Wednesday, August 3, 2016

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

Electrolytes/Blood Gas/Metabolites

B-034

A Microtiter Plate Assay for the Quantitative Measurement of Pyruvate in Whole Blood

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Background: Pyruvate is a critical cellular metabolite derived from the oxidation of glucose during glycolysis. Its measurement in blood is useful in the evaluation of patients with inborn errors of metabolism. Methods to measure pyruvate are not available commercially and laboratories that perform pyruvate testing traditionally use spectrophotometric techniques that require the use of individual cuvettes. The objective of this study was to develop a high-throughput analytical method for measuring pyruvate in whole blood.

Methods: Samples were prepared by the addition of 1 mL anticoagulated (heparin or EDTA) whole blood to 2 mL 8% (w/v) cold perchloric acid, incubated on ice for 10 min, then centrifuged to obtain a protein-free supernatant. Samples, Trizma base, and NADH were added to wells of a 96-well microtiter plate and an initial absorbance at 340 nm was measured on a Spectramax 384 Plus plate reader. Lactate dehydrogenase was added to each well and a final absorbance was measured following a 5 min incubation at room temperature. The decrease in absorbance at 340 nm due to the oxidation of NADH was used to determine the concentration of pyruvate. Performance characteristics including precision, linearity, analytical sensitivity, and accuracy were determined as were reference intervals and sample stability. The University of Utah's Institutional Review Board approved this study.

Results: Reactions with samples anticoagulated with EDTA, but not heparin, failed to reach an end-point and were considered to be unsuitable. Precision was determined using samples created by the addition pyruvate to perchloric acid and measuring pyruvate in three replicates for five days. Within-run and total CVs were both 2.4% at 0.157 mM and 5.8 and 5.9% at 0.062 mM, respectively. Linearity was determined by combining samples with high and low pyruvate concentration to prepare six samples that were tested in duplicate. The assay was linear within the measuring range of 0.06 to 0.40 mM ($y=1.007(x)+0.0008$, $R^2=0.999$). Perchloric acid-treated 0.9% saline and a 0.055 mM patient pool were each tested in 12 replicates to determine the limit of blank (LOB) and limit of detection (LOD), respectively. The LOB and LOD were calculated as 0.0158 and 0.0259 mM, respectively. Accuracy was evaluated by a method comparison study using a pool of perchloric acid-treated heparinized whole blood to which volumes of a 7 mM pyruvate standard were added to create 40 pairs of samples (0.063 to 0.369 mM). The comparison method was the previously validated cuvette-based method used in our laboratory. Linear regression yielded a slope of 0.941, intercept of 0.007 and Sy/x of 0.013. The previously established reference interval of 0.03-0.107 mM was verified using freshly collected whole blood samples from 20 healthy, fasting donors. Sample stability was determined using freshly collected heparinized blood samples (0.118 and 0.087 mM). Pyruvate was stable for four hours, two days, and four weeks at room temperature, 4°C, and -20°C, respectively.

Conclusions: The pyruvate assay in a microtiter plate format demonstrates acceptable performance characteristics for quantifying pyruvate in heparinized whole blood. Whole blood anticoagulated with EDTA should not be used for pyruvate testing.

B-035

Performance Characteristics of a Urine Oxalate Reagent System Adapted for Use with Plasma

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Background: Oxalate is the end-product of the glyoxylate and glycine metabolism and is excreted in the urine. The measurement of oxalate in plasma is used to assess the body pool size of oxalate in patients with primary hyperoxaluria, chronic renal failure, and oxalate toxicity. Oxalate in unacidified plasma can increase due to the conversion of ascorbate to oxalate. As such, plasma must be rapidly frozen or acidified after collection. The purpose of this study was to adapt Trinity Biotech Urine Oxalate Kit for use with plasma.

