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GP23-A2

Nongynecological Cytology Specimens: Preexamination, Examination, and Postexamination Processes; Approved Guideline—Second Edition

This document provides recommendations for cytology laboratories to use in developing preexamination, examination, and postexamination processes and procedures for nongynecological cytology specimen management.

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

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For additional information on committee participation or to submit comments, contact CLSI.

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Nongynecological Cytology Specimens: Preexamination, Examination, and Postexamination Processes; Approved Guideline—Second Edition

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Abstract

Clinical and Laboratory Standards Institute document GP23-A2—*Nongynecological Cytology Specimens: Preexamination, Examination, and Postexamination Processes; Approved Guideline—Second Edition* was developed for use by clinical and laboratory personnel responsible for the collection and processing of nongynecological cytology specimens. This guideline describes the path of workflow (preexamination, examination, and postexamination processes) for nongynecological cytology specimens.

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Foreword

Nongynecological cytology is primarily used to aid in the diagnosis of cancer, but also helps in the diagnosis of certain infectious diseases and other inflammatory conditions. Cytology is often preferred because the patient is spared a more invasive surgical procedure. Laboratories receive many different types of nongynecological specimens. All specimens sent for cytological evaluation should be collected and prepared using techniques that produce slide preparations that are cost effective and improve patients' medical care by enhancing diagnostic accuracy.

This guideline outlines processes for optimizing the preexamination, examination, and postexamination management of nongynecological specimens to ensure suitable specimens for diagnosis.

Overview of Changes

This guideline revises GP23-A using the QMS model described in CLSI document QMS01,¹ and the path of workflow that would be found in a nongynecological cytology laboratory. In addition to format changes and updated techniques described within this document, this guideline contains comprehensive QA measures and a patient safety checklist to help laboratories develop quality indicators to monitor and assess cytology laboratory performance.

Key Words

Cytological specimen collection, nongynecological cytology, nongynecological cytology test reporting, nongynecological specimen preparation, quality measures for nongynecological cytology

SAMPLE

Nongynecological Cytology Specimens: Preexamination, Examination, and Postexamination Processes; Approved Guideline—Second Edition

Chapter 1: Introduction

This chapter includes:

- Document scope and applicable exclusions
- Background information pertinent to the document content
- Standard Precautions information, as applicable
- “Note on Terminology” that highlights particular use and/or variation in use of terms and/or definitions, where applicable
- Terms and definitions used in the document
- Abbreviations and acronyms used in the document

1.1 Scope

This guideline provides recommendations for cytology laboratories to use in developing preexamination, examination, and postexamination processes and procedures for nongynecological cytology specimen management.

This document does not address issues related to the interpretation of the slide preparation. Cervicovaginal cytology is addressed in CLSI document GP15² and fine needle aspirate cytology is addressed in CLSI document GP20.³

1.2 Background

The primary purpose of cytological examination of nongynecological specimens is to detect malignancy, but the method may detect inflammatory or infectious disorders as well as other conditions. Reliable cytological diagnosis of nongynecological material depends on sufficient patient history and quality slide preparations. This document provides guidance on clinical and laboratory processes and procedures for the collection, processing, microscopic examination, and postexamination management of nongynecological specimens. Followed skillfully and properly, these techniques provide a foundation for high diagnostic accuracy.

In the practice of nongynecological cytology, specimens are derived from:

- Cerebrospinal tract
- Ducts and secretions
- Gastrointestinal tract
- Joint spaces
- Ocular area
- Pericardial sac
- Peritoneal space

- Pleural space
- Respiratory tract
- Skin and mucosal surfaces
- Urinary tract

Specimens may be collected by:

- Brushing and washing
- Catheter
- Direct aspiration and drainage
- Patient expectoration
- Patient voiding
- Touch preparation and scraping

This guideline addresses a number of techniques that are commonly practiced in the cytopreparatory laboratory.

1.3 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 bloodborne pathogens. The Centers for Disease Control and Prevention address this topic in published guidelines that address the daily operations of diagnostic medicine in human and animal medicine while encouraging a culture of safety in the laboratory.⁴ 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 M29.⁵

1.4 Terminology

1.4.1 A Note on Terminology

CLSI, as a global leader in standardization, is firmly committed to achieving global harmonization wherever possible. Harmonization is a process of recognizing, understanding, and explaining differences while taking steps to achieve worldwide uniformity. CLSI recognizes that medical conventions in the global metrological community have evolved differently in the United States, Europe, and elsewhere; that these differences are reflected in CLSI, International Organization for Standardization (ISO), and European Committee for Standardization (CEN) documents; and that legally required use of terms, regional usage, and different consensus timelines are all important considerations in the harmonization process. In light of this, CLSI’s consensus process for development and revision of standards and guidelines focuses on harmonization of terms to facilitate the global application of standards and guidelines.

To align the use of terminology in this document with that of ISO, the terms *preexamination*, *examination*, and *postexamination* were adopted in place of preanalytical, analytical, and postanalytical, respectively. The users of GP23 should understand that the fundamental meanings of the terms are identical in many cases. The terms in this document are consistent with those defined in the ISO 15189,⁶ ISO/IEC 17025,⁷ and ISO 9000⁸ series of standards.

The Quality Management System Approach

Clinical and Laboratory Standards Institute (CLSI) subscribes to a quality management system (QMS) 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 QMS 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

GP23-A2 addresses the QSE 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
QMS01	QMS01	M29 QMS01	QMS01 QMS03	QMS01	QMS01 QMS13	X GP15 GP33 MM07 QMS01	QMS01 QMS02	QMS01	QMS01	QMS01	QMS01

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.

GP23-A2 addresses the clinical laboratory path of workflow steps 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.

Examination ordering	Preexamination			Examination			Postexamination	
	Sample collection	Sample transport	Sample receipt/processing	Examination	Results review and follow-up	Interpretation	Results reporting and archiving	Sample management
X GP15 GP20 QMS01	X GP15 GP20 GP33 QMS01	X GP15 GP20 QMS01	X GP15 GP20 GP33 MM07 QMS01	GP33 MM07 QMS01	X MM07 QMS01	MM07 QMS01	X GP33 MM07 QMS01	X GP15 QMS01

Related CLSI Reference Materials*

- GP15-A3** **Cervicovaginal Cytology Based on the Papanicolaou Technique; Approved Guideline—Third Edition (2008).** This document discusses procedures for cervicovaginal specimen collection, as well as the preparation, fixation, staining, and storage of Papanicolaou-stained cervicovaginal cytology slides.
- GP20-A2** **Fine Needle Aspiration Biopsy (FNAB) Techniques; Approved Guideline—Second Edition (2003).** This document contains recommended procedures for performing fine needle aspiration biopsies of superficial (palpable) and deep-seated (nonpalpable) lesions/masses, from patient preparation through staining the smear.
- GP33-A** **Accuracy in Patient and Sample Identification; Approved Guideline (2010).** This guideline describes the essential elements of systems and processes required to ensure accurate patient identification. The principles in this document may be applied to manual or electronic systems. Design considerations covered include criteria for accuracy, differences in inpatient vs outpatient settings that impact patient identification, language and cultural considerations, and standardization of processes across the health care enterprise.
- M29-A4** **Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Fourth Edition (2014).** 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.
- MM07-A2** **Fluorescence *In Situ* Hybridization Methods for Clinical Laboratories; Approved Guideline—Second Edition (2013).** This document addresses fluorescence *in situ* hybridization methods for medical genetic determinations, identification of chromosomal abnormalities, and gene amplification. Recommendation for probe and assay development, manufacture, qualification, verification, and validation; instrument requirements; quality assurance; and evaluation of results are also included.
- QMS01-A4** **Quality Management System: A Model for Laboratory Services; Approved Guideline—Fourth Edition (2011).** This document provides a model for medical laboratories that will assist with implementation and maintenance of an effective quality management system.
- QMS02-A6** **Quality Management System: Development and Management of Laboratory Documents; Approved Guideline—Sixth Edition (2013).** This document provides guidance on the processes needed for document management, including creating, controlling, changing, and retiring a laboratory's policy, process, procedure, and form documents in both paper and electronic environments.
- QMS03-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.
- QMS13-A** **Quality Management System: Equipment; Approved Guideline (2011).** This guideline provides recommendations for establishing equipment management processes from selection through decommissioning of equipment used in the provision of laboratory services.

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