

Contents

Preface	xiii
Kent Lewandrowski	
Point-of-Care Testing: An Overview and a Look to the Future (Circa 2009, United States)	421
Kent Lewandrowski	
<p>Point-of-care testing is a rapidly growing area in laboratory medicine. Technologies related to point-of-care testing have unique analytical features and are used in a number of clinical applications. These attributes combined with complex regulatory requirements have made point-of-care testing a true specialty within pathology. Manufacturers continue to develop new point-of-care tests and have consolidated multiple assays to single small handheld or bench-top devices. Enterprise hospital-wide data management systems are available to facilitate improved regulatory compliance and transmit test results into the electronic medical record. Some studies have shown that point-of-care testing can improve clinical outcomes or increase the efficiency of hospital operations. In spite of these developments, many challenges remain. In some cases, the quality of point-of-care tests performed by nonlaboratory personnel does not match that of testing performed in the central laboratory. Data management connectivity remains a significant problem, especially for manually performed tests. Managing a point-of-care program to maintain regulatory compliance is also problematic. For these reasons, the future of point-of-care testing is not entirely clear. The most likely scenario will be a slow but progressive growth of point-of-care testing in the hospital, in the outpatient clinic, and in the home.</p>	
Management of a Point-of-Care Testing Program	433
Kim Gregory and Kent Lewandrowski	
<p>The approach to managing a point-of-care testing (POCT) program has evolved over recent years. Although many of the essential features of early POCT management programs remain intact, contemporary challenges including expansion of the test menu, changing regulatory requirements, and the development of more sophisticated data management connectivity require ongoing adaptation of POCT management programs. Despite improvements in test quality and regulatory compliance, significant challenges for the management of POCT will continue for the foreseeable future.</p>	
Point-of-Care Testing Informatics	449
Ji Yeon Kim and Kent Lewandrowski	
<p>Managing patient test data and documenting regulatory compliance for tests performed at the point of care have traditionally been significant problems. In many situations, manual record-keeping has proven entirely</p>	

inadequate for maintaining the integrity of the patient medical record or for providing an audit trail for quality assurance activities. Starting in the 1990s, a number of companies began to develop and market point-of-care data management systems. Over time, these data management systems have become increasingly sophisticated. It is now possible to interface multiple point-of-care devices from different manufacturers to a central data manager that is bidirectionally interfaced to the laboratory and hospital information systems. Despite these advances, many challenges remain. True real-time point-of-care “connectivity” across an entire institution has yet to be achieved, and there is still no satisfactory solution for manually performed visually read tests, some of which are commonly performed at the point of care. In the future, wireless point-of-care connectivity solutions hold great promise, but these technologies are yet to be fully developed.

Regulatory Compliance for Point-of-Care Testing: 2009 United States Perspective

463

Sharon S. Ehrmeyer and Ronald H. Laessig

All clinical laboratory testing in the United States is regulated by the Clinical Laboratory Improvement Amendments of 1988 (CLIA'88 or CLIA) and overseen by the Centers for Medicare and Medicaid Services. CLIA profoundly changed the prevailing United States regulatory philosophy by imposing uniform requirements for all clinical laboratory testing regardless of where tests are performed. In the hospital, regulatory compliance is usually ensured by regular inspections of the laboratory by either the Joint Commission or by the College of American Pathologists. These organizations may include requirements beyond the minimum standard mandated by CLIA. This article reviews the status of regulatory compliance of point-of-care testing from a perspective of the current regulations in effect in the United States in 2009.

Perspectives on Cost and Outcomes for Point-of-Care Testing

479

Elizabeth Lee-Lewandrowski and Kent Lewandrowski

Point-of-care testing (POCT) is usually more expensive on a unit-cost basis than testing performed in a central laboratory. It is difficult to manage POCT and to maintain regulatory compliance, especially in large institutions. However, some POCT technologies have improved patient outcomes (patient self-glucose monitoring in the home, tight glycemic control in intensive care settings) or hospital or emergency department operations (whole-blood cardiac-marker testing and D-dimer testing in emergency departments). In some cases, these outcomes result simply from making a new test available, rather than performing the test at the point of care. In most cases, the rapid turnaround time provided by POCT is the main factor that is ultimately responsible for the improvement in outcomes.

HIV Testing Near the Patient: Changing the Face of HIV Testing

491

Sheldon Campbell and Yuri Fedoriv

Virological, epidemiologic, and operational barriers have slowed the progress toward effective management and eradication of HIV infection,

despite significant advances in diagnosis since the early 1980s. Because early diagnosis profoundly affects the health care and survival of infected/high-risk individuals, and because the time required for conventional testing remains a barrier in many settings, rapid HIV testing has been developed for use both in the clinical laboratory and at the point of care. Recent studies have identified applications, advantages, and limitations of these assays, which may influence the development of new and more effective public health testing and screening protocols. In the United States, the Food and Drug Administration has approved the use of six rapid HIV tests. This review summarizes these modern rapid point-of-care HIV tests and their role in preventing the spread of HIV and in detecting, managing, and treating patients affected by the HIV pandemic.

Drug-of-Abuse Testing at the Point of Care

503

Stacy E.F. Melanson

Sensitive and specific assays are available to detect drugs of abuse at the point of care. This article describes the characteristics of point-of-care devices for drug-of-abuse testing with a focus on clinical utility and patient care. This article is not a comprehensive review of all available point-of-care devices. Instead, it discusses general principles of point-of-care testing for drugs of abuse.

