

Point-of-Care Testing: Is Faster Really Better?

James H. Nichols, PhD, DABCC, FACB

Professor of Pathology, Microbiology, and Immunology

Medical Director, Clinical Chemistry

Associate Medical Director of Clinical Operations

Vanderbilt University School of Medicine

Nashville, TN 37232-5310

james.h.nichols@vanderbilt.edu

Overview

- Define POCT
- Discuss quality concerns with POCT
- Identify evidence-based methods for optimizing quality of POCT

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.

POCT Potential

- Immediate results - no lab transportation
- Portable devices
- Small blood volume
- Wide menu of tests available
- Whole blood and other samples available
- Works within clinical patient flow while patient is still being examined by physician
- Improved patient outcome when POCT linked to treatment, moves patient through system faster, more cost effective despite POCT reagents costing more than core lab on a per test basis

The POCT Market

1998

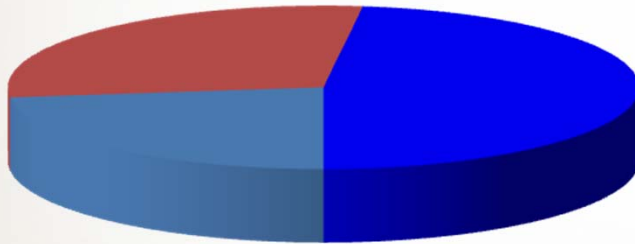
US\$ 4.9 Billion world-wide

25% of IVD testing market

Projected annual growth of 12%

Hospital POCT

POL



Blood Glucose

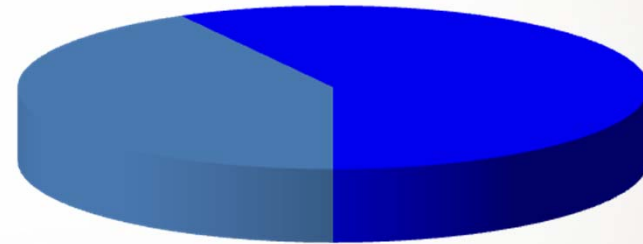
Stephans EJ. Developing Open Standards for Connectivity IVD Technology 1999;5:22,25

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

2015

US\$ 13.1 Billion world-wide

US\$ 20.2 Billion world-wide

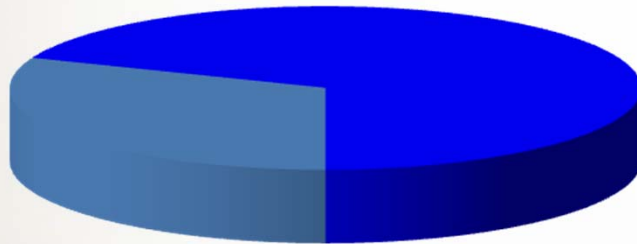
Decreased glucose growth
(managed care, price discounts)

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

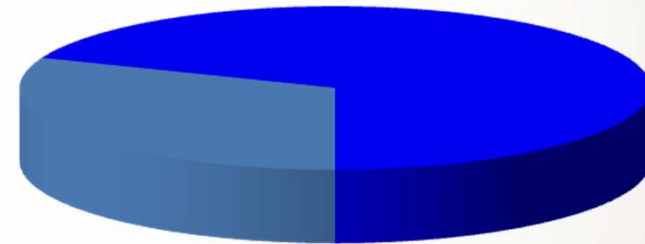
Increase IA and molecular POC
6% annual growth, glucose <5%

Central Lab (69%)

Central Lab (69%)



POCT (31%)



POCT (31%)

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

CLIA Laboratory Certificates June 2010 (212,534 Labs)

Compliance (International)	19,296 (9.1%) 23 (0.01%)
Waiver	139,078 (65.4%)
PPMP	38,216 (18.0%)
Accreditation (International)	15,944 (7.5%) 26 (0.01%)

Audience Poll

- Staff in a hematology/oncology clinic have stool guaiac cards for occult blood testing. Staff have been waiting some time for cytology results of blood in nipple discharge to triage and predict risk of breast cancer. Since occult blood cards are already available at the clinic, staff begin to use the cards to test nipple discharge. What are your thoughts on this application?
 - A. Why not? the cards are available and result turnaround time would be faster.
 - B. The test can be used, but would be an off-label, LDT.
 - C. The clinician should follow-up positive guaiac with cytology
 - D. The test should not be used, cytology is better.

POCT Issues

- Test “creep” is a real concern with POCT, when POCT intended for one application expands to other patients and clinical uses on the floor without validation
- Physician’s consider a test is a test. If stool guaiac can test occult blood in stool, it must work on other sample types.
- Not true, stool guaiac cards specifically designed and validated only for stool. Gastric guaiac tests have separate developer pH optimized for use with gastric samples!
- Off-label use would require lab validation as an LDT and high-complexity CLIA license

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.

