Wednesday, August 1, 2018

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

Automation/Computer Applications

B-012

Implementation of a web-based Quality Control Management System for Clinical Chemistry Laboratories in a Standardized Healthcare System

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Background: As we continue expanding our laboratories services at Florida Hospital Healthcare System, additional tools were needed to monitor quality control in Chemistry Laboratories. The objective of implementing Unity Real Time QC Management system was to improve monitoring analytical performance metrics more efficiently and effectively. **Methods:** This study collected 6 months of quality control data for 12 networked laboratories, across fifteen Roche 6000, two Roche 8000, and three Roche Integras instruments**.** This data was evaluated against BioRad peer group and existing Sunquest quality control system. Manual selection of statistical process rules (SPC) were determined for each analyte. Fixed means/SDs or floating means/SDs were selected to use for SPC rule evaluation. Data review was performed by using standard Levey Jennings (LJ) charts, Multi LJ chart, Youden chart, and Yundt plot. Data Analysis grid reports provided side by side comparison between peer group and own laboratory, across multiple instruments, and between own laboratory and Florida Hospital peer group. Onsite training was offered by the vendor for superusers and computer based training was deployed to medical technologists involved in QC review before implementation. **Results:** Prior efforts to monitor analytical performance reviewing quality control in Sunquest system were done inefficiently. The quality control review was time consuming and only resulted in evaluating quality control using Levey Jennings charts. Unity Real Time QC management system simplifies quality control evaluation and provides multiple tools within the program to efficiently monitor performance trends for each analyte. This program allowed us to effectively identify quality problems by collating data into statistically significant charts and plots. In addition, it helped us identify instrument and assay performance changes over time and which variables play a role in these changes (reagent lot changes, calibrations, new QC lot changes, etc). The implementation of this software improved documentation of corrective actions in the laboratory. We also noted optimization of error detection without additional QC analysis and troubleshooting. **Conclusion:** The implementation of a web-based QC Management System in a large healthcare System provides flexible options for quality control evaluation. Unity Real Time offers a robust method for data comparisons helping us to meet regulatory requirements, allowing a high-level overview of networked instruments and standardized and centralized quality control data management for the entire system.

B-013

Performance Evaluation of Atellica IM 1600 Analyzer Assays at a Medical Laboratory

M. Jlaiel, P. A. Fle, A. Fino, A. Debuyser. *Laboratoire de Biologie Medicale Bioesterel, Mandelieu la Napoule, France*

Background: In our institution, studies were performed to assess the analytical performance of immunoassays (IM) for the Atellica® IM 1600 Analyzer with respect to verification of precision and linearity, and method comparison with Siemens Healthineers assays on ADVIA Centaur® XP System. **Methods:** Precision verification was performed according to EP15-A3, method comparison per EP09-A3, and linearity per EP06-A. For precision verification, three or four concentration levels were used; each level of QC materials and sample pool were tested as one run per day with five replicates per run, for five days (25 total replicates per sample for each assay). Method comparison studies were performed using 40 serum samples that covered each assay range, from low to high; samples fell into four assay concentration ranges). The number of levels of linearity material ranged up to six depending on the assay. For each assay, three replicates of each sample level were assayed. **Results:** Within-run and total imprecision agreed with the manufacturer's claims. Within-run (repeatability) IM CVs ranged from 1.3% to 5.3% and total (within lab) IM CVs from 1.7% to 10.3%. Linearity studies have been performed for all assays. Precision and method comparison studies are summarized below.

		Precision			Method Comparison
Atellica IM Analyzer Assay	**Units**	**Mean conc. (low, high)**	**Within run %CV(SD) (low, high)**	**Total %CV(SD) (low, high)**	**Atellica IM Analyzer vs. ADVIA Centaur XP System; Deming Fit**
Fer	ng/mL	15.06, 330.47	2.7(0.40), 1.8(5.90)	10.3(1.55), 5.3(17.38)	y=0.89x-0.59
VB12	pg/mL	192.40, 765.56	4.4(8.48), 1.3(9.65)	5.1(9.89), 2.1(15.71)	y=0.93x+60.6
VitD	ng/mL	27.05, 96.9	4.6(1.26), 2.0(1.98)	7.2(1.94), 4.3((4.20)	y=0.95x-2.12
iPTH	pg/mL	37.76, 814.27	1.6(0.59), 1.6(13.09)	2.1(0.80), 2.3(18.61)	y=1.07x-0.13
TnIH*	pg/mL	10.44, 5647.85	3.9(0.41), 1.1(60.42)	4.1(0.43), 2.4(134.46)	y=0.90x+0.39
BNP	pg/mL	46.90, 1887.03	2.8(1.32), 1.5(27.46)	5.8(2.74), 3.1(58.65)	y=1.13x+3.73
PSA*	ng/mL	0.14, 15.81	2.7(0), 1.9(0.31)	4.0(0.01), 2.6(0.41)	y=0.90x-0.06
CA 199	U/mL	21.06, 271.93	4.6(0.97), 5.3(14.34)	7.4(1.55), 9.7(26.46)	y=0.89x+11.9
AFP*	ng/mL	33.72, 248.68	3.0(1.02), 3.1(7.61)	3.4(1.14), 4.7(11.70)	y=0.91x-0.145
eE2	pg/mL	34.98, 950.32	4.5(1.57), 1.7(16.56)	7.3(2.54), 4.2(39.91)	y=0.96x-1.03
ThCG*	mIU/mL	5.75, 394.32	3.6(0.21), 2.1(8.19)	3.6(0.21), 2.8(10.91)	y=1.07x+3.46
PRGE	ng/mL	1.35, 22.21	4.5(0.06), 1.9((0.42)	5.5(0.07), 3.9(0.88)	y=1.19x+0.36
TSTII	ng/dL	20.43, 1065.93	3.2(0.66), 3.3(35.26)	4.3(0.88), 7.3(78.28)	y=0.89x-8.86

Conclusions: All assays tested on the Atellica IM Analyzer demonstrated good precision and correlation to the current ADVIA Centaur XP System assays. The precision results were consistent with manufacturer's claims. *Siemens Healthineers supported the study by providing systems, reagents, and protocols, and contributed to data analysis.

B-014

Assessment of Average Patient Results for the Use of a Patient Results-Based Quality Improvement Program

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Background: Patient results based quality improvement approach has been applied in clinical laboratories. The volume of the patient test results selected for analysis may play an important role in an accurate and efficient lab quality control (QC) program. The literature found had no clear guidelines on the quantity of results needed, ranging from 10 to 100 results. In this study, we retrieved and analyzed a large amount of patient data comparing the variation of the average test results with test volumes. **Methods:** Average patient results of comprehensive metabolic panel (CMP) and volume of tests in varying time periods were extracted from July 2015 to December 2017 via Viewics® program. For each period of time with corresponding test volume, the weighted average (wAVG) of test results, standard deviation (SD), coefficient of variation (CV) for each analyte were calculated using Microsoft Excel®. **Results:** CVs and test volumes of analytes for the periods of time are shown in the Table. The results show that increased volume of results in the periods of time correlated with decreased CV. For electrolytes (chloride, CO_2, potassium, and sodium) after daily period (volume ~780) there was no significant decrease in CV, and even hourly period (volume around 40) CVs are less than 5%. For basic metabolic panel (BMP), albumin, and protein after the weekly period (volumes ~5,500, ~3,500, and ~3,500, respectively) there is no appreciable decrease in CV. CVs of enzymes (ALP, ALT, AST) and bilirubin are generally much higher than other tests. **Conclusion:** The results of CV variation of average patient results we found in the study may guide in the better selection of the volume of patient results in an application of a patient results based quality improvement program, such as real time QC monitoring and review.

	Hour		Day		Week		Month		Quarter	
Analyte	CV	Volume	CV	Volume	CV	Volume	CV	Volume	CV	Volume
Albumin	13.7%	22	8.9%	515	3.1%	3,564	2.9%	16,065	3.1%	45,866
Bilirubin	134.0%	22	53.3%	519	12.9%	3,602	7.7%	16,375	6.1%	46,873
ALP	48.8%	21	14.9%	501	5.6%	3,478	5.0%	15,690	5.0%	44,957
ALT	167.7%	21	46.3%	503	16.6%	3,496	11.0%	15,755	8.7%	44,964
AST	518.1%	21	91.2%	503	22.7%	3,494	13.2%	15,746	10.6%	44,959
BUN	35.6%	33	11.6%	784	7.3%	5,605	6.0%	25,058	6.4%	71,696
Calcium	3.9%	33	2.2%	777	0.9%	5,567	0.7%	24,966	0.6%	71,364
Chloride	1.6%	33	0.5%	777	0.3%	5,563	0.2%	24,929	0.2%	71,272
CO2	5.4%	33	2.2%	777	2.2%	5,562	2.1%	24,927	2.0%	71,267
Creatinine	46.3%	33	14.8%	782	9.9%	5,597	2.8%	25,084	2.2%	71,698
Glucose	20.2%	33	5.5%	779	1.5%	5,583	1.0%	25,009	0.6%	71,486
Potassium	4.5%	33	1.4%	781	0.6%	5,593	0.5%	25,055	0.3%	71,611
Protein	8.7%	21	4.8%	499	1.6%	3,470	1.0%	15,665	1.0%	44,736
Sodium	1.1%	33	0.4%	785	0.6%	5,636	0.6%	25,218	0.5%	72,062

B-015

Utility of CEA kinetics in predicting recurrence of colorectal cancer in India in a tertiary cancer hospital.

S. Chakraborty. *Tata Medical Center, Kolkata, India*

Incidence of colon cancers is on the increase in India. Routine testing of serum carcinoembryonic antigen (CEA) is performed in the laboratories as a marker for prognosis and prediction. It is also used as an adjunct to diagnosis with other clinical and imaging modalities. We retrieved serial data available on the electronic records from 2014 to 2016. A model was built using patients who had CEA values above 5 ng/mL but were currently stable after surgery with or without neoadjuvant chemoradiotherapy. The model was tested using a training dataset and the accuracy of prediction checked using a test dataset. A bi exponential model was built to predict CEA at time t. $CEA(t) = CEA(0)\, e^{-0.997.t} + CEA(t3)e^{(-0.6458.t)}$. Half-life for patients without recurrence was 20.2 (±3) days as against 48.7 (±8) days for patients with recurrence. The rate of clearance of CEA in the former group was 141.22 ng/mL*month respectively whereas the group with recurrence has a clearance rate of 102 ng/mL*month respectively. The accuracy of prediction was determined to be 64.3%. The model has the ability to predict cases that can present with recurrence. Further clinical validation needs to be carried out. Currently a web based application has also been made available.

B-016

Telemicroscopy: An innovative solution to an age-old problem

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Background: Telemicroscopy is the digitizing of images from a microscope and transmitting those images to another location via the internet. Multicare Health System has adopted this technology in hematology and microbiology to provide real-time support for satellite hospitals and remote clinics, especially in the areas of interpreting challenging cells on a differential and identifying organisms on a Gram stain. This telemicroscopy model allows the Core Lab to see exactly what the outlying locations are seeing in real-time and provide feedback in making an accurate decision on differentials and Gram stains, thereby improving patient care. **Methods:** When a technologist at an off-site location is looking at a slide and needs a second-opinion consultation from an experienced technologist, they call the Core Lab. A ProScope 5MP Microscope Camera (Bodelin, Wilsonville, OR), under $500, is inserted into an ocular of a Nikon or Leica microscope at the off-site location and the Micro Capture Software (Bodelin, Wilsonville, OR) is opened. When the Core Lab receives the consult request, a web conference using GoToMeeting (Logmein,Boston, MA) is initiated. The Core Lab technologist will then "Share Your Screen" from the GoToMeeting, and "Change Presenter to" the off-site location. This allows the Core Lab to dynamically look at the subject under the off-site microscope. The protected health information (PHI) are discussed over the phone, and not documented by either software. With the real-time video streaming and discussion of the clinical case, the Core Lab can give an accurate second-opinion consultation. **Results:** The technologist from the Core Lab would see images from the ProScope 5MP Camera through the GoToMeeting software. **Conclusion:** This technology offers a relatively inexpensive option for locations that do not have the clinical expertise that the Core Lab has in analyzing slides. Moreover, telemicroscopy offers a valuable educational opportunity with real-time feedback on difficult cells or organisms.

