Clinical Microbiology
NEWSLETTER

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CMN
Vol. 39, No. 23
December 1, 2017
www.cmnewsletter.com

IN THIS ISSUE

Promoting Good Laboratory Practices for Waived Infectious Disease and Provider-Performed Microscopy Testing

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Abstract

Laboratory testing at the point of patient care was documented hundreds of years ago and has greatly expanded in the last 25 years due to improvements in technology, miniaturization, and the availability of rapid tests for a wide variety of analytes and microorganisms. Since the implementation of the Clinical Laboratory Improvement Amendments of 1988, the number of non-traditional testing sites that provide testing with minimal oversight through a Certificate of Waiver (CW) or Certificate of Provider-Performed Microscopy (PPM) has increased. Concerns have been expressed about some practices, and data have identified quality gaps in these sites where testing may be performed by personnel who do not have laboratory training or experience. The Centers for Disease Control and Prevention has developed free educational tools to promote regulatory compliance and good laboratory practices in CW and PPM sites. Uptake and positive reviews of these materials indicate their value as a resource to improve testing quality.

Introduction

Laboratory testing has long played a critical role in assessing health and diagnosing disease, including the detection and identification of microorganisms responsible for a wide variety of infectious processes. Although testing trends have shown an increase in the types and numbers of tests being performed at the point of patient care, clinical testing as part of a patient examination at the bedside, including the tasting and other analyses of bodily fluids, was described as an important diagnostic tool as early as during the time of the ancient Egyptians [1]. The use and early development of the microscope as an instrument to observe bacteria and other human cells too small to be seen by the naked eye were accomplished by Anton van Leeuwenhoek, "the father of microbiology," in the late 17th century, and it is still used today as part of provider-performed microscopy (PPM) during the course of a patient visit [2]. As time passed and the technology for examining and testing human specimens evolved throughout the 1700s and 1800s, clinical observations from urine microscopy were described and reported to correlate with disease [3]. During the same period, Robert Koch, another pioneer in the field of clinical microbiology, designed four criteria to establish a causative relationship between microbial agents and infectious diseases. Koch also made several discoveries related to bacterial staining and microscopy that have significantly influenced the practice of clinical microbiology both in the laboratory and at the point of patient care [4].

Point-of-care (POC) testing using chemical analyses continued to evolve throughout the 18th and 19th centuries. An 1817 publication by Alexander Marcet described how chemical tests could be used to identify the composition of urinary calculi and proposed that physicians could use a portable chemical kit at the patient's bedside as a diagnostic aid [4,5]. The subsequent

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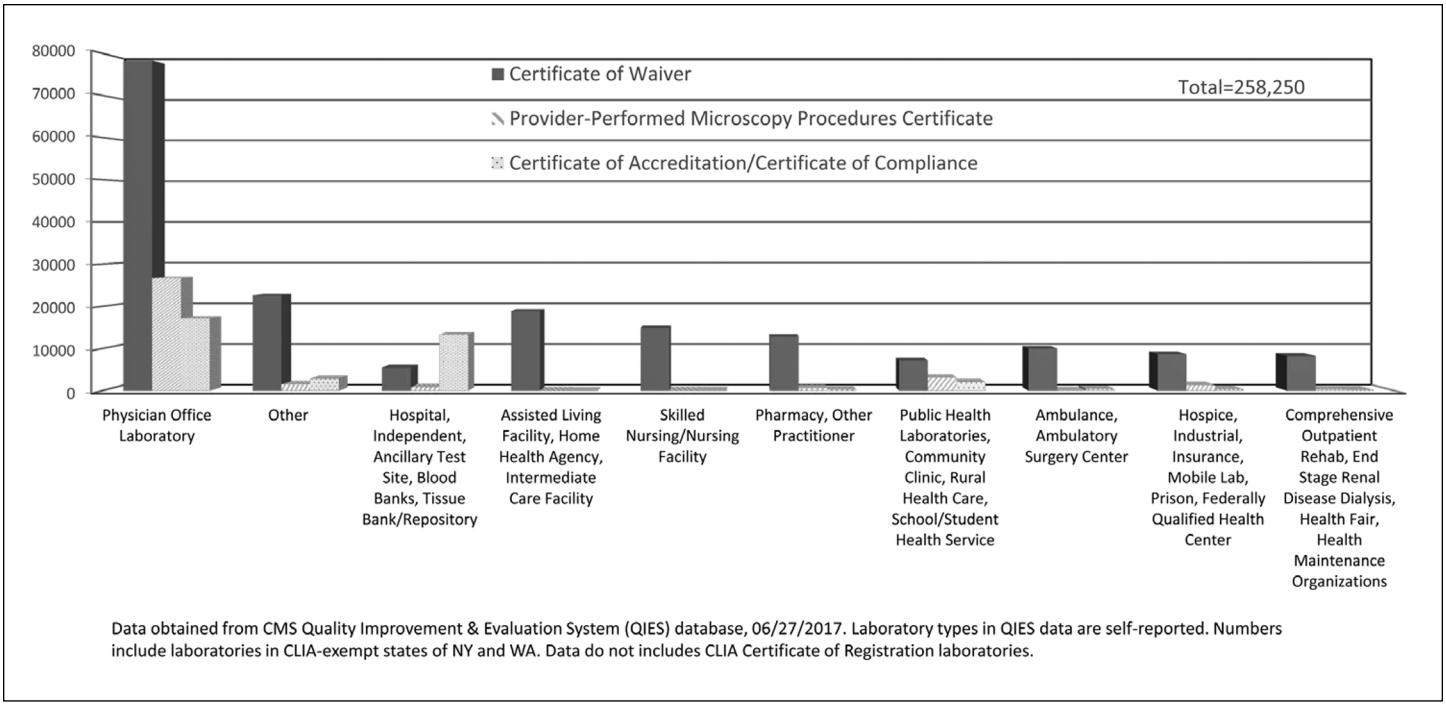

