CLINICAL AND LABORATORY STANDARDS INSTITUTE®

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POCT10-A2

Physician and Nonphysician Provider-Performed Microscopy Testing; Approved Guideline—Second Edition

This guideline provides information on specimen collection, test methodologies, procedural steps, reporting of results, and the quality assurance aspects of provider-performed microscopy.

A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process.

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Abstract

Clinical and Laboratory Standards Institute document POCT10-A2—*Physician and Nonphysician Provider-Performed Microscopy Testing; Approved Guideline—Second Edition* provides information, instructions, and performance criteria to assist providers who perform microscopy procedures (provider-performed microscopy [PPM]), with accurate reporting of diagnostic information from their observations.

These are appropriate procedures for the examining room, emergency room, or clinic environment as an adjunct to traditional clinical laboratory testing. This testing may also provide for a rapid diagnosis of the patient condition. The guideline relates information concerning specimen collection, methodologies, procedural steps, reporting of results, and the QA aspects of PPM.

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Contents

Contents (Continued)

Contents (Continued)

Foreword

Provider-performed microscopy (PPM) is a testing modality that requires the use of a microscope and is performed by physicians and/or nonphysician practitioners (referred to as "providers" in this guideline) at the time of the patient visit. Specimens used in PPM testing are considered labile or unstable after a very short period of time. PPM testing permits providers to render a rapid diagnosis that can, in turn, facilitate the rapid initiation of treatment.

Historically, providers have used certain microscopic procedures to supplement their physical examinations in the diagnosis of patients. Unfortunately, not all providers are afforded adequate training time to fully comprehend good laboratory principles that ensure accurate results. Accurate results come from following standardized practices for the entire testing sequence, including preexamination (before testing), examination (performing the testing), and postexamination (test reporting).

The purpose of this guideline is to present critical aspects that contribute to accurate test results during the following testing phases:

- Preexamination
- Examination
- Postexamination

This document is not intended as a template for complying with specific federal laboratory laws, local laws, or accrediting organization requirements, but is intended to assist providers by presenting information that will increase the reliability and utility of microscopic testing done during the course of a patient visit.

This document may be used as a key resource for those performing PPM procedures. Included in this document are topics selected to address certain characteristics of the diagnosis and management of patients in the clinical office setting. Also included are sections related to performance of laboratory testing, written with respect to performing testing in a setting outside the traditional laboratory:

- Specimen collection and handling
- Competence assessment
- Testing procedures and interpretation
- Proficiency testing
- QC
- QA
- Recommended documentation

New to this document revision is a reorganized and more comprehensive section (Section 14) for wet preparations, which identifies differences between wet preparation for vaginal and nonvaginal procedures. Added to this document are representative pictures (or images) for as many procedures as possible, to facilitate training programs using this document as a teaching tool. Although considerable effort was made to ensure each test or procedure included in this guideline includes a picture (or image), in a few cases, none were available for citing. References were included to allow the audience to acquire this information. With the inclusion of these images, Appendix C has been created to help the reader identify and locate the images within the document.

Key Words

Examination, microscopy, postexamination, preexamination, provider

Physician and Nonphysician Provider-Performed Microscopy Testing; Approved Guideline—Second Edition

1 Scope

This guideline is limited to procedures that require the use of microscopic observation with minimum specimen preparation, typically performed by a provider in near-patient testing environments. This category of testing exists due to the nontransferable nature and labile nature of the specimens addressed in these testing processes.

This guideline is intended for use in settings where near-patient testing is performed (including, but not limited to, hospitals, medical centers, academic centers, providers' offices, outpatient clinics, community and rural health centers, and medical and dental training programs). Those performing provider-performed microscopy (PPM) procedures include physicians and nonphysician providers. Preparatory steps may be performed by trained support staff. This document may also be used to train qualified individuals who are allowed to perform PPM, as outlined by the local regulations; however, it may not address the application of specific rules, regulations, and accrediting organization requirements for PPM procedures. Local, state, and federal requirements and organizational sources should be consulted, as applicable.

2 Introduction

PPM, as carried out by trained providers, produces rapid, reliable results intended for use by the provider to immediately impact patient care decisions.[a] This type of testing requires that the performing individual be responsible for all aspects of the testing process, including:

- Appropriate need for the test
- Acceptable patient preparation
- Proper specimen procurement and handling
- Positive patient/specimen identification
- Correct microscope selection, use, storage, and maintenance
- Supplies selection, use, and storage
- Test methodologies in a procedure manual
- Accurate interpretation of observed elements
- QA and competence assessment
- Documentation of results and QC activities

The appropriate uses of the described procedures may include the following:

- Examination of the fecal smear for leukocytes to suggest or exclude the diagnosis of a number of pathological conditions

- In conjunction with patient history and vaginal fluid pH, examination of vaginal secretions to detect the presence of amniotic fluid, indicating rupture of the amniotic sac (known as fern tests)

- Examination of the nasal smear for granulocytes to identify an allergic etiology for upper respiratory symptoms

[a] In the United States, according to the Clinical Laboratory Improvement Amendments (CLIA), it is the designated laboratory director's overall responsibility to ensure the accuracy and reliability of the testing performed.

