AACC PRESENTS A VIRTUAL CONFERENCE—

Practical Solutions for Patient Centered POCT

APRIL 8, 2015

Program Guide

An expanding selection of point-of-care testing technologies has created an opportunity for healthcare institutions to bring laboratory testing to a vast array of patient care settings. At the heart of many POCT programs is the clinical laboratory, which in most cases is ultimately responsible for ensuring that near-patient testing performed throughout a healthcare system is accurate, reliable, and compliant with government regulations and accreditation requirements.

Join an expert faculty and global audience of clinicians, laboratorians, point-of-care coordinators, regulatory personnel, and industry representatives to discuss the latest in:

- POCT for pain management
- Cardiac markers in the emergency department
- Options for near-patient HIV testing
- Meeting regulatory requirements in targeted and system-wide POCT solutions
- Standards for blood glucose meters and their effect on patient care

AACC *Better health through laboratory medicine.*

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Program Chair

Roger L. Bertholf, PhD, DABCC, FACB

Professor, Pathology and Laboratory Medicine, and Director of Clinical Chemistry, Toxicology, and Point of Care Testing; University of Florida Health Science Center, Jacksonville, FL.

Roger Bertholf received a bachelor's degree in chemistry from James Madison University, and received a masters in analytical chemistry and doctorate in biochemistry from the University of Virginia. He completed post-doctoral fellowships in clinical chemistry and neuropathology at U.Va. College of Medicine under Dr. John Savory before accepting a faculty appointment in the Department of Pathology, Immunology, and Laboratory Medicine at University of Florida College of Medicine. He was promoted to Associate Professor with tenure in 1994, and full Professor in 2008. Dr. Bertholf currently serves as Director of Clinical Chemistry, Toxicology, and Point of Care Testing at University of Florida Health in Jacksonville. He is a diplomate of the American Board of Clinical Chemistry, with certifications in clinical chemistry and toxicological chemistry, and also serves a member of the ABCC Board of Directors. In 2000, Dr. Bertholf was elected fellow of the National Academy of Clinical Biochemistry.

Exhibitors

AACC thanks the following exhibitors in this virtual conference:

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Session 1 - POCT Basics: Regulation, Accreditation and Compliance

9:00 AM **The Wide World of POCT Standards: CMS**
Ann E. Snyder, MT(ASCP), Center for Medicare & Medicaid Services, Baltimore, MD

- Distinction between waived and non-waived testing
- Competencies for waived and non-waived testing
- Benefits of IQCP
- Tips for maintaining CLIA certification and problems to avoid

10:05 **The Wide World of POCT Standards: CAP**
Adrienne M. Malta, MBA, MT(ASCP); College of American Pathologists; Northfield, IL

- Accreditation standards for POCT
- QC standards
- Personnel competencies
- The CAP approach for lab inspections (following one test through all stages of testing process)

10:35 **Monitoring POCT Compliance**
Olga Camacho-Ryan, University of Florida Health/Shands Hospital, Jacksonville, FL

- QA/QC
- Optimizing your data capture with middleware
- Data capture and tracking

10:55 **Roundtable Q&A with Session 1 presenters**

11:05AM **BREAK: Dedicated time for Virtual Exhibits, Poster Session and Chats**

Poster Hall Selected Presentation: Poster 5, Lois Schultz, BA MT (ASCP), Using data capture with Telcor middleware to improve glucometer operator performance.

Session 2: Special Topics in POCT

11:35 PM **POCT for Pain Management**
Gary M. Reisfield, MD, University of Florida Health/Shands Hospital, Jacksonville, FL

- Differences between POCT and lab-based UDT
- Value-added, non-laboratory benefits - opportunities for discussion and intervention with patient

12:15 PM **Q&A w/ Dr. Reisfield**

12:25PM **Cardiac Markers in the Emergency Department**
Fred Apple, PhD, Hennepin County Medical Center, Minneapolis, MN

- POCT vs. rapid-response lab
- 30 min door to result – Grounded in science?

1:00 Q&A w/ Dr. Apple

1:05 PM **BREAK: Dedicated time for Virtual Exhibits, Poster Session and Chats**

Poster Hall Selected Presentations: Poster 5, Richard Montagna, PhD, A rapid screening and confirmatory assay for HIV: simultaneous detection of anti-HIV antibodies and viral RNA.
Poster 1, Y. Paul Bao, PhD, Comprehensive bioelectronics platform developed for POC diagnostics.

All Times are Eastern U.S.

Session 3: Special Topics in POCT

2:00 PM **Options for Near-patient HIV Testing**
Yvette S. McCarter, PhD, University of Florida Health/Shands Hospital, Jacksonville, FL

- Applications of available technologies
- Adhering to the latest HIV testing guidelines
- Role of POCT testing in enabling patient follow-up

2:25 PM **Q&A w/ Dr. McCarter**

2:35 PM **Lactate POCT in the Critical Care Setting**
John G. Toffaletti, PhD, Duke University Medical Center, Durham, NC

- Clinical implications of an increased blood lactate in surgery, ECMO, in the ED, and in sepsis
- Timing of lactate measurements for monitoring crit care patients
- When and where POC measurements of blood lactate are useful

3:05 PM **Q&A w/ Dr. Toffaletti**

3:15 PM **POCT Hematology Applications**
Marcia L. Zucker, PhD; ZIVD, LLC.. Metuchen, NJ

- Coagulation options
- ACT/TEG

3:45 PM **Q&A w/ Dr. Zucker**

3: 50 PM **BREAK – Dedicated time for Virtual Exhibits, Poster Session and Chatsation**
Poster Hall Selected Presentation: Poster 18, William Jackson, PhD, Emerging point-of-care technologies enabled by aptamers.

Session 4: Standards for Blood Glucose Meters and Their Effect on Patient Care

4:15PM **Setting the Stage for the Panel Discussion**
Roger L. Bertholf, PhD, University of Florida Health/Shands Hospital, Jacksonville, FL

- Current evidence for TGC in hospitalized patients
- Analytical quality required for glucose measurements
- Are we moving toward different FDA standards for "professional use" vs. "home use" glucose instruments?
- Establishing performance of waived glucose instruments for use in critically ill patients
- Hospital validation studies for the use of POC glucose instruments in critically ill patients

4:20 PM **Panel Discussion**
Roger L. Bertholf, PhD, University of Florida Health/Shands Hospital, Jacksonville, FL
David E. Bruns MD, University of Virginia, Charlottesville, VA
Alberto Gutierrez, PhD, U.S. Food and Drug Administration, Silver Spring, MD
Ann E. Snyder MT(ASCP), Centers for Medicare & Medicaid Services, Baltimore, MD

5:10 PM *Q&A w/ Session 4 Panelists*

5:20 PM **END OF CONFERENCE**

Fred S. Apple, PhD

University of Minnesota, Minneapolis MN

Fred S. Apple, Ph.D., is Medical Director of Clinical Laboratories, Clinical Chemistry, POC Testing and Clinical and Forensic Toxicology Laboratories at Hennepin County Medical Center in Minneapolis, MN, and Professor of Laboratory Medicine and Pathology at the University of Minnesota School of Medicine.

Dr. Apple's research interests have been centered in the areas of cardiac biomarkers in acute coronary syndrome and heart failure, and forensic toxicology. His CLIA-certified research laboratory is the "Cardiac Biomarkers Trials Lab" at the Minneapolis Medical Research Foundation of Hennepin County Medical Center.

Dr. Apple has served as an Associate Editor of Clinical Chemistry for the past 14 years. He has served or serves as a member of the 'National Academy of Clinical Biochemistry' committee, the 'Joint ESC-ACCF-AHA-WHF Global Task Force' and the 'Universal Definition of Myocardial Infarction' biomarker subcommittee establishing clinical and laboratory practice guidelines for the use of biomarkers for acute coronary syndromes and heart failure. He is a member of the IFCC "Task Force on Clinical Application of Cardiac Biomarkers ". He also has served on the Institute of Medicine's Committee on Qualification of Biomarkers as Surrogate Endpoints of Chronic Disease Risk and on the NHLBI Working Group for Onsite Tools and Technologies for Clinical Cardiovascular Research and Point-of-Care.

