

Point-of-Care Testing: Guidelines and Challenges

Robert L. Sautter, PhD, HCLD (ABB), Edward H. Lipford, MD

Laboratory diagnostics play an important role in managing patients. With the pressures to reduce hospital length of stay and with newer therapy options, the laboratory has been asked to decrease the turnaround time from sample to result. Therefore, point-of-care testing (POCT), testing near the patient or bedside, was developed to generate quicker results. The goal of POCT is to provide the clinician with rapid results, which can improve patient outcomes and quickly supply therapeutic interventions as compared to those results obtained from the core laboratory.¹ Laboratory point-of-care testing is not new; however, it experienced a veritable explosion in manufacturing, clinical oversight, and regulations following the “waived provision” of the Clinical Laboratory Improvement Amendments (CLIA) of 1988.^{1,2,3} The number of laboratories holding a Certificate of Waiver increased from 67 294 in 1993 to 105 138 in 2004.³

In addition, the number of Medicare Part B waived tests performed increased from 14 million to over 23 million between the years 2000 and 2004.³ (See Table 1.) Inherent with POCT growth come challenges in performing high quality accurate testing. Decreasing laboratory errors and improving patient safety must also be considered as POCT increases.

The Centers for Medicare and Medicaid Services (CMS) regulates laboratory testing on humans through CLIA to ensure quality testing. CLIA classifies tests as “waived complexity,”

“moderate complexity,”^a and “high complexity” based upon criteria developed by the federal Department of Health and Human Services. Waived complexity tests are simple laboratory examinations that are approved for home use and which employ methodologies that are simple and accurate. They render the likelihood of erroneous results negligible or pose no risk of harm to the patient if the test is performed incorrectly. Quality standards for moderately and highly complex tests are designated for proficiency testing, patient test management, quality control, personnel qualifications, quality assurance, and quality control.² The more complex the test, the more stringent the testing requirements. A complete listing of the tests by classification can be found on the website of the Center for Devices and Radiological Health of the US Food and Drug Administration.⁴

“When considering that millions of laboratory tests are performed at the point-of-care each year, it is imperative that we, as health care providers, do everything we can to dispense quality laboratory care for all patients.”

a An additional subcategory classification under moderate complexity is “provider-performed microscopy.” It was developed as a special consideration to allow laboratories that are otherwise classified as “waived” to perform moderately complex tests utilizing microscopic analysis.²

Robert L. Sautter, PhD, HCLD (ABB), is director of microbiology and point-of-care with Carolinas Laboratory Network at Carolinas Healthcare System and a member of Carolinas Pathology Group, PA. He can be reached at Robert.Sautter@carolinashealthcare.org or PO Box 34455, Charlotte, NC 28234-4455.

Edward H. Lipford, MD, is medical director of Carolinas Laboratory Network at Carolinas Healthcare System and a member of Carolinas Pathology Group, PA.

Table 1.
Increases in Waived Analytes and Test Systems, Certificate of Waiver Laboratories, and Medicare Part B Reimbursed Waived Testing, 1993–2004

Waived testing measurement parameter	1993	1998	2000	2003	2004
No. of analytes for which waived test systems are available	9	40	53	74	76
No. of waived test systems*	203	608	832	1495	1638
No. of laboratories with a Certificate of Waiver	67 294	78 825	85 944	102 123	105 138
Percentage of laboratories with a Certificate of Waiver†	44%	50%	52%	57%	58%
No. of Medicare Part B reimbursed waived tests	§	§	14 663 751	20 781 297	23 041 693
Percentage of Medicare Part B reimbursed laboratory testing that is waived	§	§	6.5%	7.8%	8.1%
Medicare Part B payment amount for waived tests	§	§	\$69,765,453	\$112,247,706	\$128,169,398

* Numbers reflect multiple names under which individual tests are marketed and might include waived tests no longer sold.

† Does not include Clinical Laboratory Improvement Amendments (CLIA) exempt laboratories in New York and Washington

§ Not available

Source: Centers for Disease Control and Prevention. Good laboratory practices for waived testing sites, survey findings from testing sites holding a certificate of waiver under the clinical laboratory improvement amendments of 1988 and recommendations for promoting quality testing. Recommendations and reports. *MMWR*. 2005;54(RR-13):1-23.

Several regulatory bodies are primarily involved in inspections for the POCT laboratory. Point-of-care testing occurs on floors of hospitals, nursing homes, clinics, physician offices, radiology suites, and any other location where testing is classified as a regulated laboratory test. Laboratories may apply for a Certificate of Waiver, Certificate of Compliance, or a Certificate of Accreditation.^{b,3} Those that are accredited are usually accredited by private peer organizations such as the College of American Pathologists (CAP) and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). These two organizations have been inspecting hospital laboratories inside health systems for quite some time. Recently, both the CAP and JCAHO have been granted “deemed status” to inspect laboratories for CMS.⁵ Laboratories are inspected in regard to directorship, quality assurance, quality control, testing personnel (training and competency), reporting, and verification of testing procedures. Accredited laboratories are inspected on a two-year cycle. All inspections are now performed on an unannounced basis. However, those laboratories that obtained a certificate of compliance or certificate of waiver have not been inspected on a regular basis in the past due to a lack of resources available to inspect the thousands of laboratories doing this testing.

Two state pilot inspection programs of physician office laboratories (POL) with certificates of waiver showed that a significant number of laboratories had serious deficiencies with

regard to their compliance with regulations.³ Testing without employee training, failure to document procedures, or failure to follow manufacturer’s packaged instructions were among the most concerning deficiencies identified. Subsequent inspections of more than 1000 laboratories confirmed these problems nationwide. CMS plans to inspect only 2% of the waived laboratories yearly. Inspection results in several states have shown improvement; however, without oversight overall improvement may be difficult to achieve. The executive summary of the waived laboratory project from CMS included this review of compliance with manufacturer’s instructions for performance of tests:

Expanded pilot studies by the Centers for Medicare and Medicaid Services (CMS), formerly the Health Care Financing Administration (HCFA), of laboratories issued a certificate of waiver (COW) and provider performed microscopy procedures (PPMP) laboratories demonstrate that 50% of laboratories performing waived tests do not follow the manufacturer’s instructions or do not have manufacturer’s instructions. The only CLIA requirement for COW laboratories is to follow the manufacturer’s test instructions. These findings mirror those of previous pilots conducted by Colorado, Ohio, New York and most recently, the Office of the Inspector General (OIG). If these percentages are nationally representative, as many as 60,000 laboratories may not be following manufacturer’s instructions and may be performing tests incorrectly to potentially harm patients.⁶

b A Certificate of Waiver is issued to a laboratory that only performs waived tests. A Certificate of Compliance is issued to a laboratory following inspection by the state department of health that determines the laboratory is compliant with CLIA requirements. A Certificate of Accreditation is issued to a laboratory based on accreditation.

Tests designed to be performed in the point-of-care setting are manufactured to be relatively fast and easy to operate. The results should be made available while the patient is present or so that the provider can respond to him during the visit. Many point-of-care tests offer these advantages and ideally result in better outcomes for the patient.⁷ Pressures to see more patients in the office or to free space in an emergency department have stimulated a real need for faster results. However, faster is not always better if the result's timeliness has little or no impact on the outcome of care.⁸ Unfortunately, there are few studies available showing that patient outcomes improve with tests performed at point-of-care location over those performed in the clinical laboratory. Therefore, more research is needed in this area.⁷

When considering that millions of laboratory tests are performed at the point of care each year, it is imperative that we, as health care providers, do everything we can to dispense quality laboratory care for all patients. Some problems in achieving this goal include the lack of adequate accessibility of laboratory data by those in charge of oversight, poor training and low competency of testing personnel, and lack of evidence-based studies linked to patient outcomes.

