Wednesday, July 30, 2014

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

Point-of-Care Testing

B-276

Assessment of Harmonization among Siemens Point-of-care and Central Laboratory Blood Gas Platforms

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Background: Determine correlations between Siemens point-of-care (POC) and central lab blood gas platforms in order to demonstrate harmonization across the product portfolio.

Relevance: AACC's International Consortium for Harmonization of Clinical Laboratory Results has been working with a variety of stakeholders regarding harmonization among results from different methods and labs for the same measurand. [1] Malone states, "Harmonization means achieving comparable results among different measurement procedures". Further, "When lab measurement procedures give different results for the same specimen, patients may get the wrong treatment, because decision criteria are not appropriate for the procedure in use. In order to do this effectively, results need to be harmonized."

Methods: Method comparison studies were performed with whole blood among POC (RAPIDPoint®) and central lab (RAPIDLab®) blood-gas platforms in accordance with the CLSI EP-09 guideline. Correlation statistics including Deming slopes, intercepts, and coefficients of determination (r^2) were generated for the following comparisons:

- RAPIDLab 1265 Blood Gas System vs. RAPIDPoint 500 Blood Gas System
- RAPIDLab 348EX Blood Gas System vs. RAPIDPoint 500 Blood Gas System
- RAPIDPoint 405 Blood Gas System vs. RAPIDPoint 500 Blood Gas System

Results: Deming regression statistics for each comparison across intervals for each measurand are shown in Table 1. The slopes for each measurand fell between 0.96 and 1.25, with $r^2 \geq 0.9829$.

Conclusion: Harmonization at medical decision levels and average concentrations was demonstrated among Siemens POC and central lab blood gas platforms for the measurands evaluated.

[1] Malone B. AACC's Thought Leadership Series: Why Harmonization Matters.

Table 1. Method comparisons among POC and central lab platforms

Comparison	Measurand	n	Average Bias	Deming Slope	Intercept	r^2	Interval
RAPIDLab1265 Analyzer vs. RAPIDPoint500 Analyzer	pH (Units)	92	0.017	1.01	-0.024	0.9987	6.820 to 7.781
	pCO_2 (mmHg)	81	3.0	1.07	-1.0	0.9914	6.9 to 165.3
	pO_2 (mmHg)	92	7.1	1.02	4.0	0.9978	27.6 to 653.3
	Na^+ (mmol/L)	124	0.5	1.03	-3.9	0.9576	100.4 to 158.3
	K^+ (mmol/L)	105	0.10	1.10	-0.35	0.9982	0.62 to 10.00
	Ca^{2+} (mmol/L)	133	0.07	1.06	-0.07	0.9577	0.31 to 4.86
	Cl^- (mmol/L)	124	3	1.08	-5	0.9944	66 to 140
	Glu (mg/dL)	100	4	0.99	6	0.9981	26 to 603
	Lac (mmol/L)	100	-0.02	0.98	0.20	0.9870	0.31 to 27.13
	tHb (g/dL)	112	-0.1	1.01	-0.1	0.9997	2.5 to 23.8
	tBil (mg/dL)	110	1.1	1.03	0.7	0.9732	2.3 to 27.4

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Investigation of Maltose Interference on the Roche ACCU-CHEK Inform II Blood Glucose Meter

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Background: Maltose can be present in the blood of patients who were treated with peritoneal dialysis using icodextrin or maltose-containing immune globulin up to 2 weeks after the treatment. Maltose can interfere with glucose measurement using glucose dehydrogenase pyrroloquinolinequinone (GDH-PQQ) and cause falsely elevated glucose results. Patients can develop severe hypoglycemia if treated with insulin in response to these falsely elevated glucose results. The Roche (Roche Diagnostics, Indianapolis, IN) ACCU-CHEK Inform I (Inform-I) blood glucose meter uses GDH-PQQ methodology. A mutant quinone GDH is used in ACCU-CHEK Inform II (Inform-II) which can distinguish glucose from maltose. In this study, we want to determine if maltose interference has been eliminated with Inform-II using samples containing maltose and samples from patients treated with icodextrin peritoneal dialysis.

Methods: Samples containing 240 mg/dL, 360 mg/dL, and 720 mg/dL of maltose were prepared by spiking a whole blood sample with maltose. At each level of maltose, a control sample was prepared by adding equal amount of water to an aliquot of the blood sample. Glucose results in these samples were measured in triplicates with both Inform-I and Inform-II. Previously frozen plasma samples from three patients who underwent icodextrin peritoneal dialysis were also tested with Inform-I, Inform-II, and results compared with that obtained with Beckman Olympus AU5400 (AU5400) which is free from maltose interference.

Results: Glucose results in samples containing different amounts of maltose and samples from the three patients obtained with Inform-I, Inform-II, and AU5400 are shown in the table below:

Sample Containing Maltose	**Glucose with AU5400 (mg/dL)**	**Glucose with Inform-I (mg/dL)**	Glucose with Inform-II (mg/dL)	**Falsely Increased Glucose with Inform-I (mg/dL)**	**Falsely Increased Glucose with Inform-II(mg/dL)**
240 (mg/dL)		241	**114**	151	10
360 (mg/dL)		313	121	225	16
720 (mg/dL)		563	128	491	34
Patient 1	217	327	238	110	21
Patient 2	196	245	218	49	22
Patient 3	276	286	289	10	13

Conclusion: Both the Inform-I and Inform-II exhibited maltose interference which increases with maltose concentration. However, significant reduction of maltose interference was observed with Inform-II. The increases in the glucose results obtained with Inform-II in samples of patients who underwent icodextrin peritoneal dialysis were minimal, therefore, may not change the clinical decisions to manage blood glucose levels in these patients.

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Magnetic Immunoassay for Quantitative Point-of-Care Tests and Rapid Measuring of Protein Concentration

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Background: Currently, protein markers of diseases are widely detected by rapid Lateral Flow (LF) strips based on color or fluorescent labels. The measurements are carried out by recording such labels from the thin surface layer of the LF membranes only. The advantages of employment of magnetic beads (MB) as labels in bioassays are well established as the beads are not affected by color of the samples, reagent chemistry or photobleaching, are highly stable and could be counted over the whole volume of solid phase. MB can be used in quantitative immunochromatographic assays to facilitate rapid diagnostics of diseases and monitor therapy efficiency. In the present work, a rapid quantitative MB-based assay has been developed and demonstrated by measuring in human blood of concentration of the tumor marker of prostate specific antigen (PSA) used as a model. Such highly sensitive registration in wide dynamic range of concentration of PSA and other tumor markers is attractive for disease diagnostics and relapse monitoring after surgical removal of tumors.

Methods: The magnetic nanolabels were recorded over the whole volume of test zone on LF strips using original method of non-linear MB remagnetization and frequency mixing (P.Nikitin & P.Vetoshko, EP 1262766, 2001). Recently, this method was successfully used for toxin detection in complex biological media by MB counting at 3D-filter solid phase (A.Orlov et al. Anal. Chem. 2013, 85, 1154-1163). Direct comparison showed that the sensitivity of the electronic detection method is on the level of the gamma-radioactive technique for counting of MP based on the 59-Fe isotope (M.Nikitin et. al. J. Appl. Phys. 2008, 103, 07A30). Thus, MBs combined with highly sensitive detectors allow realizing many advantages of old radioimmunoassays, but in much more safe and affordable ways. In present work such advantages have been demonstrated by magnetic LF strips based on dry chemistry.

Results: It has been shown with blood samples of 25 patients that the limit of quantitative PSA detection computed in compliance with IFCC/CLSI guidelines for quantitative methods is 25 pg/mL over the wide dynamic range exceeding 3

orders of concentration magnitude. CV was less than 10% at low concentrations. Importantly, the developed dry chemistry assay features simplicity and 4 times better LOD at duration of 20 min as compared with several-hour-long commercially available ELISA kits. It has been shown that because of high sensitivity, quantitative registration, simplicity and short duration, the developed POC method combines the advantages of laboratory methods and rapid tests based on dry chemistry.

Conclusion: The replacement of traditional optical (gold, colored latex, etc.) labels in immunochromatographic assay formats by the magnetic beads combined with highly sensitive MB detection over the whole volume of the LF strips has allowed to develop a quantitative and highly sensitive in wide dynamic range of more than 3 orders of concentration magnitude immunoassay. The LOD of 25 pg/mL demonstrated by the magnetic immunochromatographic assay while detection of tumor marker PSA in human blood allows us to consider it as an attractive diagnostic POC platform for highly sensitive quantitative detection of proteins in biological fluids.

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Development of a new rapid point-of-care assay for quantitative measurement of D-Dimer in whole blood and plasma

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D-dimer is a fibrin degradation product (FDP) composed of cross-linked fibrin degraded by plasmin and well known as one of the markers for thrombotic disorders such as deep vein thrombosis (DVT), pulmonary embolism (PE), disseminated intravascular coagulation (DIC) and for coronary artery diseases. We have developed a new rapid and quantitative assay for D-dimer in whole blood and plasma. This assay is based on lateral flow immunochromatography with colloidal gold and employs two different anti-human D-dimer mouse monoclonal antibodies. The test cartridge is inserted into the immunochromato-reader "RAPID PIA ™ (Sekisui Medical Co., Ltd.)", and a sample (120µL) of whole blood or plasma is added to the well of the cartridge. After 10 minutes, the reader automatically measures the density of colloidal gold captured at the test line by the antigen-antibody sandwich reaction. The lower detection limit for D-dimer was 0.2µg/mL, and the upper quantitation limit was 15 µg/mL. No prozone effect was observed in D-dimer samples of concentrations from 15 through 244 µg/mL. The within-run C.V. (n=5) at 0.55 µg/mL, 3.5 µg/mL, and 7.1 µg/mL was 1.8%, 5.1% and 4.9%, respectively. The between-run C.V. (n=5) at 0.55 µg/mL, 3.5 µg/mL and 7.1 µg/mL was 6.3%, 4.5% and 4.7%, respectively. The method comparison with the approved IVD reagent, the principle of which is latex-enhanced immunoturbidimetry, yielded a correlation coefficient of 0.992 and an equation of Y (present method) = 1.01X - 0.17 (n = 50 citrated plasma specimens). Furthermore, a high level of correlation was observed between citrated plasma and whole blood (R:0.997 ; slope:1.03;intercept:±0.00). We concluded that this newly developed assay is accurate, precise and simple for the measurement of D-dimer in whole blood or plasma at the bedside. We believe that this assay will be a useful tool for rapid screening patients with thrombotic disorders and coronary artery diseases.

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Performance of the Nova StatStrip Glucometer in a Pediatric Hypoglycemic Population

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Background: In May of 2013, our hospital replaced the legacy glucometer with the Nova StatStrip. Our Department of Endocrinology has a fasting study protocol where patients are fasted until their blood glucose is below 50 mg/dL. At this point a variety of critical samples are drawn. However, due to the accuracy limitations of our legacy glucometer, the current protocol needs a confirmation of blood glucose concentrations from the core laboratory. Therefore, we sought to determine the performance of the Nova StatStrip in this pediatric hypoglycemic population. If the accuracy of the glucometer proved acceptable it could lead to a modification in the fasting study protocols that could lead to a decrease in the length of the study.

Objective: Our goal was to determine the accuracy of the Nova StatStrip glucometer in measuring samples close to the 50 mg/dL range in real clinical setting conditions.

Methodology: Precision of the Nova StatStrip glucometer at low glucose values was evaluated at four different values. Furthermore, quality control material and patient samples were evaluated in the Nova StatStrip, and compared to readings from our core laboratory analyzer without sample delay.

Results & Conclusions: Coefficient of Variations of the Nova StatStrip at low glucose levels was less than 4%. Comparing low glucose QC material showed no statistical difference between POC and core lab methods (n=23). Patient samples (n=30) co-relations indicated an average negative bias of 2 mg/dL when the Nova glucometer was compared to our central lab method. In addition, we saw a decrease in the rate of patient ID errors due to the use of a 2D barscan system present in the Nova StatStrip but absent from our legacy glucometer. The Nova StatStrip proved to have acceptable accuracy in measuring hypoglycemic samples when compared to our central laboratory method. These results support the use of POC glucose, in lieu of waiting for glucose results from the core laboratory, for activating our fasting study draws, shortening the length of the procedure for our patients**.**

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Analytical and technical aspects of POCT-Troponin in the Emergency Department: Comparison with central laboratory hsTnT

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Introduction The use of point-of-care-testing (POCT) for cardiac troponin involves discrepancies in comparison to central laboratory based measurements. In this analysis, troponin-discrepancies are documented and analyzed to evaluate possible reasons and generate data that is likely to help eliminating factors of insecurity in association with technical and handling issues of different platforms and assays used.

Methods Cardiac troponin-T on AQT-90 (EDTA whole blood, Radiometer) POCT is the standard troponin test in our Emergency Department. We set up parallel measurements of hsTnT (heparin-plasma, Cobas602, Roche) in the central laboratory from the same blood draw and Troponin-I (EDTA whole blood, AQT90, Radiometer) in two separate timeframes of 3 and 4 months within one year (winter and summer period). Troponin-discrepancies were defined as outlined below (Table 1). In the first timeframe immediate re-measurement of the POCT-sample was performed. Measurements of admission-samples resulting from 4946 patients were analyzed regarding discrepancies between hsTnT/TnT and TnT/TnI.

Results 183 discrepancies were detected resulting from 164 patients. 37 between TnT and hsTnT and 146 between TnT and TnI (Table 1). 19 patients showed two discrepancies (hsTnT/TnT and TnT/TnI). Characterizing the discrepancies of timeframe 1 (n=20) we found 10 discrepancies in more than one measurement and 10 non-reproducible analytical errors. In three patients AQT TnT was constantly elevated while hsTnT and AQT TnI were negative. In two patients hsTnT was elevated while AQT TnT was negative. The latter were a 94years old female with a fall and a 81years old male with acute kidney failure.

Conclusion In our population the percentage of discrepancies between hsTnT and AQT TnT did not exceed 0.75% of nearly 5000 analyzed individuals. The use of AQT TnT at the POC is technically reliable under real life conditions. Further studies need to clarify the diagnostic accuracy, specifically when lower cutoffs are used for hsTnT.

Definition of discrepancies					
TnT (AQT) vs. hsTnT (Cobas)			TnT (AQT) vs. TnI (AQT)		
	hsTnT < 45 ng/L	hsTnT > 55 ng/L		TnI < 23 ng/L	TnI > 46 ng/L
TnT < 27 ng/L	ok	discrepancy	TnT < 17 ng/L	ok	discrepancy
TnT > 33 ng/L	discrepancy	ok	TnT > 33 ng/L	discrepancy	ok
Discrepancy Details in % (n=4946)					
	hsTnT < TnT	hsTnT > TnT		TnT > TnI	TnT < TnI
Timeframe 1 (n=2344)	0.73% (n=17)	0.13% (n=3)		3.5% (n=82)	0.17% (n=4)
Timeframe 2 (n=2602)	0.38% (n=10)	0.27% (n=7)		1.88% (n=49)	0.42% (n=11)
total (n=4946)	0.55% (n=27)	0.2% (n=10)		2.64% (n=131)	0.3% (n=15)
Characterization of the TnT discrepancies of timeframe 1 (n=2344)					
	hsTnT < TnT	hsTnT > TnT			hsTnT < TnT
persistent	0.34% (n=8)	0.09% (n=2)	persistent analytical discrepancies, to be investigated for possible interferences		0.13% (n=3)
non-persistent	0.38% (n=9)	0.04% (n=1)			

Table Definitions and details of Troponin discrepancies.

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The modified method for microbilirubin determinations at low source setting-hospitals

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Background: Bilirubin determinations are often required in the routine management of newborns. Bilirubinometer requires a micro volume of blood sample and is convenient used at pediatric units as point of care testing. There is no bilirubinometer available at low source setting hospitals in rural area of Thailand. The objective of this study were to evaluated the performances of bilirubinometer and validate the performances of the modify method using a micro volume of plasma sample for bilirubin measurement in newborns.

Methods: Precision, accuracy, and linearity of bilirubinometer were evaluated. One hundred plasma samples of newborns at Phukhieo Hospital were determined for bilirubin. Sixty microliters of each blood sample was collected into heparin-containing capillary tube. All samples were immediately centrifuged, then measured for bilirubin by bilirubinometer and a modified method by the automated clinical chemistry analyzer. Paired data of bilirubin results were analyzed by using paired different T-test.

Results: Bilirubinometer has revealed good precision, accuracy, and linearity for bilirubin determination in newborns. Microbilirubin results obtained from bilirubinometer and a modified method were correlated ($r=0.978$) and paired difference data between two methods were not statistical significant differences ($p>0.05$).

Conclusion: Bilirubinometer was convenient used for microbilirubin in newborns on site and a modified method was the alternative way for low source setting in Thai Hospitals at clinical laboratory. However, laboratory should manage to provide shorten laboratory turnaround time for microbilirubin measurement.

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Implementing a point of care (POC) laboratory in order to reduce patients' length of stay in the ED as well as meet ED critical care standards.

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Background: Hospitals, providers and patients are all eager to reduce the length of emergency department (ED) visits. For hospitals, faster patient turnover means more patients can be seen, generating higher revenue. For physicians, faster turnover means releasing patients who don't need further care so they can spend more time with those who do. For patients, less time in the ED means they can return to daily life sooner and, potentially, reduce their medical costs. Speeding up the rate of turnover is dependent on reducing turnaround time (TAT) for lab results. We were interested to determine whether point of care (POC) laboratory testing, based in the ED itself, could lower TAT when compared to the performance of a satellite laboratory. To test this theory we set up a POC lab in the Bert Fish Medical Center's ED.

Methods: Although our POC lab operated within the ED, it was controlled by the main laboratory. Four emergency medical technicians, employed by the ED, managed all the testing, under the supervision of one medical technologist, a lab employee. A key difference about our approach to POC testing is that we did not use nurses to perform any testing procedures. Based on our research, nurses are already too busy to take on the additional burden of managing POC testing.

Results: In our POC, we used a more sensitive troponin assay with chemiluminecent POC testing helped improve TAT. With this test, the POC lab was 42% faster than the main lab when troponin test results were negative_54 minutes in the POC lab versus 97 minutes in the main lab. The impact was significant, since negative results made up 91% of the total. The remaining 9% positive results were retested in the main lab to exclude other cardiac conditions, so there was no time savings for this batch. In effect, testing at the POC level becomes a "lean" process because it cuts out the extra steps required for testing in the main lab.

Conclusion: Our study demonstrated that establishing a POC lab can yield a number of benefits. These include:

- Faster TAT for troponin testing, as well as testing for myoglobin and CK-MB
- Shorter ED stays, and as a result, shorter wait times for new patients in need
- Earlier detection of cardiac risk, due to the faster detection of troponin, leading to increased survivability
- Greater physician and patient satisfaction
- Improved relations between the lab and the ED, as they now work in unison

We also noted that the cost of running a POC lab is about $300,000 per year, versus $1-1.5 million for a satellite lab. In part, this is because the salaries of the medical assistants running the POC lab are lower than those of medical technologists in satellite labs. Even with the hiring of additional assistants, overall operating costs of the POC labs are lower.

Our conclusion is that given how the POC can perform more quickly and at lower cost than traditional satellite labs, hospitals should consider moving to the POC model.

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Development of a fully-quantitative lateral flow assay system for the detection of a novel combination of sepsis markers

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Sepsis, or severe bacterial infection (SBI), is the leading cause of death in intensive care units in high-income countries, and its incidence is on the rise. Sepsis is estimated to affect 18 million people worldwide and in 2003 $14.6 billion were spent on hospitalizations for the disease in the US. Sepsis diagnosis is often delayed due to inadequate diagnostic tools. Consequently, prompt diagnosis and treatment is of paramount importance to reduce morbidity and mortality associated with the disease.

We have developed an innovative point-of-care (POC) diagnostics system incorporating lateral flow assay technology to measure a novel combination of bio-markers: procalcitonin (PCT), neutrophil gelatinase-associated lipocalin (NGAL) and resistin. In combination, these markers provide a superior indication of SBI in febrile children presenting to the emergency department.

PCT, a precursor of calcitonin, is a 116 amino acid protein that has been proposed as a marker of disease severity in conditions such as septicemia, meningitis, pneumonia, urinary tract infection (UTI) and fungal and parasitic infection. NGAL, or lipocalin 2, is a 25 kD lipocalin that has a role in innate immunity and is highly up-regulated by inflammatory stimuli. Resistin has been shown to play an important regulatory role in adipogenesis, glucose homeostasis and insulin sensitivity. PCT is a well recognized marker of sepsis, and Resistin and NGAL have recently been shown to be significantly elevated in intensive care patients with sepsis.

The POC system incorporates 3 simplex lateral flow assays utilizing gold nano-particle technology to detect PCT, NGAL and Resistin. It requires no sample pre-treatment and gives fully-quantitative results within 10 minutes on a hand-held reader.

We show that the system is able to measure the bio-marker combination from human plasma, producing fully-quantitative values which are incorporated into a clinical diagnostic algorithm to assess response to therapy. The results show that the linear ranges of the individual assays span a large concentration range: PCT: 0.1-1000 ng/ml, Resistin: 5-1000 ng/ml and NGAL: 5-1000 ng/ml. We also discuss the ability of the assays to successfully differentiate between 5 clinical categories on which to base the clinical diagnosis and treatment: SBI rule out, SBI rule in, uncertain (further clinical assessment and investigations necessary), likely severe infection and likely life threatening.