Disclosure: Grant/Research Support: Abbott Diagnostics, Ortho-Clinical Diagnostics, Roche Diagnostics, Siemen's Healthcare, Trinity Biotech, Alere, Radiometer, BRAHMS, BD, bioMerieux
Salary/Consultant Fee: Philips Diagnostics
Honorarium/Expenses: Beckman Coulter, Abbott Diagnostics

Roger L. Bertholf, PhD

University of Florida Health Science Center, Jacksonville, FL

Roger Bertholf received a bachelor's degree in chemistry from James Madison University, and received a masters in analytical chemistry and doctorate in biochemistry from the University of Virginia. He completed post-doctoral fellowships in clinical chemistry and neuropathology at U.Va. College of Medicine under Dr. John Savory before accepting a faculty appointment in the Department of Pathology, Immunology, and Laboratory Medicine at University of Florida College of Medicine. He was promoted to Associate Professor with tenure in 1994, and full Professor in 2008. Dr. Bertholf currently serves as Director of Clinical Chemistry, Toxicology, and Point of Care Testing at University of Florida Health in Jacksonville. He is a diplomate of the American Board of Clinical Chemistry, with certifications in clinical chemistry and toxicological chemistry, and also serves a member of the ABCC Board of Directors. In 2000, Dr. Bertholf was elected fellow of the National Academy of Clinical Biochemistry.

Disclosure: Disclosed no relevant financial relationships.

David E. Bruns, MD

University of Virginia, Charlottesville, VA

David Bruns is Professor of Pathology, Director of Clinical Chemistry and Associate Director of Molecular Diagnostics at the University of Virginia. He is the immediate past Editor of the journal Clinical Chemistry and co-editor of the recent editions of the "Tietz Textbook of Clinical Chemistry and Molecular Diagnostics" and "Tietz Fundamentals of Clinical Chemistry and Molecular Diagnostics". He has served on the Board of Directors of AACC and has received the AACC awards for Research, Education and Lifetime Achievement.

Disclosure: Grant/Research Support: Edwards Scientific, OptiScan

Olga Camacho-Ryan, MT(ASCP), MBA

University of Florida Health - Shands Hospital, Jacksonville, FL

Disclosure: Disclosed no relevant financial relationships.

Olga R. Camacho-Ryan serves as the Laboratory Quality Manager for UF Health Jacksonville, located in Jacksonville, Florida. She obtained her Bachelor of Arts from William Jewell College in Liberty, Missouri, then went on to receive her Medical Technology certification and is ACSP/NCA board certified. Ms. Camacho-Ryan then went on and obtain her MBA from Webster University, St Louis, MO (Jacksonville Campus).

In her current capacity as Lab Quality Manager, she oversees the administrative and regulatory duties of the Point of Care Testing Department for the UF Health Jacksonville campus, overseeing approximately 1800 operators across 10 different Point of Care platforms.

She resides with her family in Neptune Beach, Florida.

Alberto Gutierrez, PhD

Office of In Vitro Diagnostics and Radiological Health, Silver Spring, MD

Alberto Gutierrez, Ph.D., is the Director of FDA's Office of In Vitro Diagnostics and Radiological Health. Dr. Gutierrez received a bachelor's degree from Haverford College, and master and doctorate degrees in Chemistry from Princeton University. Dr. Gutierrez has over 10 years of experience in research in the area of structural organic and organometallic chemistry. Dr. Gutierrez joined the FDA in 1992 as researcher and reviewer in FDA's Center for Biologics Evaluation and Research working on vaccine adjuvants and method development for determination of purity and structure of vaccine components. In 2000, he joined the Office of In Vitro Diagnostics and Radiological Health as a scientific reviewer, becoming a Team leader for Toxicology in 2003, Director of the Division of Chemistry

and Toxicology Devices in 2005 and Deputy Director of the Office of In Vitro Diagnostic Devices and Radiological Health in 2007 and Director in 2009.

Disclosure: Disclosed no relevant financial relationships.

Adrienne Malta, MBA, MT (ASCP)

College of American Pathologists; Northfield, IL

Adrienne Malta joined the College of American Pathologists (CAP) in 1996 and is currently the Senior Manager, Inspection Services for the Laboratory Accreditation Program (LAP). She is responsible for managing the Inspection Assignments team, the Accreditation Production team and the Staff Inspection team, supporting the Inspection Process Committee and implementing committee-approved program enhancements, performing inspections and CAP Accreditation Readiness Assessments (CARA)®world-wide, training domestic and international inspectors, including development of inspector training programs and other continuing education training seminars and provides support to peer inspection teams and laboratories throughout the accreditation process.

Ms. Malta received her baccalaureate degree in Clinical Laboratory Science from Michigan State University in East Lansing, MI, and received her MBA (Honors) with a concentration in Project Management from DeVry University's Keller Graduate School of Management in Chicago, IL. Ms. Malta also holds a certificate in LEAN Six Sigma from Villanova University, has another certificate in Fundamentals of Molecular Pathology from American Association for Clinical Chemistry and has been trained in ISO 17025 auditing practices.

Ms. Malta has more than 20 years of experience in laboratory medicine and management. She began her career as a Medical Technologist at St. Lawrence Hospital in Lansing, Michigan working as a second shift generalist. From there, she moved to Chicago, Illinois to work at Northwestern Memorial Hospital as a generalist Medical Technologist, supervising the second shift for the Immediate Response Laboratories and Liver Transplant Laboratory.

Ms. Malta has presented a wide variety of topics at regional, national and international Inspector Training Seminars and webinars for CAP, and has presented on various laboratory improvement and continuing education topics at numerous regional Clinical Laboratory Management Association (CLMA) meetings and Point of Care Testing networking group meetings.

Disclosure: Disclosed no relevant financial relationships.

Yvette S. McCarter, PhD

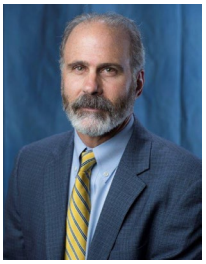
University of Florida Health, Jacksonville, FL

Yvette S. McCarter, PhD, D(ABMM) is Professor of Pathology at the University of Florida College of Medicine-Jacksonville and the Director of Clinical Microbiology at UF Health Jacksonville in Jacksonville, FL. She received her doctorate in Clinical Microbiology from the Medical College of Virginia and completed postdoctoral fellowship training in Public Health and Medical Microbiology at Hartford Hospital under the direction of Raymond Bartlett, MD. Following fellowship training she assumed the position of Associate Director of the Division of Microbiology at Hartford Hospital. She held this position from 1992-1999 and in 1999 she became the Director of the Division of Microbiology at Hartford Hospital and Director of the Microbiology Laboratory at Clinical Laboratory Partners, Newington, CT. She was also an Assistant Professor of Laboratory medicine at the University of Connecticut. In 2001 she assumed her current position at the University of Florida. Dr. McCarter is also a Diplomate of the American Board of Medical Microbiology.

Dr. McCarter is a member of the American Society for Microbiology (ASM), the American Society for Clinical Pathology (ASCP) and is a Fellow of the Association of Clinical Scientists. Dr. McCarter currently serves on the Laboratory Professional and Technical Advisory Committee and Standards and Survey Procedure Committee of The Joint Commission, ASM's Public and Scientific Affairs Board Committee on Laboratory Practices and is Vice Chair of the American Board of Medical Microbiology. Dr. McCarter is an Associate Editor for ASCP's Lab Medicine and currently serves on the ASCP LabQ editorial board and Workshops and On-Demand Webcasts committee. She currently serves on the editorial board of two scholarly journals, is an ad-hoc reviewer for 7 scholarly journals.

Dr. McCarter has authored more than 33 peer-reviewed publications, 7 book chapters and more than 50 abstracts. She has also presented more than 70 invited presentations at the local, regional, national, and international levels. She nationally recognized for her work in cost-effective, clinically-relevant microbiology. Her research interests include utilization controls in the Clinical Microbiology Laboratory, cost-effective laboratory medicine and the evaluation of new diagnostic tests and antimicrobials.

Disclosure: Disclosed no relevant financial relationships.



Gary M. Reisfeld, MD

University of Florida College of Medicine, Gainesville, FL

Dr. Reisfield specializes in the management of chronic cancer and non-cancer pain in individuals with concurrent substance use disorders, dividing his time between the University of Florida's Gainesville campus and the urban campus in Jacksonville. He is dedicated to providing care of the highest quality and to advancing the educational and research aims of the pain and substance abuse disciplines.

Dr. Reisfield's major research interest is medication adherence monitoring and he is the author of more than fifty book chapters, journal articles, and abstracts.