B-017

Fully Automated DNA Isolation and NGS Library Preparation

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Background: Although the total cost of next generation sequencing (NGS) continues to decline, considerable time and cost is required to isolate the DNA and prepare sequence-ready libraries from a variety of different human tissue sources. The goal of the present study was to simplify and fully automate these crucial steps in order to reduce the time and cost of as well as the level of training required to complete these critically important tasks. **Methods:** A microfluidic cartridge and workstation were designed to fully automate the isolation of DNA and then generate sequence-ready DNA libraries from a variety of different human sources, including buccal swabs, formalin fixed paraffin embedded (FFPE) tissue blocks, fresh frozen tissue and blood. The workstation's software was programmed to isolate the DNA and then prepare sequence-ready libraries using reagents from a number of different Illumina NGS library prep kits (including Nextera DNA Preparation, Nextera XT, Nextera Flex and AmpliSeq). Finally, the resulting DNA libraries were sequenced on HiSeq 2500 or MiSeq instruments and sequence data and quality metrics analyzed. **Results:** The automated workflow yielded DNA of sufficient quantity and quality to allow the microfluidic system to be programmed to prepare sequence-ready NGS libraries using a variety of Illumina library prep kits. The isolated DNA was of high quality, based on A260/A280 and A260/A230 ratios, and was then automatically processed by transposome-mediated fragmentation, followed by low cycle PCR to integrate the required Illumina adaptors and index codes. The libraries, purified by bead-based methods, had size distributions that were optimal for Illumina sequencing and were clean of short adaptor sequences and ligated adaptors. Sequence data derived from the automatically prepared libraries was able to be effectively aligned against the reference genome with depth and uniformity of coverage that exceeded that obtained by manual methods. Other quality metrics obtained from the sequencing runs were also excellent, including high Q30 scores, pass filter scores, and low error rates. **Conclusion:** The ability to automatically isolate DNA and prepare sequence ready libraries on a single instrument that requires very little "hands on" effort will reduce the time, cost and effort of next generation sequencing. Moreover, the ability to process a range of tissue types will allow a broad application of NGS including detection of genetic variants in germ line and somatic cells. Finally, as sequencing costs continue to decline, the percent of total costs associated with sample preparation has gone up. Therefore, simplifying and automating combined DNA isolation and library preparation will not only reduce the total time and cost of these prerequisite steps, but also appeal to third party payers as the clinical utility of NGS data justifies its diagnostic applications.

B-018

Autoverification Implementation through Middleware in a Large Hospital Core Chemistry Laboratory: Gains in Quality and Efficiency

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Background: Much of healthcare is transitioning to value-based care, and the laboratory is not exempt. Autoverification (i.e. result release without human intervention) implementation through middleware was sought to heighten the quality of laboratory results while decreasing cost (value=quality/cost). The autoverification rules were removed from the laboratory information system (LIS; Sunquest), and implemented in middleware (Data Innovations) between 4 Cobas 8000 lines (Roche Diagnostics) and the LIS. The Rules Package Guidance Document (Roche Diagnostics) supplied the foundation which was then customized: analytical measurement ranges, clinical reportable ranges, critical values, delta values, specimen integrity rules, and LIS formatting. After installation, the middleware-based autoverification rules were validated via electronic simulated testing (i.e. dry testing) and specimen testing (i.e. wet testing). The laboratory services a 1400-bed hospital, and supports outreach and outpatient centers. **Methods:** To observe any gains in value, the following metrics were observed pre- and post-middleware autoverification implementation: autoverification rates, manual reviewers needed, and ED STAT specimen turnaround time. The autoverification data was collected for 48 days before and after implementation. ED turnaround time (i.e. receipt in lab to result release in the LIS) was averaged for 6 months before and after implementation. **Results**: Overall, the autoverification rate saw a dramatic increase from 63% to 92% (**table-1**). The increase in the autoverification rate allowed the reduction of 1 manual reviewer per weekday (1 full time equivalent). In addition to the efficiency increase (i.e. reduction

of cost), gains in quality were also noted. In combination with other initiatives, the ED STAT specimen turnaround time decreased by 3 minutes. The number of specimen quality rules were increased (e.g. delta checks), resulting in the timely detection of analytical issues. **Conclusion**: An increase in the value of laboratory tests results were observed via the implementation of autoverification through middleware.
Table-1: Autoverification Rates for 48 Days Before and After Middleware Autoverification Implementation

	Pre-Implementation		Post-Implementation	
	Autofile Rate (%)	**Total orders**	**Autofile Rate (%)**	**Total Orders**
Basic Metabolic Panel	69	43674	94	44644
Comprehensive Metabolic Panel	60	74760	89	69455
Hepatic Function Panel	71	5556	87	5442
Renal Function Panel	62	3894	90	5575
TSH	74	25242	>99	27299
FT4	70	7379	>99	10042
Overall	63	312913	92	407006

B-019

Performance Evaluation of Atellica CH 930 Analyzer Assays at a Medical Laboratory

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Background: In our institution, studies assessed the analytical performance of clinical chemistry (CH) and plasma protein assays for the Atellica® CH 930 Analyzer with respect to verification of precision and linearity, and method comparison with Siemens Healthineers assays on the ADVIA® 1800 System. **Methods:** Precision verification was performed according to EP15-A3, method comparison per EP09-A3, and linearity per EP06-A. For precision verification, three or four concentration levels were used; each level of QC materials and sample pool were tested as one run per day with five replicates per run, for five days (25 total replicates per sample for each assay). Method comparison studies were performed using 40 serum samples that covered each assay range, from low to high; samples fell into four assay concentration ranges. The number of levels of linearity material (LGC Maine Standards) ranged up to six depending on the assay. For each assay, three replicates of each sample level were assayed. **Results:** Within-run and total imprecision agreed with the manufacturer's claims. Within-run (repeatability) CVs ranged from 0.2% to 5.3% and total (within lab) CVs from 0.4% to 5.3%. Linearity studies have been performed for all assays. Precision and method comparison studies are summarized below.

	Precision			Method Comparison		Precision			Method Comparison
Atellica CH 930 Analyzer Assay	Mean conc. (low, high)	Within run %CV (SD) (low, high)	Total %CV (SD) (low, high)	Atellica CH 930 Analyzer vs. ADVIA 1800 System	Atellica CH 930 Analyzer Assay	Mean conc. (low, high)	Within run %CV (SD) (low, high)	Total %CV (SD) (low, high)	Atellica CH 930 Analyzer vs. ADVIA 1800 System
GluO, g/L	0.58, 3.44	0.9(0.0), 0.5(0.0)	2.0(0.0), 1.3(0.0)	y=0.99x + 0.01	CRP_2, mg/L	6.7, 51.24	1.4(0.1), 0.8(0.4)	2.8(0.2), 1.2(0.6)	y=1.03x - 1.23
UN_c, mg/dL	15.18, 71.88	2.5(0.4), 0.5(0.4)	3.3(0.5), 1.3(0.9)	y=1.01x + 1.22	RF, IU/mL	23.96, 43.49	2.2(0.5), 0.8(0.4)	3.5(0.9), 3.9(1.7)	y=0.98x + 2.00
ECre_2, mg/L	8.13, 68.32	2.3(0.2), 1.2(0.8)	3.3(0.3), 1.2(0.8)	y=0.96x - 0.03	Na, mmol/L	115.07, 157.43	0.4(0.5), 0.2(0.3)	1.3(1.5), 1.6(2.5)	y=1.04x - 3.63
AST, U/L	46.37, 291.63	2.7(1.3), 1.3(3.9)	3.1(1.5), 1.8(5.1)	y=0.99x + 6.40	K, mmol/L	2.47, 7.33	0.4(0.0), 0.2(0.0)	1.4(0.0), 1.6(0.1)	y=1.04x - 0.16
ALT, U/L	31.57, 213.43	5.3(1.7), 1.6(3.4)	5.3(1.7), 2.9(6.1)	y=1.03x - 2.81	Cl, mmol/L	77.58, 120.80	0.3(0.2), 0.2(0.3)	0.9(0.7), 1.4(1.6)	y=1.00x + 1.50
TP, g/L	39.86, 70.36	4.5(1.8), 0.3(0.2)	4.6(1.9), 0.4(0.3)	y=0.93x + 2.02	Crea_2, mg/L	10.15, 66.43	1.4(0.1), 0.6(3.6)	1.8(0.2), 1.0(0.6)	Not done
Trig, g/L	0.89, 2.13	0.7(0.0), 0.7(0.0)	2.3(0.0), 1.1(0.0)	y=0.94x - 0.017	Ca, mg/L	55.03, 133.36	1.1(0.6), 0.5(0.7)	1.6(0.9), 0.6(0.9)	Not done
TBil_2, mg/L	6.18, 73.81	1.1(0.1), 0.3(0.2)	4.6(0.3), 3.4(2.5)	y=1.04x - 0.24	Alb, g/L	2.61, 4.47	1.5(0.04), 1.2(0.06)	1.6(0.0), 1.6(0.1)	Not done
UA, mg/L	34.52, 96.68	0.5(0.9), 0.4(0.4)	0.9(0.3), 0.7(0.7)	y=1.01x - 0.43	B2M, mg/L	678.33, 3086.4	2.2(15), 0.8(26)	2.5(17), 0.9(27)	Not done

Conclusions: All assays tested on the Atellica CH 930 Analyzer demonstrated good precision and correlation to the current ADVIA 1800 System assays. The precision results were consistent with manufacturer's claims. * Siemens Healthineers supported the study by providing systems, reagents and protocols, and contributed to data analysis.