This test has the potential to advance the effective use of bio-markers in the management of both child and adult sepsis and impact across the whole POC market by providing a better diagnosis, rapid treatment and reduced hospital admissions.

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Impact of improved glucose monitoring in the neonatal intensive care unit: an evaluation of analytical and clinical performance of the point of care Nova Statstrip

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Objective: To evaluate the analytical and clinical performance of new glucose point of care testing (POCT) in the intensive care unit (NICU).

Methods: Within-run imprecision, correlation with a plasma hexokinase assay, and interferences with hematocrit were studied on the Nova-StatStrip and SureStep-Flexx meters. Meter and lab results were analyzed over 2 years in the NICU. Outcomes

measured were rate of hypoglycemia, frequency of critical results, average length of stay (LOS), clinical sensitivity/specificity for detecting critical results, and clinical accuracy.

Results: Imprecision (CV) using control material (2.8-15.7 mmol/L, n=20) and whole blood patient pool specimens (5.1-23.7 mmol/L, n=20) ranged from 3.19-4.97% and 1.39-7.21%, respectively, for SureStep, and 1.05-4.98% and 1.51-3.71%, respectively, for Nova. Method comparison to the Ortho Vitro950 hexokinase method (n=120) revealed correlations of y= 0.867x + 0.82 (R=0.990) with a mean bias of -0.64 mmol/L for SureStep, and y=1.016x+0.04 (R=0.997) with a mean bias of -0.21 mmol/L for Nova. Hematocrit interfered with SureStep by reducing glucose measurements at increasing hematocrit (23-67%) compared to Ortho, an effect absent on Nova. Studies to assess clinical performance of the meters revealed fewer readings per NICU visit (24%, p=0.001) in patients monitored with Nova compared to SureStep. This was associated with a reduction in frequency of hypoglycemia results (53%, p=0.053) as well as a trend towards critically low ≤3.0 mmol/L (35%, p=0.112) and high results ≥9.0 mmol/L (40%, p=0.009). The sensitivity/specificity for detecting critically low results was 70.2/98.7% and 80/99.5% for SureStep and Nova, respectively. Patients monitored with Nova trended towards increased LOS in the NICU (16%, p=0.181). Clinical comparisons demonstrated correlations of y=0.983x+0.24 (R=0.931) for Nova (n=607) and y=1.1x-0.036 (R=0.869) for SureStep (n=977) compared to lab values.

Conclusion: Nova demonstrated superior precision and accuracy compared to SureStep. Improved analytical performance translated into improved detection of critical glucose results, demonstrating the importance of implementation of accurate POCT in the NICU.

Clinical performance of the Nova StaStrip and SureStep Flexx in the NICU

	Nova StatStrip	SureStep Flexx	% Change	p-value
Total number of admissions	240	250	24	-
Total results per admission	10	13.1	24	0.001
Hypoglycemia results per admission	0.16	0.34	53	0.053
Critical low results per admission	0.68	1.04	35	0.112
Mean length of stay in NICU (days/patient)	25.1	21.1	16	0.181
Sensitivity for critical low results (%)	80	70.2	-	-
Specificity for critical low results (%)	99.5	98.7	-	-

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Evaluation of new glucometers (Easy Touch GC) for bedside use

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BACKGROUND Glucometers have greatly improved the clinical care of diabetics. It shortens time for making critical decisions. It is portable, inexpensive and easy to use. Newly acquired glucometers (Easy Touch) in our hospital were evaluated by calibration and precision profile determination. The results were compared with values obtained using routine laboratory method.

METHOD Standard glucose solution 500mg/ dl was serially diluted in de-ionized water to 250mg /dl, 125mg/dl, and 100mg/dl. The solutions were analyzed with three glucometers to determine their linearity. .

Blood samples were taken in duplicate from 39 patients into fluoride oxalate containers for the determination of glucose concentrations. A set was analyzed in the Hospital Laboratory by spectrophotometric glucose oxidase method while the other was analyzed with the glucometers. Duplicate measurements of the blood samples by 3 individuals using the glucometers were performed to determine their precision profile.

RESULTS The glucometers showed good linearity using the standard glucose solutions. Their correlation coefficients were R1 = 0.883, R2 =0.983, R3 =0.949; R1, R2 and R3 represent the 3 glucometers respectively. However, the readings from the glucometers were much lower than the actual glucose concentration at ≥ 500mg/dl. This may be due to the use of de-ionized water as solvent for the standard solutions used in the calibration as against the matrix of blood. This could imply that the glucometer readings may not be accurate at critically high glucose levels.

Good correlations were obtained between the readings of the glucometers and laboratory results at blood glucose concentration <500mg/dl. Thus, the correlation coefficients were 0.824, 0.900 and 0.845 for glucometers R1, R2 and R3, respectively.

The coefficient of variations (CVs) obtained with the glucometers were 10.43%, 3.75% and 6.50% for R1, R2 and R3, respectively. With the routine laboratory method, the CVs were 10.94%, 9.84% and 11.69%. When the two methods were compared, the CVs obtained with the glucometers varied widely, whereas, the CVs of the laboratory method were fairly constant. This could imply that the performance of the glucometers was operator dependent because they were operated by 3 different individuals, which was not the case with the laboratory method that was performed by only one person.

The imprecision profile, representing, the mean differences between the readings of the glucometers and laboratory results, were 14.8 ± 4.67, 23.7 ± 6.08 and 15.5 ± 3.83 for glucometers R1, R2 and R3 respectively. These values were high and could have serious implications in the interpretation of glucose values for the management of diabetes mellitus.

CONCLUSION The readings from the glucometers showed inaccuracy at very high glucose concentrations and their performance could be operator dependent. In view of the good correlations with the laboratory method (at <500mg/dl), the glucometers should be standardized against the laboratory method regularly when used.

Keywords: Glucometer, calibration, precision.

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Comparison of the UriScan® 2 ACR regent dipsticks for Albumin and Creatinine in Urine with Quantitative Methods

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Background: Microalbuminuria is a predictive maker for renal disease and the identification of patients at high risk of developing complications of diabetes or hypertension. The UriScan® 2ACR(YD Diagnostics, Korea) is a urine chemistry point-of-care test for the semi-quantitative measurement of albumin and creatinine and calculation of albumin:creatinine ratio(ACR). The aim of this study is to comparing quantitative method and UriScan® 2ACR strip for measurement of albumin and creatinine ratio in urine.

Methods: The samples for this study used to random urine which were collected from a total 641 patients at three sites. The concentration of albumin and creatinine are measured to UriScan® 2ACR after quantifying by gold standard quantitative method.

Results: The clinical performance results of the UriScan® 2ACR strip s for detecting microalbuminuria (ACR) were showed to accuracy 86.9%. Also, the sensitivity, specificity, PPV (positive predictive value), and NPV (negative predictive value) is 89.2%, 85.6%, 77.4%, and 93.5%. The result of microalbumin measurements in the spot urine samples of UriScan® 2ACR strip were showed to accuracy 89.9%. Also, the sensitivity, specificity, PPV (positive predictive value), and NPV (negative predictive value) is 91.2%, 89.0%, 84.5%, and 93.9%, respectively. The results of creatinine were accuracy 70.0%.

Conclusion: UriScan® 2ACR strip tests had good agreement with gold standard quantitative methods. Therefore, measurement of UriScan® 2ACR strip in the spot urine sample is an efficient method for screening the general population for microalbuminuria. The dipsticks tests were easy to use, simple, and useful screening tool for point-of-care test.

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Validation of the Abbott i-STAT total β-hCG cartridge for use in rural Alberta hospitals

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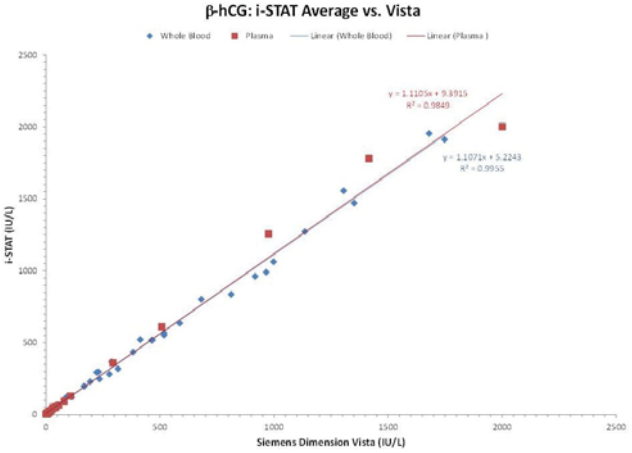
Background: Human chorionic gonadotropin (hCG) has significant clinical utility, yet many rural hospitals lack testing volume and/or instrumentation for quantitative measurement. However, many of these hospitals already have i-STAT analyzers, and Abbot's new β-hCG cartridge offers a feasible option for onsite quantitative testing. This study aimed to evaluate the i-STAT β-hCG cartridge.

Methods: Linearity, imprecision and accuracy were evaluated. For linearity, a plasma sample (hCG=1799 IU/L) was diluted from 1/2 to 1/256 and measured in duplicate. For imprecision, two levels of each of Clinica (24 IU/L and 1455 IU/L) and Bio-Rad Immunoassay Plus (6 IU/L and 21 IU/L) quality controls were measured daily over 20 days. Accuracy was assessed by measuring hCG in plasma samples on both the i-STAT and the Siemens Dimension Vista (n=37), Beckman Coulter DxI 800 (n=39), or Roche Cobas 6000 (n=42) analyzers. In addition, whole blood samples were

measured with the i-STAT; samples were then centrifuged and the plasma measured with central lab analyzers (n=43, n=34, n=52, respectively). The β-hCG ranged from <1 IU/L to 161,207 IU/L.

Results: Linearity was demonstrated from 9-1799 IU/L. Total imprecision was acceptable (Bio-Rad: mean=24 IU/L, CV=7.7%; mean=21 IU/L, CV=4.4%; Clinica: mean=24 IU/L, CV=5.1%; mean=1455 IU/L, CV=3.0%). Comparison of plasma on the i-STAT yielded acceptable correlations (Vista: regression line with slope=1.1105, y-intercept=9 IU/L, R^2=0.9849; DxI slope=0.9727, y-intercept=3 IU/L, R^2=0.9943; Cobas slope=1.0043, y-intercept=4 IU/L, R^2=0.9997). Comparison of whole blood on the i-STAT gave similar results (figure 1).

Conclusion: Linearity, imprecision and accuracy of the i-STAT β-hCG cartridge were acceptable for both whole blood and plasma samples. It can be utilized in clinical settings without access to a large chemistry analyzer with quantitative hCG. It is specifically useful for patients requiring a stat quantitative hCG result.