He believes that pain has both physical and emotional dimensions, and that the experience of pain is determined by the interaction of the pain with social, environmental, occupational, familial, and psychological factors. He feels that key goals for patients with chronic pain include reducing the pain, improving function in major life spheres, enhancing quality of life, and reducing dependence on the healthcare system.

Disclosure: Disclosed no relevant financial relationships.

Ann E. Snyder, MT (ASCP)

Centers for Medicare & Medicaid Services,Baltimore, MD

Ann E. Snyder, MT(ASCP) is a Medical Technologist for the Division of Laboratory Services, DLS ("CLIA"). She received her bachelor of science degree from the University of Maryland at Baltimore in 1982. She worked at the Greater Baltimore Medical Center (Baltimore, MD) for 25 years, where she held positions in Hematology, Stat Lab and Point-of Care Testing. In her current position, she is a Medical Technologist for the Centers for Medicare & Medicare Services (CMS), Division of Laboratory Services (DLS). Her work in DLS includes the State Agency Performance Review (SAPR) program, CLIA surveyor training, international laboratories, interpretive guidelines, and she is the lead for developing Government Performance Results Act (GPRA) goals for the division. In 2013, she received her Master's Certificate in Project Management from George Washington University. She is currently the co-lead for the workgroup that developed CMS' new equivalent control procedure, Individualized Quality Control Plan (IQCP). Other activities in this project include her participation in CLIA surveyor training and the development of informational brochures on IQCP for the public.

Disclosure: Disclosed no relevant financial relationships.

John G. Toffaletti, PhD

Duke University Medical Center, Durham, NC

Dr Toffaletti graduated with honors from the University of Florida in Gainesville with a BS degree in Chemistry and followed this with training in clinical chemistry at the University of North Carolina at Chapel Hill, where he earned a PhD in Biochemistry with Drs John Savory and Hill Gitelman. He then completed a Postdoctoral Fellowship in Clinical Chemistry at Hartford Hospital with Dr George Bowers.

Since completing these programs, he has worked in the Clinical Laboratories at Duke University Medical Center since 1979, where he is now Professor of Pathology, Director of the Blood Gas Laboratory, the Clinical Pediatric Laboratory, several Outpatient Laboratories, and Associate Director of Clinical Chemistry. He is also the part-time Chief of Clinical Chemistry at the Durham VA Medical Center. He has written or presented numerous workshops, books, study guides, chapters, and seminars on the interpretation of blood gas, cooximetry, ionized calcium, magnesium, lactate, and renal function tests. His research interests include sample collection, analysis, and clinical use of these tests.

Disclosure: Grant/research support, Board/Committee Membership/Advisory Board, and honorarium/expenses from Instrumentation Laboratory

As a member of AACC, Dr Toffaletti has served as Chairman of the Contributed Papers Committee for the 1984 and 1997 Annual Meetings, Chairman of the North Carolina Section in 1983-4, Chairman of the Clinical Chemistry News Board of Editors in 1990, Chairman of the Electrolyte/Blood Gas Division in 1991 and 1992, and Chairman of the Commission on Publications in 1993. From 1999 to the present, he has served on the Board of Editors of Clinica Chimica Acta. He chaired the Scientific Program Committee for the 2006 AACC Critical Care and Point of Care Symposium in Quebec.

Disclosure: Disclosed no relevant financial relationships.

Marcia L. Zucker, PhD

ZIVD, LLC; Metuchen, NJ

Marcia Zucker is an independent consultant specializing in all aspects of point of care diagnostics. She completed her bachelor's degree at Rensselaer Polytechnic Institute, Ph.D. at Princeton University and post-doctoral fellowship at Yale University. She is an active contributor to the scientific literature, lectures both nationally and internationally on point of care applications and maintains affiliations with several professional associations. Marcia is active in the AACC Critical and Point of Care Testing Division, the National Academy of Clinical Biochemists (NACB), the CLSI Consensus Committee for Point-of-Care Testing and CLSI guidelines development working groups.

Salary/Consultant Fee: consultant fees to manufacturers of point-of-care devices for coagulation testing

Poster Abstract 1 | Presenter

Comprehensive bioelectronic platform developed for POC diagnostics.

Georganopoulou D[1,2], *Gaustad. AG[1], Van Groll EJ[1], Hoo RS [1], Meade TJ[2],* ***Bao YP***[1]. [1]*Ohmx Corporation, Evanston IL;* [2]*Northwestern University, Evanston, IL.*

Background: The Ohmx platform, currently reagentless to the user, is designed for multiple point-of-care (POC) diagnostic applications, including ultra-sensitive protein, DNA and small molecule diagnostics. The alpha system is now automated for Lactate detection in acute settings, with an initial indication for diagnosis of lactic acidosis or Sepsis. This is developed currently in conjunction with a reagentless approach for a single test for C-reactive protein (CRP) and hs-CRP levels as well as procalcitonin to provide a full panel for sepsis monitoring.

An adaptable self-assembled monolayer (SAM) technology is presented that demonstrates quantitative, ultra-sensitive, precise and accurate measurement of numerous clinical analytes in various sample matrices (e.g. whole blood, urine, semen, prostatic fluid, saliva, etc.). Cyclic voltammetry techniques produce a self calibrating signal allowing for a rapid, fully quantitative dose response over a broad, 1000-fold range of analyte concentration.

Methods: Assays have been developed based on standard bioassay procedures (immunoassays, hybridization or enzymatic reactions) where a tagged probe / antibody, or a mediator specifically react with nanolayers on separate gold micro-electrodes. The tagged antibody of a standard immunoassay for hs-CRP, for example reacts specifically with a nanolayer on a gold microelectrode. The mediator produced during the enzymatic reaction of lactate oxidase also specifically reacts with a different nanolayer on a separate gold microelectrode. The alpha breadboard is fully developed as a programmable automated system for sample to results for all assays presented.

Results: Using commercially available calibrators, all assays developed to date demonstrate a dose response that spans the analytes' clinical relevant range. Results for the automated lactate test for sepsis detection and CRP test for sepsis and cardiovascular risk stratification are presented. An automated lactate test is presented with a TAT of 3 minutes. TAT for hsCRP is 7 minutes. The Ohmx test LOD for lactate is 0.2 mM and hsCRP is 1 pM.

Conclusions: An alpha system, utilizing a versatile bioelectronic platform, is presented with validated tests for various clinical targets including proteins, DNA and small molecules and is amenable to a reagentless approach developed for a single test that measures both CRP and hs-CRP levels as well as procalcitonin.

Poster Abstract 2

Accuracy of point of care INR measurements using CoaguChekXs Pro® in comparison to an automated coagulation analyzer Sysmex® CS2000i

Jafri L, *Hayat MH, Rashid A, Moiz B. Aga Khan University Hospital, Karachi, Pakistan.*

Objectives: To achieve therapeutic international normalized ratio (INR), point of care testing (POCT) could be performed easily with less frequent visits to the laboratory either at anticoagulation clinic or at home. Additionally, INR-POCT allows reduction of problems related to venipuncture, particularly in patients with difficult venous, provides greater convenience for patients living in remote locations and has been advocated for home monitoring and self-dose adjustment. Quality assurance for POCT is no less important than for conventional laboratory-based analyses and incorporates all measures that are taken to ensure the reliability of testing and reporting. Hence it is extremely important to compare INR results from point of care device with the results as generated by main laboratory instrument.

Methodology: This study was conducted at AKUH, from July 2013-March 2014. Twenty healthy controls and eighty warfarinized patients were enrolled to give a broad range of INR. Controls were the healthy individuals visiting our blood bank for donating blood while patients were recruited from anticoagulation clinic. Two drops of capillary blood and three ml. of citrated venous blood were collected from each subject for estimation of INR on POC device [CoaguChek XS, Roche Diagnostics GmbH, Mannheim, Germany] and laboratory instrument [Sysmex CS 2000iSysmex Corporation, Kobe, Japan] respectively. The CoaguChek XS Plus uses a human recombinant thromboplastin (ISI = 1.01) and employs electrochemical current detection to measure clot formation. Sysmex CS2000i utilizes a clotting based assay for prothrombin time estimation using Innovin® as thromboplastin reagent with an ISI of 0.9. Capillary blood was tested in duplicate on two individual strips of POC instrument and venous blood was also run in duplicate on laboratory instrument within two hours of collection.