B-020

Performance Evaluation of the Atellica IM Thyroid Stimulating Hormone 3-Ultra Assay and Impact of Biotin

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Background: The Atellica® IM Thyroid Stimulating Hormone 3-Ultra (TSH3-UL) assay is for in vitro diagnostic use in the quantitative determination of thyroid-stimulating hormone (TSH, thyrotropin) in human serum and plasma (EDTA and heparin) using the Atellica® IM 1600 Analyzer. The study objectives were to demonstrate acceptable method comparison between the Atellica® IM TSH3-UL assay, ADVIA® Centaur TSH3-UL assay, and Roche cobas® TSH assay; and evaluate the potential impact of biotin interference on the Atellica IM TSH3-UL Assay and on the Roche cobas TSH assay. **Methods:** The Atellica IM TSH3-UL Assay is a third-generation assay that employs anti-FITC monoclonal antibody (mAb) covalently bound to paramagnetic particles, a FITC-labeled anti-TSH capture mouse mAb, a tracer consisting of a proprietary acridinium ester and an anti-TSH mouse mAb conjugated to bovine serum albumin for chemiluminescent detection. The TSH3-UL does not employ the biotin-streptavidin complex in the assay design, so should have minimal biotin interference. Precision and linearity studies were performed by EP15-A3 and EP06-A, respectively. Method comparison results were performed according to CLSI EP09-A3. Sample types included adult serum and plasma (EDTA or heparin). Samples (1065) were from the site's routine thyroid testing, across the range of the assay and were tested on the Atellica IM 1600 Analyzer, ADVIA Centaur® XP System, and Roche cobas® analyzer in singleton. In case of discrepant results between the assays tested on the different analyzers, samples were repeat-tested on all analyzers. If discrepancies remained, the clinical status of the patient, FT4 and FT3 results and presence of biotin treatment were investigated. Serum samples spiked with biotin (30, 500 ng/mL) and un-spiked samples (controls) were run in duplicate with both the Atellica IM TSH3-UL Assay and Roche cobas TSH assay. **Results:** Precision and linearity studies agreed with the manufacturer's claims for the Atellica TSH3-UL assay: The assay was demonstrated to be linear from 0.0 to 120.05uIU/mL (y=1.018x+0.006). Within run repeatability CV%(SD)s for concentrations of 0.01, 0.70, 5.84, and 29.95 uIU/mL were 5.5%(0.00), 1.3%(0.01), 1.3%(0.08), 1.3%(0.39); within lab (total) CV%(SD)s were 6.3%(0.00), 2.7%(0.02), 2.4%(0.14), and 2.0%(0.61), respectively for the Atellica TSH3-UL assay. Method comparison of Atellica IM TSH3-UL Assay vs. Roche cobas TSH assay showed a

regression slope of 0.92, intercept of 0.002 and correlation coefficient (r) of 0.982; Method comparison of Atellica IM TSH3-UL Assay vs. ADVIA Centaur TSH3-UL assay showed a regression slope of 1.06, intercept of -0.001 and correlation coefficient (r) of 0.994 . The Atellica IM TSH3-UL assay recovered 5.28uIU/mL (negative control) vs. 5.33uIU/mL (500ng/mL biotin spiked); while, the Roche cobas TSH assay recovered 5.28uIU/mL (negative control) vs. 0.10uIU/mL (500ng/mL biotin spiked) thereby demonstrating biotin interference in the Roche cobas TSH assay. **Conclusions:** Precision and linearity studies agreed with the manufacturer's claims on the Atellica TSH-3 UL assay. Method comparison of the Atellica IM TSH3-UL Assay to the ADVIA Centaur TSH3-UL assay and Roche cobas TSH assay demonstrated good agreement. The Atellica IM TSH3-UL Assay showed <10% bias at a biotin concentration of 500ng/ml. ***** Siemens Healthineers supported the study by providing systems, reagents, and protocols, and contributed to data analysis.

B-021

Reducing turnaround time for ED critical results reporting through advanced LIS rules

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Reporting of critical values on Emergency Department specimens requires both timely and accurate resulting. Despite evidence that repeat testing may not be necessary for critical values within the analytic measurement range (AMR), how altering this long-standing practice reduces laboratory turnaround time (TAT) has not been reported. Moreover, how implementation of advanced laboratory information system (LIS) rules to ensure the accuracy of reported critical results has not been reported. To address this, our laboratory implemented advanced LIS rules to allow for the reporting of critical values to the ED prior to repeat testing. We assessed results before and after LIS implementation to confirm that repeat results were within the allowable error. LIS rules were established using middleware software (Data Innovations, Burlington, Vermont). Briefly, samples within the reference interval were reported via normal autoverification rules. If a sample was outside of the reference interval, it was either in the absurd range, or the critical range. Any samples within the absurd range had all results from the specimen withheld, even if other results were normal. These were checked by a medical technologist prior to release of the sample or a redraw of the specimen was ordered. All other values within the critical range were immediately called to a patient caregiver. To ensure accuracy of laboratory results, specimens with critical values were repeated. If there was a significant change from the first result, it would immediately be called to the ED. Normal autoverification rules for icterus, hemolysis index, triglycerides and delta checks were applied to each sample. We also analyzed the effect of advanced LIS implementation on TAT. In total, we examined 437 samples with critical/absurd values within the AMR from ED patients from three separate periods in 2013-2016. In the ED, repeat testing on samples with critical values demonstrated 99.5% precision, as only one sample was outside the acceptable CAP/CLIA variation upon repeat testing. This was in contrast to non-ED floors and outpatient clinics, which had a surprisingly low discordance of 5.5% between original and repeated results. Moreover, advanced LIS implementation significantly reduced additional TAT for ED specimens. The mean additional TAT for critical results was 14.2 minutes in 2013 prior to advanced LIS rule implementation. This was reduced to 11.9 minutes and 10.8 minutes in 2014 and 2016 respectively following LIS implementation. Importantly, samples taking longer than 25 minutes of additional TAT were reduced from 11.7% to 1.2% following advanced LIS implementation. We conclude that implementation of advanced LIS rules allows for immediate reporting of non-absurd critical values prior to repeat in specimens from the ED. Moreover, advanced LIS rules reduce both mean TAT and the proportion of long, additional TAT greater than 25 minutes. Together, these findings demonstrate the clinical utility of implementing advanced LIS rules to automated analyzers to improve laboratory efficiency while reducing turnaround time, ultimately leading to improved patient care.

B-022

Performance Evaluation of Immunoassays on the Atellica IM 1600 Analyzer

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Background: Studies were performed to assess the analytical performance of immunoassays (IM) for the Atellica® IM Analyzer with respect to verification of precision, linearity, detection limit, and method comparison with Siemens Healthineers lab assays on the ADVIA Centaur® XPT System. **Methods:** Precision verification was performed according to EP15-A3, method comparison by EP09-A3, linearity by EP06-A, and detection limit by EP17-A2. For precision, three or four concentration levels were used; each level of QC materials and sample pool were tested as one run each day with five replicates per run, for five days (25 total replicates per sample for each assay). Method comparison studies were performed on 44 to 50 serum samples covering each assay range, from low to high. The number of levels of linearity material ranged up to nine depending on the assay. For each assay, three replicates of each sample level were assayed. Two LoB and two LoD samples were processed in the same run running 4 replicates each day for 3 days for a total of 24 blank measurements for each assay. Two LoQ samples were processed in one run per day, five replicates per run, for five days, for a total of 25 replicates for each sample. **Results:** All within-run and total imprecision agreed with the manufacturer's claims. Within-run (repeatability) CVs ranged from 1.2% to 6.8% and total (within lab) CVs from 1.7% to 13.7%. Linearity and verification of detection capability studies were performed for all assays. Precision and method comparison studies are summarized below.

		Precision			Method Comparison
Atellica IM Analyzer Assay	**Units**	**Mean conc. (low, high)**	**Within run %CV(SD) (low, high)**	**Total %CV(SD) (low, high)**	**Atellica IM Analyzer Assay vs. ADVIA Centaur XPT System Assay**
Fer	ng/mL	22.65, 328.74	4.7(1.07), 3.3(10.83)	6.3(1.42), 4.3(14.18)	[b]y=1.05x-1.09
VitD	ng/mL	25.38, 87.10	3.8(0.96), 3.1(2.69)	11.0(2.79), 5.5(4.82)	[b]y=0.89x+0.85
iPTH	pg/mL	40.45, 840.44	2.1(0.83), 1.9(16.10)	5.1(2.05), 4.1(34.57)	[b]y=1.05x-0.56
PSA*	ng/mL	0.14, 15.13	3.6(0.00), 2.9(0.44)	3.8(0.01), 4.9(0.74)	[b]y=0.93x-0.02
AFP*	ng/mL	32.49, 243.34	4.6(1.48), 3.8(9.13)	5.6(1.80), 3.8(9.13)	[a]y=1.01x-1.36
CEA	ng/mL	2.32, 36.38	6.8(0.16), 2.9(1.07)	13.7(0.32), 5.4(1.98)	[b]y=1.02x-0.35
eE2	pg/mL	37.67, 970.31	6.8(2.54), 2.0(19.51)	8.8(3.1), 3.6(34.45)	[b]y=0.92x-8.5
ThCG*	mIU/mL	5.52, 369.88	2.3(0.13), 2.0(7.45)	4.8(0.26), 2.3(8.65)	[b]y=0.96x+2.81
PRGE	ng/mL	1.34, 23.45	4.0(0.05), 2.6(0.62)	4.7(0.06), 3.9(0.91)	[b]y=1.01x+0.04
TSTII	ng/mL	0.12, 11.57	5.0(0.01), 4.0(0.46)	5.1(0.01), 5.5(0.64)	[b]y=0.94x-0.01
TSH3UL	uIU/mL	0.01, 26.99	6.2(0.00), 1.8(0.48)	8.1(0.00), 2.8(0.75)	[a]y=0.95x+0.14
FT4	ng/dL	1.10, 3.65	2.0(0.02), 1.2(0.04)	3.6(0.04), 2.3(0.08)	[b]y=1.08x+0.03 ng/dL

[a]Passing&Bablock Fit; [b]Deming Fit

Conclusions: All immunoassays tested on the Atellica IM Analyzer demonstrated good precision and correlation to the current ADVIA Centaur XPT System assay. The precision results were consistent with manufacturer's claims. * Siemens Healthineers supported the study by providing systems, reagents and protocols and contributed to data analysis.

B-023

Performance evaluation of chemistry and plasma protein assays on the Atellica CH 930 Analyzer.

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Background: Atellica® CH 930 is the new analyzer from Siemens Healthineers. In our Hospital, we have assessed the analytical performance of chemistry assays (CH) listed in Table 1. The aim of the study was to evaluate precision, detection limit (LoD) and linearity of Atellica as well as a method comparison (MC) with ADVIA® Chemistry XPT and Dimension Vista® System. **Methods:** Precision, linearity, LoD, and MC were performed following EP15-A3, EP06-A, EP17-A2 and EP09-A3 respectively. For Precision quality control materials (QC) and sample pools were tested, as one run per day with five replicates, for five days (25 total replicates/sample/assay). The number of levels of linearity mate-

rial (LGC Maine Standards) ranged up to six depending on the assay. For each assay, three replicates per level were assayed. Two detection of blank (LoB) and two detection limit (LoD) samples were processed in the same run with four replicates each day for three days (24 measurements/assay). Two limit of quantification (LoQ) samples were processed in one run per day with five replicates, for five days, (25 replicates/sample). Finally, in the MC we assessed 40 serum samples per assay and they were processed by legacy (reference system) and Atellica in the same day. **Results:** Atellica CH assays showed a good linearity per the Maine Software Data Reduction Program. LoB, LoD and LoQ were successfully verified for all CH assays. Precision study and MC results are summarized in Table 1.

