Tuesday, July 31, 2018

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

Electrolytes/Blood Gas/Metabolites

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Study Of The Effect Of Storage Temperature And Serum-Clot Contact Time On Serum Sodium And Potassium Levels

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Background:
Sodium (Na^+) and potassium (K^+) are the most commonly measured electrolytes in the clinical laboratory. The energy dependent, sodium-potassium pump is the principle mechanism for active transport of these ions across cell membranes in-vivo. The existing glucose is spent over time in-vitro and leads to Na^+/K^+ pump failure when the separation of the blood clot from serum is delayed. Further delay in separation leads to passive diffusion of K^+ out of cells and sodium into the cells causing changes in the serum K^+ and Na^+ concentrations. Different shifts of Na^+ and K^+ have been observed when whole blood is stored at different temperatures. The delay in transport of samples from the site of collection and processing in the laboratory due to various reasons has been observed. Transport and storage of these samples at different temperatures are also not uncommon.
Objectives:
1.To find out the maximum, acceptable time delay between collection of blood and separation of serum and the optimum storage temperature that should be maintained during this period of delay for serum sodium and potassium assays. 2. To study the time and temperature dependent changes of serum potassium and sodium concentrations during this period of delay.
Method:
A descriptive cross-sectional study was performed using 50 volunteers who had been requested for serum sodium and potassium assays. Each specimen was analyzed using direct ISE method at different serum-clot contact time i.e.1, 2,3,4,6 & 24 hours and at 21-25^0 C and 2-8^0 C storage temperatures. All Quality management procedures were implemented during the analysis.
Results:
Serum potassium was initially decreased and then increased after 6 hours of serum-clot contact time and at 21-25°C and 2-8°C storage temperatures. But the initial decrease was not statistically significant ($p > 0.05$). Potassium was significantly increased at 24 hour of serum-clot contact time at both storage temperatures ($p<0.05$). There were a 16% increase of the serum potassium level at 21-25°C and a 36 % increase of the potassium level at 2-8°C after 24 hour of serum-clot contact time. The changes of serum sodium level at different serum-clot contact times and storage temperatures were statistically not significant ($p > 0.05$).
Conclusion:
The samples for serum electrolytes should be separated from the blood clot before 6 hours since collection and preferably stored at room temperature (21-25^{0}C) until such time. However, further studies are required to investigate the effect of serum-clot contact time at different points of 6 to 24 hour time interval which was not tested during this study to come to a conclusion on maximum acceptable period of delay in serum separation.

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Rapid determination of serotonin in human serum by ultra-performance liquid chromatography with fluorescence detection.

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Background: Serotonin is an important biogenic amine involved in the regulation of several physiological functions. The main diseases associated to high serum serotonin level are neuroectodermal tumors as carcinoid tumor. The objective of this work was to develop a simple and fast method for determination of serotonin in serum by UPLC with fluorescence detection for clinical diagnosis. **Methods:** 500 µL of serum were precipitated with 500 µL of trichloroacetic acid 10%. The solution was mixed for 60 seconds and centrifuged at 3000 rpm for 10 minutes. 600 µL of the supernatant were transferred to a glass tube and 400 µL of Tris(hydroxymethyl) aminomethane 1.0 mol.L^{-1} solution were added. Chromatography was performed on an Acquity UPLC system (Waters) equipped with an Acquity BEH C18 column (50 mm x 2.1 mm x 1.7 µm) - Waters held at 30°C and isocratic mobile phase. Detection was performed on a Waters fluorescence detector operated with excitation at 292 nm and emission at 337 nm. **Results**: The chromatographic run time was approximately 1.5 min. Linear range obtained from 20 to 1000.0 ng.mL^{-1} and dilution was validated for samples that exceed the curve in 4 times. The calculated Limit of detection was 6.8 ng.mL^{-1}.Imprecision intra-day was less than 1.5 % and inter-day was less than 3.8%. **Conclusion**: The UPLC method has been developed and validated successfully for the quantitative analysis of serotonin in serum and has been implemented in clinical routine laboratory.

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Performance Evaluation of the Atellica CH Ca, GluH_3, K, Na, Cl, CO2, UN_c, and Crea_2 Assays versus the Dimension EXL Assays

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Background: The purpose of the investigation was to evaluate the analytical performance of the Atellica® CH Analyzer vs. the Dimension® EXL™ Integrated Chemistry System for various chemistry assays, including Calcium (Ca), Glucose Hexokinase (GluH_3), Potassium (K), Sodium (Na), Chloride (Cl), Carbon Dioxide (CO_2), Urea Nitrogen (UN_c), and Creatinine (Crea_2). These assays are among the most commonly ordered tests in hospitals and outpatient clinics, as they provide a broad snapshot of the patient's current health. **Method:** Method comparison was used to evaluate performance. Studies were conducted according to CLSI EP09-A3, with patient-sample results compared to results from the Dimension EXL system. **Results:**

