Wednesday, August 1, 2018

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

Point-of-Care Testing

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 POC-creatinine and eGFR with central laboratory and assess the impact of POC-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 POC-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/1.73m^2). 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. POC-creatinine had the mean bias 0,02 µmol/L or 1,6% for creatinine and 0,57/1,33/-2,88 ml/min/1.73m^2 or 5,3/1,7/-4,0% for eGFR compared with laboratory method. The results demonstrated that POC 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.

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 setting where modern standard centrifuges are impractical. The design and fabrication of hand-powered centrifuge is based on principle of an ancient whirligig string toy operated by spinning. We evaluated the electricity-free centrifugation potential of the hand-powered centrifuge using human blood at point-of-care level.

Methods

We designed and fabricated plastic/paper centrifuge of 12-cm diameter size. It was composed of two circular 1-mm thick plastic/paper discs used for stationery purpose which was bound by an adhesive tapes with two small holes in the center. Two sample capillary holders were glued horizontally to the discs. An extra-strong 62-cm long fishing line passing through centre of discs was used for spinning. Phlebotomy was performed aseptically during remote field clinics and 2-3 ml blood was transferred to small tube. Then it was placed inside the sample holder and rotated by hand for 3-4 minutes. This resulted in a good separation of plasma from the cellular blood components.

Results

We found that hand-powered centrifuge can adequately separate the plasma from anti-coagulated blood within 2-3 minutes. The overall cost and weight of centrifuge is $ 0.5 USD and about 25-30g respectively, which is more practical and cost-effective than modern electric centrifuges. Although the volume of blood used was less, we were able to show good qualitative agreement in terms of centrifugation and separation of pure plasma from anti-coagulated blood between the hand-powered centrifuge and conventional electric centrifuges.

Conclusion

Re-purposing of a simple toy has resulted in a novel point-of-care electricity-free blood centrifuging 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 diseased conditions).

B-330

GEM Premier 5000 Method Comparison Study for Native Capillary Samples

M. DeAbreu, J. Cervera, E. Kovalchick, M. Velankar, N. Raymond. *Instrumentation Laboratory, Bedford, MA*

Background: Capillary blood sampling is increasingly common in medicine and provides several advantages over venous blood sampling: it is less invasive, it requires smaller amounts of blood volume and it can be performed quickly and easily in 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. Collection of capillary samples was performed according to established guidelines (pre-warming of the puncture site for increased blood flow, removal of first drop to avoid tissue fluid contamination, no milking to prevent hemolysis, removal of air gaps within the sample and mixing for sample homogeneity). At the internal site, additional contrived samples were included to span the reportable range for each 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.

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

Analyte	Slope	Intercept	r
pH	0.935	0.494	0.975
pO_2 (mmHg)	1.008	2.545	0.996
pCO_2 (mmHg)	1.000	1.000	0.980
Na^+(mmol/L)	1.015	-1.750	0.981
K^+(mmol/L)	1.000	0.100	0.995
Ca^{++}(mmol/L)	1.050	-0.016	0.998
Cl^-(mmol/L)	1.000	-1.000	0.995
Glu(mg/dL)	0.966	4.775	0.997
Lac(mmol/L)	1.000	0.000	0.995
Hct(%)	1.003	-0.407	0.987
tHb(g/dL)	1.028	-0.470	0.994
O_2Hb(%)	1.000	0.802	0.997
COHb(%)	0.988	-0.269	0.999
MetHb(%)	1.000	-0.100	0.998

B-331

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. Diaz, J. Unabia, M. Benbook, K. Avandsalehi, 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/UPT) in Ob/Gyn patients. In our Ob/Gyn clinics we perform >50,000 UA tests/year (>94% being performed manually). The same clinics 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 Clinitek Status Connect) capable of performing and transmitting to the EMR both UA and UPT results it is possible to reduce preanalytic (bar code reader), analytic (instrument resulting), and postanalytic (transmission to the EMR) errors. The objective of this study is to determine the potential time savings associated with using the Clinitek Status 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 Clinitek Status 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. Clinitek Status. 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=7 tests) **Results:** The difference of test time and total test time to perform for a Chem 6-10 UA (N=67) was significantly less for the Clinitek Status (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 Clinitek Status 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 clinics studied found a transcription error rate of 0.3-1.7% for individual UA results (N=3550 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 Clinitek Status UA system was more efficient than the manual process. Manual UPT testing was faster than the Clinitek Status although the total test time was the same. Once connected to the EMR the Clinitek Status will eliminate the transcription errors and lack of documentation of some test results. Partial study funding was received from Siemens.

B-332

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

W. D. Arnold[1], K. Kupfer[1], M. Hvidsten Swensen[1], H. E. Bays[2], M. Davis[3], L. J. Klaff[4], R. C. San George[1]. *[1]Abbott Rapid Diagnostics Division, Abbott Park, IL, [2]L-MARC Research Center, Louisville, KY, [3]Rochester Clinical Research, Inc., Rochester, NY, [4]Rainier Clinical Research Center, Inc., Renton, WA*

Background: The objective of this study was to estimate the between-instrument and between-operator components of precision for the investigational point-of-care (POC) Afinion HbA1c Dx test using fingerstick whole blood samples in a moderate complexity laboratory setting. This analysis, taken together with previous results, estimated total precision for fingerstick samples and total error for the Afinion HbA1c Dx test. **Methods:** Following a study design recommended by the Food and Drug Administration (FDA), 60 subjects were enrolled across three clinical sites and four levels of %HbA1c. Three test operators each collected two fingerstick samples from each subject and tested one sample on each of two analyzers. There were a total of 90 fingerstick measurements at each %HbA1c level. The within-run, between-operator, and between-instrument components of variance were calculated for each level using ANOVA. Total precision was calculated from the between-instrument and between-operator variance from the present study together with the within-run (including between-lot), between-run, and between-day components from two previous studies. The resulting total coefficient of variation (CV), together with bias estimates from one of the prior studies was used to estimate total error. **Results:**** The fingerstick precision components calculated from this study are shown in Table 1. Across the four %HbA1c levels the between-instrument imprecision was 0.00-0.47% CV, the between-operator imprecision 0.00-0.26% CV, and within-run imprecision 1.09-1.39% CV. The total precision was 0.882.00% and the total error ranged from 2.86-4.68%.