Audience Poll

- Pregnancy and urine dipstick testing are occurring in a shared space used by two clinical teams (pre-op and cardiac cath). Due to high staff turn-over, QC is missed about 1-2x/week, but patient testing occurs anyways. Staff who do perform QC, also fail to recognize unsuccessful results, but go on and test patients. What is the optimal solution?
 - A. Allow the practice to continue as some QC is better than no QC
 - B. Remove testing from the site altogether
 - C. Retrain all of the staff on importance of QC
 - D. Reassign QC to one team, with frequent follow-up

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 , don't understand quality control
 - Staff do not have laboratory training background
 - Testing delegated to lower level staff (TAs, MAs)

POCT Standardization

- POCT has thousands of staff, must perform same technique, repeatedly without deviation
- Standardize equipment, procedure, process
 - One manufacturer, one policy
 - Assists float staff, consider infrequent operators
 - Standardized training to common checklist
- Shortcuts may be taken without realizing consequences

Case Discussion

Falsely Decreased Glucose Results

- Complaint from an ICU of sporadic falsely decreased glucose results
- Immediate repeat test on same meter, gave significantly higher “clinically sensible” values
- Inspection of unit found nurses taking procedural shortcuts to save time
- Bottles of test strips dumped on counter in spare utility room
- Some strips not making it into trash, falling back on counter and being “REUSED”

POCT

- POCT misnomer:
 - Faster is Better!
- POCT has a number of considerations – reason considered less reliable than core lab tests
 - Staff competency
 - Regulatory compliance
 - Method limitations
 - Result documentation and connectivity
- Also consider change in metabolites from delays in transport to core lab – glucose, pO₂

Integrating POCT

- When should POCT be considered?
- How to implement?
- Many hospitals have core laboratory model with centralized testing
- Management of acute patients requires more rapid diagnostics – ED, OR, ICU
- Delays in transportation or processing drive need for POCT
- Health systems with outpatient clinics have more complex TAT issues that may drive POCT and menus different from inpatient care.

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.
- 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

Lab vs POCT Dilemma

- POCT is a different technology than core laboratory testing
- Clinical criteria may need to be adjusted based on the technical performance of the method
- Clinicians should integrate POCT into care pathways, how test result is going to be utilized in patient management.

Audience Poll

- EMRs overlay results of same name, so physicians can plot results over time. How should POCT results best be displayed in an EMR?
 - Combined in the same field (ie, all sodiums called sodium, no matter where performed).
 - Call each test method by different name (Blood gas glucose, glucose meter, core glucose, Dr. Smith's glucose)
 - Separate POC results away from lab by placing in the clinical notes section of record
 - Use different colors to display results of different methods (POC troponin blue, core lab troponin yellow)

0601491 Opened by Nichols Ph.D., James H.

Task Edit View Time Scale Options Help

As Of 8:22

Chart Summary Ref. Text Facesheet

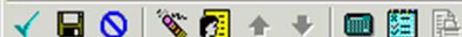
Orders Med Profile MAR Vital Signs I / O Patient Info Snapshot **Lab** Rad All Results Task List Documents Nsg/Anc Forms

Flowsheet: LABORATORY Level: LABORATORY Table Group List

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

LABORATORY		1/10/2007 8:40	1/10/2007 6:52	1/10/2007 6:44	1/10/2007 5:15	1/10/2007 5:10
<input type="checkbox"/>	Glucose Level		172 H		199 H	
<input type="checkbox"/>	Glucose, Istat					
<input type="checkbox"/>	Glucose, POC	143 H		184 H		207 H
<input type="checkbox"/>	Beta Hydroxybutyrate					
<input type="checkbox"/>	BUN		15		15	
<input type="checkbox"/>	Creatinine-Blood		1.5 H		1.4 H	
<input type="checkbox"/>	Estimated GFR, Non African American		41		45	
<input type="checkbox"/>	Estimated GFR, African American		50 *		54 *	
<input type="checkbox"/>	Calcium		6.3 L			
<input type="checkbox"/>	Calcium, Ionized pH Corrected		1.01 *C		1.02 *C	
<input type="checkbox"/>	Phosphorus		3.7			
<input type="checkbox"/>	Magnesium		0.9 L			
<input type="checkbox"/>	Alkaline Phosphatase					
<input type="checkbox"/>	GGTP					
<input type="checkbox"/>	Amylase					

PROD EN43202 12 January 2007 8:24



*Performed on: 06/20/2007 1645

By: Colburn, Caryn

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 #

Audience Poll

- How do physician's know which test to order, POC versus central lab?
 - A. Physicians should order whichever test is fastest
 - B. Physicians should order one test, nursing will decide if more convenient to perform POCT or draw a sample for core lab.
 - C. Labs should provide formal educational materials for physician ordering, like a pamphlet
 - D. Physician order entry should utilize pop-up screens to guide physician ordering