Evidence-based guidelines for point-of-care testing have been developed by the National Academy of Clinical Biochemistry (NACB) in cooperation with the College of American Pathologists and the American Society for Microbiology.⁸ The guidelines cover subjects in POCT ranging from management to technical areas such as critical care, coagulation, cardiac markers for diagnosing acute coronary syndromes, infectious diseases, and renal function tests.⁹ The monograph answers critical clinical and managerial questions using literature searches and grading outcome-generated studies into various categories of recommendations based upon the available literature. A key component in performing POCT at any site is managing the program. The monograph divides the management of POCT into quality control, technical oversight, data management, training and education of operators, and continuous quality improvement with quality indicators.¹⁰

Multidisciplinary approaches to POCT are necessary to implement a successful program.¹⁰ Administration can supply the appropriate resources to achieve this goal along with technical expertise from physicians, nursing, and the laboratory. Each health care professional must realize his/her responsibility to achieve this goal. Decisions made by the group need to be based upon factual data or observations. These data must include a balance between sensitivity, specificity, positive and negative predictive values of the tests evaluated, and the clinical need for the results. Cost for disseminating the results is also an important consideration.

Handling laboratory data electronically clearly offers an advantage over manual systems in tracking quality care issues, following patient test results, and assuring compliance with regulations.^{10,11} Remote monitoring allows technically skilled individuals to monitor performance and evaluate problems with instrumentation and suggest corrective action. A universal

connectivity information system is imperative to be able to manage the many manufacturer options in POCT. Until recently, manufacturers were reluctant to connect test systems from companies not in business relationships with each other. There are now systems that allow such a connectivity to be instituted for a fee.^{10,11,12} The performance of quality assurance and quality control is an expensive and time-consuming portion of laboratory medicine. In order to improve the quality of POCT, the NACB recommends developing a formal process of risk management and reducing medical errors by using an interdisciplinary committee to manage POCT, instituting POCT training programs, implementing data management systems, and instituting continuous quality improvement with quality indicators.⁹

It has been shown that 25% to 40% of laboratory tests are unnecessary.¹³ Furthermore, there is potential for over utilization of point-of-care testing and the potential to do harm with results.^{9,13} This makes it extremely important to make sure that all laboratory testing is warranted and that the results affect the outcome of patient management. In the critical care arena, few well-controlled outcome studies have been performed to show the benefit for POCT.¹⁴ One positive study in sepsis patients demonstrated a decrease in mortality from 47% to 31% when early directed therapy to point-of-care arterial blood gases (including direct response to pH, oxygen saturation, and lactate) was instituted rapidly. Therefore, the Laboratory Medicine Practice Guidelines (LMPG) state there is fair evidence that arterial blood gases in the point of care should be performed for intensive care unit patients.¹⁴ The evidence for other POCT is absent or less convincing.

For example, the detection of *Trichomonas vaginalis* in the physician office laboratory is usually made by performing microscopic examination of a wet preparation (WP). Unfortunately, the sensitivity of this testing is between 49% and 89%.¹⁵ Although the use of POCT is recommended by the LMPG, outcomes based upon a wet mount for *T. vaginalis* do not link this agent with premature rupture of membranes.¹⁵ The lack of sensitivity of WP necessitates a need for more sensitive tests. When tests with increased sensitivity are used in the point-of-care or core laboratory, *T. vaginalis* may in fact be associated with premature rupture of membranes.¹⁵

Point-of-care testing has the ability to improve outcomes and result in decreased mortality when performed correctly and following laboratory guidelines.^{1,14} Using good laboratory practices, POCT will be beneficial at any patient site.³ Some example benefits of POCT include faster decision making for cardiac patients, quicker optimization of treatment for anticoagulation, and increased patient satisfaction. Point-of-care testing will only increase in numbers and diversity of methods in coming years. The advent of complete electronic medical records including home health testing with regional databases will undoubtedly make more data available to the clinician. **NCMJ**

