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February 2009

GP16-A3

Urinalysis; Approved Guideline—Third Edition

Sample

This document addresses procedures for testing urine, including materials and equipment; macroscopic/physical evaluation; chemical analysis; and microscopic analysis.

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

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ISBN 1-56238-687-5
ISSN 0273-3099

GP16-A3
Vol. 29 No. 4
Replaces GP16-A2
Vol. 21 No. 19

Urinalysis; Approved Guideline—Third Edition

Volume 29 Number 4

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Abstract

Clinical and Laboratory Standards Institute document GP16-A3—*Urinalysis; Approved Guideline—Third Edition* is written for laboratory and nonlaboratory personnel responsible for the collection, transport, and analysis of urine specimens. The guideline addresses macroscopic evaluation, chemical analysis, and microscopic examination of urine. The necessary materials and equipment used in the process are considered.

Clinical and Laboratory Standards Institute (CLSI). *Urinalysis; Approved Guideline—Third Edition*. CLSI document GP16-A3 (ISBN 1-56238-687-5). Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2009.

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Suggested Citation

CLSI. *Urinalysis; Approved Guideline—Third Edition*. CLSI document GP16-A3. Wayne, PA: Clinical and Laboratory Standards Institute; 2009.

Previous Editions:

July 1991, December 1992, December 1995, November 2001

Reaffirmed:

September 2016

Archived:

July 2020

Sample

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Foreword

Important clinical information may be obtained from laboratory analysis of urine specimens. Much progress has been made since ancient times, when urine was poured on the ground and the attraction of insects to it indicated an abnormal specimen. Physical and chemical analysis of urine and microscopic examination of sediment, often performed today with sophisticated instrumentation, are as useful in physician office laboratories as they are in large clinical laboratories.

Urinalysis is a simple, rapid, and basic part of clinical laboratory testing. Its usefulness is proven in diagnosis of disease (diseases of the kidney, urinary tract, and liver, as well as metabolic disorders such as diabetes), in monitoring the effectiveness of treatment of chronic problems, and in screening for asymptomatic conditions.

Specimen collection is as important as the technical performance of urinalysis. Acceptable specimens improve the quality and reliability of urinalysis results. The working group believes this document is a practical guideline that is useful for all parties, laboratorians and nonlaboratorians alike, who are responsible for carrying out the procedure.

In this third edition, the scope was narrowed to performance of the traditional physical, chemical, and microscopic urinalysis. Previously, consideration was given to 24-hour urines and specialized urine measurand tests. New material on automated and semiautomated systems was added. Finally, some representative photomicrographs of urine sediment elements are included in this edition.

The working group believes this guideline will serve as a common reference point and facilitate communication between the site where the specimen is collected and the laboratory where the analysis is performed. By providing a clear picture of how specific actions can affect the test result or how one can give better instruction in specimen collection, the overall testing process will be improved.

Key Words

Brightfield microscopy, dipstick, flow microscopy, formed elements, microscopic results, multiconstituent controls, pathologic conditions, physicochemical results, reagent strips, refractometer, sediment, slide microscopy, urinalysis

Urinalysis; Approved Guideline—Third Edition

1 Scope

This document is written for laboratory and nonlaboratory personnel responsible for the collection, transport, and analysis of urine specimens. The guideline addresses macroscopic evaluation, chemical analysis, and microscopic examination of urine. A systematic outline for collecting, transporting, and storing specimens is included. The necessary materials and equipment used in the process are considered.

The focus of this guideline relates to urine collection and performance of the traditional, routine chemical and microscopic urinalysis. Unlike the previous edition, 24-hour urine collections are excluded, as are reference laboratory preanalytic requirements for specialized tests and detailed discussion of specific urine particle analyzer technologies.

Algorithmic approaches to evaluation of urine samples with respect to potential screening by reagent strip, with subsequent performance (or nonperformance) of culture, is beyond the scope of this guideline. See CLSI document EP12¹ for information on test comparisons for sensitivity, specificity, and predictive values in a clinical context.

2 Introduction

Urinalysis is the testing of urine with procedures commonly performed in an expeditious, reliable, accurate, safe, and cost-effective manner.

For the purposes of this guideline, the term “urinalysis” includes some or all of the following:

- macroscopic evaluation (eg, color, clarity);
- physical measurements (eg, volume for timed collections, specific gravity [SG]);
- chemical reagent strip or tablet testing; and
- microscopic examination.

Each laboratory, in consultation with its clinicians, should determine which procedures to use and the extent of the examination. These determinations should be based on an evaluation of known and published studies, as well as the type of patient population (eg, asymptomatic patient population screening yields few positive results, whereas in-hospital nephrology patients have a higher yield). The decision to perform microscopic examinations should be made by each individual laboratory based on its specific patient population.²⁻¹¹

Urinalysis is performed for a variety of reasons, including:

- to aid in the diagnosis of disease;
- to screen a population for asymptomatic, congenital, or hereditary diseases (ie, to monitor wellness);
- to monitor the progress of disease; and
- to monitor the effectiveness or complications of therapy.

