAS 800 and UF-1000i are 55.2% (Exact Agreement), and 92.2% (±1 Block Agreement). For WBC, the concordance rate between UAS 800 and UF-1000i are 78.8% (Exact Agreement), 98.5% (±1 block agreement). RBC and WBC cell recognition by both, UAS 800 and UF-1000i is considered to be equivalent. Hylaine Cast data shows a higher sensitivity on UAS 800 than UF-1000i. A well-received advantage for using digital technology, such as UAS 800, is the availability of clear full-field view of images which helps to reduce Manual Microscopy and to timely identify samples that may require further testing. It was the first experience to confirm flagellum of Trichomonas using an automated urine analyser.

**Conclusions:** As a screening method, UAS 800 with its clear full-field view of images is expected to reduce the manual microscopy rate.

**B-361**

**Electrochemical detection of Parathyroid hormone as a point-of-care testing device towards clinical applications**

A. S. Tanak1, S. Muthukumar2, S. Prasad1, I. A. Hashim1. 1University of Texas at Dallas, Richardson, TX, 2Enlisense LLC, Allen, TX, 3UT Southwestern Medical Center, Dallas, TX

**Background:** Every year, about 100,000 people develop primary hyperthyroidism in the United States, making it one of the most common endocrine disorders. Enlargement of one or more of the parathyroid gland is seen in 70% of all patients due to overactivity of the affected gland. Measuring parathyroid hormone (PTH) levels helps in the investigation and management of patients with parathyroid disorders. Reliable
B-363

Preventing Blood Loss and Iatrogenic Anemia from Diagnostic Testing: A Laboratory Medicine Best Practices Systematic Review

L. WilliamsI, N. Whitehead, S. Geaghan, C. Litwin, J. Nichols, J. Gayken, S. Kennedy, M. McEvoy, D. Ernst, P. CarrollII, CDC, Atlanta, GA, RTI International, Research Triangle Park, NC, 3Stanford University School of Medicine, Stanford, CA, 4Medical School of South Carolina, Charleston, SC, 5Vanderbilt University School of Medicine, Nashville, TN, 6Medical Laboratory Consultant, St. Cloud, MN, 7RTI International, Research Triangle Park, NC, 8Albany Medical Center, Albany, NY, 9Center for Phlebotomy Education, Coridon, IN, 10Intermountain Healthcare, St. George, UT

Objective: The CDC’s Laboratory Medicine Best Practices initiative (LMBP™) conducts systematic reviews to assess the effectiveness of quality improvement practices. With a panel of experts from relevant laboratory and healthcare disciplines, and scientists from RTI, we reviewed practices for preventing blood loss and reducing the occurrence of iatrogenic anemia from diagnostic testing, especially in critical care patients. As many as 90% of patients develop anemia by their third day in an intensive care unit (ICU). Practices to reduce blood loss are important to patients’ health and survival.

Methods: Employing the A-6 methodology, developed by the Centers for Disease Control and Prevention’s LMBP™, searches of PubMed, Embase, Cochrane, Web of Science, PsychINFO, and CINAHL retrieved 2,564 articles. Twenty-one studies were accepted for full text review based on A-6 criteria. Five interventions were reviewed: (1) small volume tubes, (2) closed blood sampling devices, (3) point of care testing, (4) educational interventions, and (5) bundled interventions that variously combined two or more interventions. The overall strength of the body of evidence was rated with respect to supportings recommendations for specific practices (or not) and categorized as High, Moderate, Suggestive, or Insufficient as defined by the A6 methodology.

Results: We found moderate strength, consistent evidence that blood conservation devices returning blood from venous and arterial lines to the patient reduced blood loss by approximately 25% in both neonatal ICU (NICU) and adult ICU patients. The effect estimate (mean difference) by meta-analysis was 24.7 (95% CI = 12.1 - 37.3). The evidence was suggestive that bundled interventions that included such blood conservation devices also reduced blood loss by at least 25%. However, the evidence was insufficient to conclude that these devices reduced hemoglobin decline or anemia risk. There was suggestive evidence that use of small volume phlebotomy tubes may reduce blood loss, but insufficient evidence to evaluate the impact on hemoglobin levels or transfusion rates. (Suggestive evidence is not sufficient for LMBP™ to make recommendations.)

