

Supporting Point of Care Testing and Informatics

Pathology Informatics Summit 2016

David McClintock, MD

May 25, 2016

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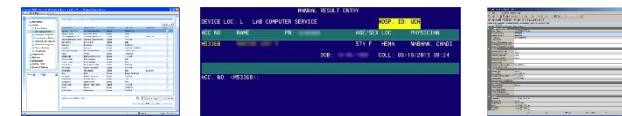
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David McClintock, MD

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Who Am I?

Medical Director, Pathology Informatics



Medical Director, Point of Care Testing



Primary CLIA holder for POC Laboratories on UCM Main Campus

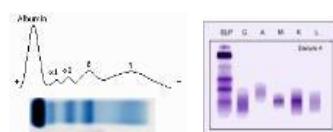
Associate Director, UChicago MedLabs



Assistant Professor, Pathology

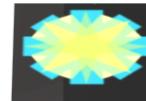
AP/CP Boarded

Protein Electrophoresis (SPEP/UPEP)



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Episode 3 – The POCT Saga Continues



PATHOLOGY
INFORMATICS
SUMMIT 2016

Brought to you by the Association for Pathology Informatics.

May 23-26, 2016
Pittsburgh, PA

*Supporting Point of Care Testing
and Informatics*

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Why am I here again??

Haven't I beaten this topic to death??

Point of care testing is here to stay...

...and its a pain to support!!

TESTING/DIAGNOSTICS

Point-of-Care Testing Continues Growth

Published on September 18, 2015



Greater speed and accuracy mark POC trends

POCT: Still A Timely Topic

It's vital that Ebola point of care testing devices have embedded mobile connectivity

Posted on October 17, 2014



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INDUSTRY NEWS

Fio to Automate Ebola Rapid Test Reading and Data Capture in West Africa

Published on January 15, 2015

[Fio Corp.](#), Toronto, has received a grant financed by the Bill & Melinda Gates Foundation to adapt its Fionet solution to connect rapid diagnostics and data in the fight against ebola.

POCT: Still A Timely Topic

Chembio bags grant to develop point-of-care test for Zika; shares up 11% premarket

Feb 19 2016, 09:24 ET | About: Chembio Diagnostics, Inc. (CEMI) | By: Douglas W. House, SA News Editor



- Chembio (NASDAQ:[CEMI](#)) is up 11% premarket on increased volume in response to its announcement that it has been awarded a \$550K catalyst grant from the Paul G. Allen Family Foundation to develop a point-of-care (POC) diagnostic test for Zika virus and related febrile illnesses.

POCT: Still A Timely Topic

Abbott to Acquire Alere, Becoming Leader in Point of Care Testing and Significantly Advancing Global Diagnostics Presence

ABBOTT GAINS LEADERSHIP IN THE \$5.5 BILLION POINT OF CARE SEGMENT, BROADENS DIAGNOSTICS FOOTPRINT AND ENHANCES ACCESS TO FAST-GROWING DIAGNOSTICS CHANNELS

- Transaction expected to be immediately accretive to Abbott's ongoing earnings per share upon close
- Acquisition will provide access to new product applications, channels and geographies
- Alere's complementary technologies will help Abbott provide better care for patients by meeting the growing demand for fast, accurate and actionable medical information

POCT: Still A Timely Topic

CAP TODAY

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APRIL 2016

IQCP without agony at the point of care

Anne Paxton

For many point-of-care testing coordinators, the prospect of developing Individualized Quality Control Plans is far from enticing. But there has never been much chance that laboratories could opt out of the Centers for Medicare and Medicaid Services' new quality control framework for much of their nonwaived testing.

Even though IQCP is an optional program,

says Kerstin Halverson, BA, MS, point-of-care coordinator at Children's Hospitals of Minnesota, the alternative—meeting the minimum QC requirements set by CLIA '88—is often impractical. "I didn't stop to calculate what it would cost to do liquid quality control on all the i-Stat cartridge types every eight hours because the number would have been through the roof," she says.