Results: Based on the Sysmex CS 2000i system, the INR measurements ranged from 0.8 to 8.04. Mean INR values were 2.33 (±1.25) and 2.54 (±1.37) on CoaguChek XS Pro and Sysmex CS 2000i respectively. Deming Regression analysis between the two methods yielded the equation: CoaguChek XS Pro =1.099(Sysmex CS 2000i) - 0.019 with a correlation coefficient 0.97.Bland Altman revealed acceptable agreement with a minimal bias of 0.21 between Sysmex CS 2000i and CoaguChek XS Pro for INR estimation. The bias between the two instruments was further assessed in the ranges of <1.5, 1.5-5 and >4.The bias was -0.78 in the lower range (INR<1.5), -0.23 in the INR range 1.5-5 and -0.45 in the higher range (INR >4). There is a positive bias in INR results from CoaguChek as compared to Sysmex CS 2000i. The concordance between results from the two instruments in subjects with INR <1.5, 1.5-4 and >4 were 82%, 93% and 100% respectively (Overall Cohens Kappa 0.91).

Conclusion: CoaguChek XS Pro generates an accurate INR measure with minimal bias and the results are comparable to Sysmex CS 2000i system. In conclusion CoaguChek is suitable for outpatient INR monitoring

Poster Abstract 3

Analytical performance, agreement and user-friendliness of six urine test strip analysers in point of care testing.

Schot MJC[1], ***van Delft S***[2]*, Kooijman-Buiting AMJ[2], de Wit NJ[1], Hopstaken RM[2]. [1]University Medical Center Utrecht, Utrecht, Netherlands and [2]Saltro Diagnostic Center for Primary Care, Utrecht, Netherlands.*

Background: Urine analysis is a widely used diagnostic procedure in general practice, most commonly used for the diagnosis of urine tract infection (UTI). Point of Care testing (POCT) analysers for urine analysis are commercially available for use in general practice. The present study compares analytical performance, agreement and user-friendliness of six different urine strip POC analysers.

Methods: The following six analysers were evaluated: Uryxxon Relax (Machery Nagel), Urisys 1100 (Roche), Clinitek Status (Siemens), Aution 11 (Menarini), Aution Micro (Menarini) and Urilyzer (Analyticon).

Results: were compared to a laboratory reference standard urine analyser, the Urisys 2400 (Roche) and the Sedimax urine analyser (Menarini, Florence, Italy) as additional reference standard for quantitative evaluation of leukocytes, erythrocytes and sediments. Analytical performance and agreement with the laboratory standards were analyzed. Subsequently, analyser characteristics were compared and user-friendliness was evaluated.

Results: Analytical performance was good for al six urine test strip POC analysers. Compared to laboratory reference standards, overall agreement was good, but differed per parameter and per analyser. Concerning the nitrite test, the most important test for clinical practice, all but one showed perfect agreement with the laboratory standard. For leucocytes and erythrocytes specificity was high, but sensitivity was considerably lower.

First-time users found the different urine test strip POC analysers easy to use. The Uryxxon Relax was found to be most user-friendly followed by the Urisys 1100. The susceptibility to flaws, either in preparation of the analyser, performing the analysis or reading the results was also considered lowest for these two analysers. First-time users were overall positive about the increase in productivity, effectiveness and accuracy by using a urine test strip POC analyser.

Conclusions: The overall performance of all six commercially available urine test strip POC analysers was sufficient to justify routine use in suspected urinary tract infections in general practice. First-time users indicate that the analysers are easy to use and expect higher productivity and accuracy when using these analysers in daily practice. Obviously the next step is to determine if the use of urine test strip analysers in the primary care setting indeed has added value. A study on this subject is currently in progress.

Poster Abstract 4

Implementation of CRP POC testing in Dutch general practice (GP)

*Hopstaken RM[1], Dijkstra IM[1], **van Delft S**[1], Verweij A[1], Harmans LM[1], de Ruiter IPC[2], Minnaard MMC[3], Verheij THJM[3]. [1]Saltro Diagnostic Center for Primary Care, Utrecht, the Netherlands, [2]Primair After Hours Medical Care, the Netherlands, and [3]University Medical Center Utrecht, Julius Center for Health Sciences and Primary Care, Utrecht, the Netherlands*

Background: In their future vision document 'GP Care in 2020', the Dutch GP colleges (LHV-NHG) state that GPs have widely adopted quality-assured point-of-care testing (POCT) in close cooperation with experts from diagnostic centers and laboratories. C-reactive protein (CRP) POCT fits the profile, scientifically proven to help differentiate pneumonia from other respiratory tract infections with one drop of blood within one consultation, thereby enhancing antibiotic stewardship. Our objective was to establish a sustainable, easily accessible, quality-assured CRP POCT method for all eligible patients in primary care within the vicinity of Utrecht, the Netherlands, and beyond.

Methods: We set out to perform a multi-faceted implementation strategy by evaluation of analytical performance and agreement of CRP POCT devices. We have designed a quality-assurance program, incorporating (a) training for GPs and practice nurses, including e-learning; (b) a Saltro POCT team; (c) actual roll-out of CRP POCT; (d) a data-connectivity program.

We then piloted CRP POCT implementation in three GP night/weekend care services and asked all involved GPs and practice nurses to evaluate the process.

Results: (a) 148 GP offices/430 GPs (± 540.000 patients) have been contracted, trained, and are using CRP POCT so far; (b) a multidisciplinary POCT team of 13 people is executing the quality assurance program, including home visits for trainings, controls of devices, and adherence to protocols; (c) the number of CRP POC tests increased steadily from 0 in 2011 to 18.696 over 2014 – devices and tests are purchased by Saltro and distributed to the GPs free of charge, and reimbursed by insurance companies after Saltro receives the test data; (d) for patient safety, central control, and automatic transfer of results, a data-connectivity circuit is piloted in five GP offices.

GPs and practice nurses positively evaluated Saltro's CRP POCT quality control (71%) and schooling (69%); occasional problems with the execution of the CRP test are experienced by 23% of practice nurses. 95% of the GPs in night/weekend care (192 GPs, ± 290.000 patients) found the test of added value and there are 10% less referrals to secondary care . No significant reduction in antibiotic use is seen – instead, antibiotic prescriptions are better targeted by the test result.

Conclusion: High-quality CRP POCT has been growing rapidly, and is fully embraced by GPs in routine care in Utrecht (NL) after introduction by Saltro in 2012. The involvement of experts from laboratory or diagnostic centers is very important for this entire process. Use in night and weekend care shows a reduction in referrals to the hospital by 10%, together with better selection of patients for antibiotic treatment. Promising results, but a remaining obstacle is the high cost for the software to enable full data-connectivity.

Poster Abstract 5 | Presenter

A rapid screening and confirmatory assay for HIV: simultaneous detection of anti-HIV antibodies and viral RNA

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The global HIV/AIDS epidemic continues to be fueled by the large number of individuals who do not know that they are infected. In low resource settings, one of the most effective means to control the spread of HIV is via education, behavioral modification, and diagnosis. Unlike developed countries, however, these settings do not have the sophisticated equipment, trained personnel and facilities required to effectively test clinical specimens. As a result, simple dip-stick tests are frequently used to rapidly screen populations for the presence of HIV antibodies, which often lack the sensitivity and specificity of more sophisticated tests and do not detect recent infections. Moreover, initial serological results cannot be confirmed by more sensitive and specific testing. Instead, developing countries often "confirm" the initial screening result with a fast and easy, but no more accurate, dip-stick test from another manufacturer.

In an effort to overcome the challenges found in low resource settings, we have developed a simple and fast microfluidic device and associated instrument. The Rheonix CARD® technology is designed to automatically analyze either blood or saliva for the presence of anti-HIV antibodies while at the same time isolating nucleic acids and detecting viral RNA using Loop-mediated isothermal amplification (LAMP). This approach not only confirms serological results by more sensitive molecular methods, but also addresses the well-known "window period" problem occurring during early HIV infection, before antibodies are detectable.

Under the control of the instrument's software, the analysis of

specimens on the CARD was achieved by directing the flow through two sets of channels of the microfluidic device. While one portion of the CARD analyzed specimens for the presence of antibodies, another portion of the CARD isolated viral RNA by magnetic bead technology and amplified viral targets using LAMP. The CARD technology results were verified by analyzing the same specimens by manual procedures and bench top instruments, confirming that highly sophisticated assays could be performed in low resource settings by individuals without specialized training or expertise. Coupled with the low costs associated with the Rheonix CARD technology, the automated platform will provide an effective means to achieve rapid serological and confirmatory molecular testing in low resource settings. Finally, since antibody and viral results are achieved simultaneously, there will be no need for a return visit, thus eliminating another concern in low resource settings.