Conclusion: Closed blood conservation systems were effective in reducing blood loss in ICU and NICU patients. The evidence is moderate strength that such devices reduce blood loss by about 25% compared to patients with conventional arterial pressure monitoring systems. Thus, the LMBP™ recommends the use of blood conservation systems with arterial or venous catheters to eliminate blood waste when drawing blood for testing. Additional high-quality studies and evidence are needed to adequately assess several other commonly proposed interventions to reduce blood loss from diagnostic testing among critically ill patients.


Table 1. Receiver operation characteristics (ROC) curve parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>AUC (95% CI)</th>
<th>Cutoff value</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
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<td>cTNI (ng/ml)</td>
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<td>NT-proBNP (pg/ml)</td>
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<td>D-dimer (mg/L)</td>
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<td>FIB (g/L)</td>
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<td>77.0</td>
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<td>PLT (10^12/L)</td>
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<td>ANGEL (degree)</td>
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<td>66.1</td>
<td>89.7</td>
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<td>MA (mm)</td>
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<tr>
<td>CI</td>
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<td>68.5</td>
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<td>G (dyne/cm^2)</td>
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<td>9.95</td>
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</tr>
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</table>

Wednesday, August 1, 9:30 am – 5:00 pm

Point-of-Care Testing

Onset of Acute Coronary Syndrome (ACS)

The Thromboelastography G Parameter (TEG-G) For Predicting
Onset of Acute Coronary Syndrome (ACS)

O. Lu, X. Wang. Clinical Laboratory of Ruijin Hospital, Shanghai, China

Background: The most prominent event that defines an ACS is the formation of an in-tra-arterial thrombus, usually resulting from activation of platelet and fibrinogen in cor- onary arteries at the site of a ruptured plaque with physical lumen occlusion by throm- bosis. The aim of this study was to investigate whether TEG (a POC method) parameters could be surrogate markers of thrombus formation process and diagnosis of ACS.

Methods: A total of 168 patients with ACS, 58 patients with stable angina pectoris (SAP) as control were enrolled. Baseline characteristics were recorded. Routine blood test, car- dice markers, routine coagulation tests and TEG were determined. Receiver operating characteristic (ROC) curve was used to evaluate the diagnosis performance of each in- dex. Logistic regression analysis was used to define the independent risk factors of ACS.

Results: Patients with ACS exhibited greater prevalence of hypertension than pa- tients with SAP (p<0.01). cTNI and NT-proBNP levels in SAP measured were sig- nificantly lower than ACS patients (p<0.01). PT was significantly different in two groups (p<0.05). FGF2, D- dimer and PLT were greater elevated in ACS patients than SAP patients (p<0.01). Most parameters (K, Angel, MA, CI and G) of TEG have significant difference be- tween two groups(p<0.01), except R value. Logistic regression analysis showed that TEG-G was an independent risk factor and auxiliary diagnostic indicator for ACS.

Conclusion: TEG-G could be used as a better predictor of activation of platelet and fibrinogen in force unit than MA, which is eligible to be a new biomarker for early diagnosis of ACS and could provide baseline information for anti-platelet therapy.
“Just-in-Time” Implementation of Molecular Point-of-Care Testing for the 2017-18 Influenza Epidemic