Table 1: Summary of Fingerstick Precision Study Results

HbA1c Level	Grand Mean %HbA1c	N (M)	Between Instrument		Between Operator		Within Run	
			SD	CV(%)	SD	CV(%)	SD	CV(%)
Low	5.33	15 (90)	0.0076	0.14	0.0000	0.00	0.0742	1.39
Threshold	6.51	15 (90)	0.0192	0.30	0.0000	0.00	0.0811	1.25
Medium	8.41	15 (90)	0.0000	0.00	0.0218	0.26	0.0919	1.09
High	12.20	15 (90)	0.0570	0.47	0.0000	0.00	0.1389	1.14

Notes: N (M) is the number of subjects (number of test results). CV is SD from ANOVA divided by Grand Mean.

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 ±6% 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. Wang[1], T. Klein[2], J. Collins[1]. *[1]University of Minnesota, St. Paul, MN, [2]Zepto 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 immunoassay process is set up based on sandwich-type format. NT-proBNP 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 diluting NT-proBNP analytes to desired concentrations in assay buffer was loaded into sample entry well which was prefilled with biotin 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. NT-proBNP with varied concentrations were spiked into human plasma, and recoveries of 85-115% are observed. 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 can

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

E. Peeters, J. Vinkenborg, A. van Reenen, T. van den Kerkhof, B. Meijering, F. de Theije, J. Nieuwenhuis. *Philips, Eindhoven, Netherlands*

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 cTnI POC test under development, which has the potential to combine the benefits of HS cTnI protocols with a POC workflow. **Objective:** Evaluate the capability of the Minicare HS-cTnI test under development to meet the criterion[1] 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/L (male) and 16 ng/L (female). This would lead to a 10% CV LoQ for the Minicare HS-cTnI 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.

[1] *F. S. Apple and P. O. Collinson, "Analytical Characteristics of High-Sensitivity Cardiac Troponin Assays" Clin Chem. 2012 Jan; 58(1):54-61.*

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 leukocyte presence in infection. The objective of this study is to compare the Siemens Multistix® 10SG reagent strips/CLINITEK Status®+ Urine Chemistry Analyzer, CLARITY CLA-URS10 reagent strips/UROCHECK 120 urine analyzer, YD DIAGNOSTICS URISCAN 10 SGL Strips/OPTIMA urine analyzer, and TECO DIAGNOSTICS URS-10 strips in their ability to detect leukocyte esterase with contrived solutions and confirming findings in native specimens.
Methods:
This 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 instrument 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/2+ 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 CLINITEK 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
[1] https://www.nichd.nih.gov/health/topics/urinary/conditioninfo/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 cobas h 232 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 cobas h 232 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 2-Level control according to the CLSI documents EP15-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 cobas h 232 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 Elecsys Troponin T high sensitive (TnT-hs) assay on the cobas e411 analyzer and CARDIAC POC Troponin T assay on the cobas 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=0.985x-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. Genta[1], E. Drumm[1], M. Kiger[1], F. Alferes[1], S. Shumate[2], A. Schoener[1], B. Boston[1], L. Wyer[2], Y. Shen[1]. *[1]Sentara Virginia Beach General Hospital, Virginia Beach, VA, [2]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 CG8+, Abbott Diagnostics), cobas c501, c311 (Roche Diagnostics). Patient specimens, with values in the interval 50 - 600 mg/dL, obtained by venipuncture were assayed in parallel and within 30 minutes with AccuChek Inform II and either i-STAT or the laboratory method in thirteen facilities. The data were collected and transferred electronically to Minitab® (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 +0.96 x) 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

the reference method (Adjusted MSE=0.8, Adjusted MS for reference methods=3.3, F=4.01, P=0.46) as the single major contributor to the unexplained variation. Similar results were obtained with forward selection (x to enter=0.25, Adjusted MSE=0.8, Adjusted MS for reference method=3.3, F=4.01, P=0.046) and backward elimination (x to remove=0.25, Adjusted MSE=0.8, Adjusted MS for reference method=3.3, F=4.01, P=0.046). The pure error test did not show statistically significant lack of fit (F=0.8, P=0.7) and this was corroborated by the lowess of the plot of the standardized deleted residuals by the glucose value. Furthermore, the plot of the relative and the absolute bias of the glucose value, as determined with the AccuChek Inform II method, versus the value, as determined with the reference methods, was within the CLIA's criterion (target value +/- 6 mg/dL, or +/- 10%, greater). **Conclusions**: The weighted polynomial regression analysis showed similar, stable performance in thirteen facilities for four years. The relative and absolute differences between the glucose values as obtained with AccuChek Inform II versus paired values as obtained with the reference methods were within the CLIA's criterion. The statistically but not clinically significant differences between regression lines for the reference methods may be due to either design and/or calibration. However, since the data were generated by an unplanned consecutive QA operation and not from a planned experimental design, the error may not have been random, but may have been due to the effect of one or several latent variables and this bias may have induced imprecision in estimating the regression parameters. Finally, both the electronic transfer of data and the use of a statistical software, such as Minitab, were of the paramount importance for conducting these studies.

B-338

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. Pizarro, I. Tomoiu, P. Oliver, P. Fernadez-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.

Medical decision levels (mg/dL)	Estimated bias (%)	95% CI	Allowable difference (%)
CREATININE			
0.3	-2.6	-12.3 to 9.5	±8.9
0.6	-5.6	-8.8 to -0.7	±8.9
1.2	-7.2	-8.9 to -4.5	±8.9
6.0	-8.4	-10.5 to -4.7	±8.9
UREA			
13	-12.9	-23.9 to -3.6	±15.6
56	7.5	4.8 to 9.6	±15.6
107	10.4	6.6 to 13.5	±15.6
200	11.9	7.5 to 15.8	±15.6

Results:

Conclusions: 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.

