CLINICAL AND LABORATORY STANDARDS INSTITUTE®

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GP16-A3

Urinalysis; Approved Guideline—Third Edition

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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Urinalysis; Approved Guideline—Third Edition

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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.

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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 EP12[1] 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.