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The Effect of Maltose on the Radiometer 837 Blood gas Analyzers

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Background: Glucose measurement can be performed on commercially available blood gas analyzers (BGAs) for faster turnaround time, which are based traditionally on either the glucose dehydrogenase reaction or the glucose oxidase reaction. Other sugars, including maltose, may interfere with these reactions, causing the glucose measurement to be falsely elevated. Octagam 5% liquid is a commercially available intravenous immune globulin. Its preparation contains maltose, which has the potential to interfere with glucose measurement on the BGAs. Patients treated with this drug who also necessitate blood glucose levels may demonstrate falsely elevated measurements if their testing is performed on the BGAs. As it is not feasible to screen every patient for interfering drug preparations before performing glucose measurements, we felt compelled to demonstrate whether the maltose's effect on glucose measurement was clinically significant when using the BGAs.

Methods: To simulate patients being treated with Octagam, two levels of clinically relevant maltose concentrations were prepared using maltose solution admixed with whole blood from patients known not to be on any medication produced with maltose or other sugar based preparations. There were a total of eleven specimens, whose glucose levels ranged from 25 to 550 mg/dL. Simulated high and low drug levels were prepared by spiking concentrated maltose into whole blood specimens, resulting in a "high level" of 6.4 g/L to simulate maximum dosage and "low level" of 1.6 g/L to simulate low dosage. The spiked samples were tested for glucose in duplicates on the Radiometer 837 BGAs. Results were then corrected for the spiked volume, and averages of the duplicates were plotted against the original glucose concentrations.

Results: The correlation coefficient (R^2) of the best fitting line for both high and low maltose levels were good. Additionally, the predicted glucose measurements at various levels can be extrapolated from the best fitting line. As seen by this best fitting line, there is no clinically significant difference between the original and spiked measurements, either in the high level or low level specimens.

Conclusions: There is no clinically significant difference between the original and spiked results. Therefore, there is no need to eliminate the use of the Radiometer BGAs as a laboratory instrument for fast and accurate glucose measurements in urgent specimens for patients undergoing treatment with maltose-containing drug preparations or to screen patients for use of such drug preparations.

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Novel POC analysis for CBC, using PixCell Medical device, HemoScreen

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Background: Point of care (POC) in the community and hospital out patients is increasing to enable rapid sample testing for anaemia, monitoring oncology treatment and reduce patient waiting times. Current devices provide single parameters within a Complete Blood Count (CBC). However, the HemoScreen developed by PixCell Medical will provide a CBC and five-part differential within minutes.

Objective: To present a novel device, HemoScreen, for performing CBC using viscoelastic-focusing and microfluidic technology linked with image-based analysis and to demonstrate its ease of use and reliability for use in POC settings.

Methodology: HemoScreen, uses a disposable cartridge with 20ul of blood, finger prick or venous sample, placed into an analytical device. Employing viscoelastic-focusing and flow-based optical imaging, the cells are focused into a single plane, analysed by image-processing and classification algorithms to calculate the cell counts and related red cell indicies. The HemoScreen will offer a safe, reliable maintenance free method for performing CBC including possible flagging for morphological abnormalities. Internal quality control includes a built-in self-test for electronics, mechanics and software, carried out before each test, and at regular intervals during device operation. EQA is undertaken using a commercial control set at three different levels, low, normal and high.

Currently, 3 samples with 10 replicates each have been processed for precision. Approximately 60 samples were tested for accuracy, following the CLSI standard criteria. The Sysmex XE-2100 served as a reference method.

Results and validation: HemoScreen precision and accuracy results are summarized in the table below:

	Precision N=30	Accuracy		
Parameter	**CV (%)**	**Correlation coefficient (r)**	**Slope**	**Intercept**
WBC (x10^9/L)	8.0	0.988	0.979	0.26
RBC (x10^{12}/L)	3.6	0.958	0.966	0.167
HGB (g/dL)	6.1	0.949	1.013	-0.125
MCH (pg)	7.2	0.809	0.916	1.91
HCT (%)	4.0	0.963	1.003	-0.048
MCV (fl)	1.0	0.934	0.976	1.691
RDW (%)	1.3	0.957	0.894	1.552
PLT (x10^9/L)	5.5	0.960	0.948	6.7

Additional studies are being performed as it has been shown that precision can be further improved by optimizing the current method.

Conclusion: The HemoScreen is an innovative device that has potential to deliver a CBC within minutes, for use in POC settings, pharmacies, physician offices, oncology, neonatal and adult ICU, or even in the home.

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Novel POC analysis for Leukocytes and five-part differential, using PixCell Medical device, HemoScreen

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Background: Point of care (POC) is increasing to enable rapid testing while reducing patient waiting times. Current POC devices provide single parameters within a Complete Blood Count (CBC). However, the HemoScreen developed by PixCell Medical will provide a CBC and five-part differential within minutes. Haemoglobin and neutrophil counts in particular are essential for the monitoring of cytotoxic chemotherapy and sepsis whereas a 5-part differential is useful in all patients. The HemoScreen will offer all the parameters at the patient bedside or doctor's office that are currently only provided by the hospital laboratory.

Objective: To introduce the HemoScreen device for Leukocytes with five-part differential technology and demonstrate ease of use, safety and reliability of the device for use within POC settings.

Methodology: HemoScreen uses a disposable self-contained reagent cartridge, which employs micro-fluidic technology. The cartridge uses 20ul of capillary blood collected directly from the finger or venous blood. Once inserted into the analyser, digital imaging, and advanced algorithms are employed to calculate CBC results. Following

RBC lysis the differential is obtained by chemical staining of leukocytes. Leukocytes are classified based on multiple attributes such as cell size, nuclei size, nuclei lobes and cellular content. Contamination and device maintenance are eliminated as the flow of liquids occurs within the cartridge.

Intra-assay precision and accuracy were conducted using venous whole blood samples analysed in accordance with CLSI standards on both the Sysmex XE-2100 (reference method) and the HemoScreen. Three samples with 10 replicates were tested for precision. For accuracy 32 samples have been processed. Further samples will be used for evaluation of accuracy, including highly abnormal patient samples to validate this device.

Results and Validation: Results of comparability study are summarized below:

	Precision N =30		**Accuracy N=32**			
Parameter (Units)	**CV (%)**	**Acceptance Criteria**	**Correlation coefficient (r)**	**Slope**	**Intercept**	**Acceptance Criteria**
WBC ($x10^6$/L)	8.0	CV <10%	0.988	0.979	0.26	r>0.95
NEUT ($x10^6$/L)	8.0	CV <10%	0.989	1.081	-0.107	r>0.95
LYMP ($x10^6$/L)	10.9	CV <15%	0.965	1.041	0.135	r>0.9
MONO ($x10^6$/L)	15.5	CV <20%	0.931	0.976	0.135	r>0.8
EOS ($x10^6$/L)	22.8	CV<40%	0.987	1.032	0.012	r>0.9
BASO ($x10^6$/L)	8.8	CV<40%	Calculations were not done due to a low count			

Conclusion: A five-part differential is essential when monitoring oncology and septic patients in a POC setting and the HemoScreen has the potential to deliver this rapidly.

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Extensive Evaluation of Sample Interferences on Point-of-Care Glucose Meters

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Background: Intensive insulin therapy (IIT) guided by tight glycemic control (TGC) reduces morbidity and mortality in critically ill patients. Accurate glucose measurements are necessary for safe TGC. However, endogenous and exogenous interferences, such as ascorbic acid (AA), beta-hydroxybutyrate (BHB), galactose (GAL), glutathione (GLUT), lactose (LAC), and N-acetylcysteine (NAC) may impact glucose monitoring systems (GMS) accuracy. These compounds may be the result of medical interventions and/or critical illness. The objective of this study was to determine the effect of these five interferences on current generation POC GMS performance and the impact of autocorrecting biosensors in improving glucose measurement accuracy.

Methods: We investigated the effects of AA, BHB, GAL, GLUT, LAC, and NAC on the Nova Biomedical (Waltham, MA) StatStrip hospital (GMS 1-5) and Xpress meters (GMS 6-10), Roche Diagnostics (Indianapolis, IN) Inform II meter (GMS 11-13), and Abbott Laboratories (Abbott Park, IL) Precision Xceed Pro (GMS 14). All POC GMSs incorporated autocorrecting features within their biosensors. Whole blood from 12 healthy adult (age≥18 years) volunteers was used for testing. Specimens were adjusted to two clinically relevant levels (moderate, high) for each interferent and at different five glucose levels (range: 50-500 mg/dL). A negative control (without interfering compound) was also included for each sample series. Samples were tested on each GMS five times for each individual glucose and interference level. Results were compared to a plasma reference. Two-way ANOVA followed by pairwise analyses compared each GMS versus the reference method at each interference level.

Results: AA significantly affected GMS 11-13 at both levels (mean [SD] bias: -56.1 [38.9] mg/dL, P<0.001), while GMS 14 was only significantly affected at high AA levels (-18.0 [31.2] mg/dL, P<0.001) only. BHB significantly affected GMS 3 (-30.8 [20.8] mg/dL, P<0.001) and 7 (-28.6 [19.5] mg/dL, P<0.001) at high interference levels, GMS 4 (-28.6 [13.6] mg/dL, and P<0.001) and 8 (-30.0 [18.3] mg/dL, P<0.001) at moderate levels. For GMS 14, BHB affected the device at both interference levels (42.4 [37.7] mg/dL, P<0.001). GAL significantly affected GMS 1 (-29.0 [15.5] mg/dL, P<0.001), 3 (-38.6 [24.3] mg/dL, P<0.001), 9 (-23.4 [18.8] mg/dL, P<0.001), 11-13 (81.6 [13.1] mg/dL, P<0.001), and 14 (-47.1 [35.4] mg/dL, P<0.001) at both interference levels. GLUT significantly impacted GMS 11-13 (43.5 [27.2] mg/dL, P<0.001). LAC significantly affected GMS 11-14 at moderate and high interference levels. NAC significantly affected GMS 11 (20.0 [34.0] mg/dL, P<0.001) and 12 (19.0 [35.6] mg/dL, P<0.001) at high levels, and significantly affected GMS 14 at both interference levels (-114.5 [44.4] mg/dL, P<0.001).

Conclusions: Accurate glucose monitoring improves glycemic control and outcomes in critically ill patients. Sample interferences results in erroneous GMS measurements and increases the risk for dangerous hypoglycemic events during IIT. GMS 1-10 was observed to be the most robust against the evaluated interfering substances. We advise caution for facilities using GMS 11-14 due to significant AA, BHB, GAL, GLUT, LAC, and NAC inferences observed by our study.