B-339

comparision of two point of care gasometers: gem premier 4000 (werfem group) and epoc (alere)

I. Peral Camacho[1], M. Viloria Peñas[1], E. Lepe Balsalobre[1], J. Guerrero Montavez[2], A. Moro Ortiz[1]. *[1]Virgen de Valme University Hospital, Seville, Spain, [2]Virgen del Rocio University Hospital, Seville, Spain*

Background: Point of care tests (POCT) are defined as "bedside assistance and wherever the patient is, or where the decisions are made by the health team, wherever they are". Given the importance of the parameters evaluated in the gasometry, it is important that the response time is reduced to the maximum, and therefore, gasometers of the POCT type are a very helpful tool. The objetive was to evaluate the correlation and transferability of the results between GEM PREMIER 4000 (WERFEN GROUP) and EPOC (ALERE) gas meters for the parameters measured relative to the acid-base balance and oxygenation and ion state. **Methods:** Prospective study, in which 66 gasometry samples were included: 24 corresponded to patients hospitalized in the Intensive Care Unit and 42 to patients from the extraction area of the laboratory of our hospital during a period of 4 months (January to April 2017). The samples were processed in parallel, 60 venous gasometries and 6 arterial blood gases, and to minimize the preanalytical error, the analysis of the samples was performed in the 2 teams following a sequential order: first in the GEM PREMIER 4000 analyzer (Werfen Group) and immediately after in EPOC (ALERE). The results were evaluated by the Pearson correlation coefficient and the bilateral significance level. **Results:**

Parameters	Pearson correlation (CI 95%)	Bilateral significance level
pH	0.986 (0.965-0.993)	0,000
Partial pressure of CO2	0.984 (0.993-0.993)	0,000
Partial pressure of O2	0.995 (0.979-0.998)	0,000
Ion sodium	0.887 (0.393-0.960)	0,000
Ion potassium	0.989 (0.975-0.994)	0,000
Ion chloride	0.945 (0.909-0.967)	0,000
Ionic calcium	0.824 (0.712-0.892)	0.000
Glucose	0.984 (0.947-0.993)	0,000
Lactate	0.985 (0.973-0.991)	0,000
Hemoglobin	0.916 (0.824-0.953)	0,000
Oxygen saturation	0.959 (0.893-0.980)	0,000
Total CO2	0.982 (0.967-0.989)	0,000
Bicarbonate	0.984 (0.974-0.990)	0,000
Hematocrit	0.956 (0.923-0.975)	0,000

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 transferable methods and therefore, the results can be interchangeable. - Given that the ALERE 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.

B-340

Assessment of Strip Lot and Meter Variation with the Nova Statstrip® Lactate Point of Care Device

A. A. Kakadekar[1], A. Andrews[2], L. Smith[3], M. E. Lyon[3]. *[1]Medical University of Lublin, Lublin, Poland, [2]University Saskatchewan, Saskatoon, SK, Canada, [3]Saskatchewan Health Authority, Saskatoon, SK, Canada*

Background: Lactate is a metabolic by-product of tissue hypoxia and is a marker of metabolic stress in the body. It holds prognostic value in many conditions including sepsis, heart failure and respiratory failure. Reproducible measurement of lactate is critical for clinical outcome in patient care. No consensus reference method for the measurement of lactate currently exists and as such assessment of method accuracy is problematic. **Objective:** To evaluate the analytical performance of the Nova Statstrip® lactate meters and strips. **Methods:** Precision was assessed using Nova QC materials as well as venous and arterial whole blood specimens. Variation in strip lot (n=3) was evaluated using one lactate meter and Nova Biomedical linearity material. Patient correlations (n=50) were conducted using three different lot number of strips

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 $y = 0.974x + 0.161$ (strip 1) $R^2 = 0.998$; $y = 0.999x + 0.122$ (strip 2) $R^2 = 0.998$; $y = 0.989x + 0.055$ (strip 3) $R^2 = 0.998$ b) Patient correlations and individual lactate strip lots $y = 0.791x - 0.145$ (strip 1) $R^2 = 0.975$; $y = 0.796x - 0.158$ (strip 2) $R^2 = 0.973$; $y = 0.819x - 0.187$ (strip 3) $R^2 = 0.984$ c) Venous cord blood correlations and individual lactate meters $y = 0.876x - 0.114$ (meter 1) $R^2 = 0.941$; $y = 0.925x - 0.330$ (meter 2) $R^2 = 0.932$; $y = 0.859x + 0.122$ (meter 3) $R^2 = 0.920$ **Conclusions:** Strip lot and meter variation detected with the Nova Statstrip® 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 hematology instrument (HemoCue, Sweden) that determines WBC-DIFF in capillary whole blood 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 294372-10). 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 ºC (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 POCT policy and guidelines, which will be particularly useful in limited-resource settings and countries faced 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 a 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 will help assure the quality of diagnostic performance and enhance standards of care worldwide.

B-343

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

E. Spanuth[1], B. Ivandic[2], J. Wilhelm[3], R. Thomae[4], K. Werdan[3]. *[1]DIAneering GmbH, Heidelberg, Germany, [2]Department of Medicine III, University Hospital Heidelberg, Heidelberg, Germany, [3]University Clinics Halle (Saale), Department of Medicine III, Martin-Luther-University Halle-Wittenberg, Halle, Germany, [4]Mitsubishi 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 underlines 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 Presepsin 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 presepsin (PSEP) in combination 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 Presepsin (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 daysThe 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 were 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 20 (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 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.