- Direct specimen examination from the perianal region to detect infestation by the *Enterobius vermicularis* parasite

- Postcoital, direct, qualitative examinations of cervical mucus to investigate infertility

- Qualitative examination of semen to confirm effective vasectomy or to investigate infertility

- Urine sediment examination to identify the cause of symptomatic presentations or abnormal chemical dipstick results

- Wet mount preparations to detect the presence of bacterial, fungal, or parasitic organisms, and other cellular elements indicative of pathological conditions

- Potassium hydroxide (KOH) preparations to detect yeast, fungal elements, and ectoparasites

3 Safety

Because the anticipated location of PPM testing is in the environment of the medical office practice, emergency room, or clinic environment, written protocols may be required by regional regulatory bodies[b] for employee safety. A safety manual (written or accessible online) with specific policies should be available where testing is located. Because these locations for direct patient care may be diverse and the provider may be the only one involved in the testing process, recognition should be made to provide safe work conditions that meet applicable regional requirements, determine appropriate personal protective equipment (PPE), and provide safe disposal of medical (infectious, biohazardous) waste. Testing supplies of a harmful or corrosive nature should be securely stored in areas where only medical personnel have access.

3.1 Standard Precautions

Because it is often impossible to know what isolates or specimens might be infectious, all patient and laboratory specimens are treated as infectious and handled according to "standard precautions." Standard precautions are guidelines that combine the major features of "universal precautions and body substance isolation" practices. Standard precautions cover the transmission of all known infectious agents and thus are more comprehensive than universal precautions, which are intended to apply only to transmission of blood-borne pathogens. Standard and universal precaution guidelines are available from the Centers for Disease Control and Prevention.[1] For specific precautions for preventing the laboratory transmission of all known infectious agents from laboratory instruments and materials, and for recommendations for the management of exposure to all known infectious diseases, refer to CLSI document M29.[2]

3.2 Personal Protective Equipment

PPE must be used as defined by the local, state, and federal regulations, and in the absence of such, PPE should be used in the following situations:

- When the performing provider's duties involve occupational exposure, appropriate use of gloves, gowns, protective (impervious) laboratory coats or cover gowns, face shields or masks, and eye protection is recommended.

[b] In the United States, for example, the US Occupational Safety and Health Administration.

The Quality Management System Approach

Clinical and Laboratory Standards Institute (CLSI) subscribes to a quality management system approach in the development of standards and guidelines, which facilitates project management; defines a document structure via a template; and provides a process to identify needed documents. The quality management system approach applies a core set of "quality system essentials" (QSEs), basic to any organization, to all operations in any health care service's path of workflow (ie, operational aspects that define how a particular product or service is provided). The QSEs provide the framework for delivery of any type of product or service, serving as a manager's guide. The QSEs are as follows:

Organization	Personnel	Process Management	Nonconforming Event Management
Customer Focus	Purchasing and Inventory	Documents and Records	Assessments
Facilities and Safety	Equipment	Information Management	Continual Improvement

POCT10-A2 addresses the QSEs indicated by an "X." For a description of the other documents listed in the grid, please refer to the Related CLSI Reference Materials section on the following page.

Organization	Customer Focus	Facilities and Safety	Personnel	Purchasing and Inventory	Equipment	Process Management	Documents and Records	Information Management	Nonconforming Event Management	Assessments	Continual Improvement
		M29	X GP21		X	X GP16 GP27 GP29 POCT08	X GP02	GP02		GP27 GP29	GP27

Path of Workflow

A path of workflow is the description of the necessary processes to deliver the particular product or service that the organization or entity provides. A laboratory path of workflow consists of the sequential processes: preexamination, examination, and postexamination and their respective sequential subprocesses. All laboratories follow these processes to deliver the laboratory's services, namely quality laboratory information.

POCT10-A2 addresses the clinical laboratory path of workflow processes indicated by an "X." For a description of the other documents listed in the grid, please refer to the Related CLSI Reference Materials section on the following page.

Preexamination				**Examination**			**Postexamination**	
Examination ordering	Sample collection	Sample transport	Sample receipt/processing	Examination	Results review and follow-up	Interpretation	Results reporting and archiving	Sample management
	X GP16	X GP16	X GP16	GP16	X GP16	X	X	

Related CLSI Reference Materials*

GP02-A5 **Laboratory Documents: Development and Control; Approved Guideline—Fifth Edition (2006).** This document provides guidance on development, review, approval, management, and use of policy, process, and procedure documents in the medical laboratory community.

GP16-A3 **Urinalysis; Approved Guideline—Third Edition (2009).** This document addresses procedures for testing urine, including materials and equipment; macroscopic/physical evaluation; chemical analysis; and microscopic analysis.

GP21-A3 **Training and Competence Assessment; Approved Guideline—Third Edition (2009).** This document provides background information and recommended processes for the development of training and competence assessment programs that meet quality and regulatory objectives.

GP27-A2 **Using Proficiency Testing to Improve the Clinical Laboratory; Approved Guideline—Second Edition (2007).** This guideline provides assistance to laboratories in using proficiency testing as a quality improvement tool.

GP29-A2 **Assessment of Laboratory Tests When Proficiency Testing Is Not Available; Approved Guideline—Second Edition (2008).** This document offers methods to assess test performance when proficiency testing (PT) is not available; these methods include examples with statistical analyses. This document is intended for use by laboratory managers and testing personnel in traditional clinical laboratories as well as in point-of-care and bedside testing environments.

M29-A3 **Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Third Edition (2005).** Based on US regulations, this document provides guidance on the risk of transmission of infectious agents by aerosols, droplets, blood, and body substances in a laboratory setting; specific precautions for preventing the laboratory transmission of microbial infection from laboratory instruments and materials; and recommendations for the management of exposure to infectious agents.

POCT08-A **Quality Practices in Noninstrumented Point-of-Care Testing: An Instructional Manual and Resources for Health Care Workers; Approved Guideline (2010).** This instructional guideline delivers laboratory science concepts and activities with the goal of increasing knowledge and quality of laboratory testing for testing personnel with no laboratory background.

* CLSI documents are continually reviewed and revised through the CLSI consensus process; therefore, readers should refer to the most current editions.

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