Poster Abstract 6

Precautions in evaluating point-of-care instruments for cardiac markers

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Background: A branch of the National Health Laboratory Service in Pretoria, South Africa, has been serving the affiliated academic hospital in the adjacent area for all essential testing including cardiac markers. Specimens are collected by the messengers, but registration into the laboratory information system delays testing and reporting, leading to unacceptable turnaround time. AQT In response to this non-conformance, we evaluated the Flex II troponin I point of care instrument in the accident and emergency unit.

Objectives: Document important factors in the planning of evaluating point of care instruments with regards to cardiac troponin I.

Material and Method: Control materials from the manufacturer were used to verify the intra and inter-run precisions at the various levels of cardiac Troponin I including 99th percentile cutoff. Paired patient samples were used to compare the results between the POCT AQT Flex II and laboratory based system (Beckman DXi AcuTropI Access). Whole blood in EDTA was used for AQT Flex II and serum was used for Beckman Dxi.

Results and Discussion: The claimed performance parameters were met on the AQT Flex II system, however out of 40 patients compared, 50% of them had discordant results. Factors that could have varied the results leading to this discordance were noted. The evaluation results were obtained by the end users themselves in order to reflect the real situation but due to staff turnover, not all the users were trained, leading to operator-related errors. Serial samples were not taken from the patients due to failure of end users to follow the protocol. The serum samples for the comparison did not arrive at the laboratory in good time, hence analysis was delayed on the Beckman system causing falsely low results. Finally the detection limits on the two systems were different and so as the reporting units.

Conclusions: Initial evaluation should be done by the laboratory trained staff and stringent adherence to the protocol is important. The need to convert one set of the results in reporting unit and the different detection limit may have contributed in the discordance; notably the current method is not a high sensitive kit. Pre-analytical delays on the laboratory based testing should be avoided. Each sample with negative or equivocal results should have serial measurements on both systems to verify the differences. Final diagnosis of selected patients using imaging methods should be correlated in interpreting these discordances. Failure to attend to these, may lead to wrong judgment of correlation or repeating the whole exercise, which is costly.

Poster Abstract 7

Liposome-based point-of-care biosensor for myoglobin

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Myoglobin, a protein serving as a molecular reserve of oxygen in muscles, is released into the blood in the event of muscle tissue damage, including myocardial infarction. Although myoglobin is not as specific as other cardiac markers, blood-myoglobin levels peak hours earlier than other common markers such as troponin and creatine kinase. It has been shown that a liposome-based myoglobin immunoassay provides many benefits over a traditional enzyme-based immunoassay, including a lower limit of detection and reduced assay time. In this study, a myoglobin sandwich immunoassay using dye-encapsulating liposomes as a signal was converted from a plate format and adapted for use in a lateral flow assay. After several optimization steps, a simple point-of-care biosensor for the detection of elevated myoglobin in whole blood was developed. The two-step assay can detect biologically relevant concentrations of myoglobin in whole blood within fifteen minutes of sample application. This project demonstrates the potential for use of dye-filled liposomes as signaling markers in point-of-care whole blood lateral flow assays.

Poster Abstract 8

Potential impact on intensive care nurses if glucometer testing were required to meet personnel standards for high complexity laboratory testing

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University Hospitals Case Medical Center, a 1,000 bed tertiary care hospital, implemented Roche Accu-chek Inform II glucose meters in August 2013. The package insert states that "the performance of this system has not been evaluated in the critically ill." Therefore, use of the glucometers in patients who are defined as "critically ill" is considered "off-label" and must comply with standards for high complexity laboratory testing, as defined by CLIA.

The purpose of this study was to determine the impact on intensive care nurses if glucometer testing personnel for ICU patients were required to meet education requirements for high complexity laboratory testing.

The study was limited to 3 adult ICUs: Medical ICU, Surgical ICU, and Cardiac ICU, comprising a total of 60 patient beds. The point-of-care coordinator generated a report of total glucometer tests performed in each of the 3 ICUs for the month of November 2014. An operator ID (OID) is associated with every glucometer result in the Telcor middleware. The OIDs were matched with the name and job description of the operator in Microsoft Outlook. The proportions of glucometer tests performed by nurses and non-nurse assistive personnel were calculated and the results are shown in the Table below.

ICU	Total Glucometer Tests	Nurses	Nursing Assistive Staff
SICU	3088	45%	55%
MICU	1383	19%	81%
CICU	954	28%	72%

The majority of glucometer tests in the adult ICUs are performed by nursing assistants, who do not meet the education requirements for high-complexity laboratory testing. Therefore, the burden of this testing would default to the nursing staff. Allowing 5 minutes per test, the additional work would be equivalent to 14 hours, 93 hours, and 57 hours per month for SICU, MICU, and CICU nurses, respectively.

The current level of nursing staff would be insufficient to comply with CLIA regulations for "off-label" use of glucometers if all ICU patients were classified as "critically ill."

Poster Abstract 9 | Presenter

Using data capture with Telcor middleware to improve glucometer operator performance

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UHCMC is a 1,000 bed university hospital that performs about 325,000 glucometer tests annually. In mid- 2013, 158 Roche Accu-chek Inform II glucometers with bar code scanning and wireless transmission were implemented in 62 locations. After initial implementation with Telcor middleware, the failure rate for glucometer result transmission to the electronic medical record (EMR) was 2.0%, or 540 tests a month. The primary objective of this study was to identify operator errors in glucometer testing using middleware data capture. The secondary objective was to reduce these errors through feedback to testing personnel.

Glucose results that fail to transmit to the EMR are captured in an "exception" queue in Telcor. The exceptions are exported to a Microsoft Excel spreadsheet daily and sorted by location and error type. Five types of operator errors have been identified: (1) scanning strip lot bar code instead of patient medical record number (MRN), (2) scanning operator ID instead of patient MRN, (3) entering a dummy MRN rather than an actual MRN, (4) scanning MRN bar code from a patient who has already been discharged, and (5) "mystery" error. A monthly report that includes the total number of glucose tests run in each location and total and percent operator errors is prepared by the point-of-care coordinator and distributed to nurse managers.

Analysis of Telcor "exceptions" identified locations and operators with higher than average exception rates. The adult Emergency Department had the highest exception rate of 10%, due to inappropriate use of dummy MRNs. Education aimed at the ED personnel reduced this error rate to less than 2%. In another location, a consistent scanning error by a single operator was responsible for the majority of exceptions. After remediation, these exceptions were eliminated. An unexpected finding was that some operators were scanning bar codes other than those on patient wrist bands. This discovery led to re-enforcement of the wrist band scanning policy. The overall exception rate for the hospital has dropped from 2.0 % in December 2013, when tracking was initiated, to consistently 1.1 -1.2% as of December 2014. This study demonstrates how analysis of transmission exceptions in Telcor can be used to identify patterns of operator errors and lead to quality improvement in glucometer testing practices.

Poster Abstract 10

Troponin I Testing in the Pediatric Emergency Department in Cases of Possible Myocardial Injury

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"*This abstract contains additional data charts. Abstract can be viewed in its entirety in virtual Poster Hall."

Objective: This is a pilot study, using the data from the first calendar year of implementation of Troponin testing data, to determine if recommended use has been in compliance with established adult guidelines for use of Troponin tests as established by the literature and by practice parameters from adult hospitals in the region.

Methodology: Data was obtained from Children's Data Warehouse. Any data components not obtained electronically were abstracted by the study team from the EMR of patients who had troponin levels drawn. Charts were retrospectively reviewed for times of symptom onset, times of presentation to hospital and times of first & second troponin levels. Values of troponin levels, patient complaints, additional tests performed related to cardiac function (ECG, Echo, CK, BNP and Chest CT) and final diagnoses were also abstracted from the EMR at the time of chart review.

Results & Discussion: Pediatric specialists tend to use multiple other testing modalities to more clearly determine the source of chest pain in the pediatric population. ECG, CXR and Echocardiography are the most common modalities used. As Pneumonia, asthma and trauma are the first, third and fourth most common diagnoses with this complaint, representing 30% of the medical diagnoses; chest radiography appears to be a reasonable and effective choice in the evaluation of pediatric chest pain. Echocardiograpy is currently the gold standard test for pediatric patients in determining myocardial dysfunction, whether from hypoxic, infectious or traumatic injury. Troponin I has value and a high positive predictive value as a test for myocardial disease in the pediatric population, even for diagnoses unrelated to ischemic coronary artery disease.