Conclusion: NT-proBNP and PSEP demonstrated strong relationship with disease severity and outcome in patient 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, Broenshoej, Denmark*

Objective:
The aim of the studies were to show how automatic mixing of an arterial blood gas (ABG) syringe (*safe*PICO, Radiometer Medical) ensures comparability of hemoglobin results obtained on the ABL90 FLEX blood gas analyzer at the Point of Care, with a laboratory hematology 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 hematology analyzer.

Syringe	n	Slope	Intercept (g/dL)	Correlation coefficient r^2	Mean difference to Sysmex (g/dL)	Confidence interval (g/dL)
A	99	0.79	3.6	0.515	-0.89	-0.5 to -1.3
B	99	1.02	-0.1	0.986	-0.22	-0.2 to -0.3

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[1], D. Kemper[1], L. van Lippen[1], J. Vissers[2], F. de Theije[1], V. Semjonow[1], E. Michielsen[3], J. Mair[4]. *[1]Philips, Eindhoven, Netherlands, [2]Future Diagnostics Solutions, Wijchen, Netherlands, [3]Diagnostiek Voor U, Eindhoven, Netherlands, [4]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 guidelines[1] 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 ($LOQ_{20\%}$) 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 droplet 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. Hamada[1], M. Morita[2], M. Maekawa[1]. *[1]Department of Laboratory Medicine, Hamamatsu University School of Medicine, Hamamatsu, Japan, [2]Research & 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 quantitation was 500 ng/mL. No prozone effect was observed in samples with fFN concentrations from 259 to 6475 ng/mL. At fFN concentrations of 75 ng/mL, 175 ng/mL, and 352 ng/mL, the within-run C.V. (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 96.3% (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.

B-347

Evaluation of the precision performance on the GEM® Premier™ 5000 at CHR Citadelle (Belgium)

A. Randazzo, J. Minon, T. El Mahi, J. de Marchin. *CHR Liège, Liège, 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, pCO_2, pO_2, 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 uselife.

Table 1: Precision performance summary

Analyte and Level	GEM Premier 5000		GEM Premier 4000		Radiometer ABL 90		Siemens RapidPoint 405		Performance criteria
	Mean	SD (or CV%)	Mean	SD (or CV%)	Mean	SD (or CV%)	Mean	SD (or CV%)	
pH (Leve 1)	7.117	0.006	7.128	0.008	7.145	0.004	7.097	0.017	0.02
pH (Level 2)	7.433	0.004	7.422	0.009	7.412	0.004	7.392	0.007	0.02
pH (Level 3)	7.674	0.006	7.650	0.014	7.602	0.003	7.589	0.010	0.02
pCO_2 mmHg (Leve 1)	71.47	2.91%	70.09	2.70%	66.25	1.53%	85.95	6.42%	4.0%
pCO_2 mmHg (Level 2)	43.69	1.06	41.97	0.82	40.61	0.66	46.6	2.5	2.5
pCO_2 mmHg (Level 3)	22.09	0.53	21.28	0.81	21.66	0.3	22.46	1.05	2.5
Glucose mg/dL (Leve 1)	81.09	1.78%	74.34	2.18%	70.28	8.79%	76.68	1.42%	5%
Glucose mg/dL (Level 2)	201.84	1.57%	189.09	3.55%	183.94	5.40%	196.62	1.36%	5%
Glucose mg/dL (Level 3)	304.03	2.22%	280.16	4.31%	273.81	4.32%	288.41	1.24%	5%
Lactate mmol/L (Level 1)	0.60	0.02	0.63	0.05	0.55	0.11	Results not provided		0.2
Lactate mmol/L (Level 2)	2.45	4.02%	2.39	3.51%	2.38	10.47%			7.5%
Lactate mmol/L (Level 3)	7.05	4.67	6.56	4.52	6.62	5.53%			7.5%

B-348

Evaluation of Whole Blood Basic Metabolic Panel Assay with ED Samples

C. Xu[1], Z. Bellio[1], P. Stack[2], B. Kilburn[2], K. Schulz[2], S. Love[3]. *[1]Instrumentation Laboratory, Bedford, MA, [2]Hennepin County Medical Center, Minneapolis, MN, [3]Department 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 electrochemical creatinine, blood urea nitrogen (BUN), and total CO_2 (tCO_2) 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, pCO_2 and hematocrit. The plasma portions were assayed on the Cobas 6000 analyzer (Roche Diagnostics) for creatinine, BUN, and tCO_2. Some of the native samples (<10% per analyte) were adjusted to expand the measured ranges. **Results:** The WB creatinine, BUN and tCO_2 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.

Table 1. Method Correlation Results for the GEM Premier WB Assays *vs.* References [(a)] Roche Cobas 6000 or [(b)] GEM Premier 4000 by [(c)] Passing-Bablok or [(d)] Deming Regression Analysis

Analyte	Slope	Intercept	r	N	Sample Range	MDL1 (Bias)	MDL2 (Bias)	MDL3 (Bias)
BUN [(a,c)]	1.04	0.85	0.999	114	3.5 - 107.5 mg/dL	6.0 (1.09)	26.0 (7.3%)	50.0 (5.7%)
Crea [(a,c)]	1.05	0.034	0.999	115	0.375 - 13.63 mg/dL	0.6 (0.06)	1.6 (0.11)	6.0 (5.2%)
tCO_2 [(a,c)]	0.90	1.87	0.983	111	6.4 - 42.3 mmol/L	6.0 (1.28)	20.0 (-0.5%)	33.0 (-4.2%)
Na^+ [(b,d)]	1.01	-1.89	0.987	127	109 - 169 mmol/L	115 (-0.3)	135 (-0.1)	150 (0.1)
K^+ [(b,c)]	1.00	0.00	0.999	132	0.6 - 16.2 mmol/L	3.0 (0.0)	5.8 (0.0)	7.5 (0.0%)
Cl^- [(b,c)]	1.00	-2.00	0.996	129	40 - 147 mmol/L	90 (-2.2%)	112 (-1.8%)	n/a
Ca^{++} [(b,c)]	1.00	0.01	0.999	128	0.21 - 4.47 mmol/L	0.37 (0.01)	0.82 (0.01)	1.58 (0.6%)
Hct [(b,d)]	1.04	-0.55	0.995	123	15 - 65 %	21 (0.3)	33 (0.8)	55 (1.7)
Glu [(b,c)]	1.05	-6.01	1.000	126	5 - 679 mg/dL	45 (-3.8)	90 (-1.7%)	180 (1.7%)
Lac [(b,c)]	1.00	0.00	1.000	131	0.4 - 20.0 mmol/L	2.0(0.0)	5.0 (0.0%)	n/a
pH [(b,d)]	0.99	0.11	0.992	120	6.81 - 7.53	7.30 (0.003)	7.35 (0.002)	7.45 (0.001)
pCO_2 [(b,c)]	1.00	0.00	0.990	120	21 - 65 mmHg	35 (0.0)	50 (0.0)	70 (0.0%)

