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Toxicology and Drug Testing in the Clinical Laboratory; Approved Guideline—Second Edition



This guideline addresses drug testing in the clinical laboratory, both for clinical and forensic purposes, and pertains to both drugs of abuse and other drugs normally encountered and analyzed by hospital laboratories. The guideline discusses the preanalytical, analytical, and postanalytical considerations for specimen collection, methods of analysