

# Point of Care Testing: Clinical Applications, and the Use of Guidelines

Barbara M. Goldsmith, Ph.D., FACB

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# Point-of-Care Testing (POCT): Definition

*“Laboratory testing performed  
outside of the clinical  
laboratory”*

“It is not the strongest of the species that survives, nor the most intelligent, but the one most responsive to change”

Charles Darwin

# Why is POC Important?

- POC includes patient self testing (PST), physician office lab (POL), and hospital based
- Estimated revenues approximately \$3B (US\$), excluding non-IVD applications and whole blood glucose testing
- Overall IVD market growth is 6-7%/year
- POC market growth 10-12%/year
- Numerous new technologies and applications entering POC (e.g. molecular, MRSA)



# Laboratory Testing-Where is it Performed Now?

## ■ Centralized

- Hospital laboratory, commercial laboratory (national, regional, independent), “core” laboratory within healthcare system, POL for group of physicians, referral labs for esoteric tests

## ■ Decentralized

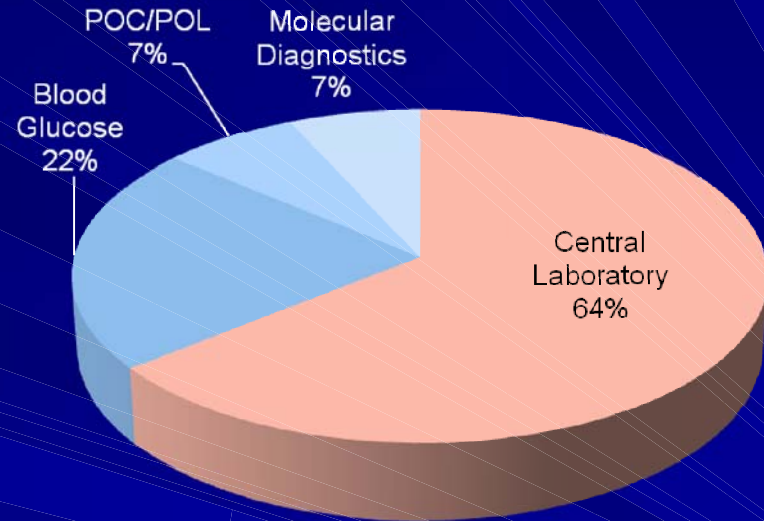
- Point-of-Care testing (POCT), physician’s office, patient (self-testing)

# Laboratory Testing – Where Will it be Performed – Future?

- Emphasis on POC?
- High volume, “non-POCT” only to central lab?
- Self-testing (patient-performed)?
- Emphasis on Physician’s office testing?
- Pharmacy (incl. pharmacies in grocery stores)?
- Other sites?

# 2007 IVD Market, by Segment

Segment	Market Size (\$ million)
Central Laboratory	24,188
Blood Glucose	8,274
POC/POL	2,648
Molecular Diagnostics	2,559
Total	37,669



# Growth in POCT

- The 2002 **World POC** testing market generated revenues worth \$3.3 billion and is expected to reach \$5.5 billion in 2009, with a compound annual growth rate of nearly 8%.
- Growth of the POC market is slightly better than the total IVD market's estimated 5-6% growth rate, and is approximately 15% of total market revenues.

# U.S. POCT Sales

- Revenues of \$1.3B in 2005
- Estimated to reach \$2.4B by 2012

Frost & Sullivan (website), January 11, 2007



# Advantages of POCT

- Faster TAT
- Small sample size
- Reduced preanalytic errors
- Eliminate or minimize preparation steps
- Improved patient satisfaction
- Faster decision making and follow-up with patient
- Better management of therapy
- Convenience

# Disadvantages of POCT

- Cost
- Training/Competency
- Concerns about inaccuracy, imprecision, performance
- Lack of connectivity
- Education/Experience level of testing personnel
- Competing priorities of testing personnel
- Maintaining quality
- Compliance requirements
- Documentation requirements
- QA more challenging

# Considerations for Implementing/Sustaining POCT

- Expectations of the program
- Clinical justification
- Organizational structure
- Who has oversight
- Who will perform the testing
- Review of Quality control/Quality assurance
- Training and competency evaluation
- Proficiency testing
- IT infrastructure/connectivity
- Billing
- Result reporting

# Training

- Testing often performed by non-laboratory personnel
- Quality of results tied to ability to perform test correctly
- POC results used to make rapid decisions for treatment; training more critical
- Well designed program can improve POCT performance
- Provide sufficient information to testing personnel
- Understand limitations of result
- Know when to request assistance

# Regulatory Oversight

- CLIA primary regulatory program governing US lab testing since 1992
- CLIA based on test complexity (waived, moderate, provider performed microscopy, high)
- CLIA administered by CMS (primary oversight) in cooperation with CDC and FDA
- Challenges to current regulatory framework include rapid technological advances, demographic shifts, lower tolerance for error, higher expectations for personal data security



# Waived Tests

“....so simple and accurate that erroneous results are negligible”

# Waived Testing

- Personnel must have specific training and orientation to perform the test
- Must follow the manufacturer's instructions when performing the test

# Regulatory Oversight

- Growth in no. of waived tests from 9 in 1993 to >1,600 test systems and 76 analytes in 2007
- CMS and CLSI developing QC procedures for specific testing technologies and environments (e.g. POCT)
- CMS has conducted studies to evaluate testing in waived- and small labs

# CMS Certificate of Waiver Surveys 2002-2004

Quality Deficiencies	No. of sites	% of sites
Following Manufacturer's Instructions		
The site did not:		
Have current manufacturer's instructions	485	12
Routinely check new product insert for changes	701	21
Based on manufacturer's instructions, the site did not:		
Perform quality control testing	866	21
Report test results with terminology or units in pkg insert	744	18
Adhere to proper expiration dates	267	6
Documentation, the site did not:		
Document name, lot no, expiration date for all tests done	1,493	45
Maintain quality control log	1,151	35
Maintain log of tests performed	1,318	31

CMS, examples of data noted above

# Certificate of Waiver Findings

## Summary:

Issues stemmed from lack of appropriate education in the use of these tests



# Applications of POCT

- Emergency diagnosis
- Treatment/monitoring
- Doctors' office testing (POL)
- Self or home testing

# Clinical Examples

- PE/DVT - d-dimer
- Trauma – hgb
- Differential Dx vaginal bldg – hCG, hgb
- DKA – glucose, pH, potassium
- Acute renal failure – BUN, creat
- AMI vs CHD – troponin, BNP