Integrating POCT with Order Entry

- How do physicians know which test to order? POCT versus central lab?
- Educational pamphlet minimally effective
- More than a 10 fold difference in cost between a glucose by central lab, glucose meter, or BG POC
- Economic downturn forced us to reexamine clinical need for stat testing given cost differences
- Two initiatives to decrease inappropriate utilization
 - Change the name to POC cartridge
 - Prevent routine ordering of test
 - Pop-up window reminder
- Initiatives reduced POC cartridge usage by 50 - 60%



Folder:

Search within: All



At location: BMC

- ABG POC Cartridge
- ABG w/Lactate POC Cartridge
- BUN POC Cartridge
- Calcium Ionized POC Cartridge
- Chloride POC Cartridge
- CO2 Est Arterial POC Cartridge
- CO2 Est Venous POC Cartridge
- Creatinine POC Cartridge
- Glucose POC Cartridge
- Hematocrit POC Cartridge
- Hemoglobin POC Cartridge
- Lytes (Na+K) POC Cartridge
- O2 Sat Arterial POC Cartridge
- O2 Sat Venous POC Cartridge
- Panel POC Cartridge
- pCO2 Arterial POC Cartridge
- pCO2 Venous POC Cartridge
- pH Arterial POC Cartridge
- pH Venous POC Cartridge
- pO2 Arterial POC Cartridge

- pO2 Venous POC Cartridge
- Potassium POC Cartridge
- Sodium POC Cartridge
- VBG POC Cartridge
- VBG w/Lactate POC Cartridge

Orders

Print 1 minutes ago

+ Add Document Medication by Hx Reconciliation

Orders Medication List

Orders for Signature

Order Name	Status	Start	Details
S30NC1; S3505; A Acct #:489275751 Admit: 11/13/2008 8:49			
Laboratory			
Potassium POC Cartridge	Order	6/9/2009 14:41	Stat, 6/9/2009 14:41

Details for Potassium POC Cartridge

Details Order Comments

Order details

Priority [Stat]
Start Date and Time [6/9/2009 14:41]
Active Encounter Order [Yes]

Detail values

06/09/2009 1441

For all POC Cartridge Orders
Priority is defaulted to Stat – can not be changed
No free text fields and can not type into Order Comments field

0 Missing Required Details

Sign

IDENTIFIED ORDER:
Potassium POC Cartridge

Reference

Potassium POC Cartridge

Search

CarePlan information

Chart guide

Nurse preparation

Patient education

Policy and procedures

Scheduling information

POC Cartridge Lab Testing

Changes

POC Cartridge testing is **10** times as expensive as routine and stat laboratory testing and **5** times as expensive as POC testing for glucose tests. BMC is the largest user of POC cartridges on the East Coast, adding significantly to our cost of care.

Please consider ordering a POC cartridge test only when there is an urgent need and *avoid its use for routine and scheduled lab tests.*

The indications for a POC Cartridge Test are:

- Emergent care of critically ill patient
- Severely anemic patients whom the Hgb is < 8 g/dl
- Patient with excessive blood draws (> 10 tubes drawn in last 24 hours)

'Pop-Up' text that appears automatically upon selecting a POC Cartridge order

OK

Audience Poll

- The laboratory has been experiencing staffing problems in accessioning leading to TAT delay in results of coagulation testing for stroke patients in the ED. Stroke accreditation requires a 45 min TAT from order to result. POC PT/INR is offered to the ED as an option to meet requirements for stroke patients .
 - A. POCT PT/INR should be used on all stroke patients.
 - B. POCT PT/INR should be limited to stroke patients on coumadin
 - C. POCT PT/INR offers the ED ability to establish bleeding risk in all patients coming to ED.
 - D. POCT PT/INR should continue to go to the core lab and lab administration should work on filling staffing needs.

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

JAMES H. NICHOLS,^{1*} THOMAS S. KICKLER,¹ KAREN L. DYER,¹ SANDRA K. HUMBERTSON,¹
PEG C. COOPER,² WILLIAM L. MAUGHAN,³ and DENISE G. OECHSLE²

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 ± 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.