Halverson saw IQCP development as a "neces-

sary evil"—optional, yes, but essential to offset the costs associated with meeting minimum QC requirements. Like many in the laboratory community, she thought that the CMS Equivalent Quality Control program, in place since 2004, was working just fine. But now that the Jan. 1, 2016 deadline for developing IQCPs has passed, she and other POC coordinators qualify as survivors of the new process. And some are saying the



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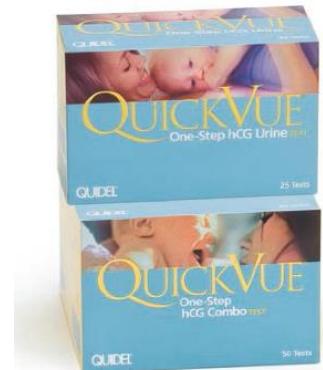
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May 23-26, 2016
Pittsburgh, PA

Session Goals

- Review the major challenges in Point of Care Testing (POCT)
- Discuss the data flow considerations for POCT
- Discuss how informatics can further support POCT in light of the continued growth of the field

Point of Care Testing



All images acquired from the vendor product websites

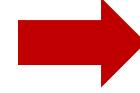
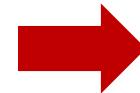
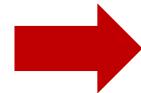
Point of Care Testing



Patient specimens, assayed at or near the patient,
with the assumption that test results will be
available instantly or in a very short timeframe to
assist caregivers with immediate diagnosis and/or
clinical intervention

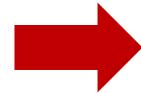
From: Plebani M. Does POCT reduce the risk of error in laboratory testing? Clinica Chimica Acta. 2009, 404: 59-64.

Time Spectrum of Patient Testing



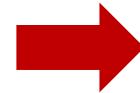
Specialty Lab

- Esoteric Testing
- Low volume
- NOT 24/7
- Heavy interpretive component
- TAT days to weeks



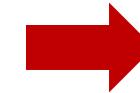
Core Lab

- Common testing
- High volume
- 24/7
- Automated platforms
- TAT < 4hrs for most test



STAT Lab

- TAT < 1 – 1.5 hrs
- Automated or special STAT platforms
- 24/7 typically if present



Point of Care Testing

- TAT 2-20 min
- Specialty devices and platforms
- 24/7 depending on location

Types of POCT

- Waived testing
 - Testing cleared by the FDA for home use
 - So simple and accurate as to render the likelihood of erroneous results negligible
 - Pose no reasonable risk of harm to the patient if the test is performed incorrectly
 - For clinical use – must follow manufacturer's instructions...but that's about it
- Non-waived testing
 - Provider performed microscopy (PPM) and moderately complex testing
 - Growing testing category as more tests and testing panels are being developed
 - Typically involves a dedicated instrument or instrument platforms



Types of POCT

- WAIVED:
 - Fingerstick glucose
 - Dipstick urinalysis
 - Fecal occult blood
 - Hemoglobin A1c
 - PT/INR**
 - Urine pregnancy testing
 - Rapid strep A
 - Influenza A/B
 - HIV**
- NON-WAIVED (moderately complex):
 - Blood gases and electrolytes
 - Activated clotting time
 - Cardiac markers

**May be non-waived depending on the assay



Major Challenges in POCT

Cost

Medical necessity

Test utilization

Analytical quality

Test performance by non-lab personnel

Regulatory concerns

Impact of POCT on hospital and central lab operations

Connectivity and Information System Management

Qualifying question

Just to prove you are a human, please answer the following math challenge.

Q: Calculate:

$$\frac{\partial}{\partial x} \left[4 \cdot \sin \left(7 \cdot x - \frac{\pi}{2} \right) \right] \Big|_{x=0}$$

A:

mandatory

Note: If you do not know the answer to this question, reload the page and you'll get another question.