Methods: Oxalate was oxidized to CO_2 and H_2O_2 by oxalate oxidase. The amount of H_2O_2 produced was determined by a colorimetric reaction that produced an indamine dye. The absorbance at 590 nm was directly proportional to the concentration of oxalate. Residual and freshly collected heparin or EDTA plasma was used for this study. Immediately before testing, samples were thawed, acidified to pH ~2.5 by the addition of 17 uL concentrated HCl to 1.2 mL plasma, and filtered through a 30 kDa centrifugal filter device. Performance characteristics including precision, linearity, analytical sensitivity, and accuracy were determined as were reference intervals and sample stability. The University of Utah's Institutional Review Board approved this study.

Results: Precision was determined using sample aliquots stored at -20°C in three replicates, once each day, for ten days. Within-run and total CVs were 1.3 and 4.4% at 17.3 µM and 9.1 and 20.2% at 5 µM, respectively. Linearity was determined by diluting a high calibrator (50 µM) with 0.01 M HCl to create a set of six samples that were tested in duplicate. The assay was linear within the measuring range of 2 to 50 µM (linear regression $y=1.00(x)+1.10$, $R^2=1.00$). The zero calibrator (0.01 M HCl) and the 3.3 µM calibrator were each tested in 12 replicates to determine the limit of blank (LOB) and limit of detection (LOD), respectively. The LOB was 1.4 µM as calculated from the mean+3 SD. The LOD was 2 µM as calculated as the LOB+3 SD of the LOD. Accuracy was determined by recovery studies performed by adding volumes of the 50 µM calibrator to two plasma samples with oxalate concentrations of 4.4 and 17.3 µM. Calculated recoveries were 104.9% and 102.6%, respectively. The reference interval of <1.8 µM was verified using 20 freshly collected plasma samples. Sample stability was determined using acidified and unacidified plasma, and acidified and deproteinized ultrafiltrates. Oxalate increased by 0.8 to 3.2 µM in unacidified plasma after two hours at room temperature. In both unacidified and acidified plasma, oxalate was stable for up to 7 days at -20°C. Oxalate in acidified and deproteinized ultrafiltrates was stable for up to 21 days at -20°C.

Conclusions: Plasma oxalate can be measured accurately using a reagent platform designed for use with urine although the assay is less precise at low oxalate concentrations. To avoid false increases in oxalate, plasma must be stored frozen or acidified and stored frozen after collection.

B-036

Development of a Reference Material for Low Level Creatinine in Human Serum Using Artificial Serum Matrices

J. E. Camara. *NIST, Gaithersburg, MD*

Background: The National Institute of Standards and Technology (NIST) provides a variety of Standard Reference Materials® (SRMs) intended for use as accuracy controls in the analysis of clinical samples. NIST has also been involved in the standardization efforts of the National Kidney Disease Education Program (NKDEP) of the National Institute of Diabetes and Digestive and Kidney Diseases-National Institutes of Health for many years, which has resulted in the production of several SRMs supporting creatinine measurements in serum and urine. NIST currently sells SRM 967a Creatinine in Frozen Human Serum, which provides two levels of creatinine in serum at adult normal and high levels to support clinical measurements for assessment of kidney disease. However, pediatric ranges for serum creatinine are significantly lower than the adult normal range. Therefore, the current SRM 967a does not support the accurate measurement of creatinine in the range necessary for measuring serum creatinine and screening for kidney disease in the pediatric population, which is a concern that has been voiced in recent years through the NKDEP. **Methods:** As it is not feasible to obtain large volumes of pediatric serum for the production of a new lower level creatinine serum material, NIST has begun an investigation into the use of commercially available artificial serum matrices as serum diluents or bases for a new material with a target value of 4 µg/g (0.4 mg/dL) creatinine. NIST obtained SeraFlx BIOMATRIX and SeraFlx LCMSMS artificial serum from Cerilliant. In addition, a pre-market SigMatrix Ultra Serum Diluent was provided by MilliporeSigma. NIST measured the background creatinine levels and performed spiked recovery studies on each material using an isotope-dilution liquid chromatography-mass spectrometry (ID-LC-MS) Reference Measurement Procedure for creatinine in serum. SRM 914a Creatinine was used as the calibrator and SRM 967a Creatinine in Frozen Human Serum was used as the control for all ID-LC-MS measurements. **Results:** The endogenous levels of creatinine in these artificial matrices were determined to be 0.50 µg/g, 3.30 µg/g, and 0.00 µg/g for SeraFlx LCMSMS, SeraFlx BIOMATRIX, and SigMatrix Ultra, respectively. In addition, none of these materials displayed interfering peaks in the internal standard