Atellica CH 930 Analyzer Assay	Mean conc. (low, high)	Within run %CV (SD) (low, high)	Total %CV (SD) (low, high)	MC Atellica CH vs ADVIA Chemistry XPT	Atellica CH 930 Analyzer Assay	Mean conc. (low, high)	Within run %CV (SD) (low, high)	Total %CV (SD) (low, high)	MC Atellica CH vs. ADVIA Chemistry XPT
GLUH_c mg/dL	60, 354	0.8 (0.5), 0.3 (1.1)	2.7 (1.7), 1.4 (4.9)	y=0.96*X - 1.60	TBil_2 mg/dL	0.6, 7.7	7.2 (0.04), 0.4 (0.03)	7.2 (0.04), 0.5 (0.04)	y=0.99*X + 0.02
UN_c mg/dL	7.3, 34	1.3 (0.10), 0.6 (0.20)	1.7 (0.12), 1.1 (0.38)	y=1.06*X - 1.39	Na mmol/L	115, 160	0.5 (0.62), 0.3 (0.45)	0.5 (0.62), 0.4 (0.60)	y=1.03*X - 5.31
Crea_2 mg/dL	0.74, 6.29	1.5 (0.01), 0.5 (0.03)	1.7 (0.01), 0.8 (0.05)	y=1.02*X - 0.01	K mmol/L	2.62, 7.4	0.3 (0.01), 0.2 (0.01)	0.4 (0.01), 0.3 (0.02)	y=1.00*X - 0.15
Ca mg/dL	5.6, 13.5	1.2 (0.06), 0.6 (0.08)	1.8 (0.10), 1.1 (0.15)	y=0.99*X - 0.08	Cl mmol/L	78.3, 121	0.6 (0.44), 0.3 (0.32)	1.0 (0.76), 0.3 (0.36)	y=1.02*X - 3.46
AST U/L	43, 295	1.4 (0.62), 0.4 (1.30)	2.4 (1.01), 0.8 (2.45)	*	APO A mg/dL	110.4, 149.8	1.0 (1.07), 2.0 (3.05)	4.9 (5.35), 3.9 (5.90)	y=1.10*X - 4.44
ALT U/L	31, 218	3.4 (1.06), 0.6 (1.28)	5.1 (1.58), 1.1 (2.40)	*	APO B mg/dL	39.7, 148.5	3.5 (1.37), 1.2 (1.78)	6.0 (2.38), 5.8 (8.58)	y=0.93*X - 1.13
TP g/dL	4.1, 7.2	0.9 (0.04), 0.3 (0.02)	1.2 (0.05), 0.6 (0.04)	y=1.02*X + 1.01	B2M mg/L	0.70, 3.08	1.8 (0.01), 2.1 (0.07)	2.0 (0.01), 2.2 (0.07)	y=1.11*X + 0.16 (vs. Vista)
ALB_c g/dL	2.6, 4.5	1.6 (0.04), 1.0 (0.04)	1.9 (0.05), 1.0 (0.04)	y=1.05*X + 0.43	CRP_2 mg/dL	0.67, 5.17	2.5 (0.02), 0.8 (0.04)	2.9 (0.02), 1.4 (0.07)	y=1.00*X - 0.05
Trig mg/dL	94, 214	0.4 (0.4), 0.5 (1.0)	1.1 (1.0), 0.8 (1.7)	y=0.99*X + 0.20	hsCRP mg/L	0.97, 7.86	2.9 (0.03), 1.1 (0.09)	6.4 (0.06), 1.5 (0.12)	y=0.96*X + 0.29

*Not done.

For MC all assays yielded p values ranging from 0.995 to 1.000 **Conclusions:** All the assays tested on the Atellica CH 930 System demonstrated good precision, linearity LoB, LoD and LoQ. Precision results were consistent with manufacturer's claims. Finally, the method comparison between Atellica CH and Legacy systems (ADVIA Chemistry XPT and Dimension Vista) was satisfactory with a very good correlation for all assays tested.

B-024

Multicenter Throughput Study of the Atellica®Solution with Common Immunochemistry and Clinical Chemistry Panels

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Objective: To assess the throughput of different configurations of the Atellica® Solution using the same experimental protocol on a set of predefined test panels across multiple sites. **Methods:** Five different panels of tests with predefined similar profiles were assessed using 400 serum samples across three sites to observe throughput capabilities in a 1 hour period. The timing period commenced when the first sample was loaded into the Atellica® Sample Handler and ended after the last result of the last tube was available. All results in process were allowed to complete and the time of completion was noted. The test panels were:

A. Na, K, Cl, Glucose, Urea, Creatinine
B. Na, K, Cl, Total Protein, Calcium, ALT
C. TSH, HIV Ag/Ab Combo (CHIV)
D. TSH, hCG
E. hCV, Syphilis, HBsAg II, CHIV

The Atellica Solution configurations varied by site

- Laboratory 1: one Atellica Sample Handler, one Atellica® CH 930 Analyzer, and one Atellica® IM 1600 Analyzer
- Laboratory 2: one Sample Handler with two Atellica CH 930 Analyzers and two Atellica IM 1600 Analyzers. (Note: only one of each analyzer was used to ensure the like-for-like comparison.)
- Laboratory 3: one Atellica Sample Handler and two Atellica IM 1600 Analyzers (Note: only panels C, D, and E were run and only one analyzer was used to ensure the like-for-like comparison.)

Results

Table 1. Throughput observed across the study sites

	Laboratory 1		Laboratory 2		Laboratory 3	
Panel	**Tests initiated in first hour**	**Results per hour after first 30 min[a]**	**Tests initiated in first hour**	**Results per hour after first 30 min**	**Tests initiated in first hour**	**Results per hour after first 30 min**
A (CH)	**1239**	**1100**	**1230**	**1170**	**NT[b]**	**NT**
B (CH)	**1236**	**1051**	**1230**	**1081**	**NT**	**NT**
C (IM)	**329**	**231**	**288**	**226**	**276**	**246**
D (IM)	**397**	**346**	**316**	**304**	**413**	**408**
E (IM)	**319**	**203**	**287**	**225**	**263**	**239**

[a]This metric accounts for system throughput after initial workload buildup. [b]Not tested

Conclusions: Various configurations of the Atellica Solution consistently provide high throughput for a varying profile of test requests and is unaffected by the test mix of chemistry tests or immunoassays. Siemens Healthineers supported the study by providing systems, reagents, protocols and contributed to data analysis

B-025

Flowing mass spectrometry data to the LIS through a locally-developed data-management interface

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Background: With its superior sensitivity and specificity, mass spectrometry assay is increasingly being used in the clinical laboratories for identification and quantification of endogenous and exogenous compounds. Unlike most automated chemistry analyzers, the complex data generated from the mass analyzer is not in a LIS readable format. In addition, an electronic interface that streamline data flow and analysis between the instrument and laboratory information system (LIS) is usually not provided by the instrument or LIS vendors. Therefore, the large volume of the data rapidly generated from these instruments is usually manually entered into the LIS by the laboratory technicians. This manual data entry is challenging in modern clinical laboratories that are equipped and staffed for high-throughput, high complexity, and rapid turn-around of laboratory results in order to best serve the complicated patient mix. To overcome this hurdle, we aimed to develop an interface between our AB SCIEX mass spectrometer and our LIS (Sunquest Information Systems). **Methods**: We developed our own electronic interface utilizing Cresco, a Java-based agent framework. The interface was designed to process text files exported from Analyst software, which interfaces with a AB SCIEX 4500 triple quadruple mass spectrometer. Input records are checked against expected analyte values and an output report, in a format that the Sunquest can recognize, is generated. Network file systems are used to facilitate transfer of analytical data between the instruments, record archive, and the LIS. Interface implementation and data transfer validation as well as training of technologists to use the interface were performed by the Special Chemistry and Laboratory IT sections of the laboratory. The technologists were trained as to data verifications as part of the result acceptance process. **Results**: The estimated time for the technologist for patient/control sample data entry, assay results data transfer, and result verification was reduced from 90 seconds /specimen to under 15 seconds/specimen. Sample identification, results data entry errors and omissions were eliminated. The filing of the result in Sunquest generated an electronic record of the technologist performing the assay runs and data management. **Conclusion**: Development and implement of a data management interface for complex chromatography instruments in clinical laboratories has resulted in a

rapid, accurate, verifiable information transfers between our instrument and LIS. This has eliminated manual data entry that is error-prone and has unblocked the bottleneck in the application of mass spectrometry assays with improved workflow.

B-026

Validation of Procalcitonin Assay on Abbott Architect i1000

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Background: Sepsis, the 10th leading cause of death in the United States is the precursor to life threatening septic shock, which has a high mortality rate. However, symptoms of sepsis are not specific making it difficult to obtain early diagnosis resulting in delay of proper therapy. Procalcitonin and C-reactive protein are used as clinical biomarkers for sepsis but procalcitonin has been shown to be more sensitive and an early marker in monitoring septic shock. Food and Drug Administration cleared the use of B.R.A.H.M.S. PCT assay (Biomerieux, France) to help providers predict the likelihood of patient dying or if the patient's condition is worsening due to sepsis. In early 2017 FDA expanded the use of this assay to aid clinicians identify when antibiotic treatment should be initiated and halted. However, guidelines in pediatrics are still evolving. We anticipate that the expanded use of procalcitonin would result in an increase in utilization of this test, therefore validation of B.R.A.H.M.S. PCT assay on an automated, high throughput platform would be beneficial. **Methods:** The guidelines by Clinical and Laboratory Standards Institute (CLSI) EP5-A2 document was adopted in performing the validation. Precision and reportable ranges on Architect i1000 were performed. Manufacturer's instructions was followed, including quality control, calibration, calibration verification, and related functions. Procalcitonin in patient samples (N = 32) were measured in Mini Vidas and in Architect for comparison. Furthermore, we also tested the effect of major sources of intereferents such as free hemoglobin (12 g/L), triglycerides (12.43 mmol/L) and bilirubin (500 µM). Statistical analyses were performed using EP Evaluator software. **Results:** Architect method showed good precision with percent coefficient of variation (% CV) < 3.5% for both inter-assay and intra-assay compared to %CV < 6.5% for Mini Vidas. The analytical range in Architect was determined to be 0.02 - 100 ng/mL with a clinical reportable range of 0.02 - 1000 ng/mL. Statistical analysis showed that the two assays have good correlation (r >0.99), slope of 1.023, and intercept of -0.760. The calculated bias is -7.435%, indicating that Architect results on average is about 7% less than the results obtained on Mini Vidas. Pooled-serum spiked with 500 µM bilirubin showed the highest bias of about 6.5%. **Conclusion:** Validation results for Architect B.R.A.H.M.S. PCT assay revealed excellent precision and accuracy. The turn-around time for both platforms were the same (20 minutes), however in contrast to Mini Vidas, Architect offers automated pipetting of samples and can perform multiple assays. Mini Vidas is exclusively used for procalcitonin testing. Therefore, shifting the test to Architect will help streamline the process and eliminate manual pipetting of samples into reaction wells. These results indicated that Architect B.R.A.H.M.S PCT assay can be used for diagnostic purposes in clinical laboratories.

B-027

Use of a Contemporary TLA System in A Busy Clinical Chemistry Lab

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Background: With increasing workload, the staffs find that they have difficulties to achieve the required Turn-Around-Time(TAT) target of 60 min for AE and out-patient samples. The staffs also feedback that they have no time for administrative work and are physically exhausted due to making numerous trips to send samples to other analyzers in the section. **Methods**: 1.Map the Current Processes by on-site observation. 2. Identify Wastes in the Process Map (8 Wastes of Lean). 3. Reduce Complexity Lean Thinking/Streamline/Simplify/Eliminate/Technology). 4. Map the Future New Processes. The key members of the biochemistry team met up for 2 half days in January 2015 to map out the current process steps. Manual processes were identified and after brainstorming for improvements, it was agreed that the tests in the 3 system required consolidation and manual pre-analytics steps need to be automated. A total laboratory automation (TLA) system (cobas 8100, Roche Diagnostics) that can automate the manual pre- and post-analytic processes from specimen centrifugation, specimen repeat/rerun with dilution, refrigerated storage and sample disposal was chosen. Installation was carried out in phases as it was same site replacement of the old systems. Phase 1: Installation of 2 lines of analytics (cobas 8000 - Chem,Chem,Ecl,Ecl) from February-June 2016. Phase 2 : Installation of the pre-analytics unit (cobas 8100 with 3 centrifuges, decapper, aliquoter, sample buffer unit). Phase 3: Installation of the post-analytics storage system (cobas p501). **Results:** Before Implementation: The three areas that staffs of the Biochemistry Section needs to go is the DXC, cobas and Architect. There are in total 23 process steps to perform testing for a specimen in Biochemistry Section. For every trip from DXC to cobas is 23m and every trip made to Architect from DXC is 16.5m. To facilitate parallel workflow process, manual aliquots of the specimen is required. There could be approximately 455 aliquots to make in a day. After Implementation: The new process is mapped and the number of steps was reduced from 23 to 3 steps. The walking distance per trip is reduced from 23m to 7m. No manual aliquots were required as it is now automated. The new system brought an increase in staff satisfaction and morale as there is now more walkaway time to perform other tasks. The TAT achievement rate of 60 minutes (from sample receipt in the LIS to result reporting) for troponins request from AE before the new automated work processes from Jan to April 16 was 96.5% (Jan 16), 95.9% (Feb 16), 96.0%(Mar 16) and 94.0%(Apr 16). With the new processes, the TAT achievement rate was improved to 97.2%(Oct 16), 97.4%(Nov 16), 98.1%(Dec 16) and 97.6% (Jan 17). (Mann-Whitney test: p - 0.0286) **Conclusion:** The new system brought an increase in staff satisfaction and morale as there is now more walkaway time to perform other tasks. The TAT for patient's sample showed improvement and there is also reduce variations in the manual process by replacing it with automated process. The team will be exploring ideas (i.e. PST specimen type) to improve the TAT for outpatient's sample.