Point of Care Informatics

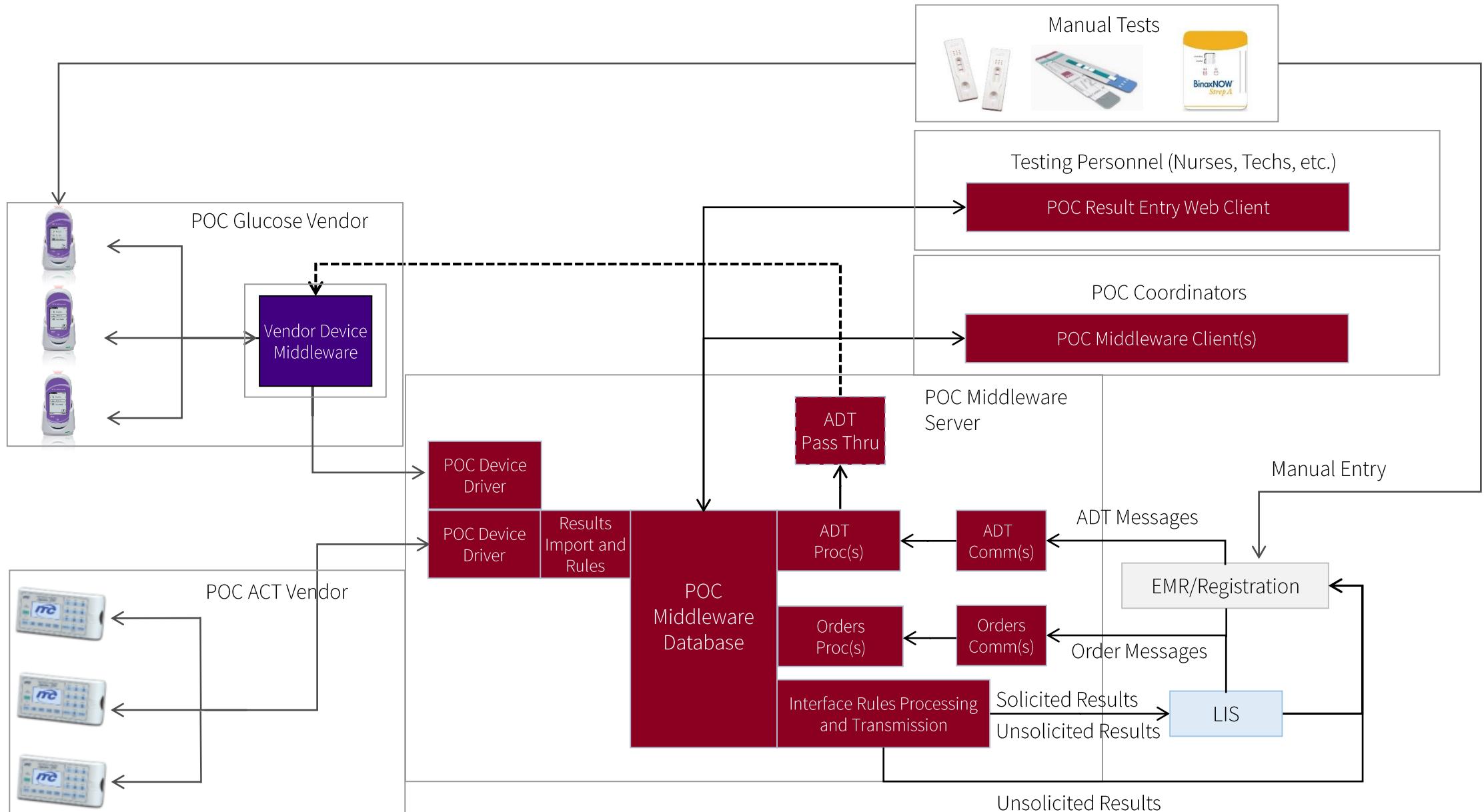
Designing a system to support the delivery of point of care testing information to the right person, in the right place and time, in the right way

POCT Information Management Today

1. Manual Records (YES, PAPER!!)
2. Direct Entry of Results into EMR
3. POC Device → Enterprise Middleware Solution → EMR
4. POC Device → Vendor Middleware → Enterprise Middleware (optional) → EMR