B-349

Evaluation of the performance of albumin-to-creatinine ratio with automated urinalysis

H. Ning. *Chang-Gung Memorial Hospital, Tao-Yan Guaw-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 NOVUS PRO12 dipstick for ACR. **Methods:** We collected 1029 random urine samples underwent urinary analytic 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 (Autokit Micro 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 98.5%. When ACR > 30 mg/g 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.

B-350

Molecular Influenza Testing on the cobas Liat PCR System in Different Clinical Settings

L. M. Evans[1], V. L. Torres[1], B. M. Goldsmith[2]. *[1]Thomas Jefferson University Hospital, Philadelphia, PA, [2]Thomas Jefferson University, Philadelphia, PA*

Background: The cobas Liat PCR System (Roche, Indianapolis, IN) performs molecular Influenza A/B testing on Universal Transport Media (UTM) inoculated with nasopharyngeal swabs. Results are available in 20 minutes, comparable to many non-molecular rapid Influenza tests. Thomas Jefferson University Hospital placed Liats at the Point-of-Care (POC) in three different clinical settings during two consecutive flu seasons to evaluate providers' courses of action and determine if an available 20 minute molecular flu test would alter treatment decisions. **Methods:** Liats were placed in TJUH Center City Emergency Department (ED), Women's Primary Care (WPC), and 700 Walnut Urgent Care Center (UCC). Nasopharyngeal swabs were ordered, collected on suspected flu patients, and used to inoculate UTM. 100uL UTM was removed and tested on the Liat. The remainder was tested by methods normally utilized by each site: ED and WPC samples were sent to TJUH Microbiology Laboratory for testing on the GeneXpert (Cepheid, Sunnyvale, CA); UCC performs rapid flu tests using the Sofia Influenza A+B Fluorescent Immunossay (FIA) (Quidel Corporation, San Diego, CA). Samples were blinded for testing and matched at the end of the study. Providers were instructed not to use Liat results. Data was collected by questionnaire, including symptoms, immunization status, diagnosis, treatment, and whether or not treatment would have changed with an available 20 minute molecular result. **Results:** Survey responses varied greatly (see table below). UCC providers responded unanimously that treatment would not have changed. Providers would have changed treatment for approximately 50% of ED and WPC patients if 20 minute molecular results were available. Decision variables included 1) no isolation 2) earlier disposition (discharge/admission/other), 3) earlier prescription of Tamiflu. Eight discrepant results were observed. **Conclusion:** Clinical use of POC molecular flu testing varies from provider to provider. Standardized guidelines would be useful in driving decision-making, perhaps a subject for future studies.

Location	If results had been available in 20 min, would treatment have been different? Yes	No	Did not follow protocol - no PT ID, nothing sent to lab, no questionnaire	No answer	Discrepant results	Practice change: more detailed responses
Urgent Care Center *n*=75	0	65	10	0	6 discrepant results Liat: Flu A Pos / Sofia: Flu A/B Neg / # 2 Liat: Flu B Pos / Sofia: Flu A/B Neg / # 2 Liat: Flu A/B Neg / Sofia: Flu A Pos / # 1 Liat: Flu A/B Neg / Sofia: Flu B Pos / # 1	• No provider would have changed his or her treatment
Women's Primary *n*=30	10	11	8	1	No discrepant results	• Eight patients would have been given Tamiflu earlier
ED *n*=120	49	45	1	25	2 discrepant results Liat: Flu B Pos / Sofia: Flu A/B Neg / # 2	• 9 patients would have been dispositioned earlier • 3 patients would not have been placed in isolation • Seven patients would have been given Tamiflu earlier

B-351

Performance evaluation of AQT90 FLEX procalcitonin assay

H. Choi, 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 (Radiometer, 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 individual were compared to evaluate the matrix influence. Results: The AQT90 FLEX PCT assay showed good linearity (linearity range, 0.17-88.8 ng/mL, $R^2 > 0.99$). 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 0.999 (95% CI, 0.998 to 0.999), 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 0.999 (95% CI, 0.999 to 1.000). 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.

B-352

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

K. Pomasl, R. Shankar, D. Takahashi, N. Thuramalla. *Arkray 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, 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.

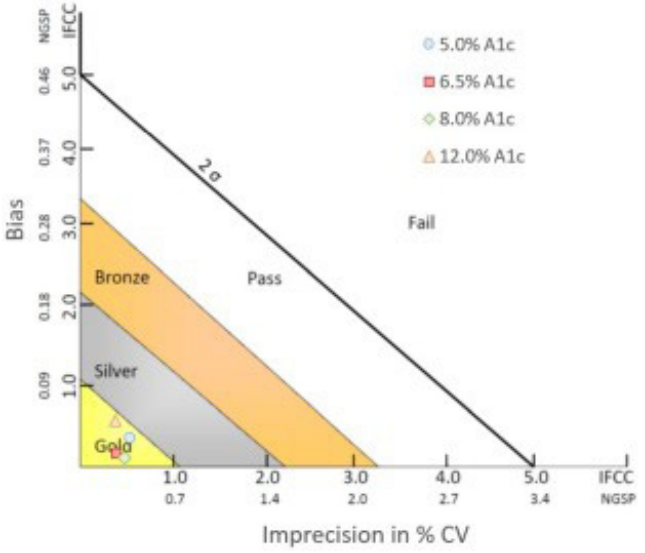


Figure 1: Bias vs. Imprecision of the HA-8180V performance on the QTM at the measured patient values.

