

# Developing and Maintaining a POCT Program

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# Objectives

- Define POCT
- Examine quality concerns with POCT
- Discuss the role of a POCT program in maintaining quality
- Offer tips for managing POCT
- Reviewing resources for POC Coordinators

# POCT Definition

- Clinical laboratory testing conducted close to the site of patient care, typically by clinical personnel whose primary training is not in the clinical laboratory sciences or by patients (self-testing).
- POCT refers to any testing performed outside of the traditional, core or central laboratory.
- Nichols JH (editor) National Academy of Clinical Biochemistry Laboratory Medicine Practice Guidelines: Evidence Based Practice for Point of Care Testing. AACC Press: 2007.

# Point of Care Testing

- Advantages

- Immediate results - no lab transportation
- Small blood volume
- Wide menu of tests available
- Whole blood and other samples available
- Works within clinical patient flow

- Disadvantages

- More expensive than traditional laboratory tests
- Quality is questionable as anyone can run the analysis
- Difficulties with regulatory compliance and documentation
- Lack of appreciation for preanalytic, analytic, postanalytic issues
- Compliance issues with billing and charge capture

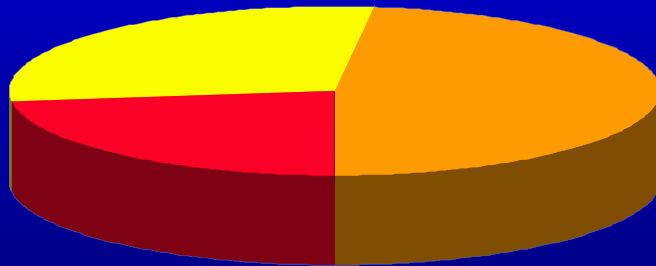
# The POCT Market

1998

US\$ 4.9 Billion world-wide  
25% of IVD testing market  
Projected annual growth of 12%

Hospital POCT

POL



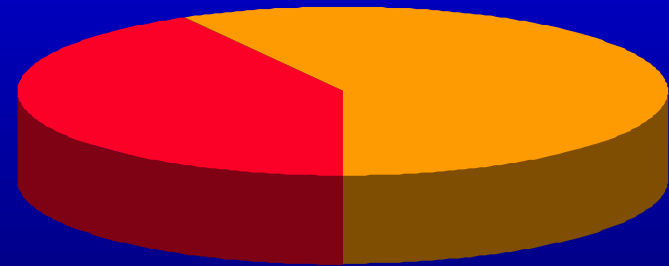
Blood Glucose

Stephans EJ. Developing Open Standards for Connectivity IVD Technology 1999;5:22,25

2003

US\$ 6.8 Billion world-wide  
33% of IVD testing market

Professional



Home Testing

Cambridge Consultants POCT Diagnostic Market Report July 2006

# Projected POCT Market

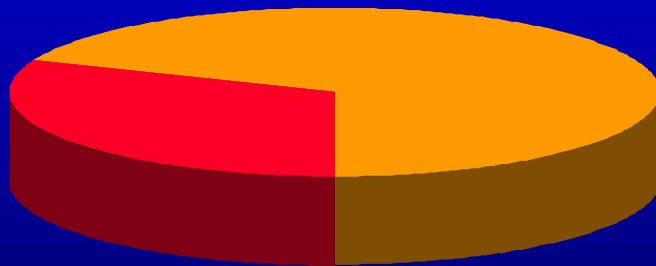
2008

US\$ 13.1 Billion world-wide

Decreased glucose growth  
(managed care, price discounts)

Increase IA and molecular POC  
6% annual growth, glucose <5%

Central Lab (69%)



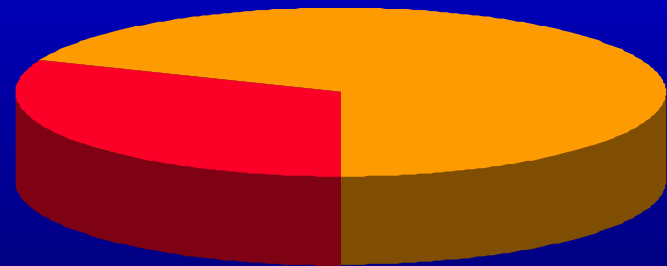
POCT (31%)

2015

US\$ 20.2 Billion world-wide

Central Lab growth in select areas  
of molecular, flow cytometry, AP  
keeps pace with POC growth

Central Lab (69%)



POCT (31%)

Emery Stephens, J POCT 2009;8(4):141-4.

# CLIA Waived Laboratories (non-exempt)

## 1995

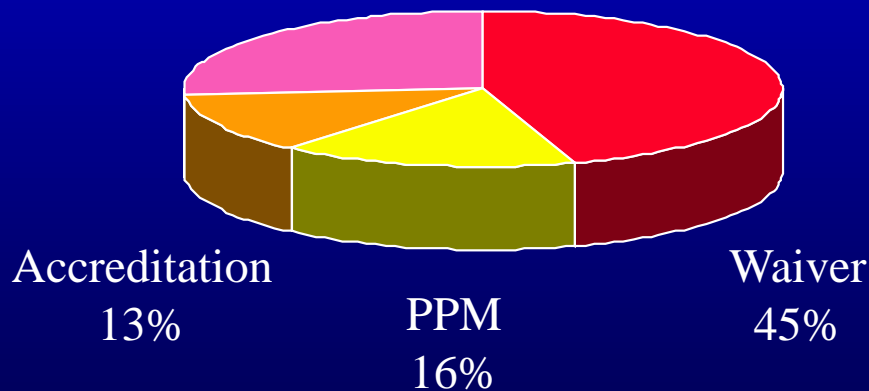
(145,124 labs)

(65,031 waived)

(82,907 POL) 62%

(28,951 waived POL) 35%

Compliance  
(CMS) 26%



## 2009

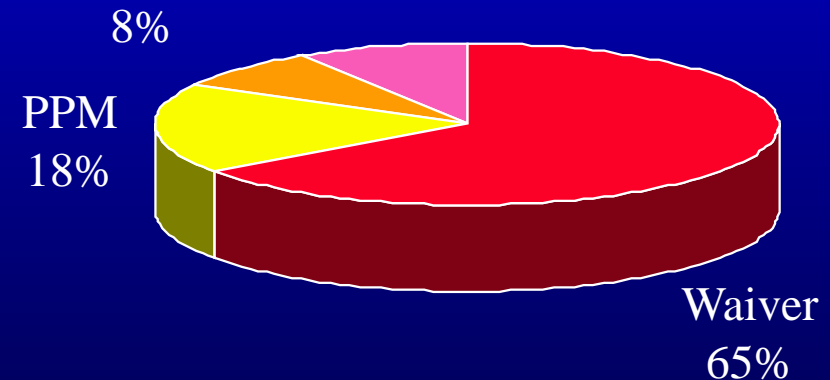
(210,312 labs)