Conclusion: Troponin measurement in pediatric populations is not seeking myocardial damage from coronary artery disease. Diagnoses sought more likely are infectious myocarditis, post arrest myocardial injury, post operative myopericarditis and traumatic myocardial disease. Pediatric specialists tend to use multiple other testing modalities to more clearly determine the source of chest pain in this population. ECG, CXR and Echocardiography are the most common modalities used. As Pneumonia, asthma and trauma are the first third and fourth most common diagnoses with this complaint, representing 30% of the medical diagnoses; chest radiography appears to be a reasonable and effective choice in the evaluation of pediatric chest pain. Nevertheless, troponin I is a useful test in the evaluation of pediatric chest pain.

The adult guideline suggesting a 6 hour follow up for normal troponin values appears to be safely applicable for the pediatric population. Providers should continue to be encouraged to check a 6 hours post symptoms troponin I level or document if the onset of symptoms is more than 6 hours from the time of drawing the level to increase specificity and positive predictive value of this test in the pediatric population.

Poster Abstract 11

Impact of glucose meter accuracy on the efficacy of glycemic control in critically ill patients after cardiovascular surgery

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Background: The impact of glucose monitor accuracy on patient outcomes during glycemic control remains controversial. We studied the impact of glucose meter accuracy on the efficacy of glycemic control, as measured by glycemic variability and time within target glucose range, among critically ill patients immediately following cardiovascular surgery.

Methods: During Period 1 (September-November 2012) patients placed on glycemic control following cardiovascular surgery had hourly insulin dose adjustments based upon glucose levels measured with an AccuChek Inform (Roche Diagnostics, Indianapolis IN). During Period 2 (December 2013-March 2014) patients in the same cardiovascular surgery intensive care unit (St Marys Hospital, Rochester MN) had insulin dose adjustments based upon glucose levels measured with a Nova StatStrip (Nova Biomedical, Waltham MA). The target glucose range (110-150 mg/dL), insulin dosing categories, and frequency of glucose monitoring did not differ between periods. Accuracy of glucose meters was assessed in a separate study comparing AccuChek Inform (n= 1602) and StatStrip (n=1093) whole blood to laboratory serum glucose using paired (collected within 5 minutes) samples. During Period 1, 45 (24 non-diabetic and 21 diabetic) patients on intravenous insulin therapy who had 12-24 consecutive (obtained within 30-120 minutes) glucose measurements performed in the cardiovascular ICU had records reviewed to determine median (interquartile range, IQR) glucose level, median (IQR) glycemic variability as measured by both standard deviation (SD) and Continuous Net Glycemic Action (CONGA), and median (IQR) percent time within target glucose range. The same information was obtained for 53 (29 non-diabetic and 25 diabetic) patients who had 12-24 consecutive glucose measurements during glycemic control during Period 2. Statistical significance of differences in median glucose levels was determined using generalized estimating equations to account for multiple measurements per patient; whereas statistical significance of differences in SD, CONGA, and time in therapeutic range was determined using a Wilcoxon rank sum test.

Results: Median (IQR) bias between glucose meter and laboratory serum glucose decreased from 11 (6,18) to 1 (-5,5) mg/dL between Period 1 (Inform) and Period 2 (StatStrip). Median glucose value among the 21 diabetic patients during Period 1 (148 mg/dL) was higher than the median glucose (141 mg/dL) among the 25 diabetic patients during Period 2 (p=0.02); likely due to an institutional initiative during Period 2 to manage intraoperative glucose levels for diabetic patients. Among non-diabetic patients median glucose during Period 1 (134 mg/dL) did not differ from median glucose during Period 2 (134 mg/dL) (p=0.16); suggesting that the overall process of glycemic control in the cardiovascular ICU did not differ between periods. Glycemic variability as measured by median SD decreased from 22.4 to 15.4 mg/dL ($p < 0.0001$); while glycemic variability by CONGA decreased markedly from 20.5 to 12.1 mg/dL ($p < 0.001$). Median time (percent) within target glucose range increased from 62.5% to 71.1% (p=0.003).

Conclusion: The results suggest that improving glucose monitor accuracy for patients on glycemic control after cardiovascular surgery improved the efficacy of glycemic control as measured by glycemic variability and time within target glucose range.

Poster Abstract 12

Comparison of Glucose Meter Performance Against Three Reference Methods: An Extensive Evaluation

Amanda N. Steele, BS; Megan Howes; Zachary Godwin, BS; ***Nam K. Tran****, PhD, MS, FACB;*

Background: Tight glycemic control (TGC) helps reduce hyperglycemia and subsequent mortality in intensive care unit (ICU) patients. Handheld blood glucose monitoring systems (GMS) are ideal for guiding intensive insulin therapy and maintaining TGC. However, while many of these GMSs are used in hospitals, they have not been fully validated in the ICUs. Complicating matters, these GMSs are validated against one of several methods. This includes plasma glucose measurements via hospital chemistry analyzers serving as a "comparative/reference method", or hexokinase (HK)-based "true reference methods" using perchloric acid (PCA) deproteinated samples. In contrast, for definitive determination of glucose, isotope dilution mass spectrometry (IDMS) is performed. The objective our study is to evaluate the performance of existing GMSs against IDMS, PCA, and plasma glucose methods.

Methods: One hundred forty-four remnant arterial blood gas samples were collected and tested on 13 GMSs. Ten GMSs were from manufacturer A (Nova Biomedical, Waltham, MA), 2 GMSs from manufacturer B (Roche Diagnostics, Indianapolis, IN), and 1 GMS from manufacturer C (Abbott Laboratories). GMS performance was compared against IDMS (Agilent HP 5975, Wilmington, DE), PCA/HK (Roche Modular P800, Indianapolis, IN), and a hospital chemistry analyzer (Beckman Unicel DxC, Brea, CA). The Shapiro-Wilkes test for normality was performed. One-way ANOVA was used for parametric data, while the Kruskal-Wallis test was used for non-parametric analysis. Pairwise comparisons were performed following a statistically significant finding via ANOVA or Kruskal-Wallis test.

Results: The data was determined to be non-parametric. Medians were compared and data range was reported. GMS performance was not significantly different from the plasma glucose reference method. However, GMSs from manufacturers B (13.4 [-9.49 to 73.6] mg/dL , P = 0.012) significantly differed from the PCA method. GMSs from manufacturers A (-10.9 [-56.8 to 36.4] mg/dL, P = 0.014), and C (-11.1 [-65 to 21.7] mg/dL, P = 0.010) significantly differed from the IDMS method. Lastly, both the PCA (-17.3 [-88.4 to 2.8] mg/dL, P<0.001) and plasma glucose (-7.9 [-53.8 to 21.8], P = 0.010) methods were significantly different from IDMS.

Conclusions: GMSs from all three manufacturers showed significant disagreement against at least one reference method. These data illustrates the disparity among GMSs and reference methods. To this end, there is a critical need to standardize measurements for GMS and hospital laboratory analyzers.

Poster Abstract 13

Extensive Evaluation of Sample Interferences on Point-of-Care Glucose Meters against an IDMS Reference Method

Megan Howes; Amanda N. Steele, BS; Zachary Godwin, BS; Nam K. Tran*, PhD, MS, FACB;*

Background: Tight glycemic control (TGC) helps reduce hyperglycemia and subsequent mortality in intensive care unit (ICU) patients. Handheld blood glucose monitoring systems (GMS) are ideal for guiding intensive insulin therapy and maintaining TGC. However, while many of these GMSs are used in hospitals, they have not been fully validated in the ICUs. Poor performance results in inappropriate insulin dosing and increases risk for dangerous

hypo- or hyperglycemic events. In recent years, sample interferences have emerged as a significant challenge for GMSs. The objective of this study was to determine the effects interferences on GMSs and the impact of autocorrecting biosensors on glucose measurement accuracy when compared to an isotope dilution mass spectrometry (IDMS) reference method.