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 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 US Centers for Disease Control and Prevention.¹² For specific precautions for preventing the laboratory transmission of all infectious agents from laboratory instruments and materials and for recommendations for the management of exposure to all infectious disease, refer to CLSI document M29.¹³

4 Terminology

4.1 Definitions

analytical specificity – ability of a measurement procedure to measure solely the measurand; **NOTE 1:** Lack of specificity may be called analytical interference (ISO 17511)¹⁴; **NOTE 2:** A type of interference in immunochemistry measurement procedures may be cross-reactivity; **NOTE 3:** Specificity of a measurement procedure should not be confused with diagnostic specificity (ISO 17511).¹⁴

catheter – a hollow tube of rubber or plastic, passed through the urethra for collecting urine directly from the urinary bladder.

centrifugation tube – a glass or plastic tube in which urine is centrifuged for the purpose of preparing sediment for microscopic evaluation; **NOTE:** Supernatant may also be tested when formed elements interfere with some chemical assays.

clean catch specimen – urine specimen that is collected from the middle of the urine stream after the first part of the flow has been voided; **NOTE 1:** Also known as “midstream” urine; **NOTE 2:** The urinary tract naturally contains bacteria that can contaminate a urine sample. The clean-catch method is used to prevent these bacteria from getting into the urine sample.

in vitro diagnostic medical device – a device, whether used alone or in combination, intended by the manufacturer for the *in vitro* examination of specimens derived from the human body to provide information for diagnostic, monitoring, or compatibility purposes. This includes reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles (GHTF/SG1/N045:2008).¹⁵

measurand – quantity intended to be measured (VIM07)¹⁶; **NOTE 1:** The specification of a measurand requires knowledge of the **kind of** quantity; description of the state of the phenomenon, body, or substance carrying the quantity, including any relevant component; and the chemical entities involved; **NOTE 2:** In chemistry, “analyte,” or the name of a substance or compound, is a term sometimes used for ‘measurand.’ This usage is erroneous because the term does not refer to quantities.

measurement accuracy – closeness of agreement between a measured quantity value and a true quantity value of a measurand (VIM07)¹⁶; **NOTE 1:** The concept “measurement accuracy” is not a quantity and is not given a numerical quantity value. A measurement is said to be more accurate when it offers a smaller measurement error; **NOTE 2:** The term “measurement accuracy” should not be used for measurement trueness and the term “measurement precision” should not be used for “measurement accuracy,” which, however, is related to both of these concepts; **NOTE 3:** “Measurement accuracy” is sometimes

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 approach is based on the model presented in the most current edition of CLSI/NCCLS document HS01—*A Quality Management System Model for Health Care*. 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:

- | | | | |
|----------------------------------|--|--|--|
| Documents & Records Organization | Equipment Purchasing & Inventory Process Control | Information Management Occurrence Management Assessments—External & Internal | Process Improvement Customer Service Facilities & Safety |
|----------------------------------|--|--|--|

GP16-A3 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.

Documents & Records Organization	Personnel	Equipment	Purchasing & Inventory	Process Control	Information Management	Occurrence Management	Assessments—External & Internal	Process Improvement	Customer Service	Facilities & Safety
GP02				X EP05 EP09 EP10 EP12 EP15 EP17 M29	GP02		EP10			M29

Adapted from CLSI/NCCLS document HS01—*A Quality Management System Model for Health Care*.

Path of Workflow

A path of workflow is the description of the necessary steps to deliver the particular product or service that the organization or entity provides. For example, CLSI/NCCLS document GP26—*Application of a Quality Management System Model for Laboratory Services* defines a clinical laboratory path of workflow, which consists of three sequential processes: preexamination, examination, and postexamination. All clinical laboratories follow these processes to deliver the laboratory’s services, namely quality laboratory information.

GP16-A3 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	X	X	X	X			

Adapted from CLSI/NCCLS document HS01—*A Quality Management System Model for Health Care*.

Related CLSI Reference Materials

- EP05-A2** **Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline—Second Edition (2004).** This document provides guidance for designing an experiment to evaluate the precision performance of quantitative measurement methods; recommendations on comparing the resulting precision estimates with manufacturers' precision performance claims and determining when such comparisons are valid; as well as manufacturers' guidelines for establishing claims.
- EP09-A2** **Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Second Edition (2002).** This document addresses procedures for determining the bias between two clinical methods, and the design of a method comparison experiment using split patient samples and data analysis.
- EP10-A3** **Preliminary Evaluation of Quantitative Clinical Laboratory Measurement Procedures; Approved Guideline—Third Edition (2006).** This guideline provides experimental design and data analysis for preliminary evaluation of the performance of a measurement procedure or device.
- EP12-A2** **User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline—Second Edition (2008).** This document provides a consistent approach for protocol design and data analysis when evaluating qualitative diagnostic tests. Guidance is provided for both precision and method-comparison studies.
- EP15-A2** **User Verification of Performance for Precision and Trueness; Approved Guideline—Second Edition (2005).** This document describes the demonstration of method precision and trueness for clinical laboratory quantitative methods utilizing a protocol designed to be completed within five working days or less.
- EP17-A** **Protocols for Determination of Limits of Detection and Limits of Quantitation; Approved Guideline (2004).** This document provides guidance for determining the lower limit of detection of clinical laboratory methods, for verifying claimed limits, and for the proper use and interpretation of the limits.
- 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.
- 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.

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