(134,778 waived)

(110,292 POL) 52%

(59,790 waived POL) 54%

Compliance  
Accreditation (CMS) 9%



CMS data 1/2010

# Point-of-Care Testing Quality Issues

- Complaints about SMBG devices represent the largest number filed with the FDA for any medical device (by 1993, over 3200 incidents, including 16 deaths).  
Greyson J. Diabetes Care 1993;16:1306-8.
- Poorly maintained urinometers and blood gas analyzers can act as an infectious reservoir for resistant microbes. Acolet D et al J. Hosp Infection 1994;28:273-86. Rutala WA et al. Am J Med 1981;70:659-63.
- Nine patients at two nursing facilities in Southern California were diagnosed with hepatitis B infection transmitted in association with blood glucose monitoring  
State of California Health and Human Services, Department of Health Services, Licensing and Certification Program. Recommendations on the prevention and control of HBV transmission in diabetic patients who require blood glucose testing. July 2000.



# CMS COW Lab Pilot Study

- 1999 Ohio and Colorado inspections found over 50% of labs had significant quality and 7 – 10% were testing beyond certificate
- 2001 CMS expanded pilot inspected 2.5% (436 waived and PPM labs) in 8 states:
  - 32% did not perform QC as required
  - 16% failed to follow manufacturers' instructions
  - 7% did not perform calibration as required by the manufacturer

# CMS COW Lab Pilot Study

- Of the waived labs, in addition:
  - 23% had certificate issues (change name, director, address)
  - 20% cut occult blood cards and urine dipsticks
  - 19% had personnel without training/competency evaluation
  - 9% did not follow manufacturer's storage and handling instructions
  - 6% were using expired reagents/kits

DHHS Office of Inspector General Enrollment and Certification  
Processes in the CLIA Program. August 2001. OEI-05-00-00251

# CMS COW Lab Follow-Up

- Lab consultation and education improve performance of laboratories during inspections
- CMS initiating on-site visits to 2% labs
- CMS listed 15 Professional Societies and groups that offer educational opportunities
- State-by-State revisits to original 8 pilots
  - Varying improvement 7/8 states (total 74% or 61/82 labs)
  - No improvement 26% (26/82 labs)

# POCT is a Complex System

- Laboratory
  - One site
  - Limited instrumentation to perform bulk of testing
  - Limited staff, focused on same equipment daily
  - Staff trained in laboratory skills
- POCT
  - Dozens of sites, hundreds of devices and thousands of operators
  - Staff are clinically focused on patient not on equipment
  - Staff do not have laboratory training background
  - Testing delegated to lower level staff (TAs, MAs)

# Baystate Health System POCT

<u>METHOD</u>	<u>SITES</u>	<u>DEVICES</u>	<u>OPERATORS</u>
Abbott XCeed Pro	46	220	2500
UriSys 1100	5	4	100
Pyloritek	2		15
Quidel Pregnancy	14		80
Quidel Strep	9		50
Hemoccult	2		50
Nitrazine pH	9		50
HIV	2		20
i-Stat-1	10	90	800
DCA2000/Afinion	6	6	40
ITC Signature Elite ACT	7	15	80
ITC ProTime PT	8	20	75
PPM	8		10