Assay	Regression Equation	r	Comparative Assay
Ca (serum)	y = 1.05x - 0.7 mg/dL	0.998	Dimension EXL CA
Ca (urine)	y = 1.07x - 1.3 mg/dL	0.996	Dimension EXL CA
GluH_3 (serum)	y = 0.97x - 5 mg/dL	0.998	Dimension EXL GLUC
GluH_3 (urine)	y = 1.00x - 7 mg/dL	0.991	Dimension EXL GLUC
GluH_3 (CSF)	y = 0.97x + 1 mg/dL	0.991	Dimension EXL GLUC
K (serum)	y = 0.93x + 0.2 mmol/L	0.999	Dimension EXL K
K (urine)	y = 1.09x - 0.8 mmol/L	1.000	Dimension EXL K
Na (serum)	y = 1.00x - 1 mmol/L	0.998	Dimension EXL NA
Na (urine)	y = 1.11x - 2 mmol/L	0.999	Dimension EXL NA
Cl (serum)	y = 1.00x + 2 mmol/L	0.996	Dimension EXL Cl
Cl (urine)	y = 0.98x + 0 mmol/L	0.997	Dimension EXL Cl
CO_2	y = 1.10x + 0 mEq/L	0.989	Dimension EXL ECO_2
UN_c (serum)	y = 1.03x + 0 mg/dL	0.999	Dimension EXL BUN
UN_c (urine)	y = 0.93x - 10 mg/dL	0.999	Dimension EXL BUN
Crea_2 (serum)	y = 0.98x - 0.02 mg/dL	1.000	Dimension EXL CREA
Crea_2 (urine)	y = 0.87x + 3.45 mg/dL	0.998	Dimension EXL CREA

Conclusions: Method comparison results for these chemistry assays showed acceptable agreement with an on-market comparative analyzer.

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Ion measurement by direct ISE vs. indirect ISE. Analytical performance evaluation according to different quality requirements.

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Background: For patient safety, medical laboratories must offer accuracy in their results. Small results variation for sodium, potassium and chloride can lead to incorrect patient evaluation or treatment. The most widely used method is ion selective electrode (ISE), by direct potentiometry (direct ISE) or indirect potentiometry (indirect ISE). **Objective:** To evaluate and compare the performance of direct and indirect ISE for three ions: sodium (Na), potassium (K) and chloride (Cl), in terms of Total

Error (TE) and sigma performance (σ). **Materials and methods:** Retrospective study based on internal quality control data recorded in Unity Real Time® interlaboratory program (BioRad) during August 2017 to January 2018. Each analyte's laboratory and peer group mean (x) and standard deviation (s) were obtained for two concentration levels of control samples: normal (N) and pathological (P). They were measured by indirect ISE in three Cobas c501 autoanalyzers and in two blood gas platforms by direct ISE, Cobas b221 from Roche Diagnostics (Mannheim, Germany) at two CEMIC´s University Hospitals. Total laboratory error (TE_L) and 6 Sigma performance (σ) were calculated for each analyzer. For methods' performance evaluation for each analyte, TE_L was compared to allowable CLIA total error (TE_a) and Biological Variation (BV) requirements. Method decision graphs combining BV specifications and 6 Sigma model were prepared with calculated imprecision and bias data. **Results:** For the two methods in both concentration levels, K reached laboratory established TEa (0.5 mEq/L) and presented an acceptable sigma value, greater than 6 for the two direct ISE analyzers; for indirect ISE, the obtained sigma was between 3 and 5. BV minimum requirement (8.4 %) was reached by all methods. For Na, only the two direct ISE analyzers reached the established TEa (4mEq/L) and presented an acceptable Sigma, between 4 and 6 Sigma, both for normal and pathological levels. BV minimum requirement (1.1 %) was not reached by any method. Cl had a similar behavior to Na. TEa (5.0%) was reached for P level only by direct ISE methods showing an acceptable Sigma, between 4 and 5. BV minimum requirement (2.2 %) was not reached. Method decision graphs showed that for Na and Cl, BV minimal requirements can only be reached by analytical procedures that present 6 Sigma performance. **Conclusion:** Routine laboratories' methodologies available today for ion measurement do not always meet the established quality specifications. Laboratories must monitor methods' performance to evaluate error and sigma performance over time. As results reflect the state of the art for these ions' measurement systems, manufacturers are responsible for the improvement of the methods they offer.