B-353

Evaluation of the cobas Liat group A streptococcus assay in the Express Care setting

N. Myhre, M. Murray, B. Karon, M. McDonah, L. Schulz, J. Myers, J. Furst, J. Maxson, A. Meek, M. Espy, M. Binnicker, L. Donato. *Mayo Clinic Rochester, Rochester, MN*

Background: The cobas Liat (Roche) is an FDA-approved and CLIA-waived point-of-care (POC) polymerase chain reaction (PCR) system for detecting group A streptococcus (GAS) from throat swabs, generating results within approximately 20 minutes. A prior study conducted at Mayo Clinic using experienced laboratory technologists and strict contamination prevention protocols showed Liat results were accurate compared to routine real-time PCR results. Here, we examine the performance of the Liat system in the hands of end users in a POC environment (i.e., staff in Mayo Clinic Express Care (MCEC) retail clinics).Methods: Patients (age 3-65 years) presenting for clinical evaluation for GAS at two MCEC locations were recruited. For each patient, two throat swabs were collected. One specimen was sent to the Clinical Microbiology laboratory for routine real-time PCR testing on the LightCycler platform (Roche), with results available within 4-6 hours. The second was analyzed at the POC by MCEC staff using the cobas Liat system. POC results were compared to central laboratory results for concordance. The crossing point (C_p) of the routine laboratory test was recorded for discrepant results. In cases of Liat assay failures, the failure was noted on the study log and the specimen was retested until results were obtained. Weekly environmental swabs of the Liat instrument and surrounding work area were collected at both locations over 13 weeks and tested for GAS environmental/amplicon contamination by the routine real-time PCR and the Liat assay.Results: A total of 468 patients were enrolled. Concordance between Liat and the routine PCR was 97.2% (455/468). Sensitivity and specificity of the Liat GAS assay were 97.6% (206/211) and 96.9% (249/257), respectively. Routine real-time PCR results were positive and Liat results were negative in 8 samples. However, 7 of those discrepant results were associated with a low positive (C_p greater than 30) by the routine PCR assay. No environmental contamination was detected by either the Liat or the routine real-time PCR tests. Assay failures were observed in 6.6% (33/501) of Liat runs.Conclusions: The Liat PCR system provides accurate GAS results in the clinic setting with no evidence of environmental contamination. The reduced result turnaround time compared to routine real-time PCR (~20 minutes vs. 4-6 hours) would allow for more rapid patient management decisions. Therefore, the Liat should be considered an option for POC GAS testing.

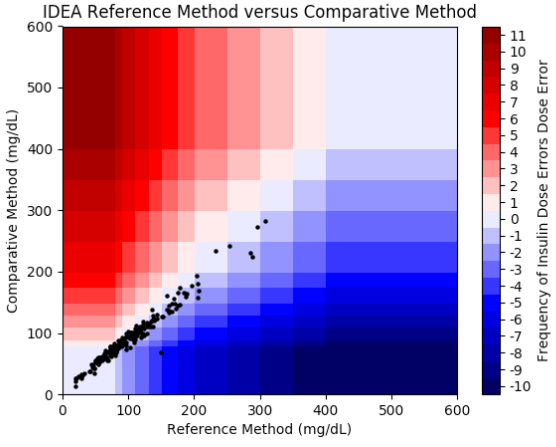
B-354

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. Lyon[2], N. K. Tran[3], J. A. DuBois[4], A. W. Lyon[1]. *[1]Saskatchewan Health Authority, Saskatoon, SK, Canada, [2]ALOL Biomedical Inc, Saskatoon, SK, Canada, [3]UC Davis, Sacramento, CA, [4]Nova 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:** The effect of 0.5 mg/dL 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. **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. A frequency histogram of the insulin dose errors of the patient results depict 94.5% of insulin doses were within +/- 1 dose, 99.5% within +/- 2 doses. **Conclusions:** 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.



B-355

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, enable perioperative coagulopathy to be better controlled. **Methods:** Retrospective cohort study including 675 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), fresh frozen plasma (9.8% vs 3.8%, p=0.008), prothrombin complex concentrate administration (0.9% vs 0.3%, p=0.599) and activated recombinant 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 protamine 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.

B-356

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

S. Morosyuk[1], M. O'Hara[2], V. Khangulov[2], S. Kazmierczak[3], A. Ahuja[1]. *[1]BD, Franklin Lakes, NJ, [2]Boston Strategic Partners, Boston, MA, [3]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. Users who performed <50 tests had a 9.3% error rate in comparison to a 5.6% error rate for users who performed >200 tests during the study period. Testing errors were associated with longer TAT. Cartridge waste (test ordered but not completed) over the two-year period for Chem8+ and Troponin was 15.6% and 11.7% respectively. **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.

B-357

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 hôpital settings as well as in ambulatory care. The aim of our study was to evaluate Nt-proBNP testing on the cobas h232® POCT system. **Methods:** The imprecision of the POCT instrument was determined with quality control materials over thirteen consecutive days. Method comparison was performed with our central laboratory Nt-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/L, respectively. The median concentrations in patients'samples were 798 ng/L (range: 22.3 to 39477) with routine assay and 655 ng/L (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 -20.2 (95% CI: -72.2 to 42.9) and no significant deviation from linearity. The Bland and Altman Plots revealed no significant biais 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 Nt-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

B-358

Impact of audits on point of care test performance in a countywide health system.