B-028

Data quality of Arkansas clinical data repository (AR-CDR)

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Background:
Researchers use clinical data collected at hospitals to conduct clinical studies. Results of these clinical studies depend on the quality of collected data. UAMS hospital has two data sources Arkansas clinical data repository (AR-CDR) and Epic system. (AR-CDR) is a rich clinical data source that regularly receive data feed from Epic, Regional programs, and other data sources. The evaluation of data warehouse quality is crucial to ensure the accuracy of clinical research results.
Methods:
We randomly selected the first one hundred diabetic patients, type 1 (ICD 10; E10) or type 2(ICD10; E11), from data warehouse who had visits between June 2016 and December 2016.We conducted a manual chart review of patients from EPIC system using the MRN, (patient ID number), as a primary key. For this pilot study we focused on three data quality dimensions: Completeness, accuracy and validity. These dimensions were measured for the following data : demographics (date of birth, gender, race, address, city, state, and zip code); laboratory results (plasma and urinary glucose, glucose POCT and HbA1C), and antidiabetic medications.
Results:
The patients in the study were consisting of more females than males (70% versus 30%) with more African American (57%) than white (43%). Validity: 100 % of the data was valid; all demographic data values are logic, and laboratory results are within the clinical reportable range. Completeness: Nearly 98.8% of the data was complete with only missing two plasma glucose and two HbA1c values. Accuracy: 100% concordance in all data elements.
Conclusions:
This study revealed that there is a complete concordance between data stored in AR-CDR and Epic data. The data in AR-CDR are complete and valid. Based on the results of this pilot study we confirm that the data warehouse has a high quality for clinical research.

B-029

Interface for the Bio-Rad D100 with Sunquest: Challenges and Solutions

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Background: Recently we purchased two Bio-Rad D100 instruments for hemoglobin A1c (HbA1c) analysis. The D100 instruments we acquired had internal HB Advisor software. The Advisor software screens the chromatograms against 32 programmed rules and flags samples that have parameters outside the limits of the stated rules. The flags were transmitted to Sunquest; however, the results were not held for review because they were considered by Sunquest as order flags and not as result flags. The discussions between our lab staff, our IT specialists, Bio Rad and Sunquest led to the

realization that the original Bio Rad interfaces do not lead to actions taken by the Advisor software when identifying the results with parameters outside the predefined limits of the rules. The aim of this work was to develop an interface allowing all results to be exported to Sunquest with non-flagged results to auto-release and flagged results to be held for review. **Method:** Various patient samples were ordered in the test environment of Sunquest. The patient samples were a mix of normal and abnormal HbA1c values, as well as some hemoglobin variant specimens. The results that were transmitted to Sunquest were manually verified for accuracy. A series of English Text Codes (ETC) were defined to be appended as appropriate to explain or assist clinicians to interpret the results, i.e., why there is no HbA1c value provided or to inform clinicians that a possible hemoglobin variant may be present to affect HbA1c results. **Results:** Initial interface allowed Sunquest to only receive non-flagged results. The second version of the interface had all results, flagged or not, transmitted to Sunquest. The third version auto-released all non-flagged results and held the flagged results in Sunquest for review. **Conclusion:** Collaboration between our lab staff, IT specialist, Bio-Rad, and Sunquest was critical to the successful improvement of interface to meet the clinical needs. The resulting interface allowed proper handling of HbA1c results with parameters outside of the predefined rules.

B-030

Impact of the Atellica Solution on User Hands-On Time

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Background: Daily maintenance, quality control, and reagent loading on analyzers consume a significant amount of technicians' time in a core laboratory. The Atellica® Solution automates daily maintenance and quality control, and provides on-the-fly reagent loading. This study assessed the impact of the Atellica Solution on operator hands-on time spent on these three activities, compared to the existing (legacy) instrumentation in our laboratories. **Methods:** Legacy instrumentation was chosen to match the Atellica Solution throughput as per the manufacturer's specifications. Equipment at Laboratory1:

- Atellica Solution: one Atellica® Sample Handler with two Atellica® CH 930 Analyzers and two Atellica® IM 1600 Analyzers; entire configuration connected to Aptio® Automation via a single connection.
- Legacy instrumentation: one ADVIA® 1800 Clinical Chemistry System, one ADVIA® 2400 Clinical Chemistry System, and four ADVIA Centaur® XPT Immunoassay Systems; each system connected to Aptio Automation via a separate connection.

Equipment at Laboratory 2:

- Atellica Solution: one Atellica Sample Handler with one Atellica CH 930 and one Atellica IM 1600 Analyzer; entire configuration connected to Aptio® Automation via a single connection.
- Legacy instrumentation: one ADVIA 1800 Clinical Chemistry System and two ADVIA Centaur XPT Immunoassay Systems; each system connected to Aptio Automation via a separate connection.

We then recreated a typical day in our laboratories during core working hours by using the workload usually processed by the legacy instruments listed above. 65% of the normal workload at Laboratory 1 was processed: 11,500 chemistry tests and 4250 immunoassay tests (15,750 in total) from 2700 tubes over 11 h. At Laboratory 2, 45% of the normal workload was processed: 6700 chemistry tests and 700 immunoassay tests (7400 tests in total) from 800 tubes over 8 hours. Tubes were batched and loaded on the automation system in 10 minute intervals to simulate arrival on a typical day. The test mix on each tube was also based on a typical day's mix in our laboratories. To achieve like-for-like comparison, in both laboratories this experiment was executed twice, with exactly the same tubes, timings, and test mix, but once with the legacy equipment and once with the Atellica Solution. Operator time spent on daily maintenance, reagent loading and quality control was recorded in both laboratories. **Results:** At Laboratory 1, time spent on daily interactions was 3 hours 50 minutes with the legacy instrumentation and 1 hour 2 minutes with the Atellica Solution. This represents a reduction of 73%. At Laboratory 2, time spent on daily interactions was 2 hours 41 minutes with the legacy instrumentation and 49 minutes with the Atellica Solution. This represents a reduction of 69%. **Conclusion:** The operator hands-on time as defined by daily maintenance, quality control management and reagent loading is considerably reduced on the Atellica Solution compared to our legacy instrumentation. This result was observed both at Laboratory 1 and Laboratory 2. Siemens Healthineers supported the study by providing systems, reagents, protocols and contributed to data analysis

B-031

Throughput Evaluation of the Atellica IM 1600 Analyzer with Varying Clinical Immunoassay Test Mix

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Background: Longer assay turnaround times (as for infectious disease assays) decrease immunoassay analyzer throughput. Labs often mitigate result reporting delays by dedicating analyzers for serology testing, resulting in staffing, capital cost, and space-usage inefficiencies. The Atellica® IM 1600 Analyzer was engineered with dual incubation rings, the outer ring initially for all assays and the inner ring for longer-dwelling assays. **Objective:** To evaluate the impact on throughput that a varying proportion of longer-dwelling assays can have, and to generate real-life throughput data relevant to a typical lab. **Methods:** Using our core lab's normal immunoassay work profile, we performed five runs of 300 tubes with a fixed number of 665 tests: 2.2 immunoassay tests per tube (our usual test-per-tube ratio). The tubes were of mixed tests and not all with the same profile in order to represent a real workload. We utilized 32 Atellica® IM assays. For each of the five runs, however, we adapted the proportion of long assays to range from 6% to 47% while keeping the number of tubes and tests constant. The longer-dwelling assays use both inner and outer incubation rings and range from 28 to 54 minutes; short assays use only the outer incubation ring and range from 10 to 14 minutes. **Results: Table 1.** System throughput with an increasing proportion of longer-dwelling assays

Proportion of long assays	Time to complete 300-tube run (all tubes sampled)	Tubes sampled during the first hour	Tests initiated in the first hour	Results reported per hour after 30 min[a]
6%	2 h 10 min	148	345	295
16%	2 h 21 min	142	346	280
27%	2 h 23 min	141	362	296
36%	2 h 26 min	138	369	308
47%	2 h 34 min	135	369	295

[a] This metric accounts for system throughput after initial workload buildup. **Conclusions:** The system throughput was not impeded by the increase in the proportion of long assays from 6% to 47% of the test mix. Siemens Healthineers supported the study by providing systems, reagents, protocols and contributed to data analysis

B-032

Performance Evaluation of Clinical Chemistry and Plasma Protein Assays on the Atellica CH 930 Analyzer Across Five Sites

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Background: Studies were performed at five different sites to assess the analytical performance of several clinical chemistry (CH) and plasma protein assays on the Atellica® CH 930 Analyzer. The assays tested were Alb, ALT, AST, Ca, Cl, Crea_2, GluH_3, K, Na, TBil, TP, Trig, UN_c, APO A1, APO B, B2M, CRP_2, hsCRP. Studies included precision verification, linearity and method comparison studies with Siemens Healthineers assay(s) (Site A: Dimension Vista® System, BN ProSpec®; Site B: ADVIA® 2400 system, Dimension Vista®; Sites C, D, and E: ADVIA® 1800 system; Site D: BN II®). **Methods:** Analytical performance studies were performed at five sites across Europe. Precision verification was performed according to EP15-A3, method comparison by EP09-A3, and linearity by EP06-A. Precision verification studies included three concentration levels; each level of QC materials was tested as one run per day with five replicates per run, for five days, yielding a total of 25 replicates per sample for each assay. Method comparison studies for select assays were performed using approximately 40 serum samples that covered each assay range, from low to high; samples fell into four assay concentration ranges. The number of levels of linearity material (LGC Maine Standards) ranged up to six depending on the assay; for each assay, three replicates per sample level were assayed.

Results: The within-run CVs ranged from 0.0% to 5.3% and the total CVs ranged from 0.0% to 8.2% across all assays on the Atellica CH Analyzer using non-pooled data at this time. Precision results agreed with the manufacturer's claims. Linearity studies were performed for all assays. At each of the five sites, for those comparisons completed to date, method comparison Passing & Bablock and Deming regression results were comparable to the manufacturer's stated IFU claims. Initial method comparison studies were performed at three sites to date. Assays tested on the Atellica CH 930 Analyzer vs. ADVIA 2400/1800 demonstrated good agreement between these three sites for UN_c [Site B(2400): y=1.06x-1.39 mg/dL; Site E(2400): y=1.00x-0.99 mg/dL; Site C(1800): y=1.03x-1.23 mg/L], Crea_2 (Site B: y=1.02x-0.012 mg/dL; Site E: y=1.05x-0.01 mg/dL; Site C: y=1.04x-3.63 mmol/L). Method comparison was completed at two sites to date for AST (Site E: y=1.05x-1.73 U/L; Site C: y=1.04x-0.16 nmol/L), and ALT (Reggio: y=1.05x-1.73 U/L; Site C: y=1.00x+150 mmol/L). Comparison of Atellica CH 930 and Dimension Vista was performed for at least two sites to date for APO B (Site B: y=0.93x-1.13 mg/dL; Site E: y=0.97x-8.2 mg/dL). **Conclusions:** Overall, all assays tested on the Atellica CH 930 Analyzer across five sites in Europe demonstrated acceptable precision. Generally, the precision results were consistent with the manufacturer's claims. The method comparison studies completed to date between Atellica CH 930 Analyzer assays and other assay(s) from Siemens Healthineers demonstrated good agreement. *Siemens Healthineers supported the study by providing systems, reagents, and protocols, and contributed to data analysis.