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Correlation of Serum Ionized Calcium to Corrected Total Calcium Generated by Two Different Formulae

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Background
In many centres within Nigeria, evaluation of calcium levels is undertaken in the form of serum/plasma total calcium(tCa). Although there is increasing availability of ion selective electrodes for ionized calcium(iCa) estimation, few centres routinely measure it. In view of the role of plasma albumin levels on tCa, formulae are used to generate corrected serum/plasma total calcium(ctCa)**,** for proper clinical interpretation. Traditionally, the conventional formula, attributed to Payne, has been used across many centres but about a decade ago, locally derived formulae that utilized albumin and total protein respectively, was published with little adaptability to clinical practice. There is a need to assess the degree of agreement between serum the physiologically active ionized calcium and the corrected total plasma calcium using the conventional and locally derived formulae respectively, as this can impact clinical interpretations of calcium status especially in the pregnant state. In this study we set out to determine the degree of correlation between measured serum iCa and ctCa derived from three different formulae adjusting for serum albumin concentration or total protein..
Methods
Two hundred and forty apparently healthy women of reproductive age attending six primary-level health care facilities in Abuja, Nigeria were recruited for the study. Ethical clearance was gotten from Federal Capital Development Authority ethical review committee. Blood samples were drawn after obtaining informed consent, in glass syringes and serum separator bottles. Laboratory analyses were by ion-selective electrode method(pH and ionized calcium) and O-cresolphthalein complex method(total calcium). The conventional formula by Payne utilizing serum albumin concentration and two locally derived formulae by Ogunkolo involving serum albumin and total protein respectively were used to generate ctCa. Analysis was by Pearson's correlation.
Results: The mean percentage of ionized calcium (iCa) to corrected total Ca (corrTCa) was 43.7% , though the range of percentage of iCa) to ctCa was across a wide spectrum of subject values (26-65%.) Assessment of the association of iCa to ctCa values showed positive correlation (r= 0.54, 0.41 & 0.29) for the three different formulae but none showed a strong correlation. However the "best fit" or highest correlation coefficient was noted with the conventional formula of Payne, though it was only a fair level of association(r= 0.54). The locally derived formulae by Ogunkolo had lower correlation coefficients than the former; in fact the formula utilizing total protein instead of albumin, was very weak in terms of correlation to iCa.(r=0.29 vs 0.41).
Conclusion: These study findings are in agreement with many other studies which have shown poor correlation between iCa and ctCa, underscoring the importance of measurement of iCa especially in severe and critical disorders where efficient calcium status determination is vital. However, in the event that measurement of iCa is not feasible, it is important that tCa measurement be corrected/adjusted by validated formulae suited to the given environment. This is imperative because it has been shown that ctCa -derived equations using local laboratory data may differ from previously published equations as was the case in our study.

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Comparison of Five Automated Serum Ferritin Immunoassays

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Background: Serum ferritin tests measure the amount of stored iron in the body and can be used for diagnosing iron-related disorders. The objective of this study was to compare the analytical performance of five automated immunoassays for the quantitation of serum ferritin. Linearity, precision, and method comparison studies were performed with the Siemens ADVIA Centaur, Beckman AU5800, Abbott Architect i2000, Siemens Immulite 2000 and Siemens BNII methods. Additionally, recovery of the World Health Organization's 3rd international standard (WHO IS) for ferritin (94/572) was assessed to further compare the performance of methods standardized to different generations of WHO reference materials. **Methods:** Linearity was evaluated by combining two serum patient pools, one with a high ferritin concentration and the other with a low concentration, to create several samples with final concentrations that spanned the analytical measurement range (AMR). Precision studies were performed using 3 levels of MAS Liquimmune QC material (Thermo Fisher Scientific, Waltham, MA, USA). Patient specimens with similar ferritin concentrations were pooled to generate 40 samples with enough volume to be run on all 5 test methods in duplicate. Recovery studies were performed by running the WHO 3rd ferritin IS straight as well as spiking it into serum at varying concentrations to determine if the percent recovery was consistent across the measurable range of the assay. **Results:** Target values for the linearity samples were individually calculated for each method using the lowest and highest measured concentrations that fell within the AMR. Linear regression analysis revealed that all 5 methods had similar slopes ranging from 1.00-1.04, intercepts ranging from -2.60 to 30.52, and correlation coefficients of 0.99. The within run and total imprecision was acceptable (coefficient of variation <10%) for all methods. Patient sample correlations revealed calibration differences that were most apparent between methods standardized to the 1st and 2nd WHO IS. Recoveries of the 3rd IS were 166%-187% for the method claiming traceability to the 1st IS (Architect), 94%-125% for methods claiming traceability to the 2nd IS (Centaur, Immulite, BNII), and 98%-109% for the method claiming traceability to the 3rd IS (AU). The Centaur and Immulite recovery data demonstrated greater recovery at higher ferritin concentrations. For the Architect and AU methods, decreased recovery was observed as the ferritin concentration increased. No appreciable ferritin recovery trend was noted for the BNII. **Conclusion:** Overall, the 5 immunoassays correlated well with each other despite being standardized to different generations of the WHO ferritin reference materials. The small differences observed in ferritin concentrations can likely be attributed to differences in calibrator standardization, antibody specificity, and ferritin isoform composition. The performance of the Architect method was the most different from the group, demonstrating a positive bias for patient samples relative to the group mean as the sample concentration increased as well as unusually high recoveries of the IS.