V. Palamalai, R. Hach. *MetroHealth, Cleveland, OH*

Background: The MetroHealth Health System is a county wide health system with over 50 point of care testing sites. Prior to August 2015, many of these sites had their own CLIA license and lab directors. Pathology provided guidance through two pathology POC staff who performed random checks and helped resolve problems as they occurred. This required each POC site to be responsible for ensuring their own compliance with regulations on a regular basis. There were also no defined ramifications for poor performance. Following an accreditation visit that indicated significant shortcomings, primarily due to the fragmented nature of the POCT program, the POCT program at MetroHealth was unified under the Pathology Department. 27 CLIA certificates were consolidated into four with all CLIAs being held by Pathology personnel. Today all POC testing is performed under 8 CLIA Certificates. The Pathology POC staff was doubled to four which made it possible for them to perform monthly audits. Auditing of these different sites was undertaken to ensure that all regulatory requirements were met and testing was being performed appropriately. **Methods:** : On-site inspections of all sites where POCT testing is done is performed on a monthly basis. The on-site inspection follows the Joint Commission requirements and an audit is generated for each site under the following categories: QC performance and documentation; QC and reagent storage and labeling; Specimen labeling; Adherence to personal protective equipment guidelines; Procedure manual review and availability; Result documentation per protocol; Preventative maintenance performed and documented; Competency testing successfully completed. There is a policy wherein sites that fail any of the categories is notified of the failure; a second consecutive failure or three failures in a five month period in the same category results in a warning notice; and a third consecutive failure or four failures in a six month period can result in loss of testing privileges. **Results:** The number of infarctions identified has decreased from 25 - 30 per month in the latter half of 2015 to about 15 per month. The categories with the most infarctions include QC performance and documentation, QC and reagent storage and labeling, and; Preventative maintenance per-

formed and documented. Most of the infarctions involve documentation issues. **Conclusion:** Auditing POCT 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

K. W. Cradic, B. E. Peters, M. R. Snyder, M. A. V. Willrich. *Mayo Clinic, Rochester, MN*

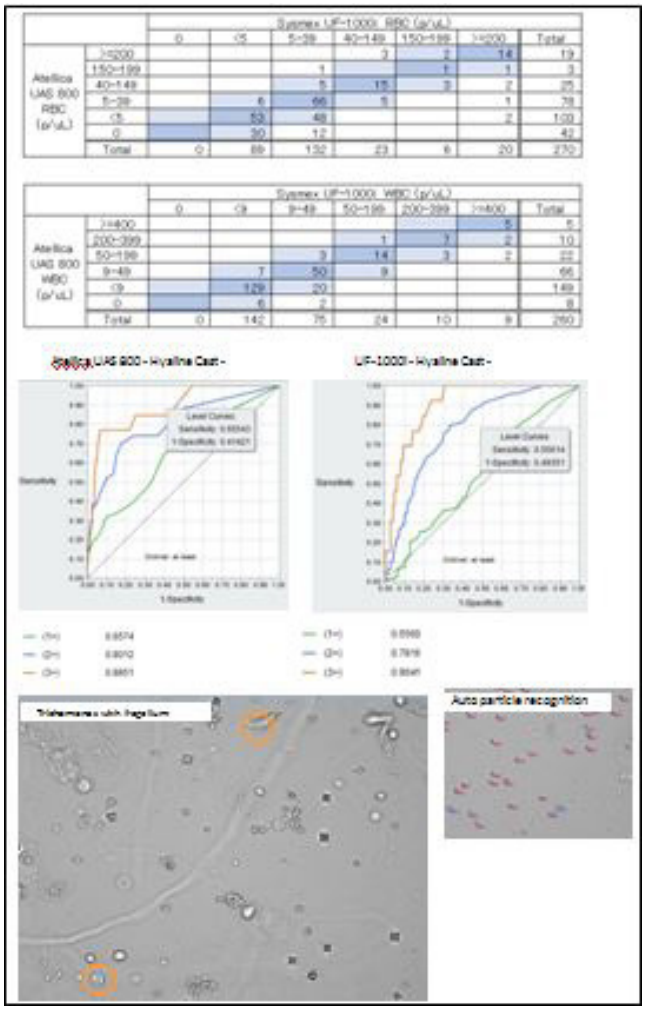
Background: One of the most useful biomarkers to help diagnose inflammatory bowel disease (IBD) is calprotectin, a primary protein released from neutrophils during an innate immune response. Elevations of fecal calprotectin are suggestive of gastrointestinal inflammation, such as Crohn's disease or ulcerative 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 (-20C). 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 assay 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 70% (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% (32 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 imprecision of the POC device.

B-360

Performance Evaluation of the Atellica UAS 800 urine particle Assay

M. Hotta[1], W. Kobayashi[1], S. Matsuda[1], A. Iwata[1], I. Maeda[1], Y. Hidaka[2]. *[1]Department of Medical Technology, Osaka University Hospital, Osaka, Japan, [2]Laboratory 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 UF1000i 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. Hyaline 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. Tanak[1], S. Muthukumar[2], S. Prasad[1], I. A. Hashim[3]. *[1]University of Texas at Dallas, Richardson, TX, [2]EnLisense LLC, Allen, TX, [3]UT 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