B-033

Performance Evaluation of Immunoassays on the Atellica IM 1600 Analyzer Across Six Sites

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Background: Studies were performed at six different sites to assess the analytical performance of several immunoassays (IM) on the Atellica® IM 1600 Analyzer. The assays tested were Fer, VitD, PSA, eE2, ThCG, PRGE, TSTII, TSH3-UL. Studies included precision verification, linearity, and method comparison with Siemens Healthineers assay(s) (Site A: Dimension Vista® System; Sites B, C, D, E, and F: ADVIA Centaur® XP/XPT System). **Methods:** Analytical performance studies were performed six sites across Europe. Precision verification was performed according to EP15-A3, method comparison by EP09-A3, and linearity by EP06-A. For precision verification, three or four concentration levels were used; each level of QC materials and sample pool were tested as one run per day with five replicates per run, for five days, yielding a total of 25 replicates per sample for each assay. Method comparison studies were performed using 40 serum samples that covered each assay range, from low to high; samples fell into four assay concentration ranges. The number of levels of linearity material ranged up to nine depending on the assay. For each assay, three replicates per sample level were assayed. **Results:** Precision results agreed with the manufacturer's claims. The within-run CVs ranged from 0.0% to 6.8% and the total CVs ranged from 0.5% to 14.6% across all assays on the Atellica IM Analyzer using non-pooled data at this time. At each of the six sites, for those comparisons completed to date, method comparison Passing & Bablock and Deming regression results were comparable to the manufacturer's stated IFU claims. Linearity studies were performed for all assays. Initial method comparison studies were performed at three to four sites to date. Assays tested on the Atellica IM Analyzer and ADVIA Centaur XP/XPT demonstrated good agreement between four sites for eE2 (Site E: y=0.92x-8.5 pg/mL; Site B: y=0.96x-1.03 pg/mL; Site F: y=1.10x-10.1 pg/mL; Site D: y=0.99x-34.3 pmol/L), three sites for PRGE: (Site D: 0.999x-0.47 nmol/L; Site E: 1.01+0.04 ng/mL; Site B: 1.19+0.36 ng/mL), PSA (Site E: y=0.93x-0.02 ng/mL; Site B: y=0.90x-0.06 ng/mL; Site F: y=0.99-0.01 ng/mL), ThCG (Site E: y=0.96x+2.8 mIU/mL; Site B: y=1.07+3.46 mIU/mL; Site F: y=1.02+1.73 mIU/mL), TSH3-UL (Site E: y=0.95x+0.14 µIU/mL; Site B: y=1.06-0.00 µIU/mL; Site F: y=1.02x-0.02 mIU/mL); and, Fer (Site C: 0.99-0.46 ng/mL; Site E: y=1.05x-1.09 ng/mL; Site B: 0.89x-0.59 ng/mL). **Conclusions:** Overall, all assays tested on the Atellica IM 1600 Analyzer demonstrated acceptable precision, and method comparison with the assay(s) from Siemens Healthineers. Generally, the precision results were consistent with manufacturer's claims.

* Siemens Healthineers supported the study by providing systems, reagents, and protocols, and contributed to data analysis.

B-034

Use of National EHR Data Warehouse to Identify Inappropriate HbA1c Orders for Sickle-Cell Patients

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Background: The glycated Hemoglobin (HbA1c) test is one of the most important diagnostic and prognostic strategies for monitoring diabetes. However, the clinical utility of this test is questionable for Sickle-cell disease patients. Sickle-cell disease is a common hematological disorder that affects millions of people worldwide. In these patients, who are homozygous for the hemoglobin variant gene, only the glycated form of the variant can be found which would have a shorter lifespan (10-20 days) compared to a normal erythrocyte (90-120 days). These patients may suffer from anemia, increasing red-blood cell turnover and requiring transfusions as treatment, which can adversely affect the assessment of HbA1c as a marker of glycemic-control. Therefore, HbA1c tests may not be reliable to independently diagnose or monitor diabetes in sickle-cell patients. Assessment of other glycemic biomarkers such as fructosamine can act as an alternative test for this population. While there have been local analyses, no prior national level analysis of this ordering practice has been performed. **Objective:** To evaluate the frequency of the inappropriate HbA1c test orders and the prevalence of fructosamine test orders as an alternative to HbA1c test for sickle-cell patients in Truman Medical Center (TMC), Kansas City, MO in comparison with sickle-cell patients from other national hospitals. **Methods:** We used a Practice-Based Evidence approach based on de-identified, HIPAA compliant, electronic health record (EHR) data in the Cerner Health Facts ™ (HF) data warehouse. TMC is a contributor to this national dataset. We evaluated the frequency of inappropriate orders of HbA1c tests by comparing the 526 sickle-cell patients in TMC with 37151 sickle-cell patients from 393 national hospitals in the data warehouse. The conditional probabilities estimated from the Generalized linear mixed model (GLIMMIX) was used to rank the TMC with other national hospitals based on the inappropriate order percentage of HbA1c Test for sickle-cell patients in a particular year while controlling for covariates such as the characteristics of the hospitals. The sickle-cell patient cohort was further analyzed for appropriate fructosamine encounters relative to HbA1c tests in TMC with other national hospitals. **Results:** TMC had a higher percentage (32%) of sickle-cell patients with HbA1c tests when compared to the national hospital cohort (11%). The results showed that TMC ranks in the bottom 25% quartile when compared to the other national hospitals with respect to inappropriate HbA1c orders. Interestingly, analyzing fructosamine encounters determined that TMC has ten-fold higher sickle-cell patients (11%) who had at least one fructosamine encounter when compared to the sickle-cell patients (1%) in the other 10 national hospitals which had fructosamine encounters. However, the majority of those patients (68%) in TMC had both fructosamine and HbA1c tests of which 27% of these patients had both the tests in the same encounter. **Conclusion:** These findings indicate that inappropriate HbA1c orders in sickle-cell patients is a potential quality concern in TMC which needs to be addressed with sustainable interventions so that overtreatment or under-treatment of the diabetic condition in sickle-cell patients are avoided.

B-035

Re-imagining protein electrophoresis interpretative workflow for the 21st century

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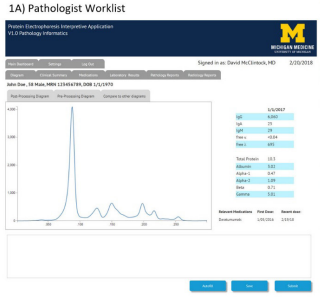
Background: Traditionally, the interpretative process for protein electrophoresis (PEP) has been time consuming and fraught with the potential for missing key information that could influence the result. Often, an elaborate paper-based workflow exists in order to get the relevant clinical and laboratory information to pathologists, with some working within three separate systems to finalize an interpretation. Fundamentally, a need exists to create a unified data "cockpit" that will allow integration of disparate data elements into a single user interface to aid PEP interpretation workflow. **Methods:** Our goal was to design a web-based application based on the following principles: 1) provide an automated, patient specific clinical data request from the EHR; 2) create a secure, flexible, and interactive user interface unifying relevant clini-

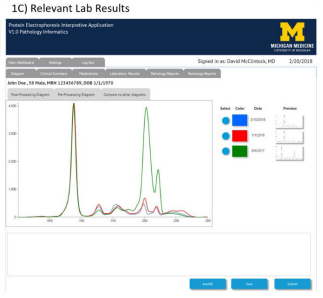
cal, laboratory, and PEP data; and 3) streamline the pathologist interpretation workflow to save both time and resources. Using recently available web services interface architecture, which enables pulling data from the EHR instead of just pushing data to it, we developed a custom web application integrating data from our EHR (Epic) and our protein electrophoresis vendor's middleware application (Phoresis, Sebia). **Results:** We successfully developed a working web services interface between the EHR and our web application that has the ability to pull patient specific clinical data from their medical record, including medication lists, laboratory results, clinical notes, and pathology and radiology reports. Additionally, we developed a way to import the native PEP data from the vendor middleware and render our own capillary electrophoresis and immunotyping diagrams within the web application. Figure 1 demonstrates four views from the web-application. **Conclusion:** The use of a modern web-based architecture to integrate multiple sources of disparate clinical data has great potential to revolutionize PEP workflows by consolidating multiple manual, labor intensive processes into a single streamlined application.

1A) Pathologist Worklist

1C) Relevant Lab Results



1B) Electropherogram with associated labs and medications



1D) Electropherograms, current and prior tracings

B-036

Performance evaluation of the UF-5000 automated urine analyzer

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Background: UF-5000 is a fully automated urine particle analyzer that is based on flow cytometry method. We evaluated the analytical performance of UF-5000. **Methods**: We assessed UF-5000 for precision, linearity and carryover rate using control materials. And a total of 268 urine samples were selected and analyzed by microscopic method and the two automation system, UF-5000 and UF-1000i. The results of analysis was compared between the automated analyzers with each other, and between UF-5000 and microscopic method. **Results**: Coefficients of variation (CVs) of control materials for the within-run precision of red blood Cells (RBC), white blood cells (WBC) and bacteria count were 3.13-9.32%, 2.41-8.56% and 3.74-6.55%, respectively, which were concordant with those announced by the supplier. And the CVs of epithelial cells and cast were 14.27-16.59% and 16.66-21.81%, respectively. In aspect of linearity, the correlation coefficient values of analytes were over 0.99. The carryover rate was less than 0.01% for RBC and WBC. And that of bacteria were 0.02%. The agreement rates within same grade between the UF-5000 and UF-1000i for RBC, WBC, epithelial cells, cast and bacteria were 88.8%, 92.2%, 89.6%, 90.7% and 79.9% respectively. The agreement rates within same grade between the UF-5000 and manual microscopy for RBC, WBC, epithelial cells, cast and bacteria were 77.5%, 77.5%, 76.3%, 87.5% and 68.8%, respectively. The agreement rates within one grade between the UF-5000 and UF-1000i, and between the UF-5000 and manual microscopy for all analytes were nearly 100%, respectively. **Conclusions**: UF-5000 showed a reliable analytical performance and good concordance with manual microscopic method.

B-037

Method Validation of Pleural and Ascites Fluids cell counts on Sysmex XN-1000 automated haematology analyser

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Background: Body fluid (BF) cell counts of white blood cells (WBC) and red blood cells (RBC) are of great diagnostic value where it aids in the diagnosis and treatment decisions of pathological conditions such as haemorrhages and inflammations. The estimation of cell counts using a haemocytometer, remains a challenge in clinical laboratories. This manual method has been considered the "gold standard" for decades, especially in fluids with low cell counts. It is often laborious, subject to high inter-operator variability and low reproducibility. The XN-1000 automated haematology analyser (Sysmex, Kobe, Japan) performs BF cell counting by using a dedicated BF mode. The aim of this study was to determine the analytical performance of the XN-1000 for counting cells in pleural and ascites fluids in the clinical laboratory of Khoo Teck Puat Hospital, a 720-bedded acute care hospital situated in the north of Singapore. **Methods:** We analysed 97 fluid samples (pleural, n = 32; ascites, n = 65) using the XN-1000 and compared the results with those obtained by the reference method. Samples with cell counts distributed over the analytical measurement range were used for correlation studies for RBC and Total Cell - Body Fluid (TC-BF). The fluids were collected in sterile containers according to established practises, then mixed till homogenous. Three millilitres was transferred into K2 EDTA vacutainers. These were then analysed for BF-TC and RBC on the XN-1000, using the open mode. While concurrently, 10 microlitres of sample was used to charge the haemocytometer to count and estimate the total nucleated cells and RBCs. **Results:** Imprecision studies yielded a coefficient of variation (cv) as follows, RBC: 2.8 and 3.7 (cell count = $0.026x10^6$/uL), 2.3 and 2.27 (cell count = $0.076 x10^6$/uL), TC-BF: 6.6 and 6.6 (cell count = $0.081x10^3$/uL), 3.1 and 3.14 (cell count = $0.313x10^3$/uL).Linearity study using serially diluted samples yielded the following findings: RBC: $R^2 = 0.9991$ (pleural) and $R^2 = 0.9992$ (ascites); TC-BF: $R^2 = 0.9963$ (pleural) and $R^2 = 0.993$ (ascites). Carryover studies show that there was no significant carryover interference between samples for RBC measurements, which was within the manufacturer's claim of 0.3 %. However, some interference is suggested for TC-BF. 26% increase in cell count could be observed in low cell count samples analysed immediately after a high cell count sample of TC-BF = $9x10^3$/uL. In the correlation study, both RBC and TC-BF demonstrated good correlation with the manual counting method: $R^2 = 0.994$ with slope of 1.14 and $R^2 = 0.986$ with slope of 1.00 respectively. **Conclusion:** Our evaluation data showed that the analytical performance of cavity fluids cell count on XN-1000 showed good agreement with the manual method.There is some evidence to suggest that preventive measures such as auto-rinse and background check should be carried out after analysing samples that have TC-BF count >$10x10^3$/uL. On average, an operator requires 15 minutes to count in duplicates by haemocytometer. The workflow is reduced to 2 minutes by automation. The incorporation of cell counting on XN-1000 eliminates the inter-operator variability and increases the productivity in our laboratory.