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Study of The Outcome Of Dysnatremia In ICU Hospitalized Patients

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Background: Dysnatremia is one of the common electrolyte abnormality in clinical settings either in general admissions or in ICU, with more prevalent in ICU settings. Dysnatremia if not promptly address may result in the increase of patient's morbidity, mortality as well as the total duration of hospital stay. Hypo/hypernatremia can occur due to variety of clinical conditions and also due to iatrogenic causes during patient's hospital stay. This study aims at revealing the frequency of dysnatremia in our ICU settings, the common etiologies behind this abnormality along with the length of ICU stay as well as mortality associated with this disorder. **Method:** A total of 102 patients admitted under ICU, in Tribhuvan Univer-

sity Teaching Hospital, were enrolled in this study over 6 months period. Patients fulfilling the inclusion criteria were involved. SPSS ver. 21.0 was used to analyze the data. ANOVA was used to find mean differences and Spearman's, chi square tests was used to establish the correlation between study variables. **Results:** Of total 102 patients with minimum age 18 years and maximum age of 88 years (mean age 57.78 ± 16.64 years), 65 (64%) patients were male and 37 (36%) were females. 40.1% of study population was found to have hypertension and 26.5% were found to have diabetes mellitus. The frequency of dysnatremia in this study was 0.225 (22.5%). Hypernatremia was present in 21% of cases and hypernatremia was seen in 2%. The mean serum potassium level was found to be higher in patients with dysnatremia than in eunatremic patients. No statistical significance was seen between dysnatremia and the comorbid conditions in this study. The mean duration of ICU stay for patients with normal serum sodium level was 5.01±0.83 and for patients with dysnatremia was 6.69±1.9. To evaluate the correlation between dysnatremia and length of ICU stay, spearman's correlation was used, which was statistically significant. Most of the patients with dysnatremia were asymptomatic (52.2%). However in symptomatic patients (47.8%), the most common symptom was confusion (54.5%). In this study, Central Nervous system was involved most which was present in 46% of study population and respiratory system involvement was found in 20%, which represented the second most common system involved. Dysnatremia was most commonly associated with stroke (33%). Strong association was also seen with Pneumonia with severe sepsis (20%). Malignancy (GI/lung/Brain) were seen in 12% of the dysnatremic population. Mortality rates associated with dysnatremia comprised 21.7% of the dysnatremic study group as compared to 17.6% of total ICU mortality. **Conclusion:** This study showed that dysnatremia occurs in ICU hospitalized patients and the length of ICU stays increases with this electrolyte abnormality. So prompt identification and management of dysnatremia should be done. However, further studies are required to reinforce this idea and the effects of early treatment of dysnatremia in ICU patients should be clarified in a prospective interventional trial.

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Discrepancies in Electrolyte Measurements by Direct and Indirect Ion Selective Electrodes due to Interferences by Proteins and Lipids

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Background: Modern laboratories use both direct and indirect Ion selective electrodes (dISE and iISE) for electrolytes estimation and often use the results interchangeably. However, studies report discrepancy in results between the two methods, mostly due to higher protein or lipid levels. However, no study reports the combined effects of proteins and lipids on electrolyte measurement. Here we study the effect of high protein and lipid levels simultaneously, on sodium (Na) and Potassium (K) levels obtained by dISE and iISE in patient samples. **Methods:** 195 serum samples were analyzed for Na and K on Roche Modular P800 by iISE and on XI-921, Caretium by dISE. Serum total protein, cholesterol and triglyceride were measured colorimetrically on Roche Modular P800. Percentage difference was calculated for serum sodium [%Diff_Na = (Na^+_{dISE}- Na^+_{iISE})*100/ Na^+_{dISE}] and similarly for potassium. Comparison was done between patient subgroups with high or normal serum proteins and lipids using Mann Whitney U test. **Results:** Table1 shows the percent differences obtained between dISE and iISE in Na and K estimations. Subgrouping was done on the basis of cut-offs of serum protein (8g/dL), cholesterol (300mg/dL) and triglycerides (<300mg/dL) levels. Significant %_Diff were observed for both Na (p= 0.005) and K (p=0.003) levels by dISE and iISE between samples with protein levels <8g/dL and ≥8g/dL. However, effect of triglyceride levels were evident only on %Diff_K (p=0.047). Cholesterol levels did not affect the %Diffs significantly nor did the combined effect of both lipids. However, %Diffs of both Na and K were found to be significantly affected by levels of protein and lipids when considered together. **Conclusion**

Summarily, interchangeable use of electrolyte results from direct and indirect ISE is not advisable in a setting of hyperproteinemia (≥8g/dL) or hypertriglyceridemia (≥300mg/dL), more so when they are coexistent.

