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1st Edition

POCT15

Point-of-Care Testing for Infectious Diseases

This report summarizes current knowledge of rapid and point-of-care testing practices used worldwide for infectious diseases.

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Point-of-Care Testing for Infectious Diseases

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Abstract

Clinical and Laboratory Standards Institute report POCT15—*Point-of-Care Testing for Infectious Diseases* is intended for use in assessing, implementing, and managing programs for the detection, control, and/or management of infectious diseases using point-of-care testing (POCT) methodologies.

Clinicians rely heavily on laboratory tests for the etiological diagnosis of infectious diseases, which guides both prognostication and management. The clinical importance of these results means that testing must be performed in an optimal manner, and the results must be interpreted with clear knowledge of the methodologies' abilities and limitations. This report summarizes current methods and practice in POCT for infectious diseases.

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Contents

Foreword

Infections are responsible for 26% of deaths worldwide and for 30% of worldwide lost disability-adjusted life-years.[1,a] Infectious diseases are the leading killers of children and adolescents and a major cause of adult mortality. Of the top 10 causes of death worldwide, three are infections. In addition, infectious diseases are major causes of illness and are associated with and contribute to poverty. Despite the ability of modern medicine to treat or prevent many infectious diseases, they remain important causes of death and disability.

Effective management of infectious diseases necessitates rapid and accurate diagnosis, and in the case of chronic infections, such as HIV, testing for disease monitoring and support for directed therapies. Because infectious diseases are often characterized by rapid onset and progression, rapid, point-of-care (POC) diagnostics streamline and facilitate effective management. Infectious diseases disproportionately affect poor and marginalized populations. Therefore, delivering diagnostic testing at the point of care has the potential to improve access to care, as well as public and individual health.

This report is intended for use by laboratory professionals, public health professionals, clinicians, and health care managers to guide the selection, implementation, and effective use of POC tests in the diagnosis and management of infectious diseases.

Rapid point-of-care testing (POCT) methodologies for infectious diseases have an enormous spectrum of applications, from routine primary care to nosocomial infections to public health outreach testing to pandemic, disaster, and biopreparedness uses. Widely accepted guidelines for use of such tests would have a broad effect on practice. Guidelines should discuss topics such as appropriate use and interpretation of POCT for infectious diseases; cost-effective practices; and quality promotion both on the analytical and systems levels, promoting appropriate and high-quality testing practices.

NOTE: The content of this report is supported by the CLSI consensus process and does not necessarily reflect the views of any single individual or organization.

Key Words

Health care–associated infections, hepatitis, HIV, infectious diseases, influenza, malaria, point-of-care, rapid tests, sexually transmitted infections, tuberculosis

[a] http://www.who.int/healthinfo/statistics/bodgbddeathdalyestimates.xls

Point-of-Care Testing for Infectious Diseases

Chapter 1: Introduction

This chapter includes:

- Report's scope and applicable exclusions
- Background information pertinent to the report's content
- Standard precautions information
- "Note on Terminology" that highlights particular use and/or variation in use of terms and/or definitions
- Terms and definitions used in the report
- Abbreviations and acronyms used in the report

1.1 Scope

This report provides recommendations for clinicians, laboratories, public health agencies, and policymakers who are responsible for assessing, implementing, performing, and using point-of-care (POC) tests to improve management of infectious diseases. It also provides recommendations for indications, limitations, appropriate use, and reporting and interpretation for the major POC tests available. In addition, this report summarizes potential uses of POC tests in community outreach and public health testing and in resource-limited settings.

The intended users of this report are point-of-care testing (POCT) professionals, including but not limited to POC coordinators, medical directors and laboratory directors of POCT programs, and microbiology laboratory directors. Users may also include public health agencies and public health policymakers.

This report is not intended to provide an overview of QC, QA, or other good laboratory practices as related to these types of POC tests. Nor is it intended to provide a comprehensive review of the emerging technologies in POCT for infectious diseases. For the most part, discussions in this report are confined to commercialized or soon-to-be commercialized technologies.

1.2 Background

POCT for infectious diseases has enormous scope, ranging from streptococcal pharyngitis testing in routine primary care to outreach HIV testing by community organizations to molecular testing of methicillin-resistant *Staphylococcus aureus* (MRSA) in the inpatient setting. It includes testing for occult *Helicobacter pylori* disease in outpatients with gastroenteritis, testing for sepsis or respiratory pathogens in critically ill inpatients, and HIV screening for persons in developing countries. The complexity of the topic is exceeded only by its potential to improve human health.

POCT15 summarizes available technologies and various tests, as well as describing the diseases in question and the role of diagnostic testing in their management. Laboratory directors, managers, and supervisors are responsible for ensuring POC test methods are only used in situations in which operator competence has been documented. Inexperienced laboratorians should be directly supervised by an experienced laboratorian or use alternate methods until proficiency is achieved.