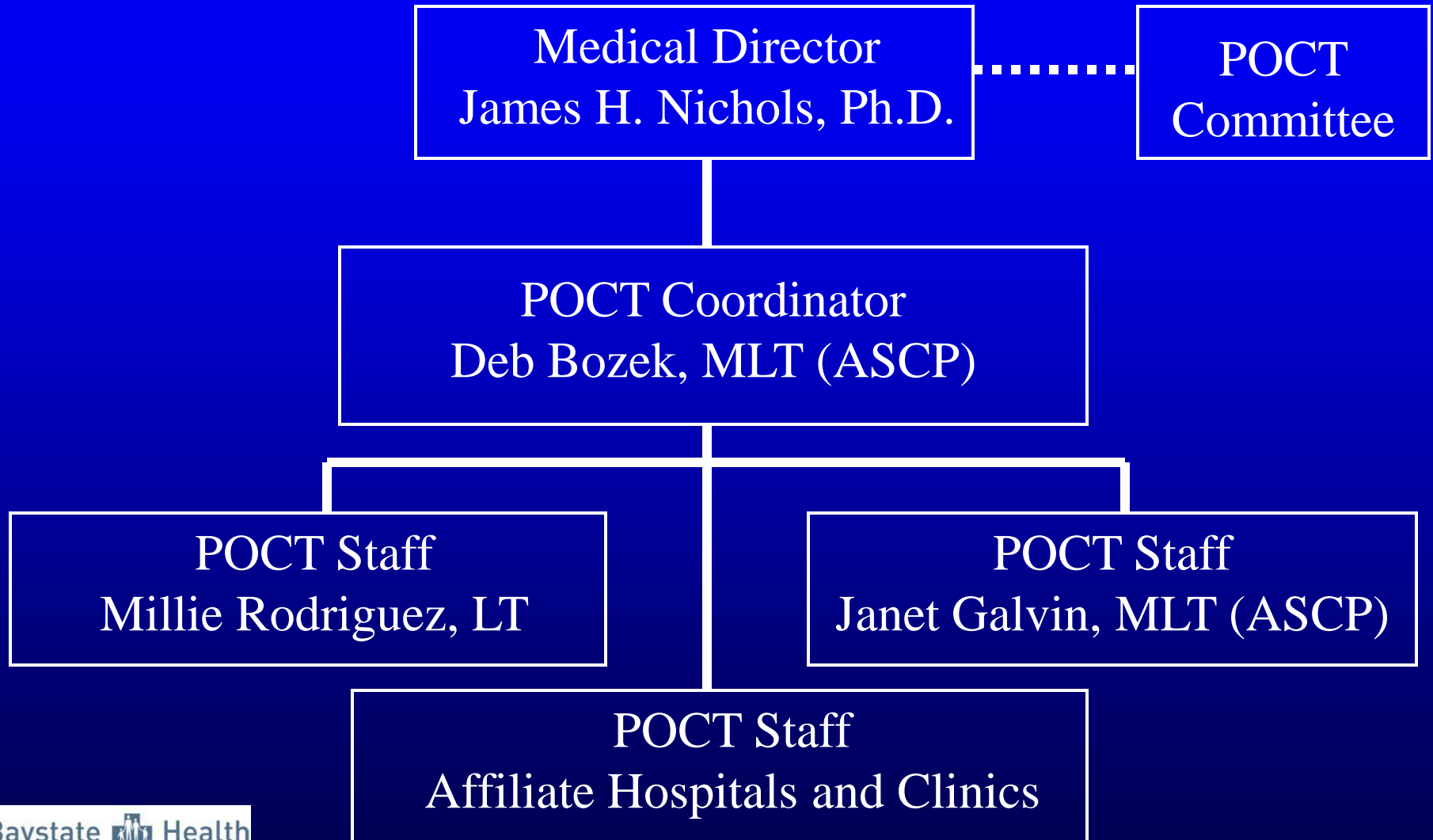
# POCT Program

- The number of devices people and testing performed POCT in an institution requires an organization and management structure
- Many institutions have a POC Coordinator (often a lab staff) and POCT Committee to oversee practice
- POCT Committee can depersonalize the review process for test approval, inspection preparation and actions to deficiencies.

# POCT Committee

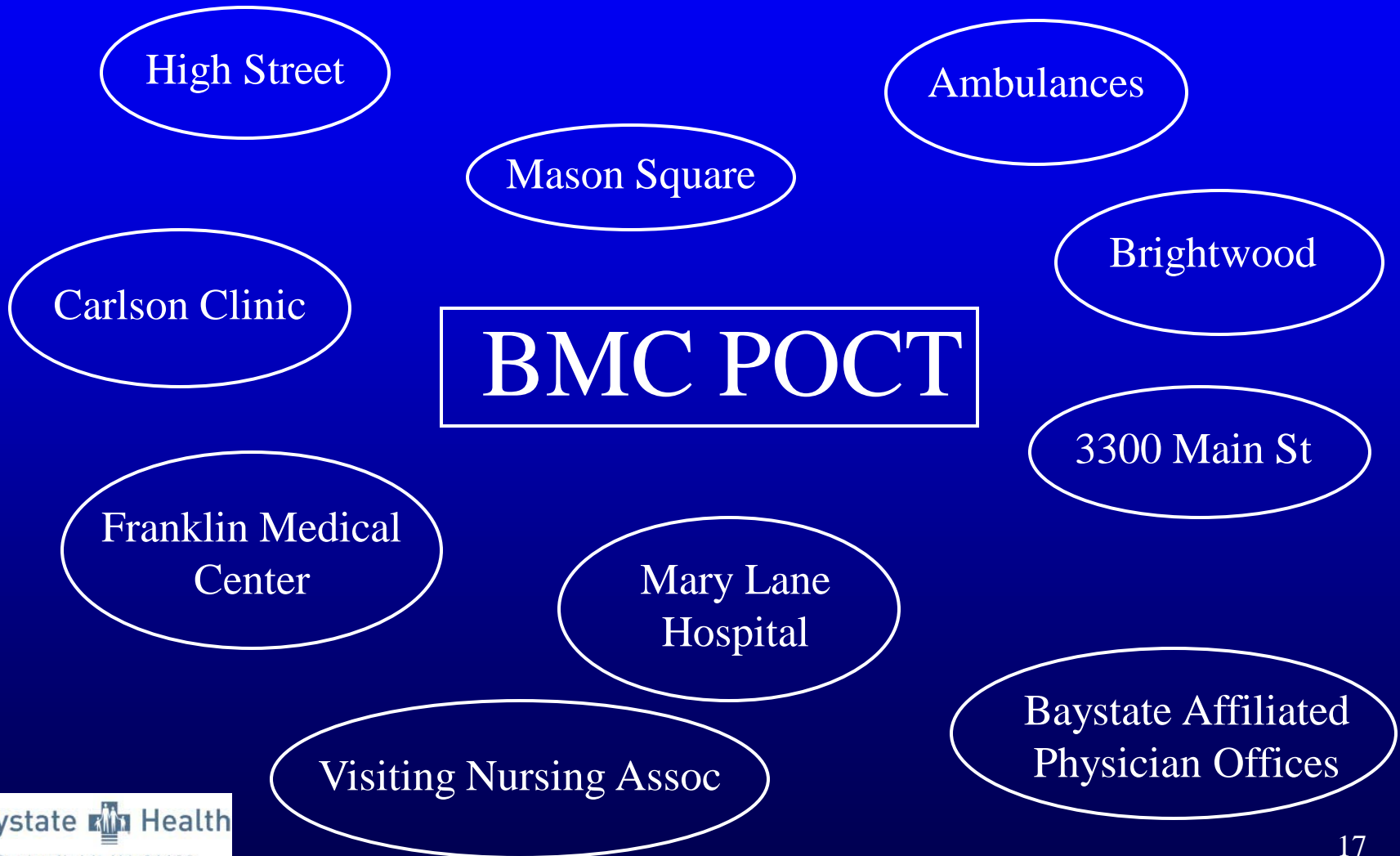
- Chair
- Lab – POC Coordinator
- Nursing – administration
- Purchasing
- Physician – user of POCT results
- Outpatient clinic representation
- Affiliate hospitals
- Other services involved – Pharmacy, Nutrition...