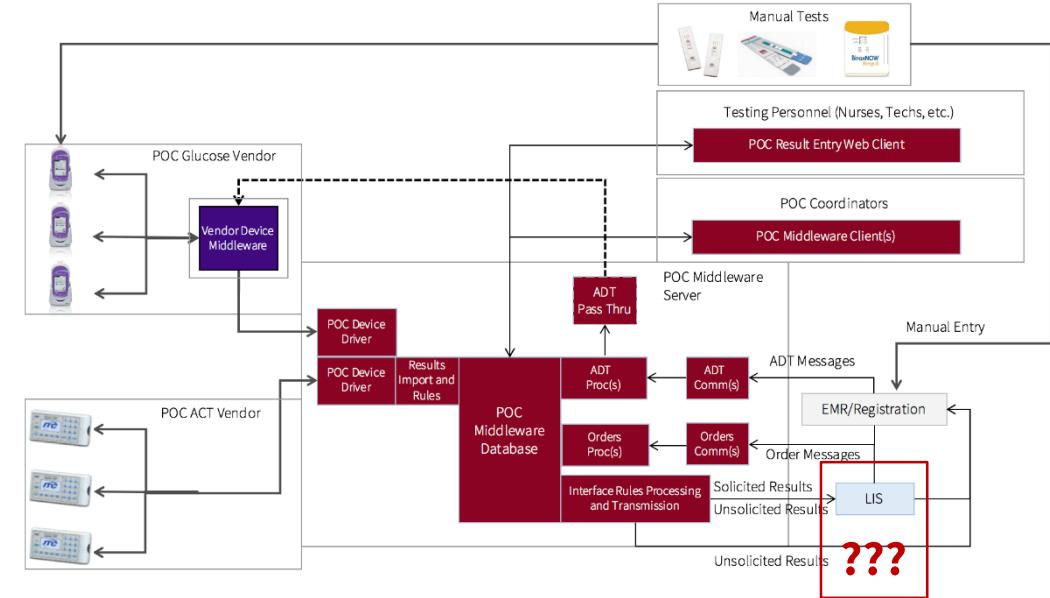
NOTE: IN ALL CASES, THE LIS IS OPTIONAL!!

Current POCT Data Flow



Is the LIS truly optional?

- Answer: YES
- Better questions:
 - Should it be optional?
 - What are the benefits of interfacing POC middleware to the LIS?



Should the LIS be optional?



- Benefits:
 - Single location of “laboratory” data
 - Potentially can utilize more advanced rules engine to act on POCT data
 - Can input POC data into LIS analytics tools (if you have them)
 - Can leverage existing interfaces from the LIS to EHR and other systems

Should the LIS be optional?



- Cons
 - \$\$\$\$ - every POC test will require an additional fee from your LIS (new instrument codes at the least)
 - Most current CP LISs were not made to support POCT
 - Direct EMR entry is much easier for nurses/tech for non-interfaced tests than a separate POC or LIS portal
 - Does it matter if you have an “integrated” LIS/EHR?

Connectivity Options in POCT

- No connectivity
- Wired
 - Electronic transfer of patient and QC results to the EMR
 - Usually "batched" transfer – mobile devices synced only a few times a day
 - Requires multiple network ports to be available in health center
- Wireless
 - "Real-time" transfer of patient and QC results to the EMR
 - Push configuration settings, operator lockout
 - IMO → Most likely feature that will help grow POCT adoption within hospitals and larger ambulatory centers



Supporting POCT through Informatics

- Issues list:
 - Exception Management
 - Competency Assessment for testing personnel
 - Better User Management and Analytics
 - Interfacing “dumb” tests

Exceptions

- POC lab values flagged for review due to:
 - Missing patient information
 - Incorrect or missing patient identifier input into POCT device
 - ADT mismatch
 - Account/Encounter number does not match known encounters in the POC middleware
 - Collection date older than allowed
 - Result outside of a predetermined range
 - Site configured rules for flagging results
 - Other (user configured, site specific)
- Exceptions require manual intervention to continue their electronic journey!