LC-MS channel, eliminating this as a possible source of bias. For spiked recovery studies, each material was spiked with multiple levels of creatinine in the clinically-relevant range of 4 µg/g to 35 µg/g and processed in triplicate by ID-LC-MS. The percent recovery results were 94 % to 98 %, 104 % to 105 %, and 100 % to 104 % for SeraFlx LCMSMS, SeraFlx BIOMATRIX, and SigMatrix Ultra, respectively. **Conclusion:** Based on the results of ID-LC-MS analysis, these three artificial serum matrix materials remain viable candidates for use as diluents of normal serum or bases for creatinine spiked materials. However, additional studies are needed to determine if such materials would be fit-for-purpose in routine clinical creatinine assays, such as enzymatic or Jaffe-based methods. NIST is currently organizing a round robin study with assay manufacturers and clinical laboratories to further evaluate candidate reference material mixtures based on these artificial matrices.

B-037

Analysis Of Biochemical Profile In Post-Operative Neuro-Oncology Patients With Hyponatremia

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Introduction: Hyponatremia is not an uncommon electrolyte disorder in post-operative neurology patients. The common causes of hyponatremia in these patients are Syndrome of Inappropriate Secretion of Antidiuretic Hormone (SIADH) and Cerebral Salt Wasting (CSW). The two conditions though present with similar characteristics, can be differentiated on the basis of clinical evidence of a contracted extracellular fluid (ECF) volume in CSW. It is important to differentiate between these two conditions as the treatment for SIADH is fluid restriction and that for CSW is vigorous sodium and volume replacement. Certain biochemical parameters help in distinguishing between SIADH and CSW in addition to clinical findings.

Objective: In this study we analysed cases of persistent hyponatremia (lasting more than three days) with hypotonicity of plasma in post-operative neuro-oncology patients. We compared the changes in select biochemical parameters with those in published literature for their utility to differentiate between SIADH and CSW

Methods: Out of 826 cases operated during a period of three years, 14 were investigated for persistent hyponatremia. Of these, six cases also showed hypotonicity of plasma. They were further analysed for change in following biochemical parameters: Blood Urea Nitrogen (BUN)/ Serum Creatinine Ratio, Serum Uric Acid, Serum Albumin, Serum Potassium, and Hematocrit. The values from the preoperative work-up were compared with those during the period of hyonatremia. An average percent change in the values was calculated for each parameter.

Results: All six cases showed hyponatremia (serum sodium<136 mmol/l), hypotonicity (serum osmolality<275mosm/kg), urine osmolality greater than serum osmolality. All six cases showed decrease in serum albumin (42.63%), serum potassium (10.26%), serum uric acid (56.52%) and hematocrit (26.67%) levels. BUN/ creatinine ratio was decreased in four cases. One case showed no change, while other case showed raised BUN/creatinine ratio with increased BUN levels, however, serum creatinine levels were not raised ruling out kidney disease. All cases were diagnosed as SIADH and responded to fluid restriction.

Conclusion: According to literature serum uric acid, serum potassium and BUN/ creatinine ratio are either decresed or remain unchanged in SIADH. Serum albumin and hematocrit show no change. In our study serum potassium, serum uric acid and BUN/creatinine ratio showed a decrease in the post-operative phase with hyponatremia which is comparable to current literature. However, serum albumin and hematocrit levels too were decreased significantly. Tracking these biochemical parameters in addition to standard tests for differential diagnosis of hyponatremia (osmolality and urine sodium levels) will be helpful in differentiating between SIADH and CSW early before clinical symptoms appear in post-operative neuro-oncology patients. However, a study with larger group of patients is required.