# POCT Management Baystate Medical Center

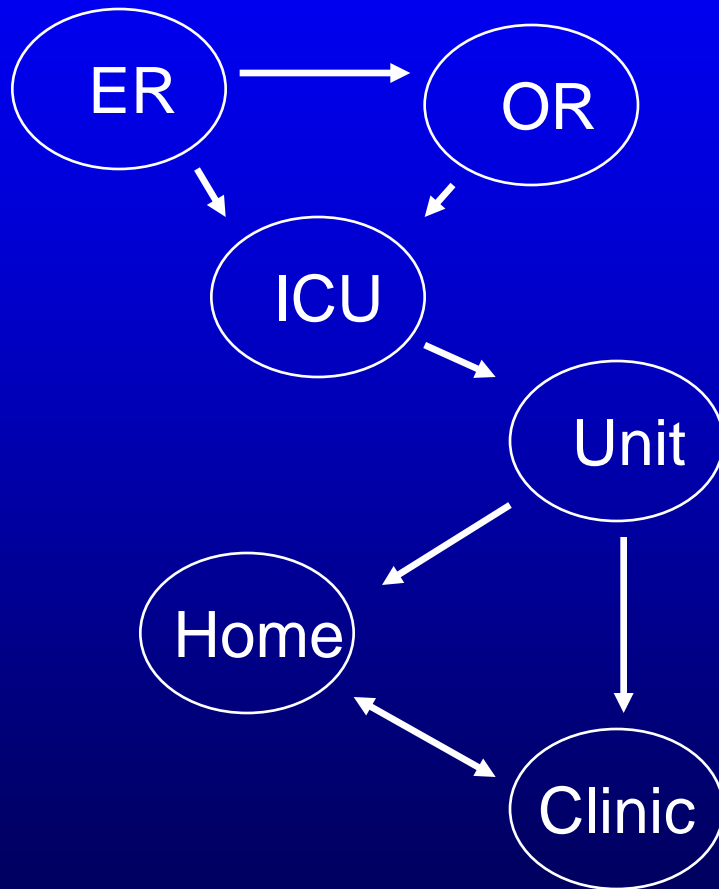




# POCT Management Baystate Health System



# Continuity of Care



POCT  
↕  
Critical Care  
↕  
Core Lab  
↕  
POL - Clinic

# Standardize

- Standardize instrumentation and methods across the health system
  - Minimizes number of different devices
  - One policy can be shared amongst sites
  - Central management system (ie oversight and data management)
  - Same methodology, clinical limitations
  - Share reference intervals (normal values)
  - Simplifies training and competency, float staff

# Connectivity and Computerization

- Computerized POCT devices automate the QA documentation (and billing) process by storing patient and operator identification with patient result, time and date.
- Electronic POCT data can be transmitted to the medical record, hospital information systems or other databases.
- Computerized POCT devices mandate performance of QC and lockout if not performed successfully. Operator lockout ensures only trained and competent staff perform testing
- Electronic data streamlines the quality review of large amounts of data
- Possibility of automating data reduction and alert algorithms to highlight problems and trends

# POCT Data Transfer



- Automatically transfer data from devices to a central database
- Reduce data collection task
- Make data accessible to authorized personnel
- Support quality control efforts

## ABBOTT QCM 3.0

Review  
Reports  
Operators  
Instruments  
Lots  
Administrative  
Log Off

Baystate Health System  
Baystate Medical Center  
Franklin Medical Center  
Mary Lane Hospital

## OPERATOR CERTIFICATION: Baystate Medical Center » All Departments » All Locations

Alarm Status

## Search Criteria

Instrument PCx

Last Name

Operator ID

Expiration Date 31

Display Records

Use this screen to view and edit operator certification information. Use the filter options to find a specific operator or to find all operators with instrument certification set to expire on a specific date. To edit or e-mail operator certification record(s) check the box(es) in the Operator Name column and click the Edit or E-Mail button.

2420 Records Found Displaying Page 1 of 25 Previous Page Next Page

E-Mail										
Operator Name	Operator ID	Original Cert. Date	Cert. Date	Recert Interval	Exp. Date	Auto Recert	Last Good QC	Last Pat Test		
<input type="checkbox"/> All										
<input type="checkbox"/> --	40238	--	--	--	--	--	05/12/2002	04/29/2002		
<input type="checkbox"/> --	00341	--	--	--	--	--	--	02/11/2002		
<input type="checkbox"/> --	02634	--	--	--	--	--	--	12/17/2001		
<input type="checkbox"/> --	03584	--	--	--	--	--	--	11/28/2001		
<input type="checkbox"/> --	03888	--	--	--	--	--	--	03/07/2002		
<input type="checkbox"/> --	04901	--	--	--	--	--	01/24/2002	03/08/2002		
<input type="checkbox"/> --	05518	--	--	--	--	--	02/13/2002	03/14/2002		
<input type="checkbox"/> --	08117	--	--	--	--	--	03/15/2002	02/14/2002		
<input type="checkbox"/> --	09500	--	--	--	--	--	--	02/11/2002		
<input type="checkbox"/> --	40917	--	--	--	--	--	--	11/16/2001		
<input type="checkbox"/> --	41897	--	--	--	--	--	--	01/09/2002		
<input type="checkbox"/> --	08025	--	--	--	--	--	--	03/03/2002		
<input type="checkbox"/> --	41253	--	--	--	--	--	--	03/04/2002		

Preview

## ICU Workload

Location Choice: Baystate Medical Center - ICU/NEURO - ICU

Instrument: PCx

Date Range: 08/01/2003 to 08/31/2003

Sort By: Instrument Serial No.

Facility: Baystate Medical Center			Department: ICU/NEURO			Location: ICU			
<u>Instrument</u>	<u>Instrument Serial No.</u>	<u>Instrument Name</u>	<u>Patient Tests</u>	<u>Control Tests</u>	<u>Proficiency Tests</u>	<u>Linearity Tests</u>	<u>Electronic QC Tests</u>	<u>Test Errors</u>	<u>Total Reagents</u>
PCx	M10370048		32	61	0	0	0	1	93
PCx	M11260030		36	55	0	0	0	1	91
PCx	M12080023	M12080023	34	59	0	0	0	2	93
<b>ICU Totals</b>			<b>102</b>	<b>175</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>4</b>	<b>277</b>
<b>ICU/NEURO Totals</b>			<b>102</b>	<b>175</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>4</b>	<b>277</b>
<b>Baystate Medical Center Totals</b>			<b>102</b>	<b>175</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>4</b>	<b>277</b>

