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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

Abstract.....i

Committee Membership..... iii

Foreword.....ix

1 Scope.....1

2 Introduction.....1

3 Safety2

 3.1 Standard Precautions.....2

 3.2 Personal Protective Equipment2

 3.3 Hand Hygiene3

 3.4 Food, Drink, Cigarettes, and Cosmetics3

 3.5 Workspace Cleaning and Disinfection.....3

 3.6 Medical (Infectious, Biohazard) Waste Disposal4

 3.7 Chemical Safety4

4 Terminology.....5

 4.1 A Note on Terminology5

 4.2 Definitions5

 4.3 Abbreviations and Acronyms7

5 Microscope.....7

 5.1 Parts of the Microscope8

 5.2 Operation10

 5.3 Care of the Microscope.....11

6 Quality Assurance.....13

 6.1 Microscopy Provider.....13

 6.2 Equipment and Supply Management.....16

 6.3 Patient Test Management.....17

 6.4 Procedure Manual18

 6.5 Quality Control19

 6.6 Proficiency Testing.....20

 6.7 Accreditation.....22

7 Fecal Leukocyte Examinations (Also Known as Stool White Blood Cells).....23

 7.1 Principle23

 7.2 Materials23

 7.3 Specimen Collection24

 7.4 Testing Procedure24

 7.5 Quality Control25

 7.6 Reporting Results.....25

 7.7 Limitations of the Procedure.....25

8 Fern Tests.....25

 8.1 Principle25

 8.2 Materials26

 8.3 Specimen Collection26

 8.4 Testing Procedure27

 8.5 Quality Control27

Contents (Continued)

8.6	Reporting Results.....	27
8.7	Limitations of the Procedure.....	28
9	Nasal Smears for Inflammatory Cells (Also Known as “Nasal Smear for Eosinophils,” “Nasal White Blood Cells,” and “Nasal Smear for Granulocytes”)	28
9.1	Principle	28
9.2	Materials	28
9.3	Specimen Collection	29
9.4	Testing Procedure	29
9.5	Quality Control	30
9.6	Reporting Results.....	30
9.7	Limitations of the Procedure.....	30
10	Pinworm Examinations	30
10.1	Principle	30
10.2	Materials	31
10.3	Specimen Collection	31
10.4	Testing Procedures.....	32
10.5	Quality Control	33
10.6	Reporting Results.....	33
10.7	Limitations of the Procedure.....	33
11	Postcoital, Direct, Qualitative Examinations of Cervical Mucus	34
11.1	Principle	34
11.2	Materials	34
11.3	Specimen Collection	34
11.4	Testing Procedure	35
11.5	Quality Control	35
11.6	Reporting Results.....	36
11.7	Limitations of the Procedure.....	36
12	Qualitative Semen Analyses	36
12.1	Principle	36
12.2	Materials	37
12.3	Specimen Collection	37
12.4	Testing Procedure	37
12.5	Quality Control	38
12.6	Reporting Results.....	38
12.7	Limitations of the Procedure.....	39
13	Urine Sediment Examinations	39
13.1	Principle	39
13.2	Materials	40
13.3	Specimen Collection	41
13.4	Testing Procedure	42
13.5	Quality Control	44
13.6	Reporting Results.....	45
13.7	Limitations of the Procedure.....	46
14	Wet Mount Preparations and Potassium Hydroxide Preparations	46
14.1	Principle	46

Contents (Continued)

14.2 Materials47

14.3 Specimen Collection47

14.4 Testing Procedures.....49

14.5 Quality Control51

14.6 Reporting Results.....51

14.7 Limitations of the Procedure.....52

14.8 Other Product Use in Potassium Hydroxide Microscopy53

References.....54

Appendix A. Microscopic Components in Urine Sediment.....56

Appendix B. Microscopic Components in Vaginal Fluid and Potassium Hydroxide Preparations,
and Ectoparasites76

Appendix C. List of Figures and Tables85

The Quality Management System Approach88

Related CLSI Reference Materials89

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

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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.