Figure 1. U.S. Laboratory Demographics, June 2017

development of reagent tablets and reagent-impregnated dipsticks to test urine, whole blood, and serum led to the potential for rapidly testing for a vast number of analytes, including some used to signal the presence of infectious agents, at the point of patient care. The availability of such technologies continues to increase. The evolution of automation, the availability of simple handheld devices, and the miniaturization of complex technology has also drastically increased the landscape of POC testing, to the extent that POC molecular testing is a current reality.

There are many advantages to using POC testing today. Generally, the required sample size is minimal and can often be taken directly from the patient with little or no processing required. The test kits, reagents, and instruments may be less expensive than those used in the clinical laboratory, and the test systems are usually smaller and require less maintenance and repair. From the clinician and patient perspectives, the rapid availability of results, sometimes during the patient's examination, offers the opportunity for prompt clinical decision making and patient treatment. This expediency can lessen the need for repeat visits or additional follow-up and, in the case of infectious diseases, may expedite the identification of the agent responsible for an outbreak. However, the availability of relatively simple POC testing devices has resulted in the potential for individuals with limited laboratory training or experience to perform rapid testing in a variety of non-traditional testing sites and thus provide results that affect patient treatment and care. Testing is now commonly performed not only in hospitals, but also in other health care settings such as physician offices, pharmacies, and nursing homes, as well as in a variety of locations that include schools and health fairs. Figure 1 shows the distribution of laboratories and other sites that perform testing, along with their Clinical Laboratory Improvement Amendments (CLIA) certificate types recorded as of June 2017. The American Academy of Microbiology recently recognized the trend toward increased POC infectious disease testing and convened a colloquium of experts to discuss relevant issues and provide recommendations. The published report from that colloquium described changing diagnostic paradigms in clinical microbiology and emphasized the role of personnel with microbiology and other clinical laboratory expertise to advise and assist in the implementation and decision support of POC testing [6].

Clinical Laboratory Improvement Amendments of 1988 and Point-of-Care Testing

Close to 30 years ago, in an effort to ensure the quality of clinical laboratory testing wherever performed, the Clinical Laboratory Improvement Amendments of 1988 (Public Law 100-578) established uniform quality standards applicable to all human testing performed for health assessment or the diagnosis, prevention, or treatment of disease, regardless of where the testing is performed [7]. The CLIA regulations implementing the law were published in the *Federal Register* in February 1992 and created three testing categories (waived, moderate complexity, and high complexity). The categories are based on the complexity of the testing performed, with the stringency of regulatory requirements increasing as the test complexity increases. A subcategory of moderate-complexity testing, PPM testing, was created in 1993 and updated in 1995 [8].

Test systems used as POC tests are frequently categorized as waived or PPM testing. Under CLIA, tests can be classified as waived if they are determined to be "simple testing with an insignificant risk of an erroneous result" [7]. Tests can meet these