B-038

Evaluation of a New ICT (ISE) Module for the Abbott ARCHITECT® cSystem™

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Background: Abbott Integrated Chip Technology (ICT) module consists of solid state ion selective electrodes (ISE) to measure sodium, potassium and chloride simultaneously in serum, plasma or urine from 15 µL samples, within 3 minutes, on the ARCHITECT Clinical Chemistry Systems. ICT module enhancements have led to extended calibration intervals, from 8 hours to 24 hours, and module use life, from 2 months to 3 months. More recently, the ICT module was further enhanced for product reliability. The objective of this study was to evaluate the enhanced ICT module performance using Six Sigma Metrics.

Methods: Quality controls, 200 to 300 human serum samples and 20 to 30 urine samples were tested everyday on each ICT module. Over 22,000 samples (66,000 tests) were tested after three months. Then precision was evaluated with 5 replicates and 2 runs per day using commercial controls over 5 days following CLSI Guideline EP5-A2. Linearity was evaluated according to EP6-A. Sigma metrics were evaluated using 9 replicates of NIST SRM 956d, where Sigma= (TEa(%)-Bias(%))/CV(%) per Westgard QC using RiliBäk TEa targets.

Results: Daily quality control results were stable and within ranges. The precision ranged from 0.23% to 0.42% for serum assays and 0.21% to 1.30% for urine assays. All assays met the linearity ranges and acceptable deviations listed in the table below. Sigma values ranged from 8 to 28.

Conclusion: The enhanced ICT Module for Abbott ARCHITECT cSystems consistently demonstrates excellent precision and linearity performance over its warranty claim of 20,000 samples (60,000 tests) or 3 months use. Sigma metrics greater than 6 demonstrate the new ICT Module has a low frequency of error and confirms the new ICT Module is well suited for use in the clinical laboratory.

Assay	**Na^+ (Serum)**			**Na^+ (Urine)**			**K^+ (Serum)**			**K^+ (Urine)**			**Cl^- (Serum)**			**Cl^- (Urine)**		
Precision (%CV), n=50	0.23			0.21			0.42			1.30			0.28			0.35		
Linearity (mmol/L)	100 - 200			20 - 400			1.0 - 10.0			1 - 300			50 - 150			20 - 300		
	≤5%			≤5% / 3 mmol/L			≤5% / 0.25 mmol/L			≤5% / 3 mmol/L			≤5%			≤5% / 3 mmol/L		
Sigma Analysis (NIST SRM 956d)	**Na^+ (Serum)**						**K^+ (Serum)**						**Cl^- (Serum)**					
	Level 1	**Level 2**	**Level 3**				**Level 1**	**Level 2**	**Level 3**				**Level 1**	**Level 2**	**Level 3**			
Certificate Value (mmol/L)	120.0	139.3	158.7				5.752	3.730	1.611				94.53	108.5	122.6			
Architect Mean (n=9)	118.3	137.9	158.7				5.780	3.720	1.684				93.76	107.6	122.2			
Bias (%)	-1.42	-1.01	0.00				0.49	-0.27	4.53				-0.81	-0.83	-0.33			
% CV (5 day precision study)	0.23						0.42						0.28					
TEa (%) (RiliBäk)	5.0%						8.0%						8.0%					
Sigma	**16**	**17**	**22**				**18**	**18**	**8**				**26**	**26**	**28**			

B-039

Sigma Analysis of Automated Chemistries Over Time

J. H. Nichols, J. Colby, J. Wiencek, A. Woodworth. *Vanderbilt University School of Medicine, Nashville, TN*

Introduction: Sigma metrics are a good estimate of clinical laboratory assay performance. Sigmas can be used to estimate risk of reporting an unreliable patient result because they incorporate both analytical performance characteristics and total allowable error for each assay.