Table 1: %Differences obtained between direct and indirect ISE electrolyte estimations in patient subgroups

Patient subgroups	No. of patients	%Diff_Na	p-value	%Diff_K	p-value
S. TG <300 mg/dL	139	3.57 (-9.94, 13.92)	0.292	2.22 (-13.51, 16.67)	0.047
S. TG >=300mg/dL	56	4.38 (-4.74, 10.13)		3.96 (-5.71, 14.81)	
S. Chol <300 mg/dL	150	3.68 (-9.94, 13.92)	0.312	2.46 (-13.51, 16.67)	0.787
S. Chol >=300mg/dL	45	4.10 (-4.74, 10.33)		3.33 (-5.71, 14.81)	
S. protein <8g/dL	139	3.43 (-4.74, 10.33)	0.005	2.22 (-13.51, 16.67)	0.003
S. protein >=8g/dL	56	5.05 (-9.94, 13.92)		4.59 (-8.00, 16.07)	
S. Lipids <300mg/dL	125	3.57 (-9.94,13.92)	0.282	2.43 (-13.51, 16.67)	0.197
S. Lipids >=300mg/dL	70	4.14 (-4.74, 10.33)		3.39 (-5.71, 14.81)	
S. Protein OR S. Lipids high	124	4.41 (-9.94, 13.92)	<0.001	4.12 (-8, 16.07)	<0.001
S. Protein & S. Lipids normal	71	2.65 (-4.32, 9.49)		0.00 (-13.51, 16.67)	

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Long-Term Sigma Metrics for Na, K and Cl Assays on Abbott Clinical Chemistry Analyzers Based on External Proficiency Surveys

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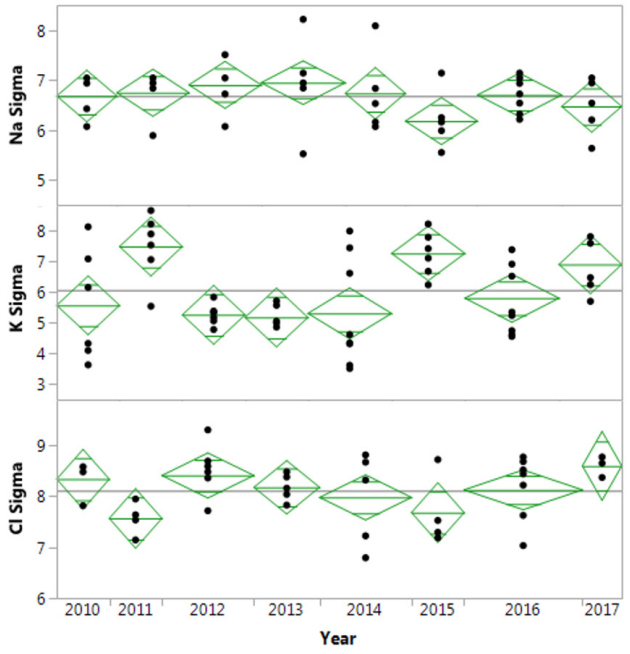
Background: Abbott clinical chemistry analyzers, including ARCHITECT® and Alinity™, use Integrated Chip Technology (ICT) consisting of solid-state ion-selective electrodes (ISE) to measure sodium, potassium and chloride simultaneously in serum, plasma or urine samples. The objective of this study was to assess the long term analytical performance of Abbott serum ICT assays (Na^+, K^+ and Cl^-) using Sigma Metric Analysis based on results from External Quality Assurance (EQA) surveys. **Methods:** Proficiency testing data for Abbott ARCHITECT were obtained from an American EQA program from 2010 to 2017. Sigma metrics were calculated using the equation: Sigma= (TEa(%)-Bias(%))/CV(%), per Westgard QC using RiliBäk TEa targets, where the bias was estimated by comparing Abbott ARCHITECT group mean with ISE diluted Method Mean, and the CV was from Abbott ARCHITECT group with an average of 425 participants. As the Method Mean is mainly determined by the other 90% of non-Abbott ARCHITECT participants, the bias may be overestimated. **Results:** The figure shows the sigma value for each proficiency sample. In serum sodium normal range (136-145 mmol/L), Abbott ARCHITECT Sodium assay had sigma values ranging from 5.5 to 8.2, with an average sigma of 6.7. In serum potassium normal range (3.5-5.1 mmol/L), Abbott ARCHITECT Potassium assay demonstrated sigma values ranging from 3.5 to 8.7 with an average sigma of 6.1. In serum chloride normal range (98-107 mmol/L), the sigma metrics for Abbott ARCHITECT Chloride assay ranged from 6.8-9.3 with an average value of 8.1. **Conclusion:** For normal serum proficiency samples over the studied period of 8 years, Abbott ICT assays demonstrated greater than 6 sigma performance on average, which translates to World Class Quality. This indicates that ICT assays on Abbott Clinical Chemistry Systems consistently provide sodium, potassium and chloride results with excellent accuracy and precision, and contribute to the delivery of measurably better healthcare.