Methods: We investigate the effects of ascorbic acid (AA), beta-hydroxybutyrate (BHB), galactose (GAL), lactose (LAC), L-glutathione (L-GLU), and N-acetylcysteine (NAC) on GMSs from manufacturers A, B, and C. Whole blood samples were collected from 12 healthy adult (age≥18 years). Interferences were tested at 3 levels for 5 glucose levels (range: 2.8 to 27.6 mmol/L). Each sample was tested 5 times. Results were compared to an IDMS method (Agilent HP 5975, Wilmington, DE) calibrated using a 4-level traceable standard (NIST, SRM 917a). Two-way ANOVA and pairwise analyses were performed to identify significant differences between GMS versus the reference for each interference level.

Results: AA significantly affected GMS from manufacturers B (mean [SD] bias: 44.1 [11.6] mg/dL, P<0.001) and C (12.5 [44.3] mg/dL, P=0.013). BHB significantly affected the GMS from manufacturer C (-33.1 [50.1] mg/dL, P<0.001). LAC significantly affected GMS from manufacturers B (62.6 [15.8] and C (-46.6 [40.2] mg/dL, P<0.001). L-GLU significantly affected GMSs from manufacturer B (32.6 [19.7] mg/dL, p<0.001). NAC significantly affected GMSs from manufacturer B (20.8 [17.9] mg/dL, p<0.001). GAL significantly affected GMSs from manufacturers B (93.8 [22.1] mg/dL, P<0.001) and C (-56.5 [38.7] mg/dL, P<0.001).

Conclusions: Accurate glucose monitoring improves TGC and outcomes in ICU patients. Critically ill patient samples may contain numerous interferences from endogenous and exogenous sources. GMSs from manufacturers B and C were significantly affected by several interferences despite their autocorrecting features. Clinicians must be aware of drug interferences in critically ill patients.

Poster Abstract 14

Performance evaluation of the epoc® point-of-care blood analysis system

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Objectives: The aim of this study was to evaluate the analytical performance of the new Alere epoc® point-of-care blood analysis system.

Design and Methods: The precision study was conducted on 3 epoc® blood analysis systems using 5 levels of quality control materials twice per day for 5 days. A blood gas syringe, a gold top tube, a grey top tube, and a lavender top tube were collected for the comparison study on cardiac perfusion patients (n=40). The blood gas syringe samples were tested on epoc® (all 3 meters), Instrumentation Laboratory GEM4000, Abott iSTAT, and Nova CCX meters. Gold top tube and grey top tube samples were tested on Roche Modular P for electrolytes, glucose and lactate. Lavender samples were tested on Beckman Coulter LH-780 for hemoglobin.

Results: The epoc® blood analysis systems demonstrated clinically acceptable precision for all analytes (from 0.07%, 0.07%, and 0.13% for pH 7.6, 7.4, and 7.0 levels; to 3.87%, 3.74%, and 7.56% for pO2 197, 103, and 56 mmHg levels). Comparison studies yielded a correlation coefficient R from 0.9201 (sodium) to 0.9969 (pO2) with the GEM4000; from 0.9071 (sodium) to 0.9965 (potassium) with the iSTAT; from 0.8793 (sodium) to 0.9957 (pO2) with the CCX; from 0.8463 (sodium) to 0.9942 (potassium) with Modular; and 0.9557 (hemoglobin) with LH-780. Average biases for all analytes were within the total allowable error limits.

Conclusions: The Alere epoc® blood analysis system is acceptable for point-of-care testing in the hospital setting.

Keywords: Point-of-care testing; blood gas analysis; epoc®; method evaluation; comparison study

Poster Abstract 15

A survey program to improve compliance with quality standards for CLIA-waived point-of-care testing (POCT).

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At University Hospitals Case Medical Center, more than 3,000 POCT personnel perform CLIA-waived POCT at more than 70 patient locations. Despite training and annual competency assessments, it is difficult to ensure that quality standards are consistently met in practice. We introduced a POCT survey program with the dual aim of auditing compliance with quality standards and educating POCT personnel about basic principles of laboratory testing. The purpose of this study was to assess the effectiveness of the survey program in identifying opportunities for improvement in our POCT program.

A POCT Survey form was created by POCT coordinators (POCCs) to audit compliance with POCT quality standards. The survey form organizes 14 quality measures into 4 categories: (1) quality control performance and documentation, (2) reagent management, (3) sample/result identification, and (4) cleanliness of work area. Each quality measure is scored as a "Yes" or "No" and an overall performance score is calculated (perfect score = 100%). Written recommendations for improvement are made on the form and are reviewed with at least one member of the POCT staff before concluding the visit. Finally, the form is emailed to the nurse manager, who is asked to respond to the recommendations.

Nine locations have been surveyed since the program began in November 2014. Performance scores for the 9 locations ranged from 50% to 87.5%. The 3 most frequent deficiencies observed were (1) failure to review monthly QC log sheets by a designated individual (100%), failure to label reagents with expiration dates (67%), and failure to perform QC at required frequency (63%). Other deficiencies observed in 20-50% of visits were: lack of troubleshooting QC failures, use of expired reagents, mixing kit/reagent lots, unlabeled patient cassettes or results, and failure to dispose of used testing materials. Two locations invited the POCCs to return for a follow-up surveys to measure improvement. Performance scores on second visits for these sites showed improvement from 71% to 93% and from 57% to 79%.

By engaging POCT personnel face-to-face, POCCs are able to educate care givers on the principles of laboratory testing in a more meaningful way. Although preliminary, our experience suggests that greater understanding of laboratory principles can lead to improved compliance with quality standards. Through the survey process, POCCs learn more about clinical environments, forge relationships with clinical care givers, and become accessible as laboratory resources throughout the hospital.

Poster Abstract 16

Comparison of Point of Care Activated Clotting Time Systems in different Clinical Settings in a Large Academic Medical Center

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**This abstract contains additional data charts. Abstract can be viewed in its entirety in virtual Poster Hall.*

Background: Point-of-Care (POC) activated clotting time (ACT) measurements are used to monitor heparin anticoagulation therapy during interventional procedures and guide management of patient hemostasis. Several ACT testing systems are commercially available using different methodologies, though no gold standard method exists. The aim of this study was to conduct comparative analyses of ACT results using three different ACT POC test systems including iSTAT (Abbott), HMSPlus (Medtronic), and ACTPlus (Medtronic) systems over the ACT range detected in different clinical procedures at our institution.

Methods: Forty-one venous whole blood samples collected from line draws from 25 adult (≥ 18 years) patients undergoing cardiopulmonary bypass, vascular surgery or cardiac catheterization procedures were tested in duplicate in both prewarm and non-prewarm modes with kaolin and celite activators as described below in Table 1. Intra-method imprecision analyses were evaluated using the difference in duplicate measurements for each ACT test method. Linear-mixed ANOVA was used to analyze the differences between method means. The HMSPlus ACT device is used in cardiopulmonary bypass procedures at our institution and was designated the reference method for further analyses. Linear regression analysis and absolute difference ± standard deviation (SD) in ACT values between each test method compared to the reference method were performed to assess correlation and bias, respectively.

Results: Range in ACT values for this study population was 100-835 sec using the HMSPlus. Each POC ACT device exhibited acceptable imprecision at low (< 300 sec) ACT values with enlarged imprecision at high (≥ 300 sec) ACT values. ACT mean values from the different methods were not statistically significant (p = 0.60). Linear regression analyses indicated that all of the ACT testing systems had good correlation (r2 ≥ 0.94) in ACT values compared to the HMSPlus. Proportional biases in ACT values were observed with ACTPlus and iSTAT-prewarm-celite ACT devices compared to the HMSPlus. Conversely, small constant bias in ACT values was found for iSTAT-non-prewarm-celite and iSTAT-prewarm-kaolin devices compared to the HMSPlus, though imprecision in the differences were large in the high ACT range (≥ 300 sec).

Conclusions: ACT values overall correlate well between POC ACT testing systems. Inter-method differences in high range ACT values are largely attributed to imprecision. Bias and imprecision profiles vary depending on low versus high ACT range and the optimal device for rapid determination of ACT may depend on the ACT target range for the clinical procedure.

Poster Abstract 17

An evaluation of blood gases, cardiac enzymes and coagulation point of care testing with the Abbott i-STAT in Nigeria.