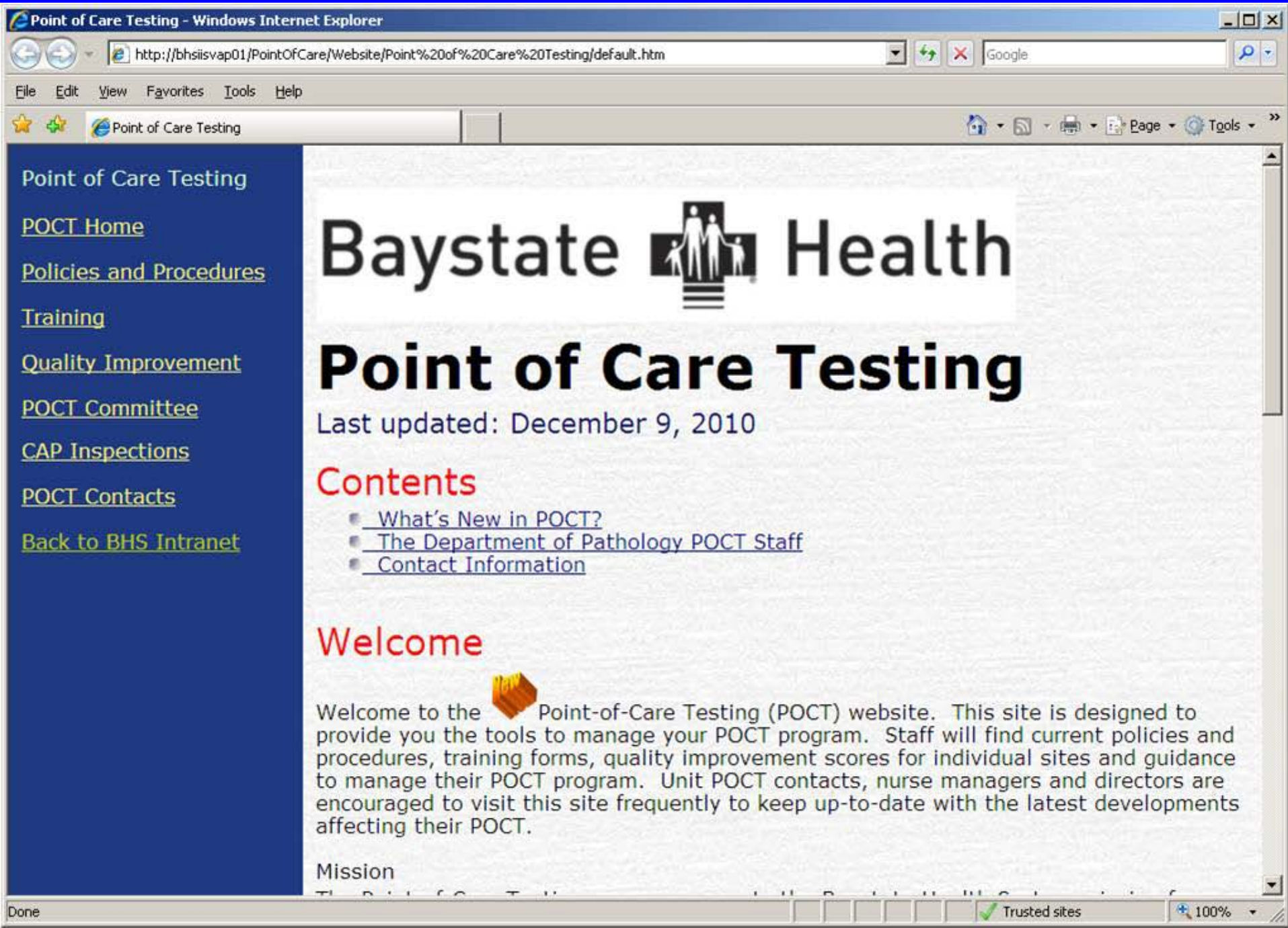
# Self-Management

- While POCT is a partnership between lab and clinical services, inspectors hold the site performing the test and CLIA director responsible
- The lab can't hold an operator's hand 24- hrs a day, sites must take charge
- Baystate has instituted a culture of self-management, starting in Jan 03.



# Baystate Self-Management

- POCT website developed with all of the tools necessary to manage POCT
- POCT sites have necessary resources, and have no one to blame but themselves for not succeeding
- Separates the lab from being responsible and in the middle of a nursing care process. Lab is available, nursing is responsible





Point of Care Testing - Windows Internet Explorer

http://bhsisvap01/PointOfCare/Website/Point%20of%20Care%20Testing/default.htm

File Edit View Favorites Tools Help

Point of Care Testing

Point of Care Testing

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[Policies and Procedures](#)

[Training](#)

[Quality Improvement](#)

[POCT Committee](#)

[CAP Inspections](#)

[POCT Contacts](#)

[Back to BHS Intranet](#)

## Policies and Procedures

Last Updated: December 10, 2010

These are the current Policies and Procedures for POCT with the latest revision date. Hard copies can be printed to update the medical unit POCT Procedure Manuals at least annually.

[HemaPrompt \(Fecal Occult Blood\) \[reviewed 8/10/2010\]](#)

[Hemochron Signature Elite \(ACT-LR/ACT+\) \[revised 10/19/2010\]](#)

[i-Stat 1 Testing Procedure \[revised 10/19/2010\]](#)

[i-Stat 1 Glucose Fact Sheet \[updated 1/29/2010\]](#)

[i-Stat 1 Cartridge or PCx Plus Strip: Which Glucose is Right for My Patient? \[updated 1/2010\]](#)

[Macroscopic Urinalysis Dipstick Chemstrip 10MD \[reviewed 8/10/2010\]](#)

[Macroscopic Urinalysis \(UriSys 1100\) Chemstrip 10MD \[reviewed 8/10/2010\]](#)

[Macroscopic Urinalysis Visual Dipstick \[reviewed 8/10/2010\]](#)

[pH Paper/Nitrazine Paper \[reviewed 8/10/2010\]](#)

[pH Paper QC Log \[updated 1/2/2003\]](#)

[Pregnancy \(Quidel QuickVue\) Urine hCG Test \[reviewed 8/10/2010\]](#)

[Proficiency Testing \(POCT\) \[reviewed 8/10/2010\]](#)

[Provider Performed Microscopy Training and Competency \[reviewed 8/10/2010\]](#)

Fast Test [reviewed 8/10/2010]

Trusted sites 100%

## Point of Care Testing

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Identified as a Category I  
Task as defined by the  
U.S Department of Labor.