REFERENCES

- 1 Price CP. Regular review: Point of care testing. *BMJ*. 2001;322:1285-1288.
- 2 Centers for Medicare & Medicaid Services, US Department of Health and Human Services. Title 42—Public Health, Chapter IV, Part 493—Laboratory Requirements, Subpart A—General Provisions. Available at: http://a257.g.akamaitech.net/7/257/2422/05dec20031700/edocket.access.gpo.gov/cfr_2003/octqtr/42cfr493.17.htm. Accessed March 16, 2007.
- 3 Centers for Disease Control and Prevention. Good laboratory practices for waived testing sites, survey findings from testing sites holding a certificate of waiver under the clinical laboratory improvement amendments of 1988 and recommendations for promoting quality testing. Recommendations and reports. *MMWR*. 2005;54(RR-13):1-23.
- 4 US Food and Drug Administration, Center for Devices and Radiological Health. Search CLIA Database. Available at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm>. Accessed March 16, 2007.
- 5 Centers for Medicare & Medicaid Services. Clinical Laboratory Improvement Amendment (CLIA). Accreditation Organizations/Exempt States. Available at: http://www.cms.hhs.gov/CLIA/13_Accreditation_Organizations_Exempt_States.asp#TopOfPage. Accessed March 16, 2007.
- 6 Centers for Medicare & Medicaid Services. Certificate of Waiver Laboratory Project. Available at: http://www.cms.hhs.gov/CLIA/08_Certificate_of_%20Waiver_Laboratory_Project.asp#TopOfPage. Accessed March 16, 2007.
- 7 Nichols JH, ed. NACB: Point of Care Testing. The National Academy of Clinical Biochemistry laboratory medicine practice guidelines: Evidence-based practice for point-of-care testing. American Association for Clinical Chemistry. Available at: <http://www.aacc.org/AACC/members/nacb/LMPG/OnlineGuide/PublishedGuidelines/poct/>. Accessed March 16, 2007.
- 8 Scott MG. Faster is better—it's rarely that simple. *Clin Chem*. 2000;46:441-442.
- 9 Nichols JH, Christenson RH, Clarke W, et al. Executive summary. The National Academy of Clinical Biochemistry Laboratory Medicine Practice Guideline: Evidence-based practice for point-of-care testing. *Clin Chim Acta*. 2007;379(1-2):14-28. Epub 2007 Jan 12.
- 10 Jacobs E, Goldsmith B, Larrison L, Richardson H, St. Louis P. Management. Chapter 1. In: Nichols JH, ed. *Evidence Based Practice for Point-of-Care Testing: A National Academy of Clinical Biochemistry Laboratory Medicine Practice Guideline*. Washington, DC: AACC Press; 2006:1-4.
- 11 Dyer K, Nichols JH, Taylor M, Miller R, Saltz J. Development of a universal connectivity and data management system. *Crit Care Nurs Q*. 2001;24:25-38.
- 12 Clinical and Laboratory Standards Institute. Point-of-care connectivity; Approved standard. Document POCT1-A2. Wayne, PA: CLSI; 2006:306.
- 13 Gopal Rao G, Crook M, Tillyer ML. Pathology tests: Is the time for demand management ripe at last? *J Clin Pathol*. 2003;56:243-248.
- 14 D'Orazio P, Fogh-Andersen N, Okorodudu A, Shipp G, Shirley T, Toffaletti J. Critical Care Chapter 5. In: Nichols JH, ed. *Evidence Based Practice for Point-of-Care Testing: A National Academy of Clinical Biochemistry Laboratory Medicine Practice Guideline*. Washington DC: AACC Press; 2006:30-43.
- 15 Campbell S, Campos J, Hall GS, et al. Infectious Disease. Chapter 8. In: Nichols JH, ed. *Evidence Based Practice for Point-of-Care Testing: A National Academy of Clinical Biochemistry Laboratory Medicine Practice Guideline*. Washington DC: AACC Press; 2006:76-87.