



# Point of Care Testing

*Specialty Courses  
for Phlebotomists*



National Center for  
Competency Testing

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# Point of Care Testing Specialty Certificate Course for Phlebotomists

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NCCT is continually refining and creating professional development products for all certified allied health professionals. We are committed to your success. This mini course was designed to help healthcare professionals understand and provide superior service to children.

The course is divided into chapters. There is an open-book quiz at the end of every chapter to help you assess your understanding of that chapter's material. Upon completing all the chapters, you can access this mini course's final examination on-line at NCCT's website, [www.ncctinc.com](http://www.ncctinc.com). Proceed to the *Testing* section, and choose the *CE Test Login* option, and log in. Choose the *Pediatrics for Phlebotomists Final Exam*.

Seventy per cent or better is considered a passing grade for this course. Upon passing the course's final exam you will receive a Specialty Certificate and a sticker from NCCT signifying that you have successfully completed this course. This sticker should be placed in your NCCT *Professional Development Log Book*. You will also receive five clock hours of continuing education credit and the course title will be placed on your *NCCT Continuing Education Transcript*.

Acquiring new skills and pursuing additional knowledge in your career field has always been the hallmark of a true professional. Read, learn, and most importantly, enjoy your profession more. Your new knowledge will not only increase your competence and importance to your team, but will also increase your own self-assurance in your ability and work.

## **Learning Outcomes**

Upon completion of the Competence Certificate Course, the professional will be able to:

1. Define point of care testing
2. Differentiate point of care testing from waived testing
3. Compare and contrast point of care testing and waived testing
4. Outline pros and cons of point of care testing
5. List and describe examples of point of care testing methods
6. Describe and outline the use of point of care instruments for performing analyses
7. Discuss pre-analytical, analytical and post-analytical variables associated with point of care testing
8. Describe specimen collection for point of care testing
9. List and describe specimen collection problems and issues associated with point of care testing
10. Describe staff training and competency programs for point of care test systems
11. Discuss basic concepts of quality assurance and quality control
12. Discuss quality control plans for point of care test systems
13. Describe appropriate result recording for point of care testing.
14. List home test methods used by patients for self-monitoring
15. Discuss future trends in point of care and home testing methods

### ***Disclaimer***

The writers for NCCT Competence Certificate Courses attempt to provide factual information based on literature review and current professional practice. However, NCCT does not guarantee that the information contained in these educational courses is free from all errors and omissions.

## Chapter 1 Definition of Point of Care Testing

Since the inception of Clinical Laboratory Improvement Amendments of 1988 (CLIA '88), the development of methods and instruments to be used at the bedside or "point of care" has rapidly expanded. Federal regulations set forth under CLIA '88 and through subsequent mandates have paved the way for development of rapid, simple methods of laboratory testing. CLIA '88 established categories of testing as well as levels of quality control and standards of care associated with each category. As Medicare and Medicaid continue to publish guidelines and mandate patient billing regulations, the need for rapid analyses, diagnosis, treatment and discharge of patients has become a day-to-day challenge in health care.

In addition, federal regulations and mandates have created a major challenge requiring that health care providers and facilities "do more with less." This challenge has created an environment where the primary care provider must accept the following challenges:

- Spend less time with each patient
- Examine and treat more patients in an established time frame
- Make accurate, rapid diagnoses
- Provide patient treatment more quickly
- Admit fewer patients to inpatient facilities
- Discharge inpatients after shorter hospital stays
- Manage more patients as outpatients

The development of more point of care testing (POCT) is assisting the health care community in meeting these challenges. The institution of POCT has become not only a challenge, but also a stumbling block for laboratories, emergency departments, intensive care units and hospital administrations. As the demand for POCT is increasing, the need to oversee and administer testing within the confines of inpatient facilities, emergency departments and outpatient environments has become blatantly apparent. There has been a paradigm shift in the manner in which both the hospital and the laboratory conduct business. Laboratory personnel are individuals who prefer a controlled work environment. A possible conflict of interest has developed as the laboratory has gradually released control of the POCT performed in remote locations. Conversely, the laboratory MAY BE held accountable for the remote testing outcomes.