Adopted: 6/21/94

Revised and Effective: 2/4/00; 5/3/01;  
3/14/02; 3/27/03; 3/23/04; 5/1/05; 7/6/05;  
4/21/06; 9/11/06; 3/5/07; 11/5/07; 12/17/08;  
6/4/09; 8/23/10; 10/20/10

Reviewed:

Reviewed:

Reviewed:

Reviewed:

Approved by:

Medical Director: James H. Nichols, Ph.D.,  
DABCC, FACB

Date:

10/19/10

Proofread by: Janet Galvin, MLT,  
ASCP, POCT

Date:

10-19-10

Prepared (Revised) by: Claudia Chiapuzzi  
MT, ASCP, POCT

Date:

10/20/10

Supersedes: 8/23/10 version

Page 1 of 10

## Baystate Medical Center i-STAT Testing Procedure

### I. Purpose

The i-STAT 1 analyzer is intended for use with i-STAT cartridges for in vitro quantification of various analytes in whole blood and with the Abbott MediSense® Precision PCx™ Blood Glucose Test Strip for the in vitro quantification of glucose in whole blood. The system incorporates a comprehensive group of components to perform blood analysis at the point of care. A portable hand-held analyzer, a cartridge with required tests and up to 95 µL of blood will provide quantitative test results for blood gas and chemistry tests within 2 minutes. Glucose results are available from the Precision PCx Blood Glucose Test Strip in as little as 20 seconds on the hand-held analyzer.

### II. Principle

#### a. i-STAT Test Cartridges

Sodium, potassium, chloride, ionized calcium, pH and pCO<sub>2</sub> are measured by direct ion-selective electrode potentiometry. In the calculation of results for sodium, potassium, chloride and urea, concentration is related to potential through the Nernst equation.

# POCT Website Afterthoughts

- Protect your content
  - Use .pdf versions or copy protected word docs
  - Only allow access behind your institutional firewalls
  - Get IS involved in serving your content
  - Becomes important with separate physician offices/hospitals under separate CLIA just adopting your policies



# Site Self-Inspection

- Key to self-management is site self-inspection
- Sites utilize same checklist that POC coordinators use to grade compliance
- Compliance tied directly to regulations
- Sites that regularly self-inspect are showing the most QA improvement

Point of Care Testing - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites Print Mail News RSS Feeds

Address http://bhsisvap01/PointOfCare/Website/Point%20of%20Care%20Testing/default.htm Go Links

Final Showing Markup Show

Point of Care Testing

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[Policies and Procedures](#)

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[Quality Improvement](#)

[POCT Committee](#)

[CAP Checklist](#)

[POCT Contacts](#)

[Back to BHS Intranet](#)

### Baystate Health System/Self Inspection Worksheet

Site \_\_\_\_\_ Date of Review \_\_\_\_\_

Signature \_\_\_\_\_

GLUCOSE	REVIEW	COMMENTS
QC Dated and In Date		
Strip Lot #:		
QC Lot #:		
Patient Volume		
# Clerical ____/ %Errors ____		

HEMOCCULT	REVIEW	COMMENTS
Slides Stored Properly and Not Exp.		
Patient Result/Pos&Neg QC Charted		

pH / NITRAZINE PAPER	REVIEW	COMMENTS
Paper and Buffers dated & in date		
QC Performed as Required		

i-STAT	REVIEW	COMMENTS
i-STAT Cartridges Dated / Not Exp.		

Local intranet

# Integration

- Just providing faster results doesn't guarantee improved patient outcome
- Improved outcomes come from better use of faster results
- POCT is not an isolated process
- POCT results should be integrated into the overall patient-care pathway
- Need to consider
  - Why was the test ordered?
  - How is the result going to be utilized in care?
  - Is POCT the most appropriate method for patient need?
- Communication with clinician is key to delivering optimal POCT interpretation and next steps.



# Clinical Outcomes of Point-of-Care Testing in the Interventional Radiology and Invasive Cardiology Setting

JAMES H. NICHOLS,<sup>1\*</sup> THOMAS S. KICKLER,<sup>1</sup> KAREN L. DYER,<sup>1</sup> SANDRA K. HUMBERTSON,<sup>1</sup>  
PEG C. COOPER,<sup>2</sup> WILLIAM L. MAUGHAN,<sup>3</sup> and DENISE G. OECHSLE<sup>2</sup>

**Background:** Point-of-care testing (POCT) can provide rapid test results, but its impact on patient care is not well documented. We investigated the ability of POCT to decrease inpatient and outpatient waiting times for cardiovascular procedures.

**Methods:** We prospectively studied, over a 7-month period, 216 patients requiring diagnostic laboratory testing for coagulation (prothrombin time/activated partial thromboplastin time) and/or renal function (urea nitrogen, creatinine, sodium, and potassium) before elective invasive cardiac and radiologic procedures. Overall pa-

0.02). For patients needing coagulation testing, wait times improved only when systematic changes were made in workflow (phase 4,  $109 \pm 41$  min;  $n = 12$ ;  $P = 0.01$ ).

**Conclusions:** Although POCT has the potential to provide beneficial patient outcomes, merely moving testing from a central laboratory to the medical unit does not guarantee improved outcomes. Systematic changes in patient management may be required.

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# CVDL Outcomes Trial

- Prior to therapeutic intervention, patients require coagulation (PT/aPTT) and/or renal function testing (Na/K, BUN/Creat)
- Phase 1 – workflow and patient throughput determined using central lab testing.
- N = 135 patients over 95 days
- Despite arriving 120 minutes early if lab work needed, 44% of results not available prior to scheduled procedure time.
- Average patient wait time was 167 minutes