B-038

Abnormal Proportion-based Reference Intervals

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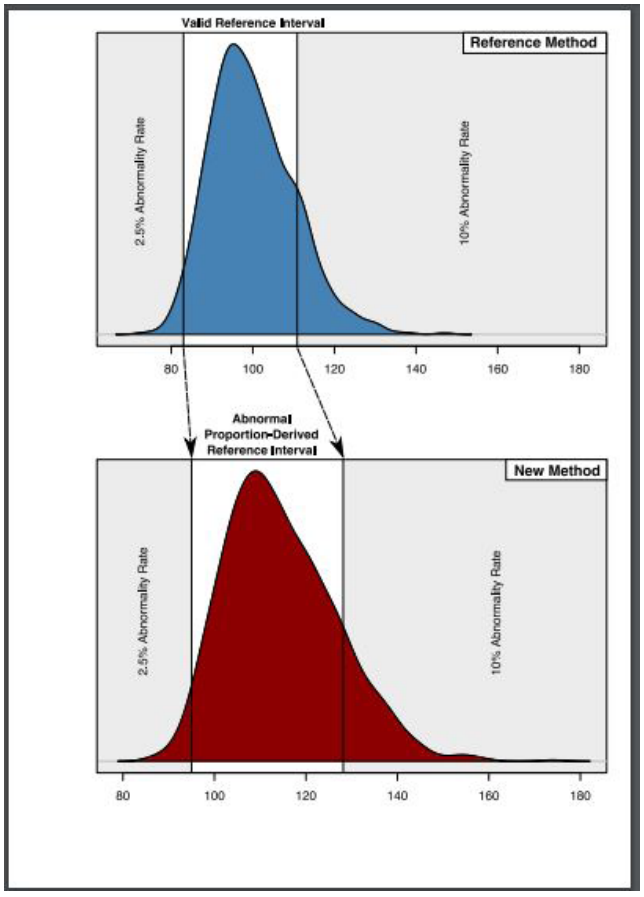
Background: While accurate reference intervals are essential for interpretation of laboratory results, they are difficult and expensive to establish and maintain. Under stable conditions, each laboratory has a consistent abnormality rate over time. Given this stable rate, we hypothesized that reference intervals could be back-calculated from the abnormality rate. The objective of this study was to develop a method to derive reference intervals from patient data using the proportion of abnormal results. **Methods**: To test the abnormal proportion-based interval hypothesis, we used patient data from a large chemistry analyzer replacement project (from Beckman Lx20 to Siemens Vista). This project included generation of reference intervals from healthy volunteers (n=200) using non-parametric methods according to CLSI guidelines. Abnormal proportion-based intervals were calculated from existing abnormality rates for common chemistry tests (proteins, electrolytes, and enzymes) using >=1000 sequential patient results. Abnormal proportion-based intervals were calculated by determining the cutoffs on the new instrument (Vista), which best matched the previous abnormality rate (Lx20); various patient sample sizes for the new instrument were tested (n=20-10,000). Proportion-derived intervals were compared against the gold-standard healthy volunteer-derived reference intervals. Accuracy was calculated as the percent difference between the gold standard reference

interval and the derived interval. This approach was also evaluated using simulated data with different distribution shapes using the statistical programming language R. **Results**: In both real-world patient data and simulations, abnormal proportion-derived reference intervals were highly accurate (>98% similar to true values). Proportion-based intervals were robust and highly accurate for any distribution of patient results. Even very small patient sample sizes of n=20 yielded 90% accuracy; larger patient samples (>500) yielded accuracy rates of >98%. **Conclusion**: Abnormal-proportions can be used to effectively transfer reference intervals between instruments within the same laboratory. Advantages of this method include application to any patient data, no data distribution assumptions, and robustness to sample size.



B-039

Automated Laboratory-based Population Health System for Hepatitis C Birth Cohort Screening

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Background: . Hepatitis C virus (HCV) is the most common blood borne pathogen in the U.S. and leading cause of liver failure, hepatocellular carcinoma, and liver transplants. Due to highly effective anti-viral medications, most patients can be cured. As a result, identifying patients with occult HCV infections has emerged as one of the most important challenges in combating this disease. In 2012, the CDC recommended universal screening of individuals born between 1945-1965 (birth cohort) due to higher risk of HCV infection. Despite campaigns to make healthcare providers and the general population aware of HCV screening guidelines, many chronic infections remain undiagnosed. The objective of this project was to evaluate the effectiveness of an automated laboratory-based population health system in collaboration with healthcare providers to improve HCV birth cohort screening. **Methods:** A birth cohort registry of active patients seen within 2 years and without prior testing for anti-HCV was maintained at the Tucson VA Medical Center. With medical staff approval, the registry was used to generate and mail automated letters to targeted patients. The letter described the purpose and recommendations for HCV screening and served as a test requisition on behalf of patient's healthcare provider. The letter provided contact information to a designated nurse for questions and encouraged patients, if needed, to discuss testing with their healthcare provider. Upon completion of testing, another letter was automatically sent to the patient with results, if negative. Patients with positive results for antibody and HCV RNA, were notified of referral to specialist for evaluation and management. **Results:** Between October 2015 and January 2018, 9186 patients received letters. A second letter was sent to subgroup of 1732 (18.9%) who remained untested after one year. Overall, 4605 (50.1%) who received letters were tested. Of these, 2150 (46.7%) orders were from patient letter requisitions while the remaining 2455 (53.3%) were orders placed by healthcare providers. Among 7454 patients receiving a single letter, 1879 (25.2%) and 2180 (29.2%) were tested by letter requisition and healthcare provider orders respectively. Among 1732 patients receiving a second letter 271 (15.6%) and 275 (15.9%) were tested by letter requisition and healthcare provider orders respectively. The average annual anti-HCV test volume (n=4051) during letter program was about twice that of the prior 3-year average (n=2175). A total of 120 (2.6%) screened patients were positive for anti-HCV of which 46 (1.0%) were positive for HCV RNA. The nurse received an average of one phone call per day and most questions were administrative (e.g. access to testing, appointments) rather than clinical. **Conclusion:** These results show that an automated laboratory-based population health screening program was effective for increasing the detection of occult HCV infections. Repeat notification of untested patients was less effective. In addition to population health screening, a similar strategy using registries for automated notifications and results reporting might likewise provide value-based collaborative support to healthcare providers to assist with managing patients who, for example, require periodic laboratory monitoring for chronic disease (e.g. diabetes), high-risk medications (e.g. oral anticoagulation) or post-treatment surveillance (e.g. tumor markers).

B-040

Statistical Software for QC/QA. A Practical Example with Minitab® for Short-term and Long-term Precision Evaluation with two cobas® c501 Instruments.

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Background. Shewhart's single observations chart (L. J. chart) and Westgard's rules were proposed for precision evaluation of methods in laboratories without statistical software. With the advent of the LIS both became available for electronic, real time quality control (QC) practices. We present two practical examples for the use of statistical software for QC, exploratory, inferential and capability data analysis. **Materials.**Two cobas® c501 instruments (Roche). Analytes: glucose (reagent lot #28132, exp. 1/31/2019, Roche); calcium (reagent lot #300983, exp. 2/27/2019, Roche). QC material (level 1, lot 31841, exp. 9/30/2018; level 2, lot 31842, exp. 9/30/2018, Bio-Rad), Unity Real Time® (Bio-Rad), Minitab® (version 17, Minitab Inc.) statistical software. Short-term precision study: five repeated assays with each control material throughout 24 hours for seven consecutive days. Long-term precision study: one assay with each control material every 8 hours for 180 consecutive days. The data were electronically transferred to Minitab and analyzed with descriptive, exploratory, inferential, QC and capability statistical techniques. **Results.** For the short-term precision study the General Linear Model (GLM) and the parallel box plots for both glucose and calcium showed that for both levels of QC material there were no statistically significant differences (P>0.05) between days and instruments. The data had a quasi-normal distribution (normal probability plot), independence (autocorrelation tests, T<1.5), there were no statistically significant differences between variances by days and instruments (P>0.05) and no parallelism was displayed by the Otelling'sT^2 graphic representation. Furthermore, the L.J. chart showed that the upper and lower control limits (mean-3s and mean+3s), as calculated with standard deviation estimated with the GLM and the appropriate correction factor, were smaller than the upper and lower specification limits as calculated with the CLIA's criterion for acceptable total error (Glucose: target value +/- 6 mg/dL, +/-10%, greater; Calcium: target value +/- 1 mg/dL). The long-term precision at 180 days showed that fluctuations of the mean were associated with new shipments of reagents. These means fluctuations were detected early with the Cumsum chart. While for glucose the means of Level 1 and 2 fluctuated within +/-1s, for calcium the means fluctuations exceeded +/-1s. These patterns could be easily demonstrated with the Shewahrt's mean chart, lowess, parallel box plots. The graphic display of Otelling's T^2 showed borderline parallelism. However, since the mean fluctuations were not associated with differences in patient specimen values (difference between reagent shipments <<0.5 mg/dL, with a total allowable error of 1mg/dL), the control mean could be adjusted so that daily QC practices were not affected by type I error. The capability analysis at six months showed for glucose level1: Cp=2.6, Cpk=2.6, level2: Cp=2.8, Cpk=2.7; for calcium level1: Cp=2.6 , Cpk=2.5, level2 Cp=1.7, Cpk=1.6. These results indicated that the methods performance was

acceptable. **Conclusions:** The ability to capture electronically QC data in real time and subsequent transfer to Minitab allowed for deep critical evaluation and immediate detection of unnatural patterns. Statistical analysis of long-term precision data with appropriate graphic displays allowed an immediate, deeper understanding of the sources and dynamics of methods variation. Furthermore, capability analysis techniques evaluated the method performance.