Objective: To evaluate the performance of our new automated chemistry system by calculating sigma metrics over time using several different sources for allowable total error (TEa). **Methods:** Performance of general chemistry methods on four Abbott Architect analyzers was estimated using 12 months of Bio-Rad quality control data from the first year of operation (November 2013 to October 2014) and compared to second year of operation (December 2014 - January 2016). Method imprecision was determined by the cumulative coefficient of variation (CV) of quality controls and percent bias was defined by comparison of laboratory mean to peer group means. Sigma was estimated for each analyzer method as [(TEa - Bias%)/CV%] using allowable total error from three sources; the CLIA evaluation limits, biological variation (Ricós C et.al. Scand J Clin Lab Invest 1999;59:491-500) and the 2011 Australasian Association of Clinical Biochemists allowable limits of performance (RCPA Quality Assurance Programs Pty Limited, Adelaide, Australia). Sigma estimates were averaged among our four chemistry analyzers to compare performance between first and second year of operation. Analysis of NIST SRM1950 standards in January 2016 allowed estimation of true bias versus Abbott Architect control peer group bias.

Results: The average sigma metrics were stable over time between our first and second year of performance for both urine and serum analytes. Lower sigmas were generated with the tighter (Ricós and RCPA) allowable error guidelines compared to

CLIA limits especially for serum albumin, ALT, direct and total bilirubin, calcium, HDL, direct LDL, chloride, creatinine, glucose, potassium, lactate, LDH, sodium, phosphorus, total protein and urine creatinine, glucose and magnesium. Bias estimated from NIST SRM1950 standards gave comparable sigmas to peer group estimates except for serum calcium, cholesterol, magnesium, total protein and urea. Several test methods met optimal sigma performance, >6 sigma, across all three sources of TEa; serum AST, CK, triglycerides and urine chloride, potassium, sodium, phosphate, total protein, and uric acid.

Conclusions: This is the first publication comparing sigma metrics for serum and urine chemistry methods over time. The average sigma is stable over time; however sigma analysis presented several limitations. Sigma estimates vary depending on TEa limits used. Tighter TEa limits lead to lower sigmas. Use of the peer group to estimate bias, may not account for true bias of the method. Sigma estimates vary with concentration of control material. This study also noted sigma variability among analyzers. Averaging sigmas across several analyzers does not account for inter-analyzer variability. This variability makes defining a single control strategy based on sigma estimates from one analyzer or a single control material challenging and unlikely to be acceptable for a group of analyzers across the entire reportable range. Laboratories should consider the lowest individual analyzer sigma estimates when setting control strategies for a group of analyzers rather than utilizing an average.

B-040

Anion gap lactate testing.should not be used to indicate the need for lactate testing.

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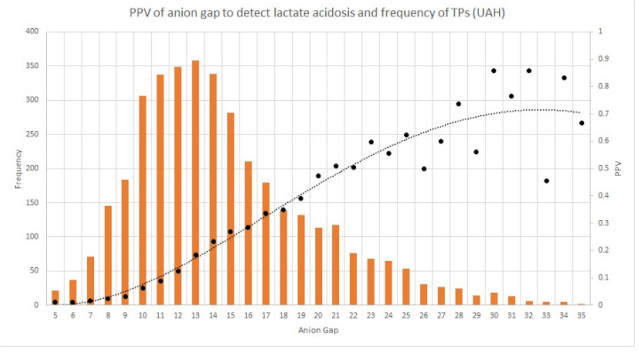
Introduction: Lactic acidosis represents the pathologic accumulation of lactate and hydrogen ion. High lactates are associated with increased severity of illness; e.g., in septic patients, lactic acidosis is associated with a threefold increase in mortality. It is important to efficiently diagnose lactic acidosis. In emergency departments (ED), serum lactate levels may not be rapidly available, and elevated anion gaps are used to indicate elevated lactates. Most Edmonton metropolitan hospitals have Radiometer blood gas/electrolyte instruments in the ED or close by. As lactate is provided with each electrolyte determination, we could determine the sensitivity of anion gap to detect lactic acidosis.

Methods: Lactic acidosis is defined as a whole blood lactate of 4 mmol or greater. For all of the electrolytes/blood gases ordered in 5 different metropolitan EDs, we determined the positive predictive value of detecting an elevated lactate for each unique anion gap as well as the number of elevated lactates.