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Evaluation of a serum ammonia assay for urinary ammonium measurement to assess renal acidification impairment

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Background: Urinary ammonium (NH_4^+) output can help predict clinical outcomes in hypertensive kidney disease (Raphael et al., JASN, 2017). Low NH_4^+ excretion is associated with impaired renal acidification and subsequent development of acidosis. Direct measurements of urinary NH_4^+ are more accurate than NH_4^+ estimates from urine anion and osmolar gaps. While FDA-approved urinary NH_4^+ assays are not readily available on automated chemistry analyzers, existing serum ammonium assays can be adapted by implementing an on-board sample dilution. For clinical relevancy, a urine NH_4^+ assay should have a measurement interval of 1-50 mmol/L. In this study, a preliminary validation of a routinely available serum ammonium assay (Randox, Ireland) was conducted on an Architect *ci*8200 analyzer for the purpose of urinary NH_4^+ measurement. **Methods:** For measurement interval determination, a specimen dilution of 1:40 was utilized. Precision (4 days, n = 15 at each level (EL)), linearity (n=3 EL), recovery (n=3 EL), reportable range (n=3 EL) and limit of quantitation (n = 15 EL) were assessed by analyzing 7 NH_4^+ levels (0.7 – 45.0 mmol/L) in 0.9% saline. Recovery studies (n = 3 EL) were conducted by spiking 6 NH_4^+ levels (0.7 – 22.5 mmol/L) into patient urine matrices. **Results:** Precision (%CV) was determined to be < 20% for values 1.4 – 3.4 mmol/L and < 6% for values 3.5 – 44.2 mmol/L. The limit of quantitation (20% CV threshold) was 1.4 mmol/L. The assay was determined to be linear in the range of 0.7 – 45.0 mmol/L with a slope of 0.99 and intercept of 0.79. Recovery in saline was 126% - 131% at 1.4 – 2.8 mmol/L and 118% - 98% at 5.6 – 45.0 mmol/L; however, recovery in urine was 97% - 114% at 1.4 – 2.8 mmol/L and 114% - 117% at 5.6 – 22.5 mmol/L. The acceptable measurement interval (total allowable error of 1.5 mmol/L or 10%; LOQ set at 20% CV) was determined to be 1.4 – 45.0 mmol/L. **Conclusion:** Preliminary investigation demonstrated adequate performance of the Randox assay for determination of urinary ammonium levels. To fully validate this assay for experimental use, a matrix-appropriate evaluation and accuracy assessment against a clinically validated method will be required.

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Use of a new data mining technique demonstrates highly predictable periods of accurate and less accurate point of care testing