B-041

A non-parametric quantile regression method to establish continuous reference intervals

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Background: Reference intervals are critical for laboratory test interpretation. For several analytes, reference values exhibit dynamic trends in relation to age, especially throughout childhood and adolescence. Therefore, reference intervals have traditionally been partitioned by age, often arbitrarily chosen as evenly spaced age groups or confirmed by less than optimal statistical methods. To accurately represent the dynamic relationship of age and analyte concentration and improve the accuracy of laboratory test interpretation, continuous reference intervals should be used. As there are numerous methods that can be used to estimate continuous reference intervals, we explore nonparametric quantile regression methods, which offer several advantages, and recommend a method for use in the field of laboratory medicine. **Methods:** Data from the CALIPER project were used to apply and explore different nonparametric quantile regression methods. We focused on two analytes, total bilirubin and alkaline phosphatase, from healthy pediatric subjects 1-<19 years of age (samples from subjects <1 year were excluded). Three different nonparametric quantile methods were used to estimate the 2.5th and 97.5th quantile curves as a smooth function of age, including local polynomial quantile regression, quantile regression with restricted cubic splines and quantile regression via B-splines with different penalties and monotonicity and non-crossing constraints. **Results:** Nonparametric quantile regression methods are robust to various departures from assumptions such as normality, symmetry, linearity, and variance homogeneity. These methods are also not sensitive to outliers and are thus very flexible and powerful methods to estimate continuous reference intervals. The reference curves for total bilirubin and alkaline phosphatase established using all three methods (i.e. local polynomial quantile regression, quantile regression with restricted cubic splines and quantile regression via B-splines with different penalties and monotonicity and non-crossing constraints) were compared. The results revealed that the quantile regression via B-splines with different penalties and monotonicity and non-crossing constraints is the most flexible method to model the nonlinear relationship between age and analyte concentration. In addition to generating smoother reference curves, the non-crossing constraint property of this method allows us to estimate the reference curves with no crossing point, while its monotonicity constraint property enables us to choose various flexibility fits (i.e. non-increasing, unconstrained, or non-decreasing). **Conclusion:** We recommend using the nonparametric quantile regression via B-splines with different penalties and monotonicity and non-crossing constraints to develop continuous reference intervals. This method uses cross validation to choose the optimal value of the smooth parameter, thus removing subjective estimations. Besides being very practical, another advantage of this method is its ability to accurately model nonlinear patterns with respect to age. In addition, due to non-crossing and monotonicity restrictions, the method produces more biologically plausible estimates. Lastly, we provide information about the methods' corresponding functions in R software to aid other laboratories to apply these methods to other databases of healthy subjects.

B-042

Utility of reactive urine strip in diabetes diagnostic screening

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Background: The glucose that is filtered by the glomeruli is almost completely reabsorbed in the proximal tubules. The presence of glucose in urine (glycosuria) is an anormal finding that usually occurs when the blood glucose concentration exceeds the renal threshold (180 mg / dl), it would indicate a possible diabetes. The aim of this study is to analyze the validity of a semiquantitative method of glycosuria screening. **Methods:** The urine of 332 patients was analyzed. The glucose in the first urine isolated in the morning was determined by two different methods: - Semi-quantitative: colorimetric method based on an enzymatic reaction (glucose oxidation), H13 urine strip, DIRUI H-800 PLUS (RAL®). The concentration of glucose is directly proportional to the color developed in the pad. The instrument measures the color change of the test strip on a scale of 100 to 1000 mg / dL. - Quantitative: glycosuria was measured by the reaction to the end point in the COBAS C311 (ROCHE DIAGNOSTIC®). The statistical analysis was carried out by determining the area under the curve (ROC). **Results:** The minimum value obtained was 0.1 mg / dL and the maximum value 2268.0 mg / dL. The average obtained was 225.74, median 5.85; standard deviation 633.13; interquartile range = 8.15. The Mann Whitney test between both methods did not show statistically significant differences ($p < 0.0001$). Glucose is positive in the test strip when the urine has a concentration higher than 46.9 mg / dL of glucose, with a sensitivity of 95% and a specificity of 100%, with an area under the curve of diagnostic accuracy = 0.953 ($p < 0.0001$). **Conclusion:** All the urines with a glucose concentration higher than 46.9 mg / dL were positive, so the test strip detects glucose values above this concentration. Despite its low sensitivity, the reactive strip is considered a good screening method for the detection of glucosuria in diabetic patients, due to its low cost and its methodological simplicity. A positive glucosuria would lead to the determination of serum glucose (which becomes more relevant in patients where blood extraction is difficult). We must warn that the interpretation of glucose levels in urine should always be validated in parallel to blood glucose levels. Given the constant increase in the prevalence of diabetes (due to the age profile of the population in our environment) and the underdiagnosis of type 2 diabetes, we observed an increase in late complications and associated pathologies. Detection through routine screening of diabetes, in Primary Care, by a semi-quantitative method such as the urine dipstick, contributes significantly to improve the quality of patient's life diabetic patient, by means of the initiation of an early treatment during the phase pre-diabetes and to reduce health spending.

B-043

Evaluation of diagnostic testing workflow between routine manual Laboratory-Developed Tests (LDTs) and an automated LDT performed on the cobas® 6800 System

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Background: Lab-Developed Tests (LDTs) serve a critical role in patient management within clinical laboratories for the detection of pathogens when a FDA-approved IVD option is unavailable. Unfortunately, LDTs are typically labor intensive and often require multiple work areas and instruments to complete the testing process and to maintain a uni-directional workflow. Additionally, multiple rounds of manual specimen identification and confirmation are required to maintain traceability within the clinical setting, further increasing the complexity of the laboratory workflow. Adoption of automated solutions may mitigate some of these burdens by providing a sample-in-result-out workflow, including multi-level specimen tracking and traceability. The **cobas**® 6800 System is a fully automated, sample-to-result system for routine or high-volume molecular testing that relies on real-time PCR detection; the open channel functionality (**cobas** omni Utility Channel) supports the development and implementation of user-defined PCR tests using TaqMan® technology.The objective of this study was to comparatively assess the workflow and timings for three routine manual LDTs, performed within clinical laboratories, with a qualitative LDT performed on the **cobas** 6800 System. **Methods:** Four LDTs in three independent laboratories, employing unique extraction and amplification units including one LDT performed on the automated **cobas** 6800 System, were observed. The total time and number of interventions/steps were captured for each activity within the pre-analytic, analytic, and post-analytic phases of the LDT process. All observations were by invitation of the clinical laboratories and of routine manual LDTs performed by trained and experienced personnel assigned to the particular assay. **Results:** Each of the three manual LDTs required ten or more interventions with a combined average of 70 steps to complete the testing process including 7-8 unique dedicated work areas throughout the laboratory, which consisted of 2-3 hoods, 2 instruments, and 2-3 computers. With optimized run sizes, the average active hands-on time for each of the three manual LDTs was over 78 minutes and total true walk-away time averaged approximately 150 minutes among the tests. Automation resulted in an overall reduction in the number of interventions and steps to 3 and 13, respectively, reduced the dependence on multiple work areas (utilizing only 2); the hands-on time was reduced by 91%, down to 7 minutes, while the true walk-away time was increased to approximately 192.5 minutes (an increase of over 28%). **Conclusion:** Through the automation process, many manual steps of traditional LDTs, including pipetting and reagent preparation, as well as the need for multi-step verifications, are eliminated. The sample-in-result-out workflow on the **cobas** 6800 System results in reduction in overall hands-on time, the dependence on multiple instruments

and work areas, while also maximizing walk-away time. On-board specimen tracking and validity checks on the automated system also allow for improved traceability and ultimately, minimize the risk of user or clerical errors.

B-044

Automating a MALDI-TOF Mass Spectrometry Replacement of Gel Electrophoresis in the Clinical Laboratory

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Background: Our high throughput clinical electrophoresis laboratory has stagnated in tests per full time employee (FTE) as manual, semi-batch runs and paper result tracking are limiting our gel-based detection of monoclonal immunoglobulins (M-proteins). We recently described a MALDI-TOF MS method (MASS-FIX) as a plausible replacement for gel-based immunofixation (IFE). However, to utilize MASS-FIX, a fully validated automated method meeting current analytical capabilities was required. The objective of this study was to clinically validate an automated version of our MASS-FIX assay suitable for replacing IFE in our high throughput clinical laboratory. Our aim was to automate pre-analytical sample processing, improve positive specimen identification, improve ergonomics by reducing manual pipetting, reduce paper data storage and improve FTE utilization without impacting turnaround time (TAT). **Methods:** Serum samples were processed in batches of 32 or 64 and loaded onto a liquid handler (Starlet, Hamilton Robotics) along with reagents and a barcoded 384 well plate. The pre-analytical steps included: 1. Pipetting immunopurification beads specific for IgG, IgA, IgM, kappa and lambda immunoglobulins (CaptureSelect, ThermoScientific) to unique wells, 2. Adding 10 mcl of patient serum, 3. Removal of nonspecific proteins by washing, 4. Eluting the purified immunoglobulin 5. Reducing the sample to separate the heavy and light chains. The resulting 384 plate was transferred to a second liquid handler designed for low-volume pipetting (Mosquito HTS, ttpLabtech) for MALDI plate spotting. MALDI-TOF mass spectra were collected using a Microflex LT (Bruker Daltonics). An integrated in-house developed software was utilized for data analysis, history tracking, and result reporting. Residual serum samples (N=1043) were run using the automated system and results were compared to prior IFE results. **Results:** The automated MASS-FIX method was capable of meeting the validation requirements of accuracy, limit of detection, sample stability and reproducibility with a low repeat rate (1.5%). Out of 1,043 samples, 338 were positive by IFE and 705 had no M-protein detectable by IFE. The overall qualitative concordance was 95.8% for IFE positive samples and 95.8% for IFE negative samples. The limit of detection of MASS-FIX was similar to IFE at 15-60 mg/dL, depending on the patient's immunoglobulin background level. The automation and integrated software allowed a single user to process 320 samples in an 8 hour shift. Software display allowed for rapid and easy identification of M-proteins. Additionally, the entire system maintains positive sample identification, greatly reduces manual pipetting and does not significantly impact TAT. The additional benefit of electronic record keeping is to regain at least 100 square feet of lab space used for paper patient history files. **Conclusion:** MASS-FIX is ready for implementation in a high-throughput clinical laboratory. In addition to the analytical improvements, the major advantages of this method over our current gel-based assay include automation, electronic record keeping and positive sample identification.

B-045

Data Mining and Visualization for Monitoring Suspected Healthcare-Associate Infection

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Background: Healthcare-associated infection (HAI) control is one of the most important work in hospital. Early outbreak detection prevent patients from getting worse disease condition and also save a lot of medical expenses. The surveillance and timely feedback of HAI-related risk assessments can be complicated, especially for a 3,000 beds hospital. The object of this study was to build a data visualization system for monitoring suspected HAI with ease. **Methods**: Database was used to store bacterial species, warning threshold, daily reports and count for every microorganism. The baseline and warning threshold for every bacteria was calculated from September 2013 to March 2015. The total, positive and daily average report count were 260,779, 66,446 and 118 respectively. Warning threshold for every bacteria was defined as the mean of daily culture report count plus 1.28 standard deviation(SD). Scheduled computer program collect daily culture report and compare with warning threshold. Once the report count is higher than the warning threshold, the program will send an email to notify infection control staff. If there were 3 and more patients has same microorganism report in the same day, the system will fire a warning signal, too. Data visualization was presented in web format with Google chart application. It include bacterial daily culture count trend, specimen distribution, and ward distribution. **Results**: The daily report count mean±SD and warning threshold for 3 of most common bacteria were *Escherichia coli* (18.5±5.7, 26), *Pseudomonas aeruginosa* (11.1±4.7, 17), *Klebsiella pneumoniae* (9.0±4.0, 14). During the system test, the warning times and rate for 3 bacteria in 61 days were 8/61, 13.1%; 3/61, 4.9% and 4/61, 6.6% respectively. The average number out of 68 ward for 3 bacteria in a month that happened an event of 3 and more patients has same microorganism report in the same day were 6.7, 5.9 and 2.6 respectively. With a retrospective study of a HAI event of normal saline contamination which was caused by *Ralstonia pickettii.* The system fired warning signal at the event start. **Conclusions**: This monitoring system provides automated data collection and summarization. It also provides data visualization as a chart view, which makes the management and prevention of the infection control more conveniently and efficiently.