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Extensive Evaluation of Hematocrit Interference on Point-of-Care Glucose Meters

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Background: Intensive insulin therapy (IIT) guided by tight glycemic control (TGC) reduces morbidity and mortality in critically ill patients. Accurate glucose measurements are necessary for safe TGC. However, confounding factors, such as abnormal hematocrit (HCT), results in inaccurate measurements on point-of-care (POC) glucose monitoring systems (GMS). Abnormal HCT is common in intensive care unit patients as a result of pathologic and iatrogenic mechanisms. Therefore, accurate POC glucose measurements are necessary for safe IIT for TGC. The objective of this study was to determine the effect of altered HCT on current generation POC GMSs and the impact of autocorrecting biosensors in improving glucose measurement accuracy.

Methods: We investigated the effects of abnormal HCT on the Nova Biomedical (Waltham, MA) StatStrip hospital (GMS 1-5) and Xpress meters (GMS 6-10), Roche (Indianapolis, IN) Inform II meter (GMS 11-13), and Abbott (Abbott Park, IL) Precision Xceed Pro (GMS 14). All POC GMSs incorporated autocorrecting features within their biosensors. Whole blood from 12 healthy adult (age≥18 years) volunteers was used for testing. Specimens were adjusted to five different HCT levels for five glucose levels (range: 50-500 mg/dL). Samples were tested on each GMS five times for each individual glucose and interference level. Results were compared to a plasma reference. Two-way ANOVA followed by pairwise analyses compared each GMS versus the reference method at each HCT level.

Results: Study results are summarized in **Table 1.** Asterisks indicate HCT significance GMS bias against the reference method.

Conclusions: Abnormal HCT is common in critically ill patients. Automatic hematocrit correction is instrumental for accurate glucose monitoring and TGC. GMS 1-10 exhibited acceptable performance at all HCT levels with the exception of GMS 3. Performance was acceptable for GMS 11-13. However, we advise caution for facilities using GMS 14 due to significant bias over a broad range of HCT levels.

Table 1. Comparison of Mean (SD) GMS Results

HCT	GMS 1	GMS 2	GMS 3	GMS 4	GMS 5	GMS 6	GMS 7	GMS 8	GMS 9	GMS 10	GMS 11	GMS 12	GMS 13	GMS 14
20	-13.8 (8.9)	-12.4 (12.3)	-13.8 (8.7)	-16.6 (12.5)	-8.0 (9.2)	-15.4 (12.9)	-14.0 (14.9)	-8.6 (10.0)	-24.4 (24.6)	-9.0 (9.9)	13.0 (9.1)	14.0 (9.2)	14.0 (7.4)	-8.8 (13.2)
30	-12.6 (5.1)	-12.6 (11.5)	-16.8 *** (12.3)	-14.0 (5.4)	-12.6 (6.4)	-6.0 (3.7)	-12.4 (9.2)	-11.2 (6.1)	-13.2 (8.4)	-9.0 (11.4)	12.2 (10.6)	13.8 (11.8)	8.8 (8.6)	-18.4 *** (12.7)
40	-15.8 (8.0)	-18.2 (16.9)	-22.2 *** (15.2)	-19.2 (11.1)	-12.2 (8.2)	-15.0 (5.8)	-13.0 (14.5)	-17.6 (12.0)	-13.2 (17.7)	-8.2 (5.3)	4.6 (12.5)	8.6 (9.2)	2.6 (10.2)	-38.8 *** (31.7)
50	-19.6 (6.7)	-22.0 (15.7)	-23.2 *** (8.2)	-18.2 (10.7)	-18.0 (12.8)	-18.8 (8.2)	-16.8 (9.4)	-20.0 (9.8)	-17.0 (9.6)	-11.6 (6.8)	0.4 (22.7)	3.2 (9.4)	-4.6 (16.5)	-52.6 *** (30.8)
65	-24.8 (12.3)	-27.2 (18.6)	-25.4 (20.6)	-25.4 (9.2)	-25.6 (16.1)	-24.6 (12.2)	-18.0 (16.8)	-25.8 (15.8)	-21.2 (12.4)	-14.6 (7.5)	-7.2 (17.6)	-7.8 (6.1)	-16.0 (18.7)	-72.8 *** (45.0)

Note: Glucose levels were measured in mg/dL
Abbreviations: Glu, Glucose; SD, standard deviation
***P<0.001 as determined by Two-Way ANOVA and Tukey's HSD

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Optimization of the turn-around-time of CRP measurement in the emergency setting by using the Microsemi® analyzer

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Introduction: C-reactive protein (CRP) is an established marker in the diagnosis and follow-up of patients with infectious diseases. In the acute setting it can help to assess and prioritize these patients and therefore improve diagnosis and further treatment. The Microsemi® CRP analyzer is a small analyzer, which determines with the use of only 18 µl EDTA-blood a complete blood cell count and CRP within 4 minutes. Furthermore, the Microsemi can be linked to a LAN for rapid result upload into a hospital information system (HIS). The aim of this study was to determine the turn-around-time (TAT) of CRP measured with the Microsemi analyzer and compared it with a fully automated method in a routine labor setting.

Material and Methods: Serum and EDTA samples from 66 patients with an urgent test-request were selected for analysis out of the daily routine. Serum-CRP was measured on a Vitros® 5600 analyser whereas the Microsemi was used to test CRP with EDTA samples . Time of blood collection was determined using the time of ordering in the order-entry system of the hospital information system (HIS). Using the laboratory information system (LIS) the time of arriving in the lab, uploading the result from the routine analyzer into the LIS, and reporting the result into the HIS

were collected. For the Microsemi the measuring time for CRP is 4 minutes. To these 4 minutes we added a mean time for other work of 5 minutes.

Results: The method comparison showed a good correlation between both assays with r = 0.9888 and CRP (Microsemi) = 1.057 x CRP (Vitros) - 0.235.

Mean time from blood collection to arrival in the lab was 32 (2-235) minutes. Mean time from arrival of the blood in the lab to reporting of the results into the HIS was 37 (21-103) minutes for the Vitros and 9 minutes of the Microsemi. Taking together it results in a mean total TAT of 69 (23 - 338) minutes for the Vitros and 41 (13-244) minutes for the Microsemi. Therefore, using the Microsemi the results could be reported in mean 28 (10-94) minutes earlier compared to the routine processing procedure.

Conclusion: Using the Microsemi for CRP measurement in the emergency situation there is the possibility to report much faster this critical parameter to the clinician without loss of analytical accuracy.

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Evaluation of Clinitest® hCG device susceptibility to high-dose hook effect by intact human chorionic gonadotropin (hCG) and hCG beta-core fragment at concentrations observed in early natural pregnancy

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Background: Qualitative detection of urinary human chorionic gonadotropin (hCG) using point-of-care testing devices is common practice in the evaluation of suspected pregnancy. False-negative findings due to high-dose hook effect are known to occur at elevated urinary concentrations of intvact hCG and/or hCG beta-core fragment (hCGβcf) with select POC hCG devices. In early pregnancy, hCG and hCGβcf concentrations vary depending on days relative to ovulation/conception. The aims of this study were to evaluate hook effect of intact hCG alone, hCGβcf alone, and combinations of hCG and hCGβcf exhibited in early pregnancy using the Clinitest® hCG device with accompanying Clinitek Status (Siemens Healthcare Diagnostics) readout. The distribution of days relative to ovulation at the time of Clinitest® hCG testing for patients presenting at 1 institution was further evaluated.

Methods: Hook effect by intact hCG and hCGβcf using Clinitest® hCG devices with Clinitek Status readout was evaluated using hCG-negative urine matrix containing 7 levels of purified intact hCG or hCGβcf (0 - $2x10^6$ pmol/L) alone, and combinations of intact hCG and hCGβcf (n=20) corresponding to physiological concentrations (± 50 pmol/L and ± 2% for concentrations ≤ 10,000 pmol/L and > 10,000 pmol/L, respectively) detected every other day in early natural pregnancy between 13 and 49 days relative to ovulation (n=37, intact hCG range 10 – $5.9x10^4$ pmol/L; hCGβcf range 10 – $2.3x10^5$ pmol/L; data courtesy of McChesney et al. Human Reprod 2005. 20(4):928-35). Prepared samples were tested in duplicate. Estimated days relative to ovulation at the time of Clinitest® hCG testing for female patients ≥ 18 years presenting to UNC Hospitals with borderline or positive Clinitest® hCG results (n=182) were calculated using retrospective analyses of estimated date of delivery (EDD), date of Clinitest hCG testing, and a gestation slide chart (Perrygraf) with assumed 40 weeks gestational age at EDD and 14 day relationship between gestational age and days relative to ovulation.

Results: Clinitest® hCG results per Clinitek Status readout for urine samples containing intact hCG or hCGβcf were as follows: positive for intact hCG at all concentrations (500-$2x10^6$ pmol/L) tested, positive between 500 to $5x10^4$ pmol/L hCGβcf, borderline at $5x10^5$ pmol/L hCGβcf, and negative at 0, $1x10^6$ and $2x10^6$ pmol/L hCGβcf. Positive Clinitest® hCG results were detected for combinations of intact hCG and hCGβcf in urine corresponding to concentrations detected in early pregnancy between 16 to 49 days relative to ovulation. The median estimated days relative to ovulation at the time of Clinitest® hCG testing among 182 pregnant females presenting at 1 institution was 38 days, with an inter-quartile range of 27.5 to 58.5 days.

Conclusion: The Clinitest® hCG device with Clinitek Status readout demonstrated no detectable hook effect by intact hCG. Hook effect at high concentrations of hCGβcf was observed though did not interfere with Clinitest® hCG detection of combined intact hCG and hCGβcf concentrations known to occur in early natural pregnancy. The majority of pregnant females presenting at 1 institution have Clinitest® hCG testing performed during early pregnancy and are unlikely to exhibit false-negative Clinitest® hCG results due to hook effect by hCGβcf.

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Comparison of Six Point-of-Care Glucose Monitoring (POCGM) Devices in Diabetic and Hemodialysis Patients.

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Background: Many patients with diabetes control their blood sugar level on a daily basis with Point-of-Care Glucose Monitoring (POCGM) devices. Accurate readings are of high importance to successfully self-manage their diabetes. There is variety of POCGM home-use devices available to measure glucose for diabetic patients. Each has a different degree of accuracy and imprecision. Therefore, in this study, we have evaluated six glucose meters from different manufacturers for patient's home-use. Patients & Methods: A total of 80 blood samples were collected from venous blood obtained from 20 healthy adults, 40 diabetic and 20 hemodialysis patients during July 2012 in our hospital. For each hemodialysis patient two blood samples were collected before and after dialysis. Blood glucose level was measured in these samples by different six POCGM devices from different manufacturers (denoted as A, B, C, D, E & F) and was compared to the reference glucose- hexokinase method Architect 16000 (Abbott). Two manufacturers (A & B) utilize strip that used the enzyme PQQ-GDH (pyrroloquinolinequinone dependent glucose dehydrogenase). The test strips utilize flavin adenine dinucleotide (FAD) with glucose-dehydrogenase (GDH) enzyme by manufacturers C, D and E. The strip from manufacturer F utilizes glucose oxygenase enzyme. Results: When the ISO 15197 standards were applied, most of POCGM devices have shown a good agreement and accuracy with the reference glucose-hexokinase method in the range of 82-98% with the exception of one device (F) which has shown only 39% agreement. All of the six devices have shown an average negative bias with the reference glucose-hexokinase method in the range of -6.2% up to -24% (p-value <0.0001). Conclusion: The home-use POCGM devices produced comparable results in relation to the glucose-hexokinase reference method. Devices that use FAD-glucose-dehydrogenase method have shown better accuracy in these studied populations.