© 2000 American Association for Clinical Chemistry

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

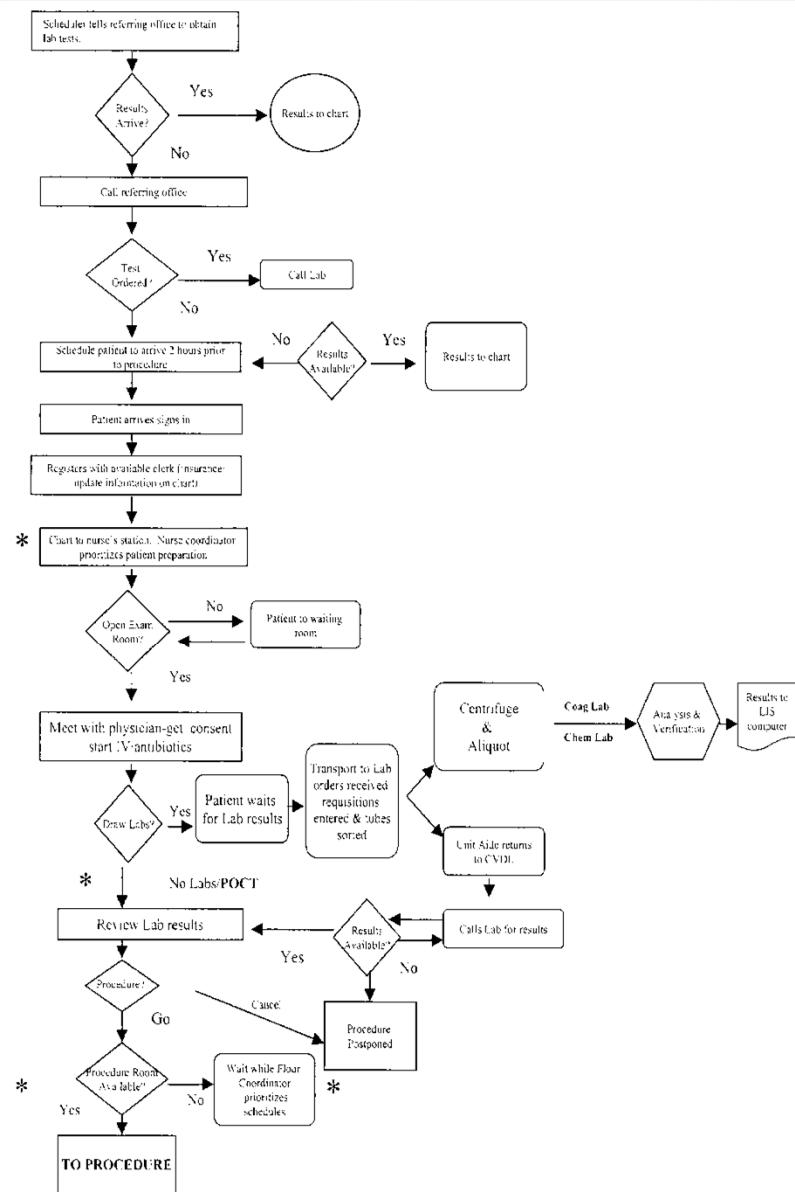


Fig. 2. CVDL patient workflow.

*: 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, $p = 0.02$)
- Take home point, the method should match the clinical need and workflow!

Audience Poll

- POC data management provides operator and QC lock-out features that ensure only trained operators perform testing and QC is analyzed and successful at defined time intervals. Data management also ties test results directly to the patient ID, however incorrect patient identification can send results to the wrong patient ID. Barcoding scanning of patient wristbands reduces the chance of manual patient ID errors, but doesn't entirely eliminate ID errors – Why?
 - A. Staff remove barcoded wristbands in the OR
 - B. Staff fail to check wristband identifiers periodically
 - C. Patients may be admitted with wristbands from previous admission or other hospitals/nursing homes
 - D. Patients may be barcoded with another patient's information

Falsey Increased Hgb Results

- Spurious increased Hgb results 18 – 23 g/dL (55 – 70% Hct) on ICU patients
- Meter, QC and reagents examined and fine, no single operator tied to trend
- Continue to experience spuriously high results, trend went on for several weeks
- One day, POC coordinator watching operator perform Hgb test in spare utility room. Operator took shortcut (procedure is to load cuvette from fresh drop of well mixed sample)
- Instead, operator was filling cuvette from drop of blood remaining from glucose test. Test strip was absorbing plasma portion of sample and artificially increasing Hgb/Hct in remaining drop!
- Remedial action to retrain entire unit staff!

Summary

- POCT is a rapidly evolving field due to escalating demands on health care for faster test results
- Faster is NOT always better!
- Many considerations in delivery of quality POCT. Need to link delivery of test to pathways of care to meet medical need.
- Don't be shy to get involved. POCT is opportunity for the lab to work more closely with healthcare team (preanalytic, analytic and postanalytic efficiency).

Self-Assessment Questions

- What is an advantage of POCT?
 1. Expense
 2. Speed
 3. Lack of limitations
 4. Ease of training
- How do we integrate tests into patient care?
 1. Demand staff document results
 2. Purchase POCT equipment
 3. Recommend tests be performed in a core lab
 4. Match test method to clinical need
- What is a limitation of POCT?
 1. Small number of staff involved
 2. Multiple tests available
 3. Variety of locations where testing is performed
 4. Speed of testing