Results: Two years of ED lactates and electrolytes from 5 Edmonton metropolitan hospitals were analyzed. The Figure shows for the University Hospital ED a histogram of elevated lactates gathered over 2 years graphed against anion gap (42,311 electrolytes and lactates performed). Also shown is the positive predictive value of the anion gap to detect lactic acidosis. If a physician used an anion gap limit of 13 to trigger the ordering of lactate, approximately 40% of the lactic acidosis would be missed. At a level of 13 mmol/L, the predictive value of an anion gap would be about 30% to indicate lactic acidosis. The graphs for the other 4 Edmonton hospitals are similar.

Conclusions: Anion gap is an inadequate marker of lactic acidosis. We recommend that lactate be done with each set of electrolytes and/or blood gases. In this way lactic acidosis should not be missed.



B-041

Performance Evaluation of an Integrated Multisensor Technology Na, K, and Cl assays on the Atellica CH Analyzer*

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Introduction: Measurements of sodium are used in the diagnosis and treatment of aldosteronism, diabetes insipidus, adrenal hypertension, Addison's disease, dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance. Measurements of potassium are used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high blood potassium levels. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis. The Atellica™ CH* Integrated Multisensor Technology (IMT) Na, K, and Cl assays from Siemens Healthcare are intended for the quantitative measurement of sodium, potassium, and chloride (Na, K, Cl) in human serum, plasma, and urine. The objective of this study was to evaluate the performance of the IMT assays on the Atellica CH Analyzer.

Methods: Assay precision was evaluated using Clinical and Laboratory Standards Institute (CLSI), guideline EP05-A3. Each sample was assayed in duplicate twice a day for 20 days. Method comparison studies were conducted according to CLSI EP09-A3 with Passing-Bablok regression of patient sample results compared with the ADVIA® 1800 Clinical Chemistry System.

Results: For Na, within-lab precision ranged from 0.8 to 1.0% CV. Serum samples ranged from 71.6 to 154 mmol/L and 1.0 to 1.5% CV. Urine samples ranged from 32.2 to 284 mmol/L. For K, within-lab precision ranged from 0.7 to 1.0% CV. Serum samples ranged from 2.70 to 7.31 mmol/L and 0.9 to 1.1% CV. Urine samples ranged from 31.2 to 258 mmol/L. For Cl, within-lab precision ranged from 0.7 to 1.5% CV. Serum samples ranged from 78.1 to 189 mmol/L and 0.8 to 1.7% CV. Urine samples ranged from 42.7 to 280 mmol/L.

In method comparison testing, 106 serum Na samples yielded the following relationship: y = 1.00x - 4.00 mmol/L. 101 urine Na samples yielded the following relationship: y = 1.01x + 0.97 mmol/. 103 serum K samples yielded the following relationship: y = 0.96x + 0.10 mmol/L. 105 urine K samples yielded the following relationship: y = 1.03x - 0.67 mmol/L. 108 serum Cl samples yielded the following relationship: y = 1.00x + 0.00 mmol/L. 102 urine Cl samples yielded the following relationship: y = 0.99x - 0.28 mmol/L.

Conclusion: The IMT assays for the Atellica CH Analyzer enable measurement of sodium, potassium, and chloride (Na, K, Cl) in human serum and urine with excellent precision and accuracy.

*Under development. Not available for sale.

B-042

Blood Collection Device Specific Bias in Hematocrit Measurements

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Background: Hematocrit and hemoglobin measurements are routinely measured for assessing risk for anemia in point of care (POC) settings using blood gas analyzers and in central laboratories using either blood gas analyzers or hematology analyzers. Hematocrit measurements in blood gas analyzers are based on electrochemical conductivity measurements and typically use heparin based blood collection devices. Laboratory based hematology analyzers measure hematocrit based on either electrical impedance or light scattering methods using EDTA based blood collection devices. The accuracy of Hematocrit measurements between different analyzers is critical for the commutability of results between POC and laboratory within a hospital system. Since the use of EDTA (hematology) or heparin (POC) based blood collection devices is common, this study aims to understand the impact of EDTA or heparin on hematocrit measurements.

Experimental Data: Blood samples were collected from 6 healthy volunteers in both heparin and EDTA based blood collection tubes. Blood samples from each collection device were run in duplicate on 2 GEM Premier 4000 analyzers for both hematocrit and hemoglobin measurements.