Day	Exceptions Cleared	Total Time
Sat Morning	6	0:25
Sat Noon	3	0:15
Sat Evening	7	0:27
Sun Morning	40	1:05
Sun Night	7	0:20
Weekend Total	63	2:32
Pages	2	10 Min
Lost Sleep	Priceless	☺

Exception Management

- POC middleware does not currently support advanced rules engine around exceptions
 - ISSUE – middleware has MRN, account/encounter number, patient location, etc., however it does not have a way to logically match exceptions
 - Potential solution:
 - POC Devices have unique identifiers, categorized by location
 - If account number not present at testing time, train users to use MRN
 - Match date/time of test performance with account/encounter number associated with patient at that time → match, then send result through, otherwise stay flagged as exception
 - Vast majority (>90% of exceptions) could be resolved this way

Competency Assessment

- Competency assessment requirements differ for waived and non-waived tests
 - Waived: CLIA requires only 1 of 6 elements annually
 - Non-waived: CLIA requires all 6 elements (if applicable), semiannually in first year of testing, annually after that

****REVISED** 04/21/2014**

GEN.55500 Competency Assessment of Testing Personnel

Phase II

The competency of each person performing patient testing to perform his/her assigned duties is assessed.

Elements of competency assessment include but are not limited to:

1. *Direct observations of routine patient test performance, including, as applicable, patient identification and preparation; and specimen collection, handling, processing and testing*
2. *Monitoring the recording and reporting of test results, including, as applicable, reporting critical results*
3. *Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records*
4. *Direct observation of performance of instrument maintenance and function checks*
5. *Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and*
6. *Evaluation of problem-solving skills*

Competency Assessment

- In central labs, competency assessed throughout the year
 - 6 elements assessed at different times, compiled together
 - Average sized lab overall may have 100-300 techs to competency
- In POCT, difficult to assess competency throughout the year
 - Typically assessed once per year - works for waived testing, however can have 1000-3000 testing personnel
 - Non-waived testing poses problems (~50-500 testing personnel)
 - Competency assessment of testing personnel must be performed by technical consultants (require specific education and work experience requirements)
 - Still reliant on paper forms to record six elements
- HUGE NEED for electronic data collection



TRAINING AND COMPETENCY ASSESSMENT ACCU-CHEK Inform II

Competency Period : (circle one) Initial / 6 months / Annual / Re-Training

Employee Name (Print) _____ ID _____

Department / Unit _____ Date _____

This page is intended to be used by a designated trainer to ensure all system components and procedures have been reviewed and discussed prior to competency testing of an end user.

ACCU-CHEK Inform II System In-Service Checklist

	METHOD OF COMPETENCY ASSESSMENT	Acceptable (Y/N)
1.	Review how to order and perform blood glucose testing.	
2	Review operator certification and competency requirements.	
3.	Review the hardware components of the ACCU-CHEK Inform II system.	
4.	Review the steps of proper patient preparation.	
5.	Explain the proper use of the lancet device and review the steps for obtaining a proper blood sample.	
6.	Indicate the location of any extra testing supplies and the proper storage of the test strips and glucose control solutions.	
7.	Review the proper testing procedure with the ACCU-CHEK Inform II meter and how a patient glucose result is documented in the EMR.	
8.	Explain the follow-up procedure for any patient glucose level that exceeds critical or reportable limits.	
9.	Review policy for quality control testing, documentation, how to handle any control results that are not in the acceptable range, and how to record corrective actions.	
10.	Review how to Clean and disinfect the ACCU-CHEK Inform II system.	
11.	Describe the basic components and functions of the ACCU-CHEK Inform II system.	

