Wednesday, July 30, 2014

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

Automation/Computer Applications

B-001

Reference values study for the urinalysis parameters measured in the sysmex uf1000

N. Z. Maluf, C. F. d. Pereira, E. V. V. Oliveira, L. L. Jaques, S. B. Ferreira, R. Balherini, M. d. Menezes, S. D. S. Vieira. *DASA, Barueri, Brazil*

Background: The urinalysis department of our Laboratory implanted the Sysmex UF1000 for the urinary cells analysis. The designed new sample flow includes the Roche Urisys 2400 for biochemical analysis and UF1000 for the urine sediment analysis. The methodology used by this equipment is flow cytometry. It performs the analysis and counting of erythrocytes, leukocytes, epithelial cells (EC), cylinders, crystal, mucus, sperm, bacteria (Bact) and yeasts. Currently, all the literature reference values for these parameters are based on the analysis by optical microscopy, which was the previous methodology used in the lab. Thus, we need to review and standardize the references values of these parameters in our laboratory. The objetive is to evaluate and standardize the reference values of the UF1000 measured parameters.

Methods: We evaluated 100 healthy individuals with no disease and medications or vitamins, to standardize the reference values for erythrocytes, leukocytes, cylinders, epithelial cells and bacteria. These individuals are FTEs from the laboratory and we ask them to participate in this study. For the statistical analysis we use dispersion graph and Gaussian distribution.

Results: After analyzing the results and statistics through the ABC curve, we found the results that is on the table. We also noted that the RBC values between 13.4 to 28.0 x 10^3/µL should be reassessed and compared with optic microscopy.

Conclusion: We concluded that the reference values for the UF1000 were higher than the obtained by the optical microscopy methodology. It uses larger amounts of sample and counts a greater number of cells, what allows it to be more accurate. After this study and with the continuous experience of monitoring patients in the last months, the new reference values got a good acceptance by the Lab professionals and physicians.

Parameters	Value - UF1000
RBC	13,3x10^3 /µL
WBC	31,5x10^3/µL
EC	3,6/µL
CASTS	1,07/µL
BACT	26,4x10^3/µL

B-003

QMS Tacrolimus Assay for the Beckman Coulter AU480, AU680, and AU5800 Clinical Chemistry Analyzers

C. Wong, D. Cheng, A. Thao, L. Ye. *ThermoFisher Scientific, Fremont, CA*

Background: The objective of this study is to evaluate the performance of Beckman Coulter AU480/AU680/AU5800 clinical chemistry analyzers for the quantitative determination of tacrolimus in human whole blood used in the management of kidney, heart, and liver allograft patients receiving tacrolimus therapy. Monitoring for tacrolimus is important for effective use to prevent allograft rejection following organ transplantation. The measurement of tacrolimus concentrations in whole blood in conjunction with other laboratory data and clinical evaluation can optimize immunosuppressive effect and minimize adverse side effects for patients.

Methods: The QMS Tacrolimus assay is a liquid stable particle-enhanced turbidimetric inhibition immunoassay. The assay is based on competition between free tacrolimus in the sample and tacrolimus derivative coated onto a micro-particle for anti-tacrolimus antibody binding sites. The tacrolimus-coated micro-particle reagent is rapidly agglutinated in the presence of anti-tacrolimus antibody reagent and the rate of agglutination is inversely proportional to the tacrolimus concentration in the sample. The rate of absorbance change is measured photometrically and is directly proportional to the rate of agglutination of the particles. A concentration-dependent classic agglutination inhibition curve can be obtained to determine the tacrolimus concentration in the sample. The assay consists of two reagents and an extraction solution for sample pretreatment. The calibrators contain tacrolimus in the human whole blood matrix at concentrations of 0, 2, 5, 10, 20, and 30 ng/mL.

Results: The performance of the QMS Tacrolimus Assay was evaluated on the Beckman Coulter AU480/AU680/AU5800 analyzers. All studies were evaluated using CLSI guidelines. On the AU480 and AU5800, four levels of Tacrolimus controls were used in the studies. The precision ranged from 4.3 %CV to 4.2 %CV for within-run and 7.2 %CV to 4.8 %CV for total run. Linearity was measured and confirmed over a range of 1.0 ng/mL to 28.7 ng/mL. The functional sensitivity was observed at 1.0 ng/mL. Patient correlation studies: AU480=1.0(AU680) - 0.08 (N=107, r=1.00), AU5800=1.02(AU680) + 0.23 (N=108, r=1.00). On the Beckman Coulter AU680 analyzer, three levels of Tacrolimus spikes and patient pools with lowest concentration at 2.9 ng/mL and highest at 25.0 ng/mL were tested twice per run, two runs per day for 20 days. The precision ranged from 1.8 %CV to 4.9 %CV for within-run and 3.9 %CV to 7.5 %CV for total run. Linearity was measured and confirmed over a range of 0.4 ng/mL to 30 ng/mL. The functional sensitivity was observed at 0.9 ng/mL. Patient correlation studies: AU680=1.14(LC-MS/MS)+0.50 (N=266, r=0.97).

Conclusion: All measured studies demonstrated acceptable performance, validating the use of the QMS Tacrolimus Assay on the Beckman AU480/AU680/AU5800 analyzers, and will provide an effective monitoring system for patients receiving Tacrolimus therapy.

B-004

Comparative study between ELISA and Chemiluminescence (CLIA) methods for the analysis of ENA-screening and specific ENA.

E. Melguizo[1], C. González-Rodríguez[1], G. Ávila García[1], Á. Fernández-Hermida[2], P. Falcó-Pegueroles[2]. *[1]Virgen Macarena University Hospital, Sevilla, Spain, [2]Menarini Diagnostics, S. A., Barcelona, Spain*

Introduction: The anti-cellular antibodies are autoantibodies directed against a variety of cellular structures (DNA, ribonucleoproteins ...). The group of specific antibodies directed against specific cellular proteins, anti-Ro/SSA, anti-La/SSB, anti-Sm, anti-RNP/U1RNP, anti-Scl-70/topoisomerase I and anti-Jo-1 / histidyl-tRNA synthetase are clinically important in patients with autoimmune diseases (Sjögren's syndrome, systemic lupus erythematosus (SLE), scleroderma, dermatomyositis and polymyositis among others).

Objetive: Our aim was to analize the degree of agreement between chemiluminescence (CLIA) Zenith-RA from Menarini Diagnostics (Florence, Italy) and the habitual ELISA from Inova Diagnostics (San Diego, USA) for anti-ENA screening, anti-Ro/SSA, anti-La/SSB, anti-Sm, anti-RNP/U1RNP, anti-Scl-70 and anti-Jo-1.

Material y method:

Serum samples from 496 patients with positive anti-cellular antibodies (title 1/160 or higher) were selected. ENA screening tests for specific antibodies were measured and in positive results, specific antibodies (anti-SSA, anti-SSB, anti-Sm, anti-RNP, anti-Scl-70 and anti-Jo-1) were measured by ELISA (INOVA diagnostics) and CLIA (Menarini, Zenit RA). Samples we classified as positive or negative according to the manufacturer cut-offs (20 U/mL for ELISA and 10 U/mL for CLIA assays, except CLIA ENA-screening wehere cut-off is 1) and the agreement degree was obtained using SPSSv19 statistical program.

Results: The results are shown in table 1. It was not possible to calculate the Kappa index for anti-Jo-1 since all samples were negative by CLIA. The rest of determinations show a good correlation between the two methods, and showed a good classification of patients with systemic autoimmune disease.

Conclusions: Both methods show a good degree of agreement in the analysis of specific anti-ENA. Given the advantages of CLIA techniques in front of ELISA (master curve for each lot of calibrators and controls, linearity and continuous access of samples) it could be a valid option for the analysis of specific anti-ENA in the clinical laboratory.

cut-offs and degree of agreement (measured by kappa index) ENA screening and specific ENAs.

	Cut-offELISA (UI)	Cut-offCLIA (UI)	kappa index	ELISA -	CLIA -	ELISA +	CLIA +
ENA-screening	20	1	0.769	295	328	201	167
anti-SSA (Ro)	20	10	0.947	82	85	126	123
anti-SSB (La)	20	10	0.914	133	153	75	55
anti-RNP	20	10	0.876	145	165	63	43
anti-Sm	20	10	0.917	190	193	18	15
anti-Scl-70	20	10	0.976	200	196	8	12
anti-Jo-1	20	10		201	208	7	0

B-005

Comparative evaluation of four assays for the automated determination of glycated hemoglobin

N. Z. Maluf, C. F. d. Pereira, C. Rosin, M. R. Ribeiro, L. K. Tirado, E. F. Moreira, A. N. Camilo, F. S. Fukuoka. *DASA, Barueri, Brazil*

Background: Recently, it has been discussed, among endocrinologists, pathologists and general physicians, which is the most accurate method for automated determination of glycated hemoglobin (HbA1c). Attempting to answer this question, in this study, we compared HbA1c results obtained from two distinct methodologies in four different analyzers to evaluate their performance and the impact in clinical monitoring of diabetes mellitus.

Materials and methods: We selected 73 samples, 16 with a percentual ≤5% of HbA1c, 20 borderline samples (upper normal range result between 5.5 and 7%), 37 samples with high percentual of HbA1c (≥7%) to perform on the following analyzers for HbA1c determination: TOSOH HLC®-G7, Bio-Rad VARIANT II, both based on the principle of High-Performance Liquid Chromatography (HPLC), ROCHE Cobas 6000 and Siemens ADVIA 2400, both based on turbidimetric methods. Among the selected samples, it is possible that some presented anomalous hemoglobin.

Results: The correlation among the analyzers is summarized in the table below.

Conclusion: There was good agreement among results of HbA1c when comparing different analyzers and distinct methodologies. Our study suggests that determination of HbA1c for clinical monitoring of diabetes mellitus can be performed using any of the automated assays systems evaluated.

HbA1c, %	Regression Equation	R^2
Tosoh, vs		
Bio-Rad	0.971x - 0.126	0.9952
Siemens	1.076x - 0.653	0.9867
Roche	1.130x - 0.526	0.9889
Bio-Rad, vs		
Siemens	1.050x - 0.770	0.991
Roche	1.095x - 0.585	0.9934
Siemens, vs		
Roche	1.047x + 0.145	0.9826

B-006

Reporting Critical Laboratory Values (PANIC) - Identifying Problems and Improving Processes

D. Weinstein, E. Neumark, J. Goldman, T. Tohami, A. Shalom, E. Weiss, G. Rashid. *Meir Medical center, Kfar Saba, Israel*

Background: Reporting critical laboratory test values to hospital wards in real-time is essential to provide immidiate treatment to critically ill patients. It is challenging for the laboratory staff due to the workload and the differences in critical values between regular departments and specialized departments, like dialysis, oncology, etc.

A routine monitoring of panic values reported by phone documented on the LIMS (Laboratory Information Management System) revealed a 40-60% gap between the number of results that should have been reported in real-time and the actual implementation. Therefore, the laboratory management initiated a major improvement project in order to minimize this gap.

Purpose: To increase reporting of real-time critical lab values in order to improve the quality of patients care. Improvement targets were reporting at least 80% of critical laboratory results in 2012 and at least 90% in 2013.