Results: As shown in the Table below, for each of the 6 donors, a systematic negative bias of 4-7% was observed between EDTA and Heparin tubes, with EDTA tubes measuring lower than heparin tubes for hematocrit. However, with hemoglobin measurements, a small random bias of no more than 0.5 mg/dL was observed, indicating that hemoglobin measurements were not affected by the anti-coagulant.

Conclusions: Blood samples collected in EDTA tubes measure 4-7 units low for hematocrit compared to blood collected in heparin tubes. Such bias can cause correlation differences between laboratory hematology and POC analyzers.

Donor#	1	2	3	4	5	6
EDTA - HCT, %	38.5	37.0	38.8	36.3	43.0	44.0
Heparin HCT, %	45.0	42.8	45.0	40.5	49.0	51.0
Delta (EDTA -Heparin)	-6.5	-5.8	-6.3	-4.3	-6.0	-7.0
EDTA tHB, g/dL	14.5	12.6	15.0	13.4	15.9	16.1
Heparin tHB, g/dL	14.5	13.1	15.1	13.7	15.9	16.3
Delta (EDTA -Heparin)	0.0	-0.5	-0.1	-0.3	0.0	-0.2

B-043

Comparison of Electrolyte and Hemoglobin Values between Four Blood Gas Analyzers and Central Laboratory Analyzers

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Background: Measurement of blood gases, electrolytes, lactate, hemoglobin and some other analytes are important in the rapid assessment of critically ill patients. These measurements are commonly performed at the point-of-care using blood gas analyzers (BGAs). With the increased availability of BGAs, it is common to find different types of BGAs within an institution. Because different BGAs use different methods, it is important to know how each instrument performs with respect to the reference method for that institution which is the central laboratory analyzer (CLA). This study compares the electrolytes sodium (Na) and potassium (K), and hemoglobin values measured by 4 different BGAs; ABL90 (Radiometer), i-STAT (Abbott Laboratories), GEM4000 and GEM3000 (Instrumentation Laboratory), used at our institution to the CLAs.

Method: A minimum of 40 left over samples collected during cardiovascular surgery (CVS) for blood gas and other analyte evaluations were analyzed by four blood gas analyzers (whole blood-based); electrolyte and hemoglobin values were compared to cobas 6000 (Roche Diagnostics) (plasma-based) and ADVIA 2120i Hematology System (Siemens Healthcare) (whole blood-based) values respectively. Cobas and ADVIA assays were used as the reference methods. In addition 21 excess whole blood samples submitted from different parts of the institution for hematology evaluation were analyzed by i-STAT and ADVIA. Results were compared by Deming regression and Bland-Altman plots.

Results: Correlation between methods for K was good with slopes between 0.97 and 1.06 and intercepts of -0.27 to 0.13 mmol/L for all 4 methods compared with the cobas. Observed bias for K versus cobas for all 4 methods ranged from 0.00 to 0.05 mmol/L. Correlation between methods for Na had slopes between 0.88 and 1.14 and intercepts of -16.4 to15.1 mmol/L for all 4 methods compared with the cobas. Observed bias for Na versus cobas for all 4 methods ranged from 1.1 to 3.3 mmol/L. Correlation between methods for hemoglobin had slopes between 0.94 and 1.16 and intercepts of -2.22 to 0.71 g/dL for all 4 methods compared with the ADVIA. Hemoglobin measurement by GEM3000 showed the biggest bias to the ADVIA at -9.21%, followed by the i-STAT at -4.38%, 2.28% for the ABL90 and 0.54% for the GEM4000. BGAs that use conductivity-based methods for the determination of hematocrit and hemoglobin can be influenced by substantial hemodilution which can happen during CVS. The negative bias observed with the GEM3000 and i-STAT could therefore be attributed to the use of samples from patients undergoing CVS. To test this assumption, 21 non-CVS samples were analyzed by i-STAT and ADVIA. Correlation between the i-STAT and ADVIA hemoglobin was good with a slope of 1.11 and intercept of -0.93 g/dL. The observed bias was 2.88%.