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**This abstract contains additional data charts. Abstract can be viewed in its entirety in virtual Poster Hall.*

In a recently presented point of care test (POCT) survey, carried out on 109 doctors in Nigeria, it was observed that over 70% of the doctors had access to or used a glucose meter while less than a 20% of them had access to or used a critical point of care device. The commonest critical point of care device in the study was the Abbott i-STAT. There are a wide range of cartridges used for a variety of tests covering general chemistry (CHEM8+, 6+, EC4+, E3+, G, Crea), blood gases (EC8+, CG8+, EG7+, EG6+, CG4+, G3+), clotting or coagulation (ACTk, ACTc, PT/INR) and cardiac markers (cTnI, CK-MB, BNP). We studied the cartridge (chemistry blood gases, coagulation and cardiac markers) orders made by hospitals in Nigeria between 2005 and 2014, we took two time points to evaluate the trend of cartridge orders, 2008/2009 and 2013/2014. For the years of 2008 and 2009, the total cartridge orders were made up of, 64.5% general chemistry cartridges, 32% blood gas cartridges, 1.5% cardiac marker cartridges and 2% coagulation cartridges. For the second time point, the more recent years of 2013 and 2014, the total cartridge orders were made up of, 37.5% general chemistry cartridges, 46% blood gas cartridges, 9.5% cardiac marker cartridges and 7% coagulation cartridges.

In conclusion, in low – medium income resource countries like Nigeria it appears initially there was a lower uptake of cartridges for blood gases, clotting and cardiac markers compared to general chemistry cartridges. However, in the more recent years we have observed a trend shifting from the general chemistry cartridges to the blood gases, cardiac markers and clotting cartridges. This data could be highlighting an increasing awareness for critical point of care testing especially for cardiac conditions and procedures in low – medium income resource countries similar to the pattern seen in medium – high income resource countries.

Poster Abstract 18 — Presenter

Emerging point-of-care technologies enabled by aptamers

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While aptamers were first described almost 25 years ago, they are only now becoming more prevalent in research-use-only assays and, soon, clinical diagnostics. Here we briefly describe several general platforms utilizing different detection principles but all employing newly discovered aptamers for molecular recognition. These assays include 1) the more familiar lateral flow strip test, 2) a label-free method for measuring molecular interactions termed "backscattering interferometry" (BSI), and 3) an in vivo nuclear

magnetic spectroscopic method using aptamer-functionalized ferrous nanoparticles termed "magnetic spectroscopy of Brownian motion" (MSB). In each case we discuss the advantages of rapidly-discovered aptamers as molecular recognition elements and how these technologies could be enabled by aptamers to bring them to the point-of-care.

The lateral flow assay (LFA) is likely the most familiar point-of-care test to the average consumer. In the case of the LFA, aptamers offer two principal advantages over antibodies – 1) superior shelf-life with no cold-chain requirements, and 2) the ability to select aptamers under non-blood conditions. Unlike antibody development by conventional immunization, aptamers can be selected to bind under specialized conditions in matrices such as urine and saliva.

The unique attributes of aptamer selection above have been leveraged to generate aptamers against 2 capsid proteins of human cytomegalovirus (hCMV) in urine-like conditions. Subsequently, we have developed quantitative BSI assays for the 2 proteins in urine with limits of quantitation below 30 picomolar. The BSI technology features a small instrument footprint with single-step, mix-and-read data collection.

Finally, data are presented on a pair of "sandwich aptamers" (binding separate epitopes) against the cytokine, interleukin-6 (IL6). Using custom instrumentation and ferrous nanoparticles labeled with 2 different aptamers, we demonstrate both in vitro and in vivo detection of the inflammatory marker. In the latter in vivo case, inflammation was induced by intraperitoneal injection of Pseudomonas aeruginosa simulating bacterial sepsis. The relative ease with which the sandwich pair of aptamers was identified as well as the many options for chemical conjugation of the aptamers to the iron nanoparticles is highlighted.

Poster Abstract 19

7 Essential Tips to Developing and Implementing IQCP's

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Background: The introduction of the Individualized Quality Control Plan (IQCP) option under CLIA ushers in a new era of QC efficiency for diagnostic testing. The basic approach advocates well established and proven ISO practices that are self-directed and self-monitored, are data driven with a focus on outcomes, and at their foundation rely on comprehensive risk assessments as the basis for improved quality assurance initiatives.

While risk mitigation concepts are well known and practiced by most laboratory and clinical personnel, many Laboratory Directors and Point of Care Coordinators do not have training in formal risk mitigation programs, and will undertake the task of preparing and implementing a formal risk mitigation plan for the first time. How well they perform this task will have legal, regulatory, and clinical implications.

Objective: The objective of this study was to go beyond the theories and principals of risk management to develop practical guidelines – a step-by-step approach – to help laboratory personnel implement IQCP's in healthcare facilities.

Methods: This study formed a consensus group of point of care test experts and asked them to identify and outline the major tasks associated with developing and implementing IQCP's. Particular emphasis was placed on satisfying federal regulatory requirements and anticipating the integration of the IQCP into an established point of care testing program. As a prerequisite, each member of the consensus group needed to be knowledgeable regarding the latest federal requirements, be familiar with the CLSI EP-23 Guideline, and already have developed numerous IQCP's for point-of-care test systems.

Outcomes: The group arrived at seven key tasks and developed specific suggestions on executing each. The tasks include:

- Developing an IQCP Implementation Strategy
- Organizing an IQCP Implementation Committee
- Creating an IQCP Policy
- Preparing a Checklist of Resources
- Designing Report Templates
- Establishing a Data Collection and Document Control System
- Dividing the Risk Assessment into Logical Sections

Each task was described in detail, and reference checklists were developed. The outcome of this research is detailed in this poster, and is made available in the manuscript: 7 Essential Steps to Developing and Implementing IQCP's

Conclusion: Developing and implementing IQCP's in diverse and varied healthcare settings can be complex, but it is an important undertaking as it can have serious implication on clinical outcomes. Furthermore, given the lack of experience, precedents, and working templates in the marketplace, the federal IQCP initiative presents some unique challenges. The investigators in this study have broken down the IQCP development process into several well-defined and manageable tasks. Furthermore, these tasks incorporate suggestions to efficiently satisfy regulatory requirements and to anticipate the actual implementation of an IQCP in a complex healthcare organization.

Poster Abstract 20

Comparison of 3 Models for Assessing Insulin Dosing Error when a Blood Glucose Monitoring System is used in Various Patient Populations

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Objectives: This 5 hospital multi-center study conducted under stringent IRB protocols and approval was conducted to assess the risk of using a whole blood glucose monitoring system in various patient populations in acute and critical hospitals and to determine if the BGMS was acceptable for use in these patients. 158 patient conditions were represented in this multi-centered study in whom 25 parent drug classes were administered (representing >7,000 different formulations). This data and the BGMS glucose test results from arterial and venous whole blood specimens were compared to IDMS aligned plasma (arterial and venous samples) hexokinase lab reference method. The models presented include Parkes Error Grid1, Karon et al Model2, and a Sensitivity & Specificity Analysis glucose results in the range <10 to >559 mg/dL. BGMS guidelines published last year address analytical performance but do not

address clinical performance and patient safety3,4. Our goal was to assess the total analytical error of the BGMS when compared to the lab reference method and stratify insulin dosing risk when using BGMS.

Methods: Arterial and venous whole blood specimens were analyzed in duplicate for glucose on the StatStrip (Nova Biomedical, Waltham, MA) were compared plasma glucose results measured within 15 minutes (derived from the whole blood specimens) on a central lab reference lab analyzer (2 Isala hospitals, Johns Hopkins, and St. Pierre plasma hexokinase IDMS aligned on Cobas, Roche Diagnostics, Rotkreutz, Switzerland and at UC Davis Medical Center, glucose oxidase on the Synchron LX20, Beckman Instruments, Brea, CA). The glucose results were then compared using the 3 models describe above. There were a total of 1815 paired patient glucose results from 1695 patients.

Results: The summary data from each the 3 risk assessment tools will be presented. Data from each model is slightly different but represent acceptable methods for assessing insulin dosing errors based on the accuracy and imprecision of the BGMS. This study did not assess the risk of the reference nor was the total error of the reference methods determined. 99.3 % of the data met the Parkes error criteria for accuracy and imprecision. Based on the Karon et al model 99% of the data were in the 10-15% Total Error lower risk insulin categories 1 and 2. <1% of the results were in higher risk insulin dosing Category 3. Sensitivity and Specificity as a rough estimate of total analytical error across the glycemic control range were in 95-99% range respectively.

Conclusion: BGMS performance (total error) in specific acutely ill patient populations can be assessed based on these models. Insulin dosing error risk assessment and stratification with a BGMS is possible and the use of these models demonstrates that StatStrip is an acceptable BGMS for use in these settings.

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