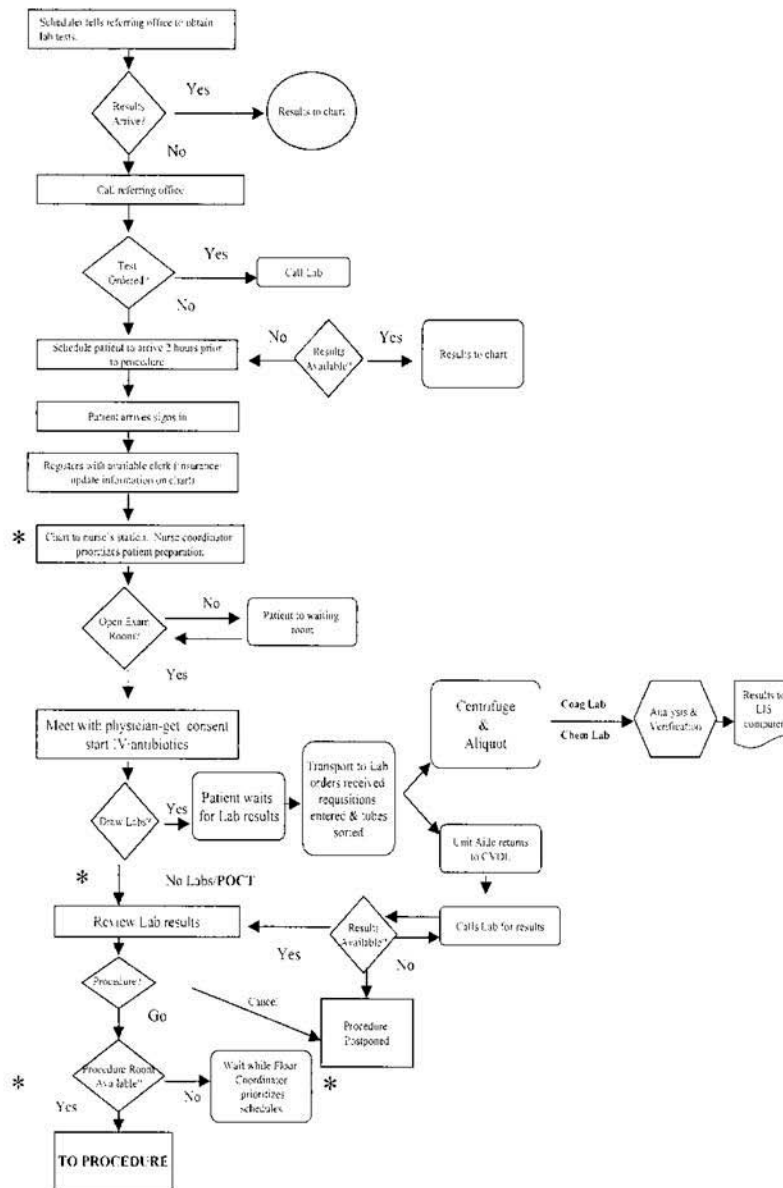


Fig. 2. CVDL patient workflow.

\* steps affected by implementation of POCT and workflow improvement initiatives. IV, intravenous drip; Coag, coagulation; Chem, chemistry; LIS, laboratory information system.

# JHH CVDL Outcomes Trial

- POCT improved wait times over core laboratory, but not significantly.
- Significant changes only occurred after unit workflow reorganized to optimize use of POCT results (implemented communication center between admit and procedure rooms); decreased wait times 63 mins for coag (N=9,  $p = 0.014$ ) and 47 mins for renal (N=18,  $p = 0.02$ )
- Hospital chose not to implement POCT once patient workflow was streamlined for efficiency

# POCT Improves Patient Outcome

- Oncology Center – 2 blocks from hospital
- Patients need estimate of renal function before administration of chemotherapy
- Hematology laboratory onsite performs cell counts and simple chemistries (i-stat)
- Creatinine sent to core lab – periodic courier pickup (every 2 hours), means patients could wait up to 4 hours before testing completed
- Need faster turnaround time for results

Nichols JH, Bartholomew C, Bonzagi A, Garb JL, Jin L. Evaluation of the IRMA TRUpoint and i-STAT creatinine assays. *Clin Chem Acta* 2007;377;201-5.

# POCT Creatinine

- Evaluated POCT creatinine (i-Stat and IRMA)

MDRD 60 mL/min	IRMA vs Jaffe	i-Stat vs Jaffe
+ Predictive Value	100%	67%
Efficiency	94%	90%
	IRMA vs Enz	i-Stat vs Enz
+ Predictive Value	78%	60%
Efficiency	96%	88%

- POCT gave higher creatinine levels, called more patients abnormal.
- Physicians had to adjust their cutoff levels for management decisions to higher creatinine (lower GFR) when utilizing POCT compared to lab
- POCT led to faster results and moved patients through clinic, resulting in increased patient and physician satisfaction

# POCT Improves Patient Outcome

- POCT creatinine improved patient care in our Heme/Onc clinic.
- But, pharmacy and clinicians had to use different cutoffs and ranges for POCT results compared to lab creatinine
- Need for test, tied to technology, and management after test result (ie pharmacy utilized to estimate GFR and alter dose of medication)
- Test integrated into pathway of care
- Care is streamlined as testing can occur when needed and treatment can follow as soon as result is available

# POCT Information Management

- POCT is a different technology
- Results are not equivalent to other laboratory methods without considering unique performance characteristics
- Baystate electronic medical record overlays results of the same name, so physicians can trend tests over time.
- POCT results cannot be freely interchangeable with other methodologies and electronic reporting must keep results separate.
- We've developed POCT flowsheets to automate reporting of POCT results.
  - POCT results in nursing notes separate from lab reported results
  - POCT results require selection of site location – linked to licensure
  - Prevents intermixing of lab and POCT results, and misinterpretation





Chart Summary Ref. Text Facesheet

Orders Med Profile MAR Vital Signs I / O Patient Info Snapshot **Lab** Rad All Results Task List Documents Nsg/Anc Forms

Flowsheet: LABORATORY

Level: LABORATORY

☒ Table
 ☐ Group
 ☐ List

03 January 2007 8:15 - 13 January 2007 8:15 (Clinical Range)

## Navigator

- ☒ BLOOD GAS
- ☒ BLOOD COUNT\_DIFF
- ☒ COAG
- ☒ HEME OTHER
- ☒ BLOOD BANK
- ☒ CHEM GENERAL
- ☒ CARDIAC
- ☒ ENDOCRINE/TUMOR MAR
- ☒ TOXICOLOGY/TDM
- ☒ MISC. CHEMISTRY
- ☒ BACTERIOLOGY
- ☒ UA/URINALYSIS
- ☒ URINE OTHER

## LABORATORY

☐ Glucose Level

Glucose, Istat

☐ Glucose, POC☐ Beta Hydroxybutyrate☐ BUN☐ Creatinine-Blood☐ Estimated GFR, Non African American☐ Estimated GFR, African American☐ Calcium☐ Calcium, Ionized pH Corrected☐ Phosphorus☐ Magnesium☐ Alkaline Phosphatase☐ GGTP☐ Amylase1/10/2007  
8:401/10/2007  
6:521/10/2007  
6:441/10/2007  
5:151/10/2007  
5:10