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Evaluation of Glucose Meter Accuracy Using Locally-Smoothed Median Absolute Difference (LSMAD) Analysis

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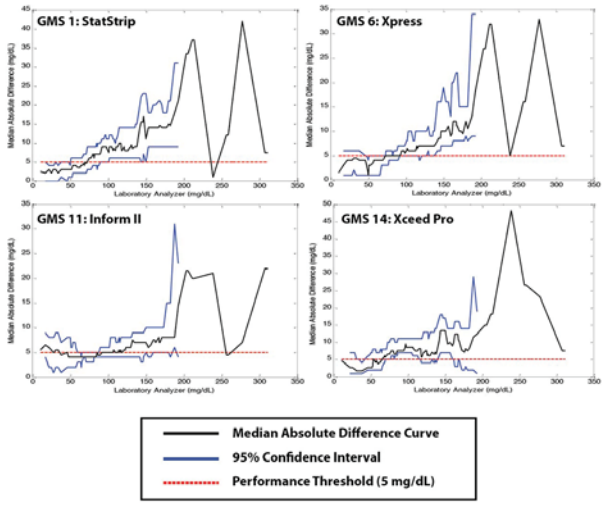
Background: Glucose monitoring system (GMS) accuracy is crucial for the management of critically ill patients. Intensive insulin therapy (IIT) is used for tight glycemic control (TGC) and relies on accurate GMS measurements. Poor GMS performance results in inappropriate insulin dosing and increases risk for dangerous glycemic excursions. Performance assessment of GMSs is instrumental for determining appropriate devices for critical care TGC. We hypothesize that traditional measures of performance may be inadequate for evaluating current generation GMSs when compared to the new locally smoothed median absolute difference (LSMAD) method.

Methods: We evaluated the performance of the Nova Biomedical (Waltham, MA) StatStrip hospital (GMS 1-5) and Xpress meters (GMS 6-10), Roche Diagnostics (Indianapolis, IN) Inform II meter (GMS 11-13), and Abbott Laboratories (Abbott Park, IL) Precision Xceed Pro (GMS 14) against a plasma reference. We collected 202 unique remnant arterial blood gas samples for paired testing. Traditional parametric statistics including ANOVA, Bland-Altman, and least square linear regression (LSLR) analyses were compared to the non-parametric LSMAD method. A 5 mg/dL tolerance threshold served as a LSMAD performance benchmark.

Results: We found no statistically significant differences via ANOVA, Bland-Altman, or LSLR analyses. With LSMAD analysis (**Figure 1**), GMS 1-10 exceeded the 5 mg/dL tolerance threshold for mean (SD) values greater than 86.9 (17.67) mg/dL. GMS 11-13 exhibited breakout points at two mean points: 11.0 and 17.0 mg/dL. For GMS 14, we observed a breakout point of 54 mg/dL.

Conclusions: Accurate glucose monitoring is instrumental for appropriate IIT in critically ill patients. Current generation GMSs have improved performance. Traditional methods used to analyze device performance proved inadequate in identifying significant differences between GMSs. In contrast, LSMAD illustrated the median performance of GMS 11-14 to be inadequate at clinically significantly hypoglycemic ranges_suggesting that these devices may be inappropriate for critical care.



B-300

Evaluation of point-of-care (POC) glucose test performance of Patient Care Technicians (PCT) and Registered Nurses (RN)

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Background: The glucose results attained by POC glucose meters are highly dependent on critical thinking and performance of the personnel performing the test. In the majority of clinical settings, either PCTs or RNs perform the POC glucose tests. The objective of this study is to evaluate the POC glucose test performance of PCTs and RNs by comparing the accuracy of their POC glucose results with the clinical chemistry (CC) lab analyzer results.

Method: Abbott's Precision XceedPro glucose meter based on the glucose dehydrogenase method was used for POC test. In the CC lab, glucose is analyzed on Beckman Coulter UniCel®DxC800 analyzers by an oxygen rate method employing a Beckman Coulter Oxygen electrode. Glucose results acquired with both POC glucose and CC lab analyzer with a difference in blood collection time of ≤5 mins were chosen and the data was collected retrospectively for 15 days, i.e., from 01.16.2014 to 01.30.2014. The average % variance between POC and CC lab tests was analyzed for the tests performed by PCTs and RNs. The POC and the CC lab test results were analyzed based on the personnel performing the POC tests by paired two-tailed t test.

Results: 402 tests were analyzed with glucose ranges of 35 mg/dL to 463 mg/dL in which 155 were performed by PCTs, 221 by RNs and 26 by other personnel. The average %variance of tests performed by PCTs compared to the CC lab was 8.40, and the results of POC and the CC lab were statistically significant (p=0.0121). Also, 51(33%), 47(30 %) and 57(37%) of these tests showed >10%, 5%-9.9% and <5 % variance respectively compared to the CC lab. For tests performed by RNs, the average % variance was 7.31, and the results by POC and the CC lab were not statistically significant (p=0.7910). Also, 52(23%), 66(30%) and 103(47%) of these tests showed >10%, 5%-9.9% and <5% variance respectively. According to CLSI, for glucose <100 mg/dL and >100 mg/dL, the difference from the POCT to CC lab test should not exceed 12 mg/dL and 12.5% respectively. 24% of tests performed by PCTs and 17% tests performed by RNs did not meet these criteria. Also in both the groups, there were 15 individuals with at least 2 tests showing >10% variance, out of which 12 were throughout the 15-day period and 5 with at least 2 tests >10% variance on the same day, there were 2 individuals who fell in both categories.

Conclusion: Overall performance by both RNs and PCTs is within the acceptable (±20%) allowable error. However, there is no statistical significance between POC and CC lab results for tests performed by RNs, whereas the tests performed by PCTs were statistically significant. Also, there are some individuals whose performance is not up to the required standards, therefore, it is important to identify these people and educate them about the potential sources of errors caused by the operators and critical thinking. It is also important to perform timely education and competency assessment on the personnel performing the POC testing.

B-301

An analytical evaluation of the Abbott i-STAT hCG test cartridge

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Background: The qualitative detection of human chorionic gonadotropin (hCG) in urine is commonly used as a rapid test to determine pregnancy status. Urine hCG tests are less analytically sensitive than quantitative serum hCG tests and are prone to false-negative results. Despite these drawbacks, urine hCG tests are often favored over serum hCG tests because they can be performed at the point-of-care. The ability to perform quantitative hCG testing in whole blood at the point-of-care would be advantageous. The i-STAT total hCG cartridge (Abbott Diagnostics, Abbott Park, IL) is a quantitative hCG test to be used with whole blood or plasma with an intended use for the detection of early pregnancy. The purpose of this study was to perform an analytical validation of the i-STAT hCG test.

Methods: hCG-free whole blood was obtained from volunteers. Residual serum and/or plasma samples sent to the laboratory for physician-ordered hCG tests were used as a source of hCG. Aliquots of the hCG-free whole blood were used to prepare samples with specific target hCG concentrations. Whole blood and plasma were used to evaluate the precision, linearity, analytical sensitivity, and accuracy of the i-STAT hCG test. Institutional Review Board approval was obtained for this study.

Results: Precision was determined from two samples analyzed in two replicates, twice per day for 10 days. Whole blood repeatability and within-laboratory CVs were 14.4 and 15.6% at 10.1 IU/L and 6.5 and 6.5% at 1176.6 IU/L, respectively. Plasma repeatability and within-laboratory CVs were 5.6 and 9.9% at 11.2 IU/L and 4.2 and 4.8% at 1273.7 IU/L, respectively. Linearity was evaluated from six samples prepared to span the claimed analytical measuring range of 5-2,000 IU/L. For whole blood, linear regression produced a slope of 0.99, a y-intercept of 6.1, and an r2 of 0.999. For plasma, linear regression produced a slope of 1.0, a y-intercept of 1.6, and an r2 of 0.999. Analytical sensitivity was determined from a set of five samples prepared to contain 0, 5, 10, 15, and 20 IU/L of hCG and each analyzed in 10 replicates. The limit-of-blank, defined as the mean+3 SD of the 0 IU/L sample, was 0 IU/L for whole blood and plasma. The limit-of-detection, defined as LOB+3 SD of the 5 IU/L sample, was 2.9 and 1.7 IU/L for whole blood and plasma, respectively. The limit-of-quantitation, defined as the hCG concentration that yielded a CV of ≤20% was 8.0 and <5 IU/L for whole blood and plasma, respectively. Accuracy was evaluated using 20 samples tested in one replicate on the i-STAT and compared to corresponding plasma hCG concentrations measured on the Architect Total β-hCG (Abbott Diagnostics) assay. For whole blood (i-STAT) vs. plasma (Architect), Deming regression produced a slope of 0.96, a y-intercept of -33, and r of 0.997. For plasma (i-STAT) vs. plasma (Architect), Deming regression produced a slope of 1.09, a y-intercept of -22.6, and r of 0.994.

Conclusions: The Abbott i-STAT total hCG cartridge demonstrates acceptable performance for quantifying hCG in whole blood or plasma.

B-303

Evaluation of Accu-Chek Inform II® performance with cobas c501® and Modular P800® Using Specimens from Patients in Emergency Department, Medical-Surgical and Intensive Care Units.