Methods: During 2012, an Excel program was developed in the lab in order to determine the percentage of the reported panic values from each laboratory. The introduction of a simple periodic report in an easy and automated manner revealed several problematic laboratories on one hand, and on the other, increased the awareness among laboratory staff and their commitment to report panic values. This new parameter was chosen to be one of the quality criterions in laboratory surveys. After implementation of this program and increased awareness among laboratory staff, panic values reporting by each lab increased gradually and steadily to >80% in 2012 with a continuous increase in 2013.

Conclusions: The availability of the report and the ability of the managers and staff to present it quickly improved quality, and allowed real-time monitoring of failures in reporting critical results. This report allowed us to know exactly- where, when and who did not report critical results and to address each problem. Results during 2012-2013 indicated that this led to a fundamental change in the conduct of the lab staff and their commitment to report the PANIC values in real-time.

As an outcome of this project, and due to its importance, this feature will be implemented in all laboratories of Clalit Health Care Services as a new module in the LIMS software. This implementation will take into account the lab's experience and knowledge. Such a module will allow control of the rules for complex alarms, managing alerts via pop-up windows, and producing statistics reports for different sectors in a convenient and flexible way.

B-007

Performance Evaluation of Siemens Dimension EXL 200 Integrated Chemistry System for a Regional Medical Center.

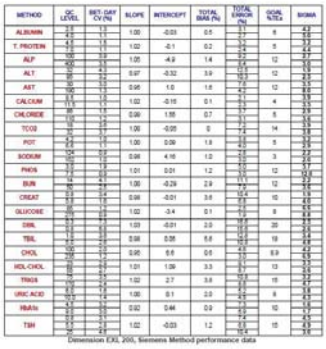
A. KHAJURIA, B. Robeson, J. Hafermann, G. Palmer, T. Walters. *Marshfield Clinic, Marshfield, WI*

***Background*:** The Dimension® EXL™ 200 Integrated Chemistry System offers LOCI® advanced chemiluminescent technology and automated, productivity features for the smaller-sized laboratory. Chemistry and immunoassay integration allows simultaneous processing to maximize workflow efficiency. Manufactures design their analytical systems to achieve certain performance characteristics for intended use and all instruments from a particular vendor may not have equivalent performance specifications. In a clinical laboratory risk management should begin with the verifications of those characteristics based on the performance goals to assess the suitability for the intended use.

***Methods*:** A test menu of 22 analytes was evaluated on Dimension EXL 200 for precision, reportable range, accuracy, detection limit and analytical specificity. The patient comparisons were done with another Dimension EXL 200 to have method comparability for the analytes. Assay performances were evaluated against performance criteria established in our laboratory. The statistical analysis was done by Analyse-it and method performance was calculated as Sigma metrics value [(Tea-Bias)/CV]. A Sigma 3.0 value is the minimum performance and 6.0 Sigma is considered world class performance.

***Results*:** Method performances evaluated on Sigma scale against our established quality performance criteria showed Glucose meeting a Sigma >6.0, five assays were <3 and rest varied between >3 and ≤5.5 Sigma. Chloride, BUN, creatinine and triglycerides showed <3 Sigma at low concentrations. HbA1c assay was unable to meet the performance goal requirement of 6% proposed by CAP & NGSP.

***Conclusion*:** Estimation of performance of a method is greatly influences by the stability of method under routine operating conditions and may not always mimic the controlled testing environment of vendors. Sigma metric performance assessment tool is a good measure to evaluate the performance of analytical processes. The data shows that most of methods on Dimension EXL 200 perform in the scale of 3 to 5.5 Sigma.



Dimension EXL 200, Siemens Method performance data

B-008

Diagnostic paths - towards computational evidence

Z. Liniger, G. Lindner, G. M. Fiedler, A. B. Leichtle. *Inselspital - Bern University Hospital, Bern, Switzerland*

Background: For the establishment of rapid, efficient, and financeable laboratory diagnostics in an ICD-10-funded hospital environment, defined diagnostic paths are of ever-growing importance. Usually they are set up as hierarchical trees or flow charts, leading to altered diagnostic suggestions depending on the outcome of previous tests (step-by-step diagnostic schemes). These guidelines are designed to focus diagnostic efforts on the most selective analytes, thereby avoiding unnecessary testing and providing a test panel sufficient to cover the most important side diagnoses. By overall reducing the number of recommended tests, they can help to improve cost effectiveness - especially in a health care compensation system that includes all diagnostic testing in a flat charge (as e.g. the recently introduced Swiss DRG system).

Diagnostic paths arise from different sources: single publications, recommendations of the different medical associations, and from the (inter-)national societies of Laboratory Medicine. However, all of these recommendations bear a severe drawback: they are agreements of experts in the field and therefore reflect opinions, not evidence.

Methods: Along with the rapid evolution of computational tools for parallel, GPU-based and grid- or cloud-based computing and the development of powerful statistical strategies an appealing resolution for this aforementioned lack of evidence emerges: To utilize already collected laboratory data, to merge it with diagnostic information and to derive which analytes are selective and likewise superior for the setup of a diagnosis. The conventional diagnostic path recommendations can be replaced by diagnosis-specific models inferred from the laboratory and classification data, a process that does not imply prior "expert knowledge" in terms of opinions which parameter to measure, but that is based only of the numerical evidence contained in the dataset and that delivers disease probabilities, assisting the physician to balance decisions for further diagnostic and therapeutic procedures. In a proof-of-principle study we utilized laboratory data and diagnostic information of n>15'000 patients of the Inselspital's Department of Emergency Medicine and computationally determined, which lab tests are indispensable and which ones are unnecessary for establishing the top ICD-10 coded diagnoses via the estimation of posterior inclusion probabilities with bootstrapped confidence intervals of a set of lab tests.

Results: Our results clearly show the feasibility of our new approach: For myocardial infarction e.g. our algorithm without any prior knowledge of the disease nor any pathophysiological basis suggests a panel of lab test similar to current guidelines - solely based on computational principles, our patient population, and laboratory data already generated thereof.

Conclusion: In a highly digitalized hospital environment, the present lack of evidence for diagnostic paths is unjustifiable: All diagnosis-related classification of all patients - hospitalized or out-patient - are electronically registered, and usually all lab tests are also electronically available. These data, stored away and laid untouched for decades, could improve and streamline diagnostic testing and implicitly generate benefit for the patients - the tools therefor are ready.

B-009

New Instrument Interface Standard to Enable Improved Interoperability with Integrated Information Systems.

J. B. Jones[1], E. Heierman[2], R. Bush[3], E. Olson[4]. *[1]Geisinger Health System, Danville, PA, [2]Abbott Diagnostics, Irving, TX, [3]Orchard Software, Indianapolis, IN, [4]Siemens Healthcare, Raleigh, NC*

The In Vitro Diagnostic (IVD) Industry Connectivity Consortium (IICC) has worked with several standards organizations to develop a new interoperability (i.e. instrument interface) standard that provides plug-n-play connectivity between IVD analyzers and IT systems, eliminating the need for unique analyzer interfaces. Currently, the Clinical and Laboratory Standards Institute (CLSI) LIS1 and LIS2 specifications (also known as ASTM) provide limited guidance on the structure and content of the data being exchanged in instrument interfaces. These older standards are highly flexible and have been implemented in many different ways thus creating barriers to integration and interoperability. In addition laboratories must validate these unique interfaces every time a new analyzer is installed, and often encounter lengthy implementation cycles before they can go "live".

IICC established partnerships with the CLSI (Clinical Laboratory Standards Institute), IHE (Integrating the Healthcare Enterprise), and HL7 (Health Level 7) standards organizations in order to leverage existing work, accelerate the creation of a plug-n-play standard, and promote worldwide adoption.

The resulting IICC standard is documented in an IHE Laboratory Analytical Workflow (LAW) profile. This profile provides the following capabilities, most of which are not supported by the LIS2 (ASTM) standard:

1) Support for Immunoassay, Chemistry, Hematology, and Microbiology testing

2) Unique identification of each order request at the test or test panel level

3) Improved query for orders

4) Selection of query as the default mode

5) Simplified order download

6) Ability for an analyzer to accept/reject orders

7) Improved device identification for test logging

8) Contributing substance identification for test logging

9) Basic and enhanced message interface to support IVD instrument rule evaluation

10) Support for LOINC to identify test requests and observations

11) Unique identification of runs

12) Support for hematology images, graphs, and plots

13) Support for transmission of raw values

To confirm that the LAW profile could support plug-n-play connectivity, vendors representing seven IVD analyzer and three IVD IT systems have participated in the 2012 European IHE and 2014 North American IHE "Connectathons." The IHE team defined ten test cases representing major LAW scenarios and focused on immunoassay and clinical chemistry orders. Each IVD analyzer tested interoperability with each IVD IT system through the execution of the test cases. The testing was monitored by IHE independent representatives. Each IVD IT system used the same interface implementation to communicate with each of the seven instruments.

All 13 testing events were successfully completed, allowing all participating vendors to register an IHE Integration Statement documenting that their implementation successfully integrated with the other vendors through the use of the LAW profile.

This new IICC instrument interface standard is now available for adoption by IVD instrument vendors (ivdconnectivity.org). Its use should greatly simplify interoperability between different IT systems in the more integrated healthcare continuum that is currently evolving under federal guidelines of "Meaningful Use".

B-010

Measuring Reproducibility of analysis in a proficiency testing (PT) scheme using modified control materials. A novel approach using big data analysis.

O. Panagiotakis[1], D. Rizos[2], K. Makris[3], A. Haliassos[1]. *[1]ESEAP Greek Proficiency Testing scheme for Clinical Laboratories, Athens, Greece, [2]Hormone Laboratory, Aretaieion Hospital, Medical School, University of Athens, Athens, Greece, [3]Clinical Biochemistry Department, KAT General Hospital, Kifissia, Greece*

The evaluation of reproducibility in proficiency testing (PT) schemes is based on the analysis of the same sample multiple times during a cycle. This can be tempting for participants to detect the replicated samples and to report already known target values. In order to overcome this possibility ESEAP designed a study involving the analysis of two replicates of a sample and two other samples, derived from the initial, but diluted or concentrated by 10% by modification of the serum volume lyophilized per vial.

The aim of our study was to investigate the interference of samples' modification to the estimation of reproducibility.

The 290 laboratories of ESEAP from Greece and Cyprus participated in this blind study during the 2013 cycle of Clinical Chemistry scheme. We excluded the results from the laboratories that haven't reported all four samples, from those excluded from the normal bias analysis and from the laboratories that reported a method change during this cycle. We evaluated 4 results from 209 laboratories for 21 different parameters, the two as received (samples 1&2) and the other two after correction with the appropriate factor for the dilution (sample 3) or concentration (sample 4) and we calculated the mean value for each sample. We evaluated the 6 possible comparison couples for each parameter using t-test. Our results are presented at the followinf table:

Couples of Samples	Analytes																					
	Glucose	Urea	Creatinine	Sodium	Potassium	Total Protein	Albumin	Cholesterol	HDL Cholesterol	Triglycerides	Uric Acid	Total Bilirubin	Calcium	Phosphate	Magnesium	Iron	SGOT (AST)	SGPT (ALT)	γ-Glutamyl Transferase	Creatine Kinase	Amylase
1 & 3	+	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	+	+	-	+	-
1 & 4	-	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	-	-	+	+	+
1 & 2	-	-	-	-	-	-	-	-	-	+	-	-	-	+	+	-	-	-	-	+	+
3 & 4	-	+	-	+	+	+	+	+	+	+	+	+	+	+	+	+	-	-	+	+	+
4 & 2	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	+	-
2 & 3	-	+	-	+	-	+	+	+	+	+	+	+	+	+	-	+	-	-	+	-	-

(- = statistically non-significant difference, + = statistically significant difference)

A pattern (**in bold**) emerged for the majority of the analytes showing that the first unmodified and the diluted sample, as also the two unmodified and the concentrated and the second unmodified showed statistically non-significant difference in contrast to the other three combinations that where statistically different.