treatment includes surgical excision of the hyperfunctioning gland, where successful resection is confirmed by measuring PTH levels. Current lab-based methodologies are time-consuming, require larger sample volume and dedicated laboratory facilities. To overcome current drawbacks, it is advantageous to develop a point-of-care device that reports PTH concentration in real time, requires small sample volume, and minimal training. The objective of this study was to develop a user-friendly biosensor for highly sensitive and rapid detection of PTH using ultra-low sample volume of human serum and whole blood. **Methods:** We have developed an affinity-based electrochemical biosensor that contains nanostructures selectively grown on the sensor electrode surface. This helps in a size based matching environment for the biomolecules and enhances sensitivity. The immunosensor consists of anti-PTH antibody directed towards 1-84 intact molecule, as a capture probe bound to the electrode surface using dithiobis succinimidyl propionate which is a thiol-terminated crosslinker. The sensor response for the targeted PTH analyte in the range from 1 pg/mL to 1 ng/mL was evaluated using an electrochemical technique where binding of PTH on the sensor results in frequency dependent impedance change. Cross-reactivity of the sensor-antibody was tested against adrenocorticotropic hormone (ACTH), parathyroid hormone-related protein (PTHrp) and cortisol to measure the selectivity of the sensor to PTH molecule. Sensor performance was evaluated across 8 replicates in both human serum and whole blood. **Results:** Biosensor surface characterization was performed using scanning electron microscopy to confirm uniform deposition of nanostructures for obtaining maximum sensor response. Quantification of PTH concentration (1 pg/mL-1ng/mL) in human serum and whole blood were assessed using change in impedance. Noise threshold for the biosensor was calculated as three times the standard deviation of blank over baseline impedance value. The biosensor demonstrated 10 pg/mL as the limit of detection with a dynamic range from 10 pg/mL to 1 ng/mL in the clinically relevant measurement range. Cross-reactivity of ACTH, PTHrp and cortisol were within the calculated noise threshold of the sensor, thereby indicating the specificity of the electrochemical biosensor. Furthermore, the response time of the sensor was less than 15 minutes. **Conclusion:** We developed an affinity-based electrochemical biosensor by leveraging semiconducting nanoscale properties for detection of PTH molecule. Using electrochemical based impedance response, we have quantified PTH concentrations (10 pg/mL- 1 ng/mL) in human serum and whole blood. We have also demonstrated a fast response time for detection of PTH using 40 µL sample volume. The sensor showed a high degree of specificity and sensitivity to PTH molecule. These results from the preliminary data in both human serum and whole blood samples show a proof-of-translatability as an ideal point-of-care diagnostic device for PTH detection, real-time in a clinical setting.

B-362

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

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

Background: The most prominent event that defines an ACS is the formation of an intra-arterial thrombus, usually resulting from activation of platelet and fibrinogen in coronary arteries at the site of a ruptured plaque with physical lumen occlusion by thrombosis. The aim of this study was to investigate whether TEG (a POCT 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, cardiac markers, routine coagulation tests and TEG were determined. Receiver operating characteristic (ROC) curve was used to evaluate the diagnosis performance of each index. Logistic regression analysis was used to define the independent risk factors of ACS. **Results:** Patients with ACS exhibited greater prevalence of hypertension than patients with SAP (p<0.01). cTNI and NT-proBNP levels in SAP measured were significantly lower than ACS patients (p<0.01). PT was significantly different in two groups, while FDP was significantly increased in ACS patients (p<0.05). FIB, 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 between 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 (odds ratio [OR], 2.760; 95% confidence interval [CI], 1.939-3.928). The area under ROC curve of TEG-G was 0.899. The optimal cut-off value for the diagnosis of ACS was 9.95 dyne/cm^2, while the sensitivity was 80% and the specificity was 87.9%. **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.

Table 1. Receiver operation characteristics (ROC) curve parameters

	AUC (95% CI)	Cutoff value	Sensitivity (%)	Specificity (%)
cTNI (ng/ml)	0.743 (0.676-0.810)	0.04	57.0	82.8
NT-proBNP (pg/ml)	0.739 (0.667-0.811)	150.35	72.1	69.0
D-dimer (mg/L)	0.656 (0.575-0.737)	0.36	53.9	74.1
FIB (g/L)	0.783 (0.717-0.850)	2.85	77.0	70.7
PLT (×10^9/L)	0.687 (0.614-0.760)	202.00	45.0	88.5
ANGLE (degree)	0.823 (0.764-0.882)	69.40	66.1	89.7
MA (mm)	0.899 (0.855-0.943)	66.6	80.0	87.9
CI	0.814 (0.754-0.875)	1.55	68.5	82.8
G (dyne/cm^2)	0.899 (0.855-0.943)	9.95	80.0	87.9

B-363

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

L. Williams[1], N. Whitehead[2], S. Geaghan[3], C. Litwin[4], J. Nichols[5], J. Gayken[6], S. Kennedy[7], M. McEvoy[8], D. Ernst[9], P. Carroll[10]. *[1]CDC, Atlanta, GA, [2]RTI International, Reserach Triangle Park, NC, [3]Stanford Untiversity School of Medicine, Stanford, CA, [4]Medical University of South Carolina, Charleston, SC, [5]Vanderbilt University School of Medicine, Nashville, TN, [6]Medical Laboratory Consultant, St. Cloud, MN, [7]RTI International, Research Triangle Park, NC, [8]Albany Medical Center, Albany, NY, [9]Center for Phlebotomy Education, Corydon, IN, [10]Intermountain 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[1], 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 abstracts. 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 supporting recommendations for specific practices (or not) and categorized as High, Moderate, Suggestive, or Insufficient as defined by the A6 methodology.[1] **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.

1. Christenson RH, Snyder SR, Shaw CS, et al. Laboratory medicine best practices: systematic evidence review and evaluation methods for quality improvement. Clin Chem. Jun 2011; 57(6):816-825.

B-364

"Just-in-Time" Implementation of Molecular Point-of-Care Testing for the 2017-18 Influenza Epidemic

K. Lima, X. Ivanova, S. Gillott, 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 unanticipatedly high prevalence of the H3N2 viral strain. According to the Center 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 (RIDT) 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 yielding 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.

B-365

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. Navarro[1], R. Hren[2], A. Boltyenkov[3]. *[1]University Mackenzie, Sao Paulo, Brazil, [2]University, Dalhousie University, NB, Canada, [3]Handelshochschule 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 heath care costs in the United States. This finding has important potential implications for management of the diabetic population and reimbursement of HbA1c testing methodologies.