172 H

199 H

143 H

184 H

207 H

15

15

1.5 H

1.4 H

41

45

50 \*

54 \*

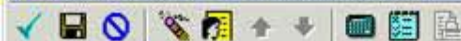
6.3 L

1.01 \*C

1.02 \*C

3.7

0.9 L



\*Performed on: 06/20/2007 1645

By: Colburn, Caryn

X POC Urinalysis

## POC Urinalysis

### Color

- ☒ Colorless  
☐ Straw/Light yellow (Normal)  
☐ Yellow (Normal)  
☐ Amber/Dark yellow (Normal)  
☐ Green  
☐ Pink  
☐ Red  
☐ Brown  
☐ Orange

### Appearance

- ☐ Clear (Normal)  
☐ Hazy (Normal)  
☐ Cloudy (Normal)

### Glucose

- ☐ Negative (Normal)  
☐ Trace (100 mg/dl)  
☐ 1+ (250 mg/dl)  
☐ 2+ (500 mg/dl)  
☐ 3+ (> or = 1000 mg/dl)

### Bilirubin

- ☐ Negative (Normal)  
☐ 1+ small  
☐ 2+ moderate  
☐ 3+ large

### Ketones

- ☐ Negative (Normal)  
☐ Trace (5 mg/dl)  
☐ 1+ (15 mg/dl)  
☐ 2+ (40mg/dl)  
☐ 3+ (80mg/dl)

### Specific Gravity

- ☐ < or = 1.005  
☐ 1.010  
☐ 1.015  
☐ 1.020  
☐ 1.025  
☐ > or = 1.030

### Blood

- ☐ Negative (Normal)  
☐ Trace  
☐ 1+ small  
☐ 2+ moderate  
☐ 3+ large

### pH

- ☐ 5.0  
☐ 5.5  
☐ 6.0  
☐ 6.5  
☐ 7.0  
☐ 7.5  
☐ 8.0  
☐ 8.5  
☐ > or = 9.0

### Protein

- ☐ Negative (Normal)  
☐ Trace  
☐ 1+ (30 mg/dl)  
☐ 2+ (100 mg/dl)  
☐ 3+ (300 mg/dl)

### Urobilinogen

- ☐ 0.2 mg/dl  
☐ 1 mg/dl  
☐ 2 mg/dl  
☐ 4 mg/dl  
☐ > or = 8.0

### Nitrite

- ☐ Negative (Normal)  
☐ Positive

### Leukocytes

- ☐ Negative (Normal)  
☐ Trace  
☐ 1+ small  
☐ 2+ moderate  
☐ 3+ large

\*Organization/CLIA #



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Listservs are free and easy. The best way to see if one is right for you is to give it a try by clicking on the links below. For questions about the listserv program, please contact the [Webmaster](#).

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- Listserv is free of charge
- Open to anyone (including non members)
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- Provides opportunity to connect with colleagues and discuss issues

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## Evidence Based Practice for POCT

### The National Academy of Clinical Biochemistry Laboratory Medicine Practice Guidelines

#### Draft Guidelines

#### Evidence Based Practice for POCT

This document is in final review and we are no longer accepting comments.

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# 2010 Teleconference SERIES

SEPTEMBER-DECEMBER



Programs are intended to help pathologists, managers, supervisors, and laboratory professionals.

## Deciding Factor: Selection Criteria for Point-of-Care Testing Devices (588-614-10)

**Speaker:** Marcia L. Zucker, PhD, Director, Clinical Support, Response Biomedical Corporation, Vancouver, BC, Canada

**Date/Time:** September 16 • 1:00–2:00 PM Eastern (US) Time

**Description:** There is an increasing trend in health care delivery toward decentralized, point-of-care testing (POCT) for a growing number of analytes. Implementation of POCT includes an evaluation of various POCT options, assessment of the potential costs and benefits of the POCT under consideration, and identification of any required process changes to ensure that maximum benefit to both providers and patients is realized.

This session will provide an overview on selection of POCT devices based on the patient care setting and clinical needs. This includes clinical and operational needs assessment, evaluation of candidate systems, and considerations involved in system implementation.

**Learning Level:** Intermediate

**Objectives:** At the conclusion of this program, the participant will be able to

- Identify resources for information on potential POCT systems.
- Evaluate clinical and operational requirements for POCT implementation.
- Identify the critical requirements for successful implementation of novel POCT.

**Related CLSI document:** Selection Criteria for Point-of-Care Testing Devices; Approved Guideline (POCT09-A)

## Ensuring That Hematology Analyzers Tell the Truth (588-615-10)

**Speaker:** Albert Rabinovitch, MD, PhD, NovoMetrics, Inc., Mountain View, CA, United States

**Date/Time:** September 23 • 1:00–2:00 PM Eastern (US) Time

**Description:** An automated hematology complete blood count (CBC) analyzer must provide physicians with reliable medical data for patient management. Truthful data depend on robust system design, which is initially validated by the manufacturer and then verified by the end-user laboratory. Because CBC analyses are performed on a heterogeneous suspension of blood cells, particular attention to various preexamination aspects is critical to success in generating accurate patient results. Although automated hematology analyzers share the same quality control (QC) principles as automated chemistry analyzers, they also have unique characteristics that require

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Kost, Gerald J.; Kost, Laurie E.; Suwanyangyuen, Audhaiwan; Cheema, Simrin K.; Curtis, Corbin; Sumner, Stephanie; Yu, Jimmy; Louie, Richard F. Point of Care: The Journal of Near-Patient Testing & Technology. 9(2):53-64, June 2010. doi: 10.1097/POC.0b013e3181d9d45c

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• Advantages and Disadvantages

• History

• Overview of Current and Projected Technology

• Pathologist Roles

• Pathologist as Laboratory Director

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• Pathologist's Regulatory Role in Addition to CLIA

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# CAP POCT Toolkit

- For laboratory directors of POCT
- A resource for any pathologist wanting to learn about POCT or who has responsibility to guide or direct POCT
- Useful for residents or those recently assigned to POCT
- Living document, built on content by submission of cases, etc (like Wikipedia, only peer reviewed)
- Organized into overview and then follows US CLIA regulations for rules and responsibilities of lab director with in depth discussion on specific roles and functions of the lab director. (like test selection, validation, etc)

# Summary

- POCT is an increasingly popular means of delivering laboratory testing closer to the site of patient care.
- A faster result isn't necessarily a better result
- Quality concerns require laboratory involvement and supervision of testing process
- Integration of POCT into patient care pathways ensures a link of test to patient outcome.
- Continued role of POCT program as a resource to clinical staff for policy, practice, education, troubleshooting and application of POCT results