Our data show that the possible interference due to the modification of the samples is smaller than the uncertainty of measurements of the identical samples (1&2) thus our approach can be used for the estimation of reproducibility.

B-011

Rapid Consistent Turnaround time (TAT) of Lab Results through an Innovative Centrifugation Protocol

J. Baker[1], S. Johnson[1], R. Wonderling[2]. *[1]MultiCare Health System, Tacoma, WA, [2]Abbott Diagnostics, Abbott Park, IL*

More than a billion laboratory tests are performed each year in the United States influencing 64% to 74% of the medical decisions. Labs have to provide accurate results and as quickly as possible for the STAT tests. So, turnaround time (TAT) of test results is a critical component in patient care.

MultiCare Health System (Tacoma, WA) laboratory has been providing excellent TAT for several critical lab tests over the past several years. We have recently achieved a "Received to Result" mean TAT time of 23.1 minutes (N=2743, SD=7.2 minutes, median=21 minutes) using "Abbott ARCHITECT Enzymatic Creatinine test" as a proxy for our Comprehensive Metabolic Panel (CMP) This test requires the longest analytical time in a CMP, thus equating to 90% of CMP results reported in 30 minutes. In case of cardiac assays, 90% of all Troponin results are reported within 35 minutes and 85% of all BNP results are reported within 35 minutes.

Centrifugation time is a major bottleneck and becomes the rate-limiting step and greatly reduces the laboratory specimen throughput. To improve TAT, we switched from the conventional slow spin procedure (6 minutes spin at 3500 RPM) to the new fast spin procedure (1 minute spin at 12,000 RPM). There was no noticeable difference in the results obtained after a fast spin compared to the slow spin when we tested 41 different patient samples in 16 different tests. After this off-automation track high speed centrifugation step for STAT samples, the samples are placed on the TLA (Total Lab Automation) track system for processing as usual. Thus the STAT TAT target is met with the advantages of TLA.

Manufacturers of blood collection tubes typically recommend slower speeds and times for centrifugation. Using a fixed rotor refrigerated centrifuge (Beckman Coulter Allegra Model X30R and F1010 rotor assembly) allows faster speeds and shorter times for separation of plasma from cells. Gel barrier plastic collection tubes are highly resistant to breakage or failure during centrifugation at this higher speed and no statistical change in hemolysis is present. However, balance tubes in the centrifuge should be replaced monthly as a precautionary step as they show visual bending of the tube after this period of centrifugation.

Most laboratories are constantly pressured to deliver results more quickly. A viable option to improve sample handling in the laboratory is total laboratory automation which has been shown to dramatically improve laboratory TAT and clinical throughput. However, even when using automation, centrifugation is still a major bottleneck for STAT specimens and becomes a rate limiting step. Performing off-automation track centrifugation of STAT specimens using this Innovative Centrifugation Protocol (with 2 centrifuges each with 6 tube capacity) has allowed MultiCare Health System to achieve quick and consistent turnaround times for stat chemistry results.

B-012

Simoa HD-1: a fully automated digital immunoassay analyzer capable of single molecule counting, sub-femtomolar sensitivity, and multiplexing

D. H. Wilson, C. W. Kan, A. J. Rivnak, T. G. Campbell, T. Piech, D. M. Rissin, P. Patel, E. Frew, G. Provuncher, A. Schroff, R. E. Meyer, M. Fishburn, L. Chang, D. R. Fournier, D. C. Duffy. *Quanterix Corporation, Cambridge, MA*

Objective: The aim of this work was to develop the next generation immunoassay analyzer capable of several orders of magnitude greater sensitivity than current best-in-class conventional immunoassay systems. The technology utilizes single molecule array (Simoa) technology to usher in fully automated digital immunoassay and multiplexing capability to the clinical laboratory. Simoa technology isolates individual paramagnetic beads in arrays of femtoliter-sized wells and detects single enzyme-labeled proteins on these beads using sequential fluid flows in microfabricated polymer array assemblies for ultra-sensitive signal measurements. These array assemblies have been incorporated into a low cost disk consumable. The array approach for assay signal quantification allows for rapid digital data acquisition and high throughput, enabling development of a fully automated system for low-cost measurement of clinically relevant biomarkers with high precision and unprecedented sensitivity across a broad dynamic range.

Methods: Detection of single molecules using Simoa has been reported previously. In brief, proteins are captured on antibody-coated paramagnetic microbeads (2.7-mm diameter) and labeled with single enzymes, followed by partitioning single beads into arrays of femtoliter-sized wells and sealing the arrays in the presence of a fluorogenic substrate. We developed a low cost disk consumable that enables standard fluidics handling instrumentation to load and seal assay beads into the arrays using only fluidic flow. Beads with single enzyme label molecules are isolated in single wells in the presence of a substrate, and fluorescent product is allowed to build up within the 40 femtoliter confines of the wells. The fluorescence signal quickly concentrates in such a small volume, allowing detectable signal from a single enzyme label in only 30 seconds. Depending on the analyte concentration, hundreds to many thousands of single molecule signals are counted simultaneously using a fluorescence microscope optical system and image analysis software. Next we integrated this array and imaging module together with a standard fluidics-handling platform that performs sequential cuvette processing of paramagnetic bead-based ELISA reagents. The reagents employ antibody-coated capture beads, biotinylated detector antibodies, and streptavidin-ß-galactosidase as the signal enzyme. A standard bead-based immunoassay is performed, and then the beads are transferred to the Simoa module for signal development and digital quantification.

Results: Prototype single-plex digital immunoassays were developed for PSA, Troponin, IL-6, and Aβ42. A prototype cytokine 6-plex was also developed. LoD's ranged from 0.002 to 0.05 pg/mL. The LoQ of the PSA assay was estimated as 0.037 pg/mL. These sensitivities ranged to over 1000-fold greater than conventional immunoassay. Imprecision for the prototype assays was evaluated over 10 runs across five days in a CLSI format. CVs were generally less than 10%. Spike recovery and linearity met standard criteria for acceptability. The system throughput is 68 tests/hour, and over 4 logs of dynamic range were demonstrated. The prototype 6-plex gave equivalent precision and sensitivity performance to single-plex versions of the same assay.

Conclusion: The data indicate we have developed a next generation fully automated immunoassay analyzer capable of orders-of-magnitude greater sensitivity than conventional state-of-the-art immunoassay systems.

B-013

Capability Analysis for Procalcitonin Assay Performed with the miniVidas® Method.

V. M. Genta[1], R. Murray[1], E. Ravago[1], B. Boston[1], S. Spingarn[2], W. Tang[1]. *[1]Sentara Virginia Beach General Hospital, Virginia Beach, VA, [2]Sentara Norfolk General Hospital, Norfolk, VA*

Background: Procalcitonin blood values have been linked to both increased risk and severity of sepsis. Consequently, in-hospital assays assure availability of timely results for prompt medical intervention. In our institution we evaluated the capability of the miniVidas method with phase1 (short-term) and phase2 (long-term) precision verification studies. **Methods:** After a miniVidas instrument (IVD1210422, BIOMERIEUX) was installed by the manufacturer's representative, a phase1 study was performed by assaying two levels of QC material (level1 lot#1031940; level2 lot#103150, BIOMERIEUX) with five independent assays for five consecutive days.

Phase2 study was performed by assaying two levels of control material once a day for 100 days. The observations were transferred to Minitab® (Version 16, Minitab Inc.) statistical software. The observations were analyzed with descriptive, exploratory, inferential and diagnostics univariate and multivariate statistical techniques. For the process capability analysis the UCL and LCL were calculated using the mean of phase1 study +/-(0.5xtotal error allowed by CAP). **Results:** Phase1 study. Descriptive statistics: Level1 mean=17, s=0.7, C.V.=3.9%, min=16, Q1=16.8, median=17, Q3=17.8, max=19; Level2 mean=1.57, s=0.05, C.V.=3.2%, min=1.4, Q1=1.55, median=1.58, Q3=1.59, max=1.64. For level1 histogram, normality plot and Anderson-Darling (A-D) test (level1 P=0.4) showed quasi-normal distribution; for level2 A-D test showed non-normality (P=0.005) due to a possible outlier (obs. #14 = 1.4 ng/mL), the histogram and the normal probability plot showed a quasi-normal distribution. Tests for equality of variances showed discordant results; for both levels Bartlett's test P<0.05, Levene's test P>0.5. Estimates of daily s with Bonferroni's 95% C.I. showed that the values of s for level1 of day 2 and for level 2 of day 14 were larger than the others and had larger 95% C.I. Parallel boxplots and ANOVA with Tukey's multiple comparisons showed that while for level 1 there were statistically significant differences between daily means (P=0.004), for level 2 there were no statistically significant differences(P=0.06). However, the maximum mean difference for level1 = 1.4ng/mL was not significant for either QC or clinical practices. The plots of the autocorrelation function showed statistically significant autocorrelation for the first two observations only. The plots of Hotelling's T-square and generalized variance did not show either parallelism or non-randomness. The individual point QC charts for level 1 and 2 were constructed using the estimates of mean and s (for s = s/0.98, corrected for bias) with LCL= mean-3s, UCL= mean+3s. Phase 2 study: Level1 mean=16.5, s=0.8, C.V.=4.8%, Level2 mean=1.6, s=0.07, C.V.=4.3%. The individual points charts for both levels of contol did not show trends, shifts,outliers or autocorrelation. There were no statistically significant differences between either means or s for Phase1 and Phase2 studies (P>0.05).The capabilities indexes Cp (level1=2.4, level2=2.3) and Cpk (level1=2.8, level2=2.7) were similar indicating centering of the mean, their values (> 2) indicated acceptable six-sigma performance. **Conclusion:** These studies showed that the phase1 study design was adequate to estimate mean and s for the individual points QC charts.Furthermore, phase2 studies indicated that the method's reproducibility and capability were adequate to monitor the variability within the total error specifications. Finally, appropriate statistical software was essential for the analysis of the observations.

B-014

Performance Evaluation of three URiSCAN series for routine urinalysis

K. Ko, M. Kwon, H. Woo, H. Park. *Kangbuk Samsung Hospital, Department of Laboratory Medicine, Seoul, Korea, Republic of*

Background: Urinalysis is one of the important diagnostic screening tools in clinical practice. Correct urinalysis results offer information of the renal and genitourinary system. The URiSCAN devices (Yeongdong Diagnostics, Seoul, Korea) are one of the most commonly used urine analyzers in Korea. Our study aimed to evaluate the analytical performance of the three URiSCAN devices for routine urinalysis in comparison with Roche urine analyzers.