K. Lima, X. Ivanova, S. Gillett, S. Yee, A. Melliza, N. Tran. University of California, Davis, Sacramento, CA

Background: The ability to timely implement next generation testing to aid in diagnosis and treatment during current health crises is critical for any institution. “Just-in-time” planning optimizes resource allocation while ensuring maximum benefit. The 2017-18 influenza season has proven challenging for health care providers given the unexpectedly high prevalence of the H3N2 viral strain. According to the Centers for Disease Control, between October 1, 2017 and January 27, 2018 approximately 15,000 laboratory confirmed influenza-associated hospitalizations have occurred. Many hospitals rely on antigen-based rapid influenza detection tests (RIDTs) for screening of influenza infection. While RIDTs provide quick results (<15 minutes), their poor sensitivity has resulted in the United States Food and Drug Administration reclassifying them as Class II devices effective January 2018—forcing many institutions to find alternative methods. To meet this need, our goal was to conduct “just-in-time” implementation of a point-of-care (POC) molecular assay for viral detection during the 2017-2018 influenza season. Methods: Thirty POC molecular analyzers (cobas Liat, Roche Diagnostics, Indianapolis, IN) analyzers were obtained for 16 of our health system clinics, the emergency department (ED), and the clinical laboratory. Precision was assessed on all 30 instruments for the influenza A/B assay by analysis of two-level within day (n=5) testing and two-level daily testing for ten days. The same precision testing scheme was performed on a subset of instruments (n=4) to validate the combined influenza A/B and Respiratory Syncytial Virus (RSV) assay for use in the ED and clinical laboratory. In addition, de-identified positive and negative patient universal transport media samples for influenza A/B, and RSV were tested on the molecular POC analyzer and compared results to a predicate analyzer (GenMark Diagnostics, Carlsbad, CA). An educational program was implemented to train 562 device users and provide proper test utilization for molecular testing. Results: The POC molecular influenza A/B assay demonstrated sensitivities of 100% [Flu A (6/6); Flu B (4/4)] and a specificity of 100% [Flu A (15/15); Flu B (17/17)] for each target when testing remnant patient samples for method comparison. Likewise, the influenza A/B and RSV samples showed 100% positive (7/7) and negative (13/13) agreement for each target across four instruments. Of the 1,020 two-level controls (positive and negative) tested across the 30 instruments during precision analysis, all tests yielded a result corresponded correctly. We determined inadequate mixing as a common source of pre-analytical error and incorporated these findings into the waived user training scheme. Operator education began in parallel using a “train the trainer” model coupled to laboratory test best practice notifications for physicians. Total time from commencement of performance verification to clinical implementation was 64 days. Post-implementation results show no statistically significant changes in ordering practices and only two reported cases of pre-analytical error requiring repeat testing. Conclusion: The Roche cobas Liat has high precision and clinical sensitivity specificity for the Influenza A/B, and combined Influenza A/B and RSV assays. Implementation and distribution of molecular POC testing to clinics and emergency departments can be completed using a “just-in-time” model to respond to current public health crises while optimizing resource utilization.

The importance of health economics modeling in assessing costs of point-of-care HbA1c testing of patients with diabetes mellitus type II in the United States

F. Navarro1, R. Hren2, A. Boltynkov3. 1University Mackenzie, Sao Paulo, Brazil, 2University, Dalhousie University, NB, Canada, 3Handelshochschule Leipzig, Leipzig, Germany

OBJECTIVES: To show the importance of health economics modeling when assessing costs of HbA1c testing and to calculate the financial impact of the point-of-care methodology in the United States. METHODS: We developed a budget-impact model (BIM) that compared strategies of using point-of-care (POC) versus conventional laboratory-diagnostics (LD) HbA1c testing in patients suffering from diabetes mellitus (DM) type II. In BIM, we followed a cohort of 2,900,000 patients diagnosed with DM type II in the United States for the period of 15 years and estimated the costs of complications (amputation, cataract extraction, kidney failure, heart failure, stroke, and microvascular disease) using the local data. To assess the validity of the assumptions and robustness of the model, a thorough sensitivity analysis was undertaken. RESULTS: In patients with DM type II, POC HbA1c testing resulted in the saving of $2,824 billion (on average, $974 per patient in the cohort) when compared to conventional LD testing. The sensitivity analysis showed robustness of our findings. CONCLUSIONS: Our health economics analysis predicts that the POC HbA1c testing in patients suffering from DM type II may reduce overall health care costs in the United States. This finding has important potential implications for management of the diabetic population and reimbursement of HbA1c testing methodologies.