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Background: Glucose meters, offering a rapid evaluation of patient blood glucose values at the point-of-care, promote prompt medical intervention. The interchangeability of the glucose meter results with those obtained with the laboratory method is essential for their seamless interpretation. The performance of the glucose meter method may be affected by the blood matrix of patients treated in different hospital units. We report the results of a limited study comparing Accu-Chek Inform II with the laboratory method using blood specimens from patients treated in Medical-Surgical Unit (MSU), Intensive Care unit (ICU) and Emergency Department (ED).Methods: Patient specimens: 1230 (MSU 520, ICU 290, ED 420). Glucose meters: Accu-Chek Inform II (Roche Diagnostics), Strip lot #471353; Laboratory Methods: cobas c501 and Modular P800 (Roche Diagnostics).The patient specimens were collected by venipuncture in green-top tubes and assayed in parallel and within 30 minutes with both methods. For 324 patients the HCT value was available.The observations

were collected in Minitab® (Version 16, Minitab) statistical software and were analyzed with multivariable weighted least squares regression analysis (MWLSR), locally weighted scatterplot smoother (lowess), regression diagnostics and graphic representations.Results: The scatterplot of the glucose meters values (y axis) by the laboratory methods values (x axis) by the hospital unit, showed a linear relationship between methods. This was confirmed by the lowess. This plot showed increased variability for increasing glucose values; this prompted the use of a weighted least squares regression model. The absolute (for values 30-100 mg/dL) and relative (for values 101-600 mg/dL) difference plots showed that for the grand majority (99%) of specimens the differences were within the total error (CLIA's criterion target value +/- 6mg/dl, or +/-10%, greater).The MWLSR model (y=3+1.0x+2Unit+0.7HCT) showed that while there were no statistically significant differences between regression lines for HCT (P=0.42), there were statistically significant differences for Units (P<0.0001). The slope for ED (beta1=1.01) was statistically significantly different from those for MSU (beta1=0.95) and ICU (beta1=0.95). However, these differences were not clinically significant. The pure error test by data subsetting showed possible lack of linearity for high values.The lowess for the plot of the standardized deleted residuals by the fitted value showed a slight curvature for values >400mg/dL and 9 potential outliers (3<|value|<4).The leverage (Hi<0.1), Cook's distance (<0.05) and DIFTs(<|0.06|) did not show any influential observations. Conclusion: This study showed that there was a linear relationship between Accu-Chek Inform II method and the laboratory methods (cobas c501 and Modular P800). For the grand majority of the specimens, the absolute and relative differences were within the CLIA's criterion for total error. Consequently, these results suggest that the two methods can be used interchangeably with the laboratory methods for evaluating patient glucose blood levels. However, due to the limited number of specimens some matrix effects secondary to either disease or treatment may not have been manifest. Further studies should be performed to corroborate these findings.

B-304

Analytical validation of a blood glucose meter device in the emergency department of a university hospital

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Background: The university hospital in Belo Horizonte is a 500 bed tertiary hospital. Despite federal regulation that demands the use of hospital equipments, the glucose meters (and its strips) in the emergency department are appropriate for domestic use only, and they are not monitored by laboratory staff. Furthermore, their analytical performance has not been validated. As part of a project of implementation of glucose meters suitable for hospital use, we conducted analytical validation of the Precision XCEED PRO (PXP®) – Abbott, quality control and calibration in the emergency department, which is reference for several clinical conditions in the public health system.

Methods: Imprecision, accuracy and linearity were evaluated as part of the validation plan. Within-run imprecision was first evaluated using two level QC solutions tested 10 times each. Between-run imprecision was conducted running each control four times for five days. Accuracy was performed comparing 20 results of PXP® with Vitros® 5600 in the core laboratory. A capillary sample was collected to perform glucose testing in PXP®. Immediately after, one fluoride tube and one arterial heparin tube were collected and sent to the core lab to be tested in Vitros® 5600. The experiment was conducted for five days, so at least five patients were tested each day. Linearity was performed using a five level linearity kit from *RNA Medical*. Each level was tested in quadruplicate.

Results: Within-run imprecision was 3.45% for control 1 (mean = 88.7mg/dL) and 3.26% for control 2 (mean=273.0 mg/dL). Between-run imprecision within 5 days were 6.47% (mean = 88.9mg/dL) and 4.35% (mean = 287.2mg/dL). All values were considered acceptable. Comparison between capillary samples and fluoride plasma were performed with correlation coefficient (r) = 0.99, slope = 1.087, intercept = -4.53 and 95% of samples with results in the acceptable range < 20% of total error, according to ISO 15197 specifications. Comparison between heparin samples and plasma fluoride were performed also with correlation coefficient (r) = 0.992, slope = 0.969, intercept = -4.53mg/dL and all samples with results in the acceptable range < 20% of total error. Linearity was evaluated ranging from 24mg/dL to 427 mg/dL with software QCM®3.0.

Conclusions: Precision EXCEED PRO (PXP®) is suitable for hospital environment. Validation experiment performed with this particular device showed that its performance meets the quality requirements established by the laboratory and the literature.

B-306

Evaluation of the Performance of a Commonly-Used Glucometer in a Tertiary Hospital in Nigeria.

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Background:Point-of-care-testing (POCT) for glucose is the most common type of near patient testing performed at various sites within the Lagos University Teaching Hospital (LUTH). A previous study at our hospital among POCT operators found among others, a lack of awareness concerning evaluation of POCT devices and the use of quality control materials for POCT; absence of liaison with the central laboratory for the verification of suscpicious results, and absence of external quality assurance programs for POCT. This finding prompted us to evaluate the accuracy of the Accu-Chek® Active (Roche) glucometer, which is the glucometer in use at 90% of the sites performing POCT for glucose, including the emergency units and the diabetic clinic.

Methods:The study was approved by the Health Research and Ethics Committee of LUTH and was conducted over a four-week period. Glucose levels in capillary blood samples from 31 diabetics and 18 non-diabetics attending the Lagos University Teaching Hospital (LUTH) were measured with an Accu-Chek Active glucometer calibrated to plasma samples. All glucometer readings were conducted by the same individual, in order to reduce operator variability. Venous plasma was collected from the patients into fluoride oxalate vacutainers within five minutes of finger-prick tests. The central laboratory measured the plasma glucose on Siemens Dimension® Xpand® Plus analyser. The laboratory analysis was performed within one hour after sample collection. Precision studies were not conducted as control solutions for Accu-Chek Active are apparently not easily available in Nigeria. Accuracy was assessed with Pearson's correlation, % bias and Bland-Altman plot of the results from the two methods. The ISO 15197:2013 and the American Diabetes Association (ADA) requirements for glucose testing were employed in assessing quality. Data was extracted on Microsoft Excel® and analysed using Analyse-It® for Excel software version 2.30, Leeds, United Kingdom.

Results:The glucometer results were highly correlated with those of the central laboratory (r=0.99), bias ranged from 0.0 to 20.0%. Higher bias levels were observed with high glucose results. A Bland-Altman plot of the difference between each pair of results (glucometer and central laboratory), against the central laboratory result, showed increasing variability of glucometer results at high glucose levels. The glucometer met the ISO recommendation with 95.9% of the results having a bias <15%, however, it did not meet the ADA requirements of <5% bias for glucose testing.

Conclusion:The Accu-Chek Active glucometer had a high correlation with the central laboratory method but showed increased variability at high glucose levels. This may have implications for patient care particularly at the diabetic outpatient and emergency care units where insulin-dose adjustments are made according to glucometer readings, without verification of results from the central laboratory.

B-307

Utilization of a Superior Monoclonal Antibody Pair against Procalcitonin in Development of Fluorescence-based Lateral Flow Immunoassay

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Background: After the first report in 1993 on Procalcitonin (PCT) in patients with bacterial infection elevated significantly, the use of PCT in identifying the bacterial or non-bacterial origin of systemic inflammation has been gaining widespread support. Because the level of PCT in the blood stream of healthy individuals is below 0.5 ng/ml, we aimed to generate a set of specific monoclonal antibodies with higher affinity and develop a rapid and sensitive POCT test for use in the emergency rooms and clinical laboratories.

Methods: Balb/c mice (6-8 weeks) were immunized with recombinant PCT emulsfied with Freund's or Titermax adjuvant. Four times of intraveneous injections were given at 50μg per injection in 3 week intervals. ELISA were conducted for monitoring PCT-specific sera titer, four mice with the highest titer were selected for the cell fusion. Three days before the fusion, the last shot was done intraveneously. The splenocytes of the four mice were fused with the mouse myeloma cell line SP2/0 using PEG-1500. The microplate wells exhibiting hybridoma growth were screened for the production of anti-PCT antibodies with both direct and indirect methods. Positive hybridoma cultures with higher titer and specificity were selected and subcloned by three round of limited dilutions. All the 98 MAbs were purified by protein A-sepharose affinity chromatography and were evaluated by colloidal gold-based LFT. The LFT test containing 4763 kinds of combination in which each MAb was coated as the

capture antibody and the others were detected as the detecting antibody. After that, 18 matched MAb pairs were selected for further development of fluorescence-based lateral flow immunoassay (FLFIA) and the antibody pair (PCT79/PCT83) was shown to have the best sensitivity, specificity, stability and coincidence rate. Furthermore, the results from clinical samples tested by FLFIA with this antibody pair (PCT79/PCT83) were compared and evaluated with those of electrochemiluminescence immunoassay (ECLIA) method.

Results: Ninety-eight hybrid clones were screened eventually using the above-mentioned methods. After the evaluation in colloidal gold tests,18 matched MAb pairs were screened from 4763 combination. In FLFIA, the best antibody pair (PCT79/PCT83) was selected with the sensitivity of 0.1 ng/ml, detection range of 0.1~100 ng/ml; inter-assay CVs <15%. The results from clinical samples revealed that our strip using the antibody pair (PCT79/PCT83) correlates well with the ECLIA method (R=0.988).

Conclusion: We described here that we have generated a superior MAbs pair against PCT which is proved to have promising potential applications in development of FLFIA. They seem to be the ideal candidate antibodies suitable for development of a quantitative POCT.

B-308

Bioelectronic Platform for Sensitive and Versatile Diagnostic Applications*

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Background A new bioelectronic platform is described that is designed for multiple Point-of-Care (POC) diagnostic applications, including protein, DNA, and small molecule diagnostics. A self-assembled monolayer (SAM) technology is presented that demonstrates quantitative, ultra-sensitive, precise, and accurate measurement of a number of clinical analytes in biological samples (e.g. whole blood, urine, semen, prostatic fluid, saliva, etc). Cyclic voltammetry techniques measuring a ratiometric signal allow for a rapid, self-calibrating, fully quantitative dose response with broad dynamic range (over 4 logs of analyte concentration). This capability allows any applicable clinical assays to be executed on the Ohmx platform, using a minimal sample volume (1-50 uL), with performance levels similar to reference lab tests. The analytical performance of the sensor, and the clinical validation for multiple analytes (Hemoglobin A1c, hs Troponin I, TSH, hs CRP, DNA, and lactate) are discussed.

Methods Following standard solution bioassays (immunoassays, hybridization, or enzymatic reactions) an electrophore substrate specifically reacts with the self-assembled monolayers on the gold micro-electrodes. For all assays, a dose response spanning the analytes' relevant clinical range was obtained using commercially available calibrators. Further clinical validation is presented with 50 clinical samples tested for A1c, 72 samples tested for Troponin I and 50 samples for TSH. The clinical samples were provided by hospital collaborators and pre-tested with clinical immunoanalyzers. A correlation statistical study is shown between the Ohmx test and reference methods.