Methods: A total of 1,273 urine specimens were enrolled in this study between June 2013 and November 2013. We performed urinalysis using three URiSCAN devices; Optima, Pro II and Super+, and compared to other urine analyzers (Roche Diagnostics, Switzerland); Urisys 1100, Cobas u411 and Urisys 2400. Each Roche analyzer was selected with consideration of complexity of each URiSCAN device. The results of three analyzers for blood, bilirubin, urobilinogen, ketone, protein, nitrite, glucose and leukocyte were considered concordant if they were within ±1 grading difference in comparison with the results by Roche analyzers. Moreover, the screening of leukocytes and erythrocytes using both systems were compared with microscopic examinations.

Results: Good correlation between three URiSCAN devices and their corresponding methods were observed (range of correlation coefficient: 0.602 to 0.989, p<0.001). Overall agreement rates for eight test items were acceptable: 84.9% - 100% for Optima *vs.* Urisys 1100; 96.8% - 100% for Pro II vs. cobas u411; and 99.3% - 100% for Super+ vs. Urisys 2400. The sensitivity and specificity of the URiSCAN Optima were 62.7% and 95.4% for leukocytes, 91.4% and 78.1% for erythrocytes; for URiSCAN Pro II were 79.6% and 86.4% for leukocytes, 62.2% and 96.9% for erythrocytes; for URiSCAN Super+ were 82.5% and 87.4% for leukocytes, 92.9% and 83.8% for erythrocytes.

Conclusions: The three URiSCAN devices showed high agreement rates with the corresponding Roche urine analyzers and microscopic examination. Therefore, these three URiSCAN series would be useful for clinical laboratory performing in routine urinalysis.

B-015

Improvement of work processes in the laboratory after introduction of the Automate 1250 System

E. Neumark, E. Weiss, J. Goldman, A. Shalom, G. Rashid. *Meir Medical center, Kfar Saba, Israel*

Background: In early 2012, the automated "Automate 1250" system (Beckman Coulter) was introduced to the Chemistry, Immunology and Endocrinology Laboratories at Meir Medical Center. This computerized robotic system sorts and archives laboratory samples. It is designed to treat pre-analytical processes (such as decapping, sorting and if necessary aliquoting samples, followed by samples distribution to designated workstations) and post-analytical processes (archiving samples). Prior to introducing the system, work processes in the 3 laboratories were mapped. Immunology Laboratory processes were different from other laboratories since most of the blood samples that arrived were aliquoted to several tubes in order to run on different analyzers. This resulted in delays and results were only available 1-3 days after receiving the samples, depending on how often the equipment was operated. We present in this work the improvement that was made in the Immunology Laboratory.

Aim: This study investigated several workflows to decrease immunology TAT (Turn Around Time). This was accomplished by using the Automate 1250 to route samples for immediate testing on analyzers that operated daily in the original tubes, and then to send the aliquoted samples to analyzers that operated less frequently.

Results: Analyzing for several months how the Immunology tests were processed, the various tests requested for each blood sample, and their distribution between analyzers, was the basis for the improvement in the lab. If the analyzer on which the most tests were performed was run daily, more than 50% of the samples would not be aliquoted, and the test results would be available within a day. Due to these observations, Immunology Laboratory staff began working on a method whereby they analyzed samples immediately upon their arrival in the first round of the Automate 1250. All the original samples were sent to the analyzer that ran most of the tests. This change in procedure affected other processes in the lab, which were not directly linked to the Automate 1250 system, and all together it resulted in a significant decrease in turnaround times:

Before the improvement: Average result availability before the use of Automate 1250 was 2.7 days _ 17% longer than the specified result time.

After the improvement: Average result time decreased to 1.1 days, only a 2% deviation in the specified result time.

Conclusions: Using the Automate 1250 system increased Immunology Laboratory efficiency, resulting in shorter TAT times and improved service. TAT time reduced from 2.7 days before the introduction of the new system to the lab to 1.1 days, affecting 60% of the samples. This resulted in safer patient care and improved service quality. Following the above results, the use of the Automate 1250 system was extended to other laboratories.

B-016

QMS Everolimus Assay for the Beckman Coulter AU480, AU680, AU5800 Clinical Chemistry Analyzers

C. Wong, D. Cheng, H. Naqvi, K. Yokobata. *ThermoFisher Scientific, Fremont, CA*

Background: The objective of this study is to evaluate the performance of the Beckman Coulter AU480/AU680/AU5800 clinical chemistry analyzers with the QMS Everolimus Assay for the quantitative determination of everolimus in human whole blood used in the management of organ allograft transplant patients receiving everolimus therapy. Monitoring for everolimus is important for effective use to prevent allograft rejection following organ transplantation. The measurement of everolimus concentrations in whole blood in conjunction with other laboratory data and clinical evaluation can optimize immunosuppressive effect and minimize adverse side effects for patients.

Methods: The QMS Everolimus assay is a liquid stable homogeneous particle-enhanced turbidimetric inhibition immunoassay. The assay is based on competition between drug in the sample and drug coated onto a microparticle for antibody binding sites of the everolimus antibody reagent. The everolimus-coated microparticle reagent is rapidly agglutinated in the presence of the anti-everolimus antibody reagent and in the absence of any competing drug in the sample. The rate of absorbance change is measured photometrically. When a sample containing everolimus is added, the agglutination reaction is partially inhibited, slowing down the rate of absorbance change. The concentration-dependent classic agglutination inhibition curve can be

obtained with the maximum rate of agglutination at the lowest everolimus concentration and the lowest agglutination rate at the highest everolimus concentration. The assay consists of ready-to-use reagents, calibrators (value-assigned concentrations at 0, 1.5, 3, 6, 12, and 20 ng/mL) and controls (value-assigned concentrations at 4, 8, and 15 ng/mL).

Results: The performance of the QMS Everolimus Assay was evaluated on the Beckman Coulter AU480/AU680/AU5800 analyzers. All studies were evaluated using CLSI guidelines. Three levels of everolimus controls were used in the studies. The precision ranged from 7.1%CV to 6.4%CV for within-run and 10.5%CV to 8.1%CV for total run. Linearity was measured and confirmed over a range of 1.5 ng/mL to 20 ng/mL. The least detectable dose on the AU480/AU680/AU5800 yielded 0.3 ng/mL. Patient correlation studies: AU480=0.90(Hitachi 917) + 0.18 (N=107, r=0.99), AU680=0.94(Hitachi 917) + 0.0 (N=100, r=0.99), AU5800=0.99(Hitachi 917) + 0.13 (N=106,r=0.98).

Conclusion: All measured studies demonstrated acceptable performance, validating the use of the QMS Everolimus Assay on the Beckman Coulter AU480/AU680/AU5800 analyzers, and providing an effective monitoring system for patients receiving everolimus therapy.

B-017

Error Rate Testing for the Accelerator p540 Preanalytical Sample Processor Vision System

A. DeFrance, B. Smith, K. Reed, Y. Smith. *Abbott Laboratories, Irving, TX*

Introduction: The ACCELERATOR *p*540 is a fully automated perianalytical sample processor that performs sample loading, identification, decapping, aliquoting, and sorting operations. A Vision System was added to the p540 aliquoter unit to identify cap color, if present.. Parameters link the cap color to the specimen type. Middleware determines compatibility of specimen type for the tests ordered. Depending on that determination the tube can either be further processed, or moved to an error location subject to user preference.

Methodology: The vision system library contains 35 common cap colors. Additionally, it can be trained to read other cap colors. The vision system consists of a digital camera that acquires images of racks as they are presented to the aliquoter. This picture is available for operator viewing. The cap color as detected by the camera and the pixel data for each cap is sent to the p540 software. The software analyzes the data and determines whether the cap matches a trained color. In the error rate test, 12 different caps were tested on two different systems. These caps consisted of a mixture of rubber, plastic and screw caps of various colors. Some caps were part of the library and some were trained.

Results: The table below summarizes the p540 Vision system error rate testing.

p540 Error Rate Testing								
	System 1				System 2			
Cap Type	Trained/ Library	Original error rate	Retrain	Error rate	Trained/ Library	Original error rate	Retrain	Error Rate
Greiner: lavender	Trained	0%	No	0%	Trained	0%	No	0%
Greiner: white	Library	100%	Yes	0%	Library	100%	Yes	0%
Terumo: red	Library	12%	Yes	0%	Library	8%	Yes	0%
Terumo: green	Library	20%	Yes	0%	Library	0%	No	0%
BD-Plastic: lt green	Library	0%	No	0%	Library	0%	No	0%
BD-Plastic: gold	Library	0%	No	0%	Library	0%	No	0%
Sekisui: tan	Library	0%	No	0%	Library	0%	Yes	0%
Sekisui: gray	Library	16%	Yes	0%	Library	36%	Yes	0%
BD-Rubber: red	Library	0%	No	0%	Library	0%	No	0%
BD-Rubber: blue	Trained	0%	No	0%	Trained	0%	No	0%
Sarstedt: orange	Library	100%	Yes	0%	Library	80%	Yes	0%
Sarstedt: lavender	Library	0%	No	0%	Library	4%	Yes	0%

Conclusion: The error rate of the p540 vision system is low. As seen in the retrain column, if the cap color exists in the library the system may or may not initially identify the correct color. However, it is a simple process to train any cap color. This ability to train any cap color keeps the error rate low and allows for changes in the color manufacturer's caps without having to reconfigure the camera.

B-018

Utilising Information Technology (IT) to improve work processes at the Satellite Laboratories

S. Lim, C. Yeo. *Singapore General Hospital, Singapore 169608, Singapore*

Background: Singapore General Hospital (SGH) Clinical Biochemistry Laboratory has under its charge; 9 satellite laboratories that are situated in polyclinics (public-funded primary healthcare facilities). These satellite laboratories offer phlebotomy services and some onsite laboratory tests, although the bulk of the specimens are sent back to the central laboratory for analysis. HbA1c (Glycated Haemoglobin A1) constitutes a significant 38% of the onsite testing repertoire. The objective of this study was to utilise information technology to improve the otherwise manual processes for handling HbA1c results and to achieve a standardised workflow across the 9 satellite laboratories. Laboratory turnaround time (TAT) for HBA1c was used as a performance indicator to measure the success of this endeavour.

Methods: HbA1c analysers were connected to the Laboratory Information System by the first quarter of 2012. Standard procedures for specimen registration and processing and result verification were instituted at the laboratories in the last quarter of 2012 and autoverification (AV) of HbA1c test results was piloted at 2 laboratories in July 2013. TAT, defined as the time taken from registration at the lab to result verification.

Results: Significant improvement in TAT was observed at all the satellite laboratories after the introduction of LIS connectivity and a standardised workflow. By the end of 2012 >90% of HbA1c results were completed within 30 minutes, a betterment over the pre-study rate of 50% completion within 30 minutes. This improvement was also sustainable from 2013. AV was piloted in July 2013 at 2 of the satellite laboratories to explore its effect on the TAT. Data showed that TAT slipped initially due to operator unfamiliarity but improved in the following months, enabling both laboratories to complete >80% HbA1c testing within 15 minutes.