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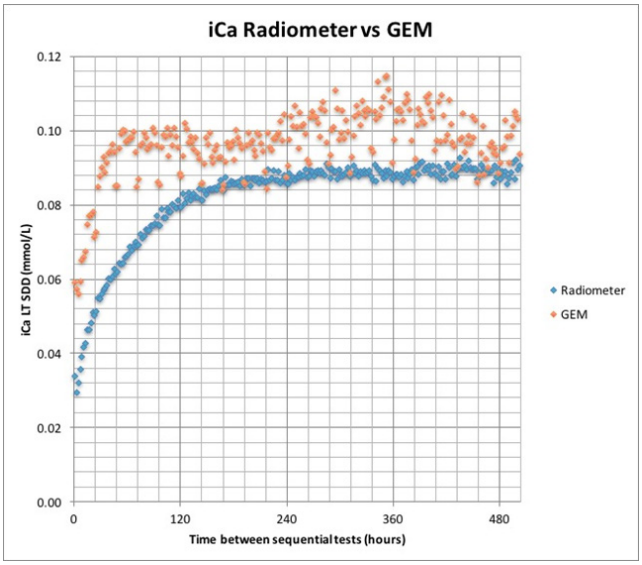
Introduction: Analytical systems with built in quality control (QC) tend to analyze minimal external QC due to the additional expense and effort as well as the disconnect between instrument status and out of limits external QC. For many of these devices, the user has little comprehension of the internal QC error detection capabilities. **Methods and Materials:** We have developed a methodology that evaluates the variation of repeated, sequential intra-patient data to yield measures of biologic, preanalytic and analytic variation. The method involves procuring large series of patient data available in laboratory information systems and grouping consecutive intra-patient result pairs into period bins that reflect the interval of time between consecutive tests. **Results:** The Figure shows the long term variation as measured by the standard deviation of duplicates (SDD) for all possible within patient iCa pairs separated by 2 hour time intervals from 2 hours to 500 hours. The two years of patient data were those of intensive care unit (ICU) patients from the Calgary Foothills Hospital or the Edmonton University of Alberta Hospital who had blood gases and electrolytes measured by tandem Instrumentation Laboratory GEM 4000 or Radiometer ABL 800 instruments, respectively. The Figure demonstrates distinct patterns: 1) the lower variation of the Radiometer iCa, 2) the higher variation at the shortest interval for both the Radiometer and GEM, 3) the regular increase in variation of the Radiometer, 4) regular, short term 24 hour decrements in the GEM that approach those of the Radiometer and 5) generally increased variation in the GEM beginning at the tenth day.**Conclusions:** For the periodic (every 24 hours) ability of the GEM systems to achieve the low Radiometers' variation, we hypothesize that the intermittent, excellent variation is associated with a process that is repeated every 24 hours and coincides with the ICU's early morning run of patient samples.



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An equation for correction of potassium in hemolyzed specimens

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Background: Clinical laboratory tests play a significant role in medical decision making. Of the factors that may affect accuracy of laboratory results, in vitro hemolysis is the most frequently encountered. While several analytes are subject to such interference, potassium (K) is probably the most widely recognized one. In this study we developed and validated a simple equation that may be used to accurately estimate actual K concentration in hemolyzed specimens. **Methods**: Proposed equation is: eK= K-HI/([Hgb]*10)*Hct, where K is measured potassium, HI is hemolysis index, corresponding to plasma hemoglobin concentration in mg/dL, Hgb is whole blood hemoglobin in g/dL and Hct is hematocrit. A total of 1072 de-identified, residual pa-

tient samples collected in lithium heparin plasma separator tubes were used for this study. The specimens were split into two major groups: a baseline group (n = 544), with minimal to no hemolysis interference (HI <100), and a test group (n = 528), consisting of matched hemolyzed samples with HI 100-500. The eK values for test samples within 0.5 mmol/L of corresponding baseline K values were considered acceptable, as per CLIA defined total allowable error (TAE). To ensure that eK values are not skewed by external factors that may change K level in vivo, we generated a subset of 72 matched patient samples, excluding patients on KCl treatment, IV insulin, acidosis or those undergoing a surgical procedure requiring anesthesia. More stringent acceptance criteria of TAE of 8.4% (based on inter- and intra-individual variability) and HI of 50 for baseline samples were also used. **Results**: Our initial analysis of over 500 matched specimens demonstrated that K levels may be successfully corrected in hemolyzed specimens with HI up to 400. However, significant number of outliers falling between 0.5 and 1.0 mmol/L was observed, suggesting that patients K levels may have changed between the baseline and test specimen collection due to treatment or other medical intervention. The analysis of a more stringently extracted patient subset where all the potential factors (intervention, treatment, etc) that may change K levels clinically were excluded, revealed that for 64 of 72 (89%) patient samples eK was within 8.3% of baseline K. It is also of note that for 96% (69/72) samples, eK value was within 0. 5 mmol/L of baseline and, in 65% (47/72) cases, eK value within 0.25 mmol/L of baseline. **Conclusions**: Accurate and timely estimation of potassium in the setting of hemolysis has a potential to significantly improve quality of patient care by reducing the specimen rejection rate and minimizing delay in necessary interventions. We have shown that by incorporating patient's own hematological parameters (Hgb and Hct), intra-cellular K contribution can be calculated and used to adjust measured K in the setting of in vitro hemolysis. Future studies include clinical validation of this equation on both critically ill and normal patient populations, using both serum and plasma specimens.