Conclusion: All 4 BGAs showed acceptable performance compared to the cobas for electrolyte measurement. The negative bias observed with i-STAT and GEM3000 hemoglobin results in CVS patients may confound the interpretation of the patient condition including the need for transfusion, if multiple methods are used within the same institution.

B-045

Analytical Performance of Creatinine Methods: A Proficiency Testing Provider Perspective

B. Aslan[1], P. M. Yip[2]. *[1]Institute for Quality Management in Healthcare, Toronto, ON, Canada, [2]University Health Network and University of Toronto, Toronto, ON, Canada*

Background: The National Kidney Disease Education Program (NKDEP) has developed recommendations to improve the standardization of creatinine measurements. Standard reference materials (SRM 967) and accuracy-based proficiency testing (PT) programs have been invaluable in achieving standardization efforts. The Institute for Quality Management in Healthcare (IQMH) provides ISO 17043:2010 accredited PT programs for creatinine. Data was analyzed for method bias and imprecision to evaluate changes in performance.

Methods: The retrospective review included 79 survey materials that were distributed between May 2005 and May 2015. Spiked human sera were used as PT specimens. Reference results were obtained using an IDMS-traceable measurement procedure. Participant results were assessed against the reference results with pre-determined criteria. Robust statistics based on ISO 13528:2005 were used to calculate peer group means and standard deviations to eliminate the effects of outliers. All participants used commercially-available assays traceable to IDMS.

Results: Creatinine concentrations in PT samples ranged between 0.72-8.94 mg/dL (64-790 µmol/L). Method CV and bias were investigated across 439 peer groups. Median (inter-quartile range) of the peer group CVs and biases are presented in Table 1. Overall, CVs and biases showed a slight negative correlation with reference results (r= -0.297 and -0.203, respectively). Therefore two separate groups were made based on creatinine concentration. Over time peer group biases declined which was more prominent at high concentrations ≥1.1 mg/dL (97 µmol/L). In this group, peer group medians decreased from 6.8% (2005) to 2.4% (2015). Peer group CVs did not change significantly in the group with values ≥1.1 mg/dL, while an increase was observed for values <1.1 mg/dL from 3.6% (2005) to 5.3% (2015).

Conclusion: Biases and CVs demonstrated variation between manufacturers for serum creatinine assays. While imprecision is not yet optimal for all methods, creatinine method bias has improved, most notably for concentrations above 1.1 mg/dL.

Peer group performance for creatinine assays during 2005-2015

	Creatinine <1.1 mg/dL			Creatinine ≥1.1 mg/dL		
Method	N	Median CV (%)	Median Bias (%)	N	Median CV (%)	Median Bias (%)
All Methods	46	5.2 (4.4-6.3)	2.9 (1.2-6.9)	23	3.2 (2.4-4.0)	1.7 (1.2-4.3)
Abbott	37	3.1 (2.2-4.0)	4.7 (2.2-8.5)	30	2.2 (1.7-3.3)	2.8 (1.2-5.4)
Beckman Coulter	46	4.4 (3.7-5.1)	5.8 (3.0-8.6)	30	2.0 (1.9-2.7)	2.0 (0.6-4.6)
Ortho	46	2.5 (1.9-3.2)	4.8 (2.3-9.9)	30	2.0 (1.8-2.3)	2.6 (1.6-5.6)
Roche	32	3.7 (2.6-5.4)	4.7 (2.2-6.2)	22	2.4 (1.8-3.2)	2.3 (0.6-3.5)
Roche (BMC)	42	3.4 (2.8-4.2)	2.5 (1.2-4.9)	28	2.4 (1.8-3.2)	1.6 (0.7-3.8)
Siemens (Bayer)	34	2.6 (1.9-3.8)	4.6 (2.4-8.3)	21	1.7 (1.4-2.3)	2.2 (0.7-3.8)
Siemens (DB)	30	6.2 (4.9-8.3)	7.6 (3.5-10.8)	18	3.5 (1.8-4.8)	3.5 (3.1-4.7)