Conclusion: Online connectivity of the analysers and standardisation of work processes have definitely improved the efficiency of onsite HbA1c testing at the satellite laboratories. Auto-verification of test results, with careful planning, can also improve TAT. Our next steps will be to sustain the work process improvements, implemented AV for the remaining 7 satellite laboratories and study the impact of our enhanced practices on the overall operations of the polyclinics.

B-019

Implementing the "Integrated Laboratory" tool for ANF tests in a high-functioning laboratory

F. B. Flumian[1], R. Mansur[1], R. J. Marani[1], A. Cintra[2], F. O. Paiva[1], G. Lakos[3], R. Vrunski[2], M. D. Freire[4], N. Gaburo[1]. *[1]DASA, Sao Paulo, Brazil, [2]Werfen Medical, Sao Paulo, Brazil, [3]INOVA Diagnostics, San Diego, CA, [4]DASA, Rio de Janeiro, Brazil*

Background: The "gold standard" method used to screen for antinuclear factor (ANF) is Indirect Immunofluorescence (IIF) on HEp-2 cells. However, this methodology presents some problems, such as subjectivity in interpreting the standard reading, a lack of trained technicians and the test's low standardization. On the other hand, ANF diagnosis has great clinical importance, which justifies the increasing demand, year after year. Given this scenario, laboratories processing a large number of ANF screening tests on a daily basis require alternatives that meet this high test volume while not compromising diagnosis quality and accuracy.

Objective: To present the implementation of "Integrated Laboratory" system and the Quanta-link® software that integrates the Quanta-Lyser® and NOVA View® equipment with the laboratory's LIS.

Methods: The validation of the equipment used to prepare the HEp-2 slides (QUANTA-Lyser®) utilized 40 samples, 20 positive and 20 negative, and the positive samples were from different titers and standards. Quanta-Lyser®'s reproducibility was verified using 4 positive samples and 4 negative samples. The samples were replicated 5 times in the same session. Both the AFN automated reading equipment, NOVA View®, and the training to read AFNs were used every day. Therefore, 200 AFNs/day were visualized, with comparative readings between the NOVA View® reading equipment and the manual microscope reading, which was carried out by a team of 8 technicians trained to read AFN.

Twenty one collaborators from different areas of the company were involved in

configuring the systems, infrastructure and participated in the technical-diagnostic process in order to make this validation possible.

Results: The implementation process lasted 5 months. In the first phase, the presentation of the project and the installation and validation of Quanta-Lyser® were carried out, followed by the installation, calibration, training and validation of NOVA View®. In the second phase, the implementation of the DAPI reading and the learning curve was carried out, as well as the implementation and configuration, training and validation of QUANTA Link®. In the third and last phase, the training and validation of the system as a whole was developed. When compared to the previous method used, the results found were: a 2.64% reduction in repetitions, a 10% reduction in false positive results, a 70% reduction in

the use of paper and a 53.6% reduction in the release time of negative samples and 7.1% reduction for positive samples. Qualitative results can also be highlighted: Improved standardization of the results release, greater precision in diagnosis, significant improvement in the traceability of samples, reduction in the manual entry of results, ensuring reduction in possible transcription errors, and reduction in the causes of repetitive strain injury.

Conclusion: Implementing the "Integrated Laboratory" was a great challenge for DASA's manual immunology sector, as it was a project that involved many collaborators from different sectors and companies, and broke paradigms in the traditional diagnosis of AFN. It provided important gains for the department's costs and productivity, with an important gain in analytic quality. The project also led to the integration of various departments within the company and produced knowledge that can be used in future projects

B-020

Evaluation of Calibrator and System Stability for Beckman Coulter Access 2 System

N. Akbas[1], A. Algeciras-Schimnich[1], N. A. Baumann[1], D. R. Block[1], J. R. Budd[2], S. Gaston[2], G. G. Klee[1]. *[1]Mayo Clinic, Rochester, MN, [2]Beckman Coulter, Chaska, MN*

Introduction: It is standard practice in clinical laboratories to calibrate assays prior to use and recalibrate at the pre-established calibration expiration time. All automated assays have a time frame for calibration curve stability set by manufacturers which are monitored with quality control and assurance systems to ensure calibration integrity in clinical labs.

Objective: In this research, we investigated the stability performance of calibrators and the system for three automated assays (human luteinizing hormone (hLH), total triiodothyronine (TT3) and vitamin B12) performed on the Beckman Coulter Access 2 analyzer.

Methods: Thirty data sets were collected over forty-three days for six levels of calibrator by testing as unknown and analysis of results was compared to acceptance criteria. Each data set consisted of four replicates of calibrator levels S0, S1, S4, and S5 and three replicates of calibrator levels S2 and S3. Three levels of serum quality control pools for the same three assays also were analyzed for comparison. In addition, one replicate for three levels of quality control materials (QC1 through QC3) were performed. The maximum number of days before the calibration exceeds the defined calibration limits were calculated using a time regression analysis program (provided by Beckman Coulter) for calibrator levels and QC levels. Two separate models (percent change versus day model and concentration change versus day model) were used for analysis. The initial calibration curve was constructed using total number of twelve calibrator measurements. Percent coefficient of variation (% CV) for each calibrator and QC levels were calculated for each data set.

Results: Time regression analysis of hLH showed stability that was beyond the manufacturer's stated stability limit (28 days) for all calibrator and QC levels using both analysis model. The observed CVs were less than 3.5% for all calibrator and QC levels except QC3 which had CV of less than 5.5%. Results of analysis showed extended stability compared to manufacturer's suggested stability (14 days) for TT3 at all levels of calibrators and QCs using both analysis models. TT3 assay had CVs of less than 5% for higher levels of calibrator (S2 through S4) and QC (QC2 and QC3) while CVs were less than 10% for lower levels (S1 and QC1). Most of the results for vitamin B12 were beyond the recommended 21 day stability: 6 of 7 analyses using percent versus day model and 4 of 7 analyses using concentration versus day model had greater stability. The observed CVs were less than 7% for calibrator levels and less than 16% for QC levels.

Conclusions: Results indicated that measured stability was increased for all three assays when data was analyzed using percent change as opposed to the concentration change model. hLH and TT3 assays were stable longer than the manufacturer's recommendations. Results of four analyses for vitamin B12 did not meet the manufacturer's suggested stability limit. It is important to recognize the current research study includes both calibrator and system stability in a manner not typical of the manufacturer's intended use.

B-021

A multicenter study on the performance of Grifols' Erytra®, a fully-automated high throughput analyzer, for Kell grouping in US population

J. Roback[1], S. Barclay[1], J. M. Moulds[2], G. Denomme[3]. *[1]Emory University Hospital, Atlanta, GA, [2]LifeShare Blood Centers, Shreveport, LA, [3]BloodCenter of Wisconsin, Milwaukee, WI*

Background: After the antigens of the ABO and Rh blood groups, Kell antigen (K) is the next most immunogenic. The Kell locus is highly polymorphic and gives rise to many antigens. The most important ones, K and Cellano (k), are produced by two major codominant allelic genes. Exposure to K antigen can stimulate an IgG type antibody that can trigger transfusion reactions and hemolytic disease of the fetus and newborn. However, pre-transfusion K antigen typing is not routinely performed in the US. The objective of this study was to test Erytra® (Grifols, Barcelona, Spain), a fully-automated high throughput analyzer for pre-transfusion testing, to establish its performance for K grouping versus comparative method.

Methods: K typing was performed on 2669 samples selected from routine workload representing a very diverse population of donors and patients (46% and 54%, respectively) in 2 US sites. The 8-column DG Gel® 8 ABO/Rh+Kell cards (Grifols) containing monoclonal antisera were used for test procedures. Comparative method was traditional tube testing. Positive Percent Agreement (PPA), Negative Percent Agreement (NPA) and OPA (Overall Percent Agreement) between the Erytra and the comparative method were calculated at the 95% confidence level. At least a 99% concordance was considered acceptable.

Results: Of the 2669 tests performed, the Erytra detected 222 K positive and 2447 K negative. The concordances with the comparative method were 99.09% for PPA with a 95% lower confidence bound (LCB) of 96.75%; 99.84% for NPA (99.58% LCB); and 99.78% for OPA (99.20% LCB). Of the 6 discrepancies found (0.22 %), 4 samples were positive by the Erytra and negative by the reference system (all of them were confirmed as true positives by the Erytra), and 2 samples were negative by the Erytra and positive by the reference system (all of them were concluded to be true negative in favor of Erytra). Further investigation revealed that the 2 false negatives were apparently due to clerical or technical error in performance or predicate test.

Conclusion: The Erytra test performance in the Kell determination with its DG Gel 8 cards was safe and effective, consistently obtained the expected results in all the repetitions and was substantially equivalent to the FDA-licensed reagents and FDA cleared instruments used in the study. The Erytra system can be acceptable for K antigen detection by routine pre-transfusion tests in US centers.

B-022

Workflow efficiency of Erytra® in a hospital transfusion service environment

L. C. Winn[1], S. Leonard[1], C. Sánchez[2], S. Solé[2]. *[1]Grifols, Emeryville, CA, [2]Diagnostic Grifols, S.A., Parets del Vallès, Spain*

Background: Automated blood grouping systems for hospital blood banks, transfusion services and donor centers should demonstrate high loading capacity and self-organization to provide maximum processing power. The Erytra® (Grifols) is the newest generation fully automated blood bank system for blood group determination and pre-transfusion compatibility testing using the gel agglutination technique that has been recently approved by the FDA. The objective of the study was to assess the workflow efficiency of the Erytra in a hospital transfusion service environment in terms of turn-around times from process start to finish, efficiency and advantages of the 8-column cards and the ease of use and acceptance by the laboratory staff.

Methods: Patient samples collected in ACD, EDTA or sodium citrate were tested for ABO/Rh+K (Grifols DG Gel® 8 ABO/Rh + Kell card) and antibody screening (Grifols DG Gel Anti-IgG card and Search Cyte 0.8%) using the Erytra automated blood banking system. The Erytra was loaded with increasing number of samples. The following performance metrics were assessed: time to first result (TTFR), turnaround time from first result to last result (cadence), manual "hands on" time required and walk-away time. "STAT" (urgent) samples could be inserted at different times during the regular testing. Operators followed the Package Insert Instructions for Use for the Grifols DG Gel 8 cards, Red Blood Cell Reagents and for the Erytra system. For the ease of use and acceptance evaluation, the following activities were tracked: Set-up, QC, sample preparation, sample sort and loading, routine testing, post-run procedures, consumables used, IT/data review, space requirements, and ergonomics.

Results: Consecutive loads of 96, 120, 144, 168 and 192 samples for the ABO/Rh+Kell typing and antibody screening in the Erytra gave similar values of cadence from 42 to 46 samples per hour. This means that increasing loads had no negative effect on the Erytra performance. STAT samples did not modify the cadence of the routine samples. Most valued feature of Erytra by the staff was related to cards and reagents continuous loading and traceability tracking. Cards and reagents were considered easy to load, thus shortening time to start processes. In addition, software allowed accurate and timely notification of cards tracking and reagent status. Being a see-through instrument was also a valued feature since its well lighted interior provided a clear view of all operating processes.