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Method Comparison of Radiometer ABL90 FLEX versus ABL835 FLEX for Bilirubin in Arterial, Umbilical Cord, and Venous Whole Blood from Neonatal Subjects

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Background: Total bilirubin (tBil) is routinely measured in neonatal patients to monitor jaundice and guide clinical management. Blood gas analyzers with capability to measure tBil in whole blood offer an option to monitor tBil in neonates using low sample volume, which may be especially useful in neonatal intensive care units. An additional advantage may be conferred if non-laboratory personnel such as nurses and respiratory therapists can perform the analyses on analyzers close to patients. The objective of the study was to verify that the neonatal tBil measured on the Radiometer ABL90 FLEX analyzer (ctBil parameter) is a suitable replacement for current test method for arterial and venous whole blood samples, using the ABL835 FLEX as the predicate device. **Methods:** The study was performed at two academic medical centers in the United States with Institutional Review Board approvals. tBil was measured in arterial or venous whole blood by clinical laboratory technician or technologist on the ABL835 FLEX as part of routine clinical care. If there was sufficient residual specimen, non-laboratory personnel (e.g., nurse or respiratory therapist) measured tBil on the ABL90 FLEX. Spiked umbilical cord blood specimens were used for the remainder of the comparisons. **Results:** The table below shows the method comparisons between ABL835 FLEX (predicate) and ABL90 FLEX.

	Arterial	Venous	Cord (Spiked)
N	44	42	17
R	0.983	0.991	0.997
Equation	Y = 0.98x -0.54	Y = 0.98x -0.32	Y = 0.97x -0.58
Standard error	0.53	0.62	0.68
Range (mg/dL) - ABL90	1.7 - 13.6	1.6 - 28.1	1.8 - 37.3
Range (mg/dL) - ABL835	2.3 - 13.3	2.1 - 29.0	2.8 - 38.2

The ABL90 FLEX has limit of blank of 1.1 mg/dL, limit of detection of 1.6 mg/dL, and limit of quantitation of 1.6 mg/dL. The ABL90 FLEX requires 65 µl sample for tBil when used in syringe mode compared with approximately 95 µl in the ABL800 FLEX series. **Conclusion:** There was excellent correlation between ABL835 FLEX and ABL90 FLEX for measurement of tBil in neonatal patients across a wide range of tBil concentrations. ABL90 FLEX tBil measurements may be performed by non-laboratory personnel, providing more options for testing near patient locations.

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Quantitation of Glycocholic Acid and Unconjugated bilirubin in Human Bile for Gall Bladder Diseases by Flow-injection MS/MS Using Standard Addition.

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Background:
Bile and its constituents are directly in contact with the biliary epithelium, making bile an ideal fluid for quantification. The emergence of endoscopic retrograde cholangiopancreatography has made sampling of bile possible without surgery. Recent findings reveal that changes in the levels of Glycocholic Acid (GCA) and Unconjugated Bilirubin (BLB) in bile are associated with Cholangiocarcinoma and Cholelithiasis respectively. Hence, we have developed the first quantification method for determination of GCA and BLB in human bile using dilute and shoot flow-injection MS/MS with standard addition to avoid column carry over and matrix effects.
Methods:
Bile samples were first diluted with methanol: DMSO (1: 3) and aliquots were used to prepare calibrators (12.5-200.0 ng/mL) by spiking GCA, BLB and internal standard for standard addition. The samples were then centrifuged and 10uL of supernatants were transferred to auto sampler vials. Flow Injection was performed by pumping 90% methanol into the ESI source of triple quadrupole tandem mass spectrometer by-passing the column compartment of HPLC at 0.3 mL/min for 2.5 minutes. Quantitation was done in negative MRM with mass transitions for GCA, BLB and IS set at 464.1-74, 583.6-285.3 and 401.2-249.1 respectively. Standard addition plots were made using peak area ratios to determine concentration of analytes in the samples.
Results:
We have developed a dilute-and-shoot FI-MS/MS method for the quantitation of GCA and BLB in human bile and applied it to clinical samples. Our method was validated according to the FDA guidelines. Additional transitions were monitored throughout the analysis for both GCA and BLB to ensure specificity. The method was found to be linear with a mean correlation coefficient of 0.99 for both GCA and BLB in the range of 12.5-200 ng/mL. The %RSD for the LLOQ was less than 15%. Accuracy, intra and inter-day precision were determined using three QCs at 31.25, 70.71 and 160.00 ng/mL. The %RE of intra, inter assays for GCA were 7.38-14.88, 9.52-14.80 and BLB were 0.09-8.67, 0.52-2.66 respectively. The %RSD of intra and inter-assays for GCA were less than 7.23 and 9.02. The %RSD of intra and inter-assays for BLB were less than 10.81 and 14.07. The absolute and relative matrix effects matrix effects of GCA were less than 9.72 and 12.6 respectively. The absolute and relative matrix effects matrix effects of BLB were less than 9.91 and 1.86 respectively.
Conclusion:
Our method is very advantageous in a clinical setting. First, there is no need for sample purification prior to analysis. Our method is sensitive even after 800,000 times dilution. Standard addition minimizes matrix effects caused by matrix components if at all present in diluted samples. Flow-injection eliminates the problem of column carryover which would otherwise require high solvent usage for the maintenance of a clean column. Third, the method is very fast with a run time of 2.5 min enabling high through put analyses of over 570 samples a day.