Results The Ohmx HbA1c is a single measurement test in 2 uL of whole blood, a TAT of 3 minutes with a linear response ranging from 2.7% (6.0 mmol/mol) to 19.8% (192.9 mmol/mol), an intraday precision of CV less than 3% and with R^2= 0.93 linear correlation with BioRad clinical immunoanalyzer. The Ohmx troponin I assay is a high sensitivity assay that has an LOD of 1 pg/mL with a TAT of 15 min, with CVs from 3-10% and a linear correlation with R^2= 0.95 with Siemens immunoanalyzers. TheTSH Ohmx test has an LOD of 0.0024 uIU/mL, a TAT of 15 min and R^2= 0.9 correlation with the Beckman Coulter DXI. SNP differentiation is shown for DNA factors II, IV, and MHTFR, and a lactate test is shown with a linear range from 0.2 to 28 mM.

Conclusions There is significant correlation between the Ohmx tests and clinical immunonalyzers. Analytical and clinical performance for all POC tests offered rivals performance of reference labs. The platform versatility is shown with tests that include proteins, DNA, and small molecules with a cartridge that has a COGS of $0.40.

*Assays currently under development and not for clinical use

B-309

Analytical and Diagnostic Characteristics of High-Sensitivity Troponin Assays: Examination of PATHFAST cTnI

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Background The analytical characteristics of high-sensitivity cardiac troponin (cTn) assays comprise an imprecision (CV) at the 99th percentile value ≤ 10% and measurable concentrations above the limit of detection (LoD) and below the 99th percentile in at least 50% of healthy individuals. The PATHFAST cTnI assay (Mitsubishi Medience Corporation, Japan) has already shown promising analytical validity and is usable for point-of-care testing. We thought to evaluate it`s analytical and diagnostic characteristics and to examine whether the assay could be classified as "high-sensitive".

Methods To establish the analytical criteria cTnI was determined using PATHFAST in 120 healthy individuals (60 men and 59 women, 21-69 years old, median 42 years) in whom cardiac disorders were excluded by extensive evaluation including cardiac magnetic resonance imaging and NT-proBNP < 125 ng/L. The diagnostic characteristics were investigated by comparison of cTnI and cTnT (Roche`s high-sensitivity assay cobas® hs-cTnT) in 181 patients admitted to the chest pain unit at presentation, 3 and 6 hours later. The results were related to the discharge diagnoses.

Results The cTnI concentrations measured in the healthy individuals ranged from 0.4 to 17.2, mean 2.1 (95% CI:1.6-2.6) ng/L, without age dependency. Men revealed higher levels than women, means (IQR) were 2.8 (1.2-2.6) and 1.1 (0.7-1.3) ng/L. The CLSI nonparametric method revealed a 99th percentile value of 16 ng/L below the manufacturer recommended value of 20 ng/L. The quantification of cTnI above the LoD (1.0 ng/L) and below the 99th percentile was possible in 79 of 120 individuals. The imprecision profile according to NCCLS revealed 20%, 10% and 5% CVs at cTnI concentrations of 2, 3 and at 20 ng/L, respectively. In the patient group the discharge diagnosis was non-ST-segment elevated myocardial infarction (NSTEMI) in 72 patients. The cTnI median values at 0, 3 and 6 hours were 46, 166 and 399 ng/L, respectively. To evaluate the diagnostic validity for detection of NSTEMI the results of PATHFAST cTnI and cobas hs-cTnT were compared by ROC analysis. AUC values at 0, 3 and 6 hours were 0.919, 0.962 and 0.958 for cTnI and 0.923, 0.964 and 0.969 for hs-cTnT, respectively. cTnI revealed AUC values for absolute changes from admission to 3 hours and from admission to 6 hours of 0.920 and 0.931 in NSTEMI patients.

Conclusions PATHFAST cTnI demonstrated complete fulfillment of the analytical criteria for high-sensitive cTn assays: The imprecision (CV) at the manufacturer recommended 99th percentile value was 5%. Quantification of cTnI was possible in 65.8% of healthy individuals. The examination of the diagnostic characteristics revealed complete concordance with cobas hs-cTnT detection of NSTEMI as well as for assessment of absolute changes of cTn values (rise and/or fall) during the course over time in NSTEMI patients. PATHFAST cTnI showed highly sensitive detection of NSTEMI with increasing sensitivity at admission and after 3 to 6 hours, not going along with decreased specificity. The PATHFAST cTnI assay allows high-sensitivity determination of cTnI within 16 min from whole blood samples and might be useful at the point-of-care setting for early rule- in and rule-out diagnosis of NSTEMI.

B-311

Evaluation of a point-of-care HbA1C method in an underserved community clinic and measurement of the impact of implementing a high-quality assay with immediate results.

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Background: Measurement of hemoglobin A1c (HbA1C) assesses glycemic control and provides an estimate of the average glucose concentration (eAG) over the previous 2-3 months. The American Diabetes Association recommends that %HbA1C be measured twice annually for diabetic patients meeting glycemic goals, in an effort to reduce the risk of microvascular disease. In this study, we evaluated a NGSP-certified CLIA-waived point of care (POC) method for HbA1C by finger-stick and measured the impact on workflow and compliance with pay-for-performance goals in an underserved community clinic.

Methods: The boronate affinity Afinion AS100 HbA1C POC assay (Alere Analytics) was evaluated for performance by the clinic nursing staff, in addition to the laboratory technologists. Precision studies, across various cartridge and QC lots, included the calculation of intra- (n=10) and inter-assay (n=30, 150 days) coefficients of variation (CV) for two levels of manufacturer QC (6% and 8% HbA1C). Method correlation against the Cobas Integra 800 Tina-quant HbA1C immunoassay method (Roche Diagnostics) was assessed through linear regression, mean bias, Bland-Altman plots and evaluation of clinical concordance. This included EDTA samples (n=27) and concurrent venipuncture/capillary samples (n=20). EDTA samples collected from patients with HbC and HbS were also included. Compliance with our institution's pay-for-performance goal of measuring HbA1C twice annually (6±3mo) for diabetic patients, was compared before and after implementing POCT.

Results: The intra- and inter-assay precision was <2% and ≤3% CV, respectively. For HbA1C ranging from 3.9-14.9%, the method correlation for EDTA samples (y=0.94x+0.37, r2=0.99) and paired venipuncture/capillary samples (y=0.93x+0.28, r2=0.97) showed excellent agreement. The mean (±SD) of bias of %HbA1C was -0.1%(±0.3) and -0.2%(±0.2) for EDTA and paired venipuncture/capillary samples, respectively. There was no significant bias observed for samples with the hemoglobin variants included. Overall, clinical concordance was 91%(43/47) for %HbA1C within the ranges of 10%(5/6), where the absolute bias was less than ±0.5%. Representing 32% of all HbA1Cs ordered at this clinic, 189 tests were performed by POCT in the first two months, allowing for real-time therapy assessment and feedback to diabetic patients. Of these samples, 146(77%) were collected without any additional laboratory testing ordered for the patient that would have required venipuncture. Perhaps more important, this means 43(23%) patients, who had venipuncture for other laboratory testing, also had POCT performed for the sole benefit of the real-time assessment. Introduction of POCT was associated with an initial 6% increase in the clinic's compliance with a pay-for-performance goal of serial testing performed within nine months. In addition, POCT was provided for 57(32%) patients whose prior HbA1C determination exceeded these performance goals.

Conclusion: Accurate representation of long-term method performance is possible when the evaluation is conducted by the end-user. Compared to the immunoassay method, the Afinion HbA1C POC method demonstrated excellent precision, accuracy, and clinical concordance. With on-going cross-checks, this study demonstrates the potential for these methods to be used interchangeably; including eAG calculation, screening for, and diagnosis of diabetes. Replacing venipuncture collection with POCT was shown to initially, increase compliance with pay-for-performance goals.

B-312

A Whole Blood POC Enzymatic Creatinine Assay that Meets the eGFR Reporting Requirements by NKDEP

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BACKGROUND: Estimated Glomerular Filtration Rate (eGFR) from serum creatinine is considered a better assessment of renal function than serum creatinine alone. To assure the reported eGFR is within clinically acceptable error limits, the NKDEP Laboratory Working Group has recommended the total error (TE) limits for creatinine measurement in the critical creatinine range (1-1.5 mg/dL). A rapid whole blood creatinine assay with eGFR in the point of care test (POCT) environment is gaining attention. This publication assessed the TE of our biosensor based whole blood creatinine assay per NKDEP recommendations for eGFR capability.

METHODS: Performance of the creatinine assay was assessed based on the NKDEP Whole Blood Protocol, and was tested on six GEM Premier analyzers after appropriate modifications to accommodate the creatinine sensors. Heparinized whole blood samples with creatinine concentrations from 1.0-1.5 mg/dL were collected. The hematocrit levels were adjusted to form four sample test groups: plasma, low Hct (20-30%), normal Hct (no adjustment), and high Hct (50-60%). Whole blood samples were assayed in random order with 10 replicates per sample type per cartridge, followed by plasma samples (N=10). Three level IDMS traceable reference serum pools were assayed before and after the test samples. The samples were tested in parallel on an ABL 800 Flex analyzer (Radiometer) as reference.

RESULTS: The sample results were normalized to the IDMS traceable reference serum. The mean creatinine was 0.993 mg/dL, the 3.5% bias (95% CI: 3.03%, 4.01%) vs. ABL, and the 3.5% imprecision (95% CI: 2.8%, 4.2%) were both within the 5% and 8% limits of NKDEP recommendations. The bias and within-run precision per cartridge were plotted against the acceptable TE budget for reporting eGFR (Fig.1).

CONCLUSIONS: The biosensor based creatinine assay under development demonstrated analytical performance in whole blood with a TE meeting the NKDEP recommendations for reporting eGFR.

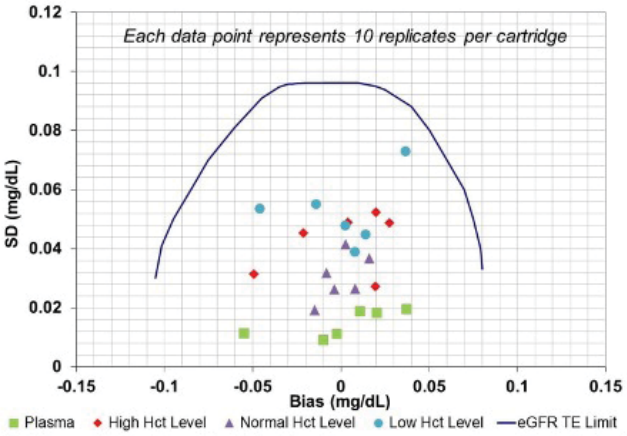

Fig. 1 Bias and imprecision of whole blood Creatinine assay recovery at normal Cratinine level