The POCT staff is often comprised of non-laboratorians. This presents additional challenges for the laboratory staff since POCT quality control may remain under the ever-broadening umbrella of the laboratory. Remote locations for POCT, has resulted in the development of point of care (POC) coordinators and POC teams within the confines of the hospital or clinic. The scope of these teams and the administration of POC programs will be discussed in a later section.

Home testing is yet another arm of the POC octopus. Home testing began with the development of glucose meters for diabetic monitoring. These meters proved to be a useful method of diabetic control. Home testing has expanded to include home pregnancy testing, hemoglobin A<sub>1C</sub> monitoring and anticoagulant therapy monitoring to mention a few. Point of care testing can be fraught with issues that are beyond the scope of the doctor's office or hospital laboratory. Regardless of the issues, the home test industry continues to grow at an astronomical pace.

## **Unit A General Definition**

Point of care testing (POCT) is testing performed outside of a traditional centralized laboratory. The ancillary facility may be a satellite laboratory but more often is an alternate site out of the central laboratory's jurisdiction. In addition, the staff members are not laboratory employees. As the name implies, POCT is performed at the "point of care." The point of care is proximal to the site of clinical care delivery. Test results are available within minutes of initiation of testing. The proximity and timeliness of POCT allows the practitioner to receive results and initiate treatment in a shorter period of time. POCT has decreased the number of hospital admissions as well as the time that a patient remains in emergency departments and urgent care facilities. The convenience of POCT has also led the health care community to request more POCT technology. Manufacturers have continued to develop and market an ever-expanding scope of POCT and instruments. This expansion has included the home testing market.

## **Unit B Differentiation of Point of Care Tests and Waived Tests**

Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) established a hierarchy of testing that incorporates difficulty to perform, necessary quality control and documentation of controls and results. Complexity levels are established for individual analytes or test panels by the Centers for Medicare and Medicaid Services (CMS). The hierarchy contains three complexity levels. The three levels were designated: waived, moderate complexity and high complexity. A waived test is an examination or procedure that is "cleared by the United States Food and Drug Administration (FDA) for home use."<sup>(18)</sup> Waived tests should "employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible, or pose no reasonable risk of harm to the patient if the test is performed incorrectly."<sup>(18)</sup>

Moderate and high complexity testing are categories of testing that are more complex. In contrast to waived tests, performance of these tests requires advanced training, knowledge and skills. Likelihood of error is not negligible and errors may result in serious consequences for the patient. Hence, CMS has deemed that these tests must subscribe to more rigorous controls.

A fourth subset of tests, provider-performed microscopy, as defined by CLIA '88, is "a subset of tests classified as moderately complex that are performed by a practitioner. Only the bright-field or phase-contrast microscope can be used. Polarized microscopy of synovial fluid for crystals is excluded. The specimens are labile such that a delay in performing the test could compromise the accuracy of the test results. Quality assurance is difficult since these microscopic evaluations have no control materials available."<sup>(10)</sup> This provider-performed microscopy (PPM) is a category of testing that is performed at the point of care. Accrediting agencies such as CLIA and Commission on Laboratory Accreditation (COLA) require written policies and procedures for PPM as well as documentation of training and competence. On-site accreditation visits are not required for this sub-set of testing.

The level of test performance of any laboratory or facility is determined by the highest complexity rating of a test performed in the facility. For example, if a laboratory performs all waived testing with one test kit that is moderate complexity, that laboratory is a moderate complexity lab and must follow the CLIA guidelines for moderate complexity testing. Laboratories that are performing only waived testing are granted a certificate of waiver (COW) by CLIA. The laboratory must follow all of the CLIA guidelines for the COW and provide adequate documentation of laboratory practices, training and competency as required by CLIA. On-site accreditation visits are not required and the COW is renewed every two years.



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