User Management

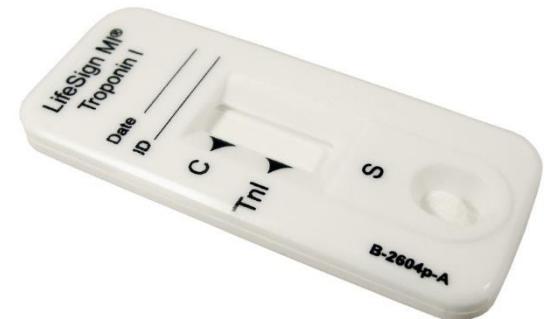
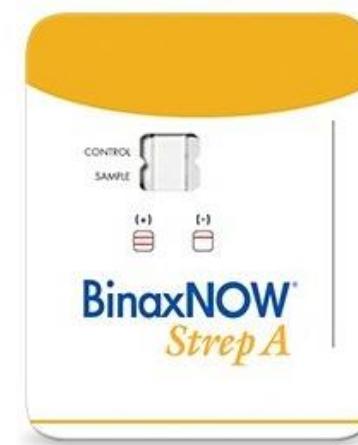
- POC has to manage hundreds to thousands of testing personnel
 - Once an operator has been competencies, must record assessment and update user record in POC middleware
 - Instruments with QC lockout enabled have to be updated
 - If QC is the only element being recorded, can automate process
- Need to store diplomas and/or transcripts for non-waived testing personnel

Analytics

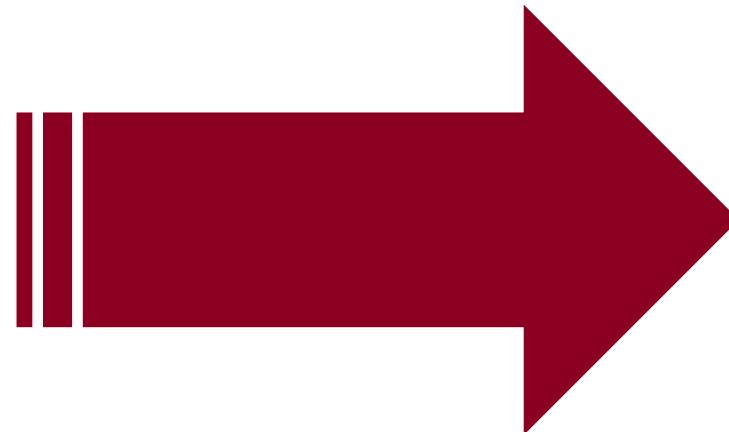
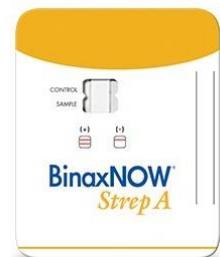


- Requests to do POCT revolve around fast turn around times
- Need analytics solutions that combine clinical and laboratory data
- Can help with (to name a few):
 - Support for new POC testing
 - Optimization of POC clinical workflows
 - Continuous validation of POC test performance
 - Comparison of central lab and POCT where possible
 - Monitoring of IQCP parameters
 - Monitoring of POC operator competency status
 - Many more metrics and dashboard opportunities

How do you interface these??



Take advantage of existing hardware!!



Other Test Entry

- Manual input of other test results into an already interfaced POC device
- Encourages real-time result entry
- Eliminate results going to flowsheet rows, physician notes, etc.
- Trending of POC results possible since all values now go to lab portion of EMR reliably
- Allows for increased automation of regulatory oversight of manual tests
- Nurses/techs already using these devices



Alternate option

- Image analysis
 - Perform qualitative or quantitative image analysis on test strips/cartridges
 - Single reader with multiple test profiles
 - “Camera in a box” type of setup

EXAMPLE: COMP ACT

- Point of care test aiming to provide objective, real-time monitoring of complement and immune activity
 - Test performed on COMP ACT cartridge
 - Sample analyzed via image analysis
 - Cartridge inserted into "box" with camera
 - Quantitative measurement performed
 - Result provided on accompanying screen



Summary

- Additional informatics support is needed to meeting the growing demand for Point of Care Testing
- The LIS does not necessarily add value to POCT
- Future endeavors in POCT Informatics need to focus on:
 - Improved result automation with clearing of exceptions
 - Improved tools to perform and record competency assessment
 - Improved user management tools
 - Interfacing “dumb” POC tests and eliminating manual result entry

THANK YOU!

Questions?

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