Conclusion: High workflow efficiency Erytra was demonstrated through its increasing performance with increasing sample loads. Erytra was particularly valued for its ease of loading and tracking cards and reagents, which lead to efficiency and time savings.

B-023

Optimization of Sample Workflow with Total Laboratory Automation: The experience of a 4,5 million tests/month Clinical Laboratory

S. V. L. Argolo, M. L. Moreira, C. F. A. Pereira, O. F. Silva. *DASA, Rio de Janeiro, Brazil*

Background: Central laboratories today face significant challenges: increasing number of samples and tests; the need to find ways to reduce costs; limited technical staff; to minimize laboratory errors; and, to provide results in lower turnaround times (TAT). Laboratory automation can be the solution for most of these issues, but in an operational cenario of 4 to 5 million tests/month, the developed solution has to be carefully and individually studied.

Objective: To evaluate the improvements in efficiency and productivity obtained by the implementation of a high volume laboratory automation in a large clinical laboratory.

Methods: We installed, with support from Roche Diagnostics Brazil, two FlexLab® System 3.6 from Inpeco, included in each system an Input Output Module, Rack Output Module, Bulk Input Module and Decapper Module. In the first one, were connected the following platforms: 2 Cobas 775, 3 Modular EEE, 2 UniCel DxI and 1 ImmunoCap 1000. In the second were connected the following platforms: 1 Cobas 775, 1 Cobas 777, 1 Cobas 8000 EEE, 3 Modular EEE, 2 UniCel DxI and 1 ImmunoCap 1000. We then compared pre versus post implementation data, regarding number of tests processed by tube, TAT, and number of tests by technician.

Results:There was a significant decrease of time consuming in load platforms and all the actions related to it, increasing productivity, reduction of number of tubes collected with important gain in costs and a decreased TAT for most parameters. We had an increase in number of tests per tube by 34%, saving around 48.000 dollars per month. The productivity per technician was increased in 15% and TAT was reduced, in average, by 32%.

Conclusion: At the time we started the studies to implement this solution, we were processing, at the serum area, 2,6 million tests/month using equipments from different suppliers, and also used a sorter to manage the destination of the tubes. All equipments were loaded manually by the technicians. This new technology implemented at our large clinical analysis laboratory allowed us to improve TAT, productivity and reduce production costs, and to deal with almost 3,2 million tests/month. With the new platform we were able to absorb an increase of 20% in number of tests, without increases in personnel costs. Reorganization of the laboratory using automation can be the solution to support the growing of large laboratories.

B-024

Comparison between the determination of glycated hemoglobin through automation system and front-loaded on a clinical chemistry analyzer

N. Z. Maluf, L. K. Tirado, M. D. C. Freire. *DASA, Barueri, Brazil*

Background: Automation systems provide cost efficiency and increased productivity, by integrating test menu and automating manual steps. However, some assays present specificities on sample handling. The determination of Hemoglobin A1c (HbA1c), a diabetes marker, requires mixing the blood samples immediately before testing. Generally, accurate results will be achieved if the sample is tested within 10 minutes after mixing. If the sample sits for too long, the red blood cells will settle, only plasma will be aspirated and false lower results could be reported. In this context, laboratories discuss if performing HbA1c through automation system would be appropriated. Here, we compare HbA1c results when samples are front-loaded on chemistry analyzer with samples loaded on automation system, considering the 10-minute limitation.

Methods: 166 blood samples were tested for HbA1c using the automated pretreatment kit on Siemens ADVIA Chemistry 2400. The samples were first mixed and loaded on a STAT tray on Siemens ADVIA LabCell (100 capped tubes and 66 decapped). Samples were run in batch, without any other samples on the track. The aspiration time of the samples were obtained from CentraLink Data Management System. Then, these samples were mixed and front-loaded on Siemens ADVIA Chemistry 2400. The test was performed in triplicate, mixing the samples between each run. The time to aspirate all the samples in the tray was measured

Results: The correlation data is summarized in the table below

Conclusion: Correlation results between compared measurements were satisfactory. However processing through automation system took longer than the manufacture recommendations (10 min. after mixing). Our study suggest that is possible to process HbA1c tests in batch on ADVIA LabCell under ideal circumstances of sample homogenization and system monitoring.

Table 1 - Linear regression and correlation coefficients between automation vs. front-loaded measure

Sample Handling	N	Total Aspiration Time (min)	Linear Regression	Correlation coefficient (R^2)
capped tubes	100	19	1,0516x-0,7496	0,9434
deccaped tubes	66	12	0,9782x-0,1449	0,9726

B-025

Manual Verification of Aldolase Reference Materials and Validation of an Aldolase Assay on an Automated Chemistry Analyzer

J. Wiencek[1], E. Olson[2], K. Lembright[2], S. Lawson[2], S. Wang[2], E. Reineks[2]. *[1]Cleveland State University, Cleveland, OH, [2]Cleveland Clinic, Cleveland, OH*

Background: Aldolase (ALD) is a useful marker of muscle damage and is still frequently ordered in conjunction with creatine kinase. A commercial ALD kit (Roche Diagnostics, Indianapolis, IN) is available as a manual method. The test principle of this kit utilizes the disappearance of NADH UV absorbance in a coupled reaction. Although we were interested in employing the reagents of this kit for use on an automated platform, initial calibration materials from third parties were found to be unreliable for quality control(QC) and calibration purposes. Using a validated spectrophotometer and the manual method, we verified a set of QC and calibration materials. These materials, along with method comparison studies, were important in transferring the ALD test to an automated platform.

Methods: A Beckman DU800 spectrophotometer (DU800) was first used to asses ALD QC (Roche) following their kit's established protocol. Patient samples (n=16) and a third party calibrator were further assayed and compared to values obtained by an outside reference laboratory. After this analysis, the kit was modified to work with the P800 automated analyzer (Roche). Calibration of the analyzer was required to establish a *k*-factor in its system. The average value of replicate ALD measurements (n=6) determined by the DU800 was assigned to the calibrator to be used in this procedure. Once this parameter was defined, studies were performed to determine linearity, precision and method comparison of ALD activity in patient samples (n=42).

Results: Roche QC (PreciNorm and PreciPath) assayed on the DU800 fell within the recommended ranges of ALD activity of 12.4 ± 0.8 and 24.4 ± 1.8 units/L, respectively. Deming regressions of 16 patients analyzed with both the DU800 and a reference laboratory showed a slope of 0.998, an intercept of -0.12 units/L, and a correlation coefficient of 0.9632. The labeled value of a third party calibrator stated the product's lot contained 18.7 units/L of ALD; however the DU800 and a reference laboratory reported values of 21.2 and 21.7 units/L, respectively. Using this data, the *k*-factor was established on the P800 and the automated method was determined to be linear over a range of 1.8 to 53.1 units/L. Also the analysis of inter-day precision over 20 days revealed a CV of 4.6% for PreciNorm and 2.2% for PreciPath. Final method comparisons between patient samples (n=42) with the P800 and a reference laboratory showed a Deming regression with a slope of 1.070 an intercept of -0.19 units/L, and a correlation coefficient of 0.9136.

Conclusion: We established confidence in the third party calibration material and vendor QC materials by verification on a manual platform. Our data established that the manual Roche ALD kit can be adapted to an automated method valid for routine clinical service.

B-026

Automated Band Neutrophil Counts by the CellaVision DM96 Digital Blood Imaging System

H. Broome[1], H. Bengtsson[2]. *[1]University of California, San Diego, La Jolla, CA, [2]CellaVision AB, Lund, Sweden*

Background: Early recognition of sepsis is critical for instituting life-saving therapy. Recent studies shows that the neutrophil band count remains one of the most predictive, readily-available tests for positive blood cultures (1, 2). CellaVision DM96 images blood smears and pre-classifies nucleated cells into leukocyte differential categories including band neutrophils. Before posting results from the DM96, clinical laboratory scientists (CLS) must confirm or re-classify the cells in the differential categories (3). The objective of this study was to compare pre-classification and post-reclassification results of DM96 blood smears from emergency department patients to evaluate the reliability of the DM96 reliably to screen for increased band neutrophils.

Methods: From a total of 180 consecutive complete blood counts plus differentials performed on ED patients, 64 smears were selected that had DM96 pre-classification band counts ranging from 0% to 48%. After two CLS independently reclassified the DM96 results from these 64 blood smears, the pre-classified and post-reclassified results were analyzed for correlation and agreement using post-reclassification band percentages as the reference method.

Results: Correlation coefficient (R^2) = 0.66 with a linear regression equation of: pre-classification band % = 1.06 x (average post-reclassification band percentage) + 0.09. Using a cutoff of 25% bands for the pre-classification DM96 and 15% bands for the average of the two CLS post-reclassification results, the positive agreement was 71%, and the negative agreement was 100%. There were two discrepant values with high band % by the DM96 pre-classification (26%; 28%) but normal by the two CLS post-reclassification (0.9% and 1.7%; 6.1% and 0.9%).

Conclusion: This preliminary study suggests that DM96 pre-classification band counts reliably screens for increased band counts using a cutoff of 25%. Additional studies need to be done with more samples with high band counts to determine the optimum cutoff and to determine the sensitivity, specificity, and predictive value of the DM96 pre-classification band percentage. These results suggest the DM96 pre-classification probably is more sensitive than specific since the two discrepant samples had higher DM96 pre-classification results and since pre-classification showed a positive bias compared to post-reclassification. High sensitivity with a reasonable specificity is acceptable for a screening test.

References:

1. Chase M et al. Predictors of bacteremia in emergency department patients with suspected infection. American Journal of Emergency Medicine. 2012;30:1691-1697.

2. Drees et al. Bandemia with Normal White Blood Cell Counts Associated with Infection. American Journal of Medicine. 2012 125:1124.e9-1124.e15

3. Kratz et al. Performance Evaluation of the CellaVision DM96 System. American Journal of Clinical Pathology 2005; 124:770-781.

B-027

Automated review of laboratory information system quality assurance (QA) reports using text analysis

B. P. Jackson, J. M. Toohey, M. S. Berntsen, L. J. McCloskey, D. F. Stickle. *Jefferson University Hospitals, Philadelphia, PA*

Background: Laboratory accreditation requirements include regular review of results reporting. At our hospital, a quality assurance (QA) report generated by the laboratory information system (LIS) is printed and reviewed daily to verify proper reporting of all critical results, linearity failure results, and delta checks. In most cases, the review process is entirely algorithmic -- there is a fixed series of steps and rules by which most results either "pass" or "fail" review. Such a process was amenable to automation. Our objective was to produce a computer program to "read" and assess all pertinent text elements of the QA report so as to eliminate manual review of as many results as possible.

Methods: Programming was conducted using Visual Basic (VB). The LIS QA report for a given day was produced as a text file sent to a computer hard drive. The executable VB program (QADR.exe, named for QA Data Reduction) read the QA report so as to extract and group cases of critical results, linearity failures, or delta checks. Information content related to assessment of each condition was extracted from the original report as defined by non-null characters in fixed locations in the original text file. For critical results, the program verified whether results were called back according to standardized comment codes. For linearity failures, the program verified that results were reported as appropriate for the individual analyte (e.g., not reported as ">" for analytes that should have been repeated on dilution). For delta checks, results were excluded from further consideration by a variety of rules, such as if the time between the LIS-generated delta check results exceeded 72 hours. Results not meeting acceptance criteria were assigned a "non-verified" code and automatically printed for manual review. The results of automated review were recorded in a summary text file for all results, and both the original LIS QA report and the summary text file were archived in electronic form.