Tight Glycemic Control and Point-of-Care Testing

511

David Alter and Greg Deines

Until recently, inpatient glycemic management focused solely on the diabetic patient with few reported studies that discussed hyperglycemic management of the nondiabetic patient. For the last 35 years, the prevailing notion was that hyperglycemia in the acutely ill nondiabetic inpatient was a consequence of illnesses as well as a marker of its severity. It was also thought to be an adaptive response to injury necessary for survival and not necessarily a prognostic indicator of morbidity or mortality. In this article, we discuss the current school of thought regarding prognostic implications of nondiabetic inpatient hyperglycemia, its management (tight glycemic control), and the relationship of point-of-care testing to tight glycemic control.

Fecal Occult Blood Testing

523

Kimberly W. Sanford and Richard A. McPherson

Colorectal cancer (CRC) is the third most common cancer in the United States. A reduction in cumulative mortality occurs when patients are routinely screened by fecal occult blood tests (FOBT) and early lesions are removed. These point-of-care tests detect minute amounts of blood released from precancerous and cancerous colon lesions. Positive test results should be followed up with complete diagnostic testing to treat precancerous lesions and diagnose patients at earlier stages of cancer, thereby increasing overall survival. More complex assays are designed

to detect genetic changes in cells released from malignant and even pre-malignant lesions. This article provides information on the screening and diagnostic tests available for CRC detection as well as the advantages and disadvantages of each.

Point-of-Care Testing in Coagulation

543

Elizabeth M. Van Cott

Point-of-care (POC) assays are available for a variety of coagulation tests. These assays are generally simple to perform and have a more rapid turnaround time than their central-laboratory counterparts. This article discusses the current status of coagulation POC methodologies, focusing on the potential clinical uses and the limitations of platelet function testing, prothrombin time/international normalized ratio, D-dimer, and activated clotting time (ACT). Additional studies are eagerly awaited regarding potential future uses of POC coagulation testing, including the role of platelet function testing and ACT heparin management systems.

Point-of-Care Testing and Molecular Diagnostics: Miniaturization Required

555

Frederick L. Kiechle and Carol A. Holland

Turnaround time for molecular diagnostic tests is critical in detecting infectious agents, in determining a patient's ability to metabolize a drug or drug class, and in detecting minimal residual disease. These applications would benefit from the development of a point-of-care device for nucleic acid extraction, amplification, and detection. The ideal device would have a low cost per test, use a disposable unit use device for all steps in the assay, be portable, and provide a result that requires no interpretation. The creation of such a device requires miniaturization of current technologies and the use of microfluidics, microarrays, and small-diameter capillary tubes to reduce reagent volumes and simplify heat conduction by convection during nucleic acid amplification. This ideal device may be available in 3 to 5 years and will revolutionize and expand the global availability of molecular diagnostic assays.

Point-of-Care Testing for Cardiac Markers in Acute Coronary Syndromes and Heart Failure

561

Kent Lewandrowski

Advances in technologies for immunoassay testing have enabled the development of 15-minute whole-blood assays for cardiac markers in the evaluation of patients with acute coronary syndromes (ACS) and congestive heart failure. In many cases, the analytical performance of these assays is equivalent to that of testing in the central laboratory. Rapid whole-blood point-of-care assays for troponin, creatine kinase isoenzyme CK-MB, myoglobin, and B-type natriuretic peptides have facilitated efforts to restructure conventional approaches to ACS and heart failure in the emergency room. Improvements in outcomes, including decreased

emergency room and hospital length-of-stay, decreased overall cost, and earlier discharge of low-risk patients, have been documented following implementation of these technologies.

Provider-performed Microscopy 573

Frederick L. Kiechle and Isabel Gauss

Point-of-care testing (POCT) is defined as analytic testing performed outside the central laboratory using a device or devices that can be easily transported to the vicinity of the patient. This article discusses rules and regulations concerning POCT, especially those covering provider-performed microscopy (PPM). Types of PPM are also covered, including the fern test, tests for the presence on fecal leukocytes and pinworms, and examinations of urine sediment and seminal fluid. The coordination of PPM within a hospital is also covered.

Point-of-Care Testing for Disasters: Needs Assessment, Strategic Planning, and Future Design 583

Gerald J. Kost, Kristin N. Hale, T. Keith Brock, Richard F. Louie, Nicole L. Gentile, Tyler K. Kitano, and Nam K. Tran

Objective evidence-based national surveys serve as a first step in identifying suitable point-of-care device designs, effective test clusters, and environmental operating conditions. Preliminary survey results show the need for point-of-care testing (POCT) devices using test clusters that specifically detect pathogens found in disaster scenarios. Hurricane Katrina, the tsunami in southeast Asia, and the current influenza pandemic (H1N1, “swine flu”) vividly illustrate lack of national and global preparedness. Gap analysis of current POCT devices versus survey results reveals how POCT needs can be fulfilled. Future thinking will help avoid the worst consequences of disasters on the horizon, such as extensively drug-resistant tuberculosis and pandemic influenzas. A global effort must be made to improve POC technologies to rapidly diagnose and treat patients to improve triaging, on-site decision making, and, ultimately, economic and medical outcomes.

Selected Topics in Point-of-care Testing: Whole Blood Creatinine, Influenza Testing, Fetal Fibronectin and Patient Self-testing in the Home 607

Kent Lewandrowski

This article reviews selected topics in point-of-care testing including: whole blood creatinine testing, influenza testing, fetal fibronectin, and patient self-testing. Each of these topics reflects an important new application of point-of-care testing and together they illustrate the many niche applications for these technologies.