Results: After VB program development, a validation period of one month was used to compare manual and automated reviews of the LIS QA reports. With program refinement, automated review contained no comparison errors. Following this period, automated review was adopted as the routine procedure for QA review. Prior to adoption of automated review, printed QA reports were 20-30 pages, and approximately 30 minutes were required daily for QA review. After adoption, summary printed reports for non-verified results were 1 page maximum, and less than 10 min total was required for daily QA review. In projection, it is estimated that automated QA review will save more than 3 man-weeks per year in labor. Moreover, automated QA review is a definitively "green" undertaking, in that it will eliminate printing and archiving of more than 7000 pieces of paper per year.

Conclusions: Automated review of LIS QA reports was accomplished using a custom computer program performing text analysis. The program was successful in assessing common "pass/fail" criteria to an extent that greatly reduced manual effort and costs associated with daily results review.

B-028

Characterization and stability of time-of-day patterns of running averages as potential inputs to patient-based quality control algorithms: examples for basic metabolic panel analytes in a university hospital

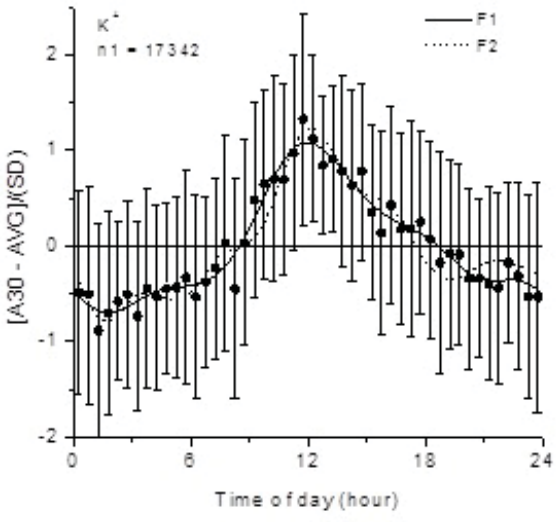
B. P. Jackson, L. J. McCloskey, D. F. Stickle. *Jefferson University Hospitals, Philadelphia, PA*

Background: Regular patterns of time-of-day (TOD) variation of running means of patient data are potentially useful as inputs in patient-based quality control (PBQC). Characterization of TOD patterns and their stabilities are initial steps to determine whether use of patterns might improve PBQC. For 7 analytes of a Basic Metabolic Panel (BMP) at a university hospital, we mathematically characterized average TOD patterns (t = 0-24 hours) of running means of patient data for one month intervals, and assessed the stability of such patterns across successive months' data.

Methods: Successive one-month datasets (M1, M2) for patient measurements were obtained for BUN, Ca2+, Cl-, CO2, creatinine (Cr), K+ and Na+. Running means of length 30 (A30) were calculated across M1 and M2, with data restricted to samples within each analyte's reference range. Independently for both M1 and M2, average A30 as a function of time-of-day (TOD) was calculated for 48 half-hour intervals across 24 hours. From these data, TOD-dependence of A30 was characterized mathematically using low-frequency ($\omega \leq 12\pi$/day) Fourier transforms to produce continuous, smooth functions F1(t) and F2(t). Stabilities of TOD patterns were evaluated by correlation (r2) between F1(t) and F2(t).

Results: An example TOD pattern is shown for K+ in Figure. The TOD-dependence of A30 for K+ was relatively stable, as demonstrated by high correlation between F2(t) and F1(t) (r2 = 0.929). Across the remainder of BMP analytes, there was marked variation in apparent cross-month stability of patterns as assessed by r2: Cr (0.299), BUN (0.765), Na+ (0.811), Cl- (0.849), CO2 (0.870), Ca2+ (0.973).

Conclusions: Methods presented here exemplify an approach to characterization of TOD patterns in running means and assessment of their stability. The stability assessment results provided a logical order among BMP analytes for further evaluation of the potential utility of TOD patterns as inputs to PBQC algorithms at our institution.



B-029

Optimization of Sample Work-Flow and Testing Efficiencies with a Paradigm Shift in Automated Systems for Clinical Molecular Diagnostics Laboratories

C. Newhouse[1], T. W. Myers[1], E. Smith[1], S. Boyle[1], V. Namasivayam[1], A. Nelson[1], D. Schoener[1], S. L. Moseley[2], P. Rodriguez[2], M. Lewinski[1], J. Osiecki[1], S. Roehrig[1]. *[1]Roche Molecular Systems, Inc., Pleasanton, CA, [2]Roche Diagnostics Corporation, Inc., Indianapolis, IN*

Introduction: Similar to trends faced by clinical chemistry laboratories 20 years ago, today's molecular diagnostics laboratories are increasingly challenged with balancing volume growth across an expanding menu of tests, while maintaining meaningful productivity and efficiency gains. The challenges currently faced by clinical molecular diagnostic labs extend from complexities in tubes standardization; increasing demand for testing from multiple sample types; fluctuations in demands for specific tests; subjectivity in result reporting to increased demands on labs to streamline workflows with less hands-on time for applications. With the constant pressure of these variables, there is potential for work-flow inefficiencies to increase costs and potential risk for human error associated with result generation.

Objective: To detail a paradigm shift in design features for automation in clinical molecular diagnostic testing. A description of how innovative integrated analyzer design features could address the current challenges faced by labs responding to volume growth in molecular testing.

Methodology: Design features of two fully automated, integrated Real-Time PCR testing systems, the **cobas**® 6800 System* and **cobas**® 8800 System* will be detailed. These systems include automation of sample transfer, processing and target detection, including onboard assay specific reagent cassette storage and handling. A dedicated lane for urgent bypass testing accommodates the need for sample prioritization. The **cobas**® 6800 System and **cobas**® 8800 System can accept multiple primary and secondary tube types with no pre-sorting or "batching" of tubes or racks. Through universal sample preparation and PCR profiles (**cobas omni** process) the instrumentation can process samples for 3 different assays simultaneously for detection of HIV, HBV, HCV, and CMV. By taking up to 3 aliquots from one specimen, up to 3 assays can be run from a single patient sample. Sample input parameters include 200uL and 500uL EDTA plasma for testing of HIV-1. A user defined channel for lab developed tests provides flexibility and benefits of automation using the **cobas omni** process. The instrumentation requires very little user interaction and maintenance.

Results & Conclusion: The first 96 results are available in less than 3.5 hours with an additional 96 results every 90 minutes for **cobas**® 6800 System (or 30 minutes for **cobas**® 8800 System). The **cobas**® 6800 System can report up to 384 patient results in 8 hrs. The **cobas**® 8800 System accommodates higher volumes with up to 960 patient results in 8 hrs. User interactions are limited to loading and unloading and periodic removal of waste, reducing hands on time and risk for human error. Collectively, the combination of the new system design and assay design enhancements provide a level of automation that approaches systems used in clinical chemistry, facilitating a paradigm shift for routine clinical molecular diagnostics laboratories and advancements for both laboratorians and patients.

*The **cobas**® 6800 System and **cobas**® 8800 System are in development and not available for sale in the US.

B-030

Laboratory Automation with the Beckman-Coulter Power Express produces improved turnaround times for stat and routine chemistries

C. P. Yeo, D. S. L. Lee, C. S. P. Chiong, J. S. Y. Wong, P. R. Chincholkar, K. S. L. Lim, C. H. C. Tan, W. Y. Ng. *Singapore General Hospital, Singapore, Singapore*

Background The Singapore General Hospital (SGH) Clinical Biochemistry Laboratory, with its need to provide 24/7 coverage for stat and routine chemistry tests to SGH and its affiliated cancer and heart centers, has constantly strived to achieve optimal performance and service delivery. In 2007, the laboratory introduced laboratory automation in the form of the Beckman-Coulter Power Processor Laboratory Automation System (PP LAS). With its 2007 workload of 5.94 million tests increasing at a rate of 5-7% a year, the laboratory quickly outgrew its LAS's capacity. In 2013, in tandem with plans to move into new purpose-built facilities, design considerations were made to assimilate further refined workflow and specimen routing strategies and to install the latest generation of LAS - now coined the Beckman-Coulter Power Express (PE). **Method** The LAS inlet was placed next to the pneumatic tube station which receives deliveries from Emergency, Intensive Care and other campus sites. The PE LAS with three centrifuges, decappers, aliquoters and two 5000-tube refrigerated stockyards was linked to 2 DxI800s, 1 AU680 and 2 AU5822s. Turnaround time (TAT) was defined as that between specimen arrival in the laboratory and result release (sans auto-verification) to EMR. TAT for stat specimens from Emergency and Intensive Care was the key performance indicator for the laboratory. **Results and Discussion** Pre-PE-LAS TAT for stat specimens was 95% in 45 minutes and 70% in 35 minutes; a good performance achieved through expending much effort into manually moving stat specimens ahead of routine specimens on the LAS tracks. With PE LAS, TAT was sustained but with significantly less manual effort. Data also showed that the PE LAS provided faster turnaround for routine test orders from the specialist outpatient clinics and wards, hitting >80% in 45 minutes (a vast improvement over previous <20% in 45 minutes). The improvement in TAT and workflow could be attributed to: (1) priority identification design layout of the stat/routine laboratory that places the PE LAS close to the specimen reception area, (2) an improved LAS and the much higher capacity of the online analysers. The important features of the Power Express LAS are: (a) a dynamic inlet that allows seamless input of up to 4 types of specimens (stat, routine, pre-centrifuged and archival) without the need to initiate the pause or standby mode, (b) ability to support up to 4 centrifuges (we installed 3 and have space for a fourth) and therefore significantly reducing the occurrence of oft-cited bottlenecks at the LAS centrifuges, (c) 4-laned specimen transportation track that allows stat specimens to bypass routine specimens, (d) online RFID specimen identification that circumvents previous issues with barcode readers and (e) online high-throughput analysers. **Conclusions** With close proximity to specimen reception, workflow refinements and favourable new features of the latest Beckman-Coulter Power Express LAS, quicker result reporting has been shown. In addition, provision for a fourth centrifuge and high capacity of the online analysers permit further growth in the coming years.

B-031

Look before you leap: Developing optimized automated rule sets for reporting hemolyis, icterus and lipemia based on a priori outcomes analysis

J. M. Boyd[1], R. Krause[1], G. Waite[2], W. Hui[2], E. Yadzi[2], D. Wilmik[2], I. Seiden Long[1]. *[1]Department of Pathology and Laboratory Medicine, University of Calgary and Calgary Laboratory Services, Calgary, AB, Canada, [2]Gamma Dynacare Medical Laboratories, Brampton, ON, Canada*

Objective: The new CLSI C56A guideline directs labs to generate their own policies for hemolysis(H), icterus(I) and lipemia(L) reporting by automated methods. Here we describe a process to review and optimize reporting policies for test results with known interference prior to implementation.

Methods: Table 1 describes proposed commenting and cancelling policies generated using CLSI C56A vs baseline policies from two high volume community laboratories. Identical Proposed Rules were applied to the test result data sets from each lab. Test Data: Lab A, Roche Modular platform, IBM AS400 Custom LIS reporting 541236 tests, for 72 analytes over 1 week. Lab B, Roche Cobas C8000 with Cerner Millennium/Roche PSM reporting 391515 tests for 45 analytes over 2 weeks. Any test receiving >5 flagged results was considered for generation of Optimized Rules including analyte level and clinical significance. Number of Commented and Cancelled tests was counted for each lab and rule set.

Results: Optimized rules were only required for hemolysis. Comment and cancellation test counts at baseline were compared to optimized rules for each lab. Hemolysis

rules for Lab A: baseline(comment:3656, cancel:NA) vs optimized(comment:155, cancel:19) reduced hemolysis flagging by 96%, while for Lab B: baseline(comment:0, cancel:277) vs optimized(comment:107,cancel:2) reduced result cancellation 99%. Icterus rules for Lab A: baseline(comment:492) vs. optimized(comment:0) reduced flagging 100%, while in Lab B: baseline(comment:0) vs optimized(comment:13) increased flagging. For lipemia Lab A: baseline(comment:2383) vs optimized(comment:24) reduced flagging 99%, while in Lab B baseline(comment:74) vs optimized(comment:193)increased flagging 62%.

Conclusions: Implementation of identical rule sets in Labs A and B indicated that the outcomes of automated HIL reporting are significantly lab dependent . This process of testing and optimization of HIL reporting rules prior to implementation by *a priori* outcomes analysis demonstrates the clear benefit of impact assessment for reporting policies with automated HIL rule sets.

Table 1: Baseline, proposed and optimized reporting rules

		Baseline Rules	Proposed Rules	Optimized Rules
Hemolysis	Lab A	Test result reported, Manual visual inspection of sample with application of HIL flag, no comment	Test result reported, Automated HIL detection and application of rules, comment on direction of interference up to H of 600, cancel H>=600	Test result reported, Automated HIL detection & application of rules, comment on direction of interference up to H of 600, cancel H>=600, only when CLINICALLY SIGNIFICANT*. * defined as a degree of interference sufficient to generate a test result outside of the normal range for the test
	Lab B	Test result not reported, Automated HIL detection and application of rules with test cancellation		
Icterus	Lab A	Test result reported, Manual visual inspection of sample with application of HIL flag, no comment	Test result reported, No cancellation, Automated HIL detection and application of rules, comment on direction of interference	Same as proposed rules
	Lab B	Test result reported, no flag, no rules in place		
Lipemia	Lab A	Test result reported, Manual visual inspection of sample with application of HIL flag, no comment	Test result reported, no cancellaton, Automated HIL detection with comment AFTER Manual ultracentrifugation process applied	Same as proposed rules
	Lab B	Test result reported, Automated HIL detection with comment AFTER Manual ultracentrifugation process applied		

B-032

Identification of Erroneous Potassium Results Using a Laboratory Data-Derived Machine Learning Algorithm

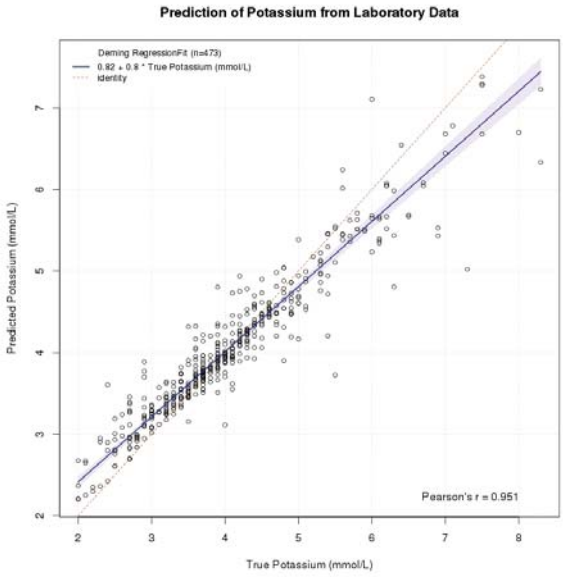
C. R. McCudden, M. Henderson. *The Ottawa Hospital, Ottawa, ON, Canada*

Background and Objectives: Potassium is a critically important analyte with many preanalytical considerations. While laboratories have procedures to avoid reporting erroneous results, it is difficult to identify if a given potassium result is accurate. The objectives of this study were: 1) to use commonly available laboratory data to develop a machine learning algorithm to predict potassium concentrations 2) determine the performance of the algorithm for error detection.

Methods: LIS data was used to develop a random forest regression model to predict potassium results. The prediction algorithm was trained using known, accurate potassium concentrations with commonly available hematology (complete blood count) and biochemistry (basic metabolic panel) data. Data included 2876 result sets (80% for model training, 20% for testing) from 1642 patients with encounters at 174 different hospital/clinic locations over a two-year period. 'Accurate potassium' was defined as values where blood gas (GEM4000) and chemistry analyzer (Vista 1500) values were within +/- 0.4 mmol/L. Error simulation (introduced bias from 0.5-2.0 mmol/L) was used to determine the performance of the algorithm to detect inaccurate results, which were identified by the difference between observed and predicted potassium.

Results: A comparison of the predicted and accurate potassium concentrations is shown below. The most important predictors were creatinine, urea, sodium, anion gap, and WBC. Based on simulations, the algorithm detected an error of 0.5 mmol/L with a sensitivity of 78% and specificity 74% and an error of 1.0 mmol/L with a sensitivity of 86% and specificity of 96%.

Conclusions: The model described herein represents a powerful new quality tool whereby predicted concentrations could be used to prevent reporting grossly inaccurate potassium results. This is particularly valuable given the clinical importance of potassium and abundance of preanalytical considerations. Routine application of the model (e.g. as a autoverification rule) could prevent reporting of inaccurate potassium results due to unforeseen preanalytical factors.



B-033

Differentiation between glomerular and non-glomerular hematuria by an automated urine sediment analyzer

P. V. Bottini, B. D. Andreguetto, K. Krempser, J. Lauand, C. R. Garlipp. *Univesity of Campinas, Campinas, SP, Brazil*

Background: Differentiation between glomerular and non-glomerular hematuria by observation of the erythrocytes morphology using phase-contrast microscopy has been very well established for almost 35 years. However, it is a time-consuming and labor-intensive procedure that requires skilled personnel. Some years ago, an automated urine sediment analyzer based on the KOVA® method with on-screen review of the images was introduced. The aim of this study was to evaluate the performance of this image based automated sediment analyzer (UriSed, also called sediMAX® in some countries) as an alternative to the phase-contrast microscopic analysis of erythrocytes morphology.

Methods: We studied 312 urine samples with hematuria (erythrocytes>5/hpf). Samples were analyzed by UriSed and all the images reviewed by an experienced analyst. Parallelly the urine samples were centrifuged (10 mL, 5 minutes, RCF = 400) and the sediment (0.5 mL) was placed on a slide and examined under a coverslip by phase-contrast microscopy. Erythrocytes morphology was analyzed by both methods by different observers. Based on the presence of codocytes and/or acanthocytes, samples were classified as non-glomerular (absence of codocytes or acanthocytes) and glomerular (presence of codocytes, acanthocytes or both). Kappa correlation was used to assess the agreement between both methods.

Results: Our data showed an agreement of 97.4% between erythrocytes morphology analyzed by both methods (kappa=0.9484, p<0.001). From 312 samples, 140 of them (45%) presented isomorphic erythrocytes and hematuria was classified as non-glomerular by both methods whereas in 164 samples (52.5%) we observed the presence of codocytes and/or acanthocytes by phase contrast microscopy and by UriSed being classified as glomerular hematuria. Only 8 samples (2.5%) had discordant results. Five

of them revealed the presence of codocytes by phase contrast microscopy which were not displayed on UriSed. On the other hand, 3 samples classified as non-glomerular by phase contrast microscopy presented codocytes on UriSed images.

Conclusion: UriSed is a precise and accurate alternative to the gold standard phase-contrast microscopy that allows a better workflow and may significantly improve turnaround time.

B-034

Moving Patient Averages: A Pilot Study Using Error Simulation

R. Ybabez, J. Boysen, A. Zblewski, B. Hendrix, C. Wittwer, L. Rossini, S. Chanakarnjanachai, L. Duncan, D. Block, N. Baumann. *Mayo Clinic, Rochester, MN*

Background: Robust quality control (QC) processes in clinical laboratories are required to ensure stable operation of analytical systems and to provide reliable test results. There is potential added value in using real-time patient data to supplement traditional statistical QC. The concept of monitoring moving averages of patient results has been discussed for decades, and recently middleware programs that can calculate moving averages continuously and in real time have become commercially available. The objectives of this study were to evaluate Moving Averages software by: (i) collecting moving average patient data for three common analytes (calcium, chloride and creatinine) in a high volume clinical laboratory, (ii) configuring analyte-specific protocols and (iii) testing the protocols using simulated systemic errors.

Methods: All patient data were generated using Roche Cobas 8000 reagents and analyzers. Moving Averages (Data Innovations, Inc) protocols were configured for calcium, chloride, and creatinine. For each analyte, the mean of patient results and Sp (standard deviation of the patient population) were calculated over a 2 week time period. Sa (standard deviation of the analytic method) was obtained from the standard deviation (SD) of in-use QC at concentrations near the patient population mean concentration. Sp/Sa was calculated and power function charts (Cembrowski, GS et al. (1984)) were used to estimate the appropriate number of patient test results to average (N). Exclusion criteria were applied to calcium and creatinine protocols to exclude values >4SD from the mean and results from patients in dialysis units were excluded for creatinine. Systemic 2SD errors were simulated by analyzing consecutive patient samples with results approximately 2SD above the patient mean. The concentrations of analyte in the simulated error samples were: calcium, 9.5-9.8 mg/dL; creatinine, 1.3-1.4 mg/dL; chloride 104-106 mmol/L. The number of patient samples with simulated errors needed to trigger an error warning was calculated.

Results: Sp/Sa and suggested number of patient test results to average (N) were 9.8 and N=200 for calcium, 4.6 and N=50 for chloride, and 6.4 and N=70 for creatinine. Error simulation showed that 2SD error warning thresholds were triggered after 140 patients for calcium, 50 patients for chloride, and 47 patients for creatinine. A second simulation study was performed using protocols with different N for each analyte (calcium, N=100; chloride, N=30; creatinine, N=30) and yielded 2SD error warnings after 75, 30, and 26 patients for calcium, chloride and creatinine, respectively.

Conclusion: Moving Averages may help laboratories detect systemic errors in real-time. Three analytes (calcium, chloride, and creatinine) were used to evaluate the program and optimize parameters for detecting a simulated 2SD error. Errors simulated using preliminary estimates of the number of patient test results to average (N) suggested that a smaller N (fewer patient results averaged) may allow errors to be detected earlier and before large numbers of patient results are affected. The ability to detect a shift in patient results on a continuous basis and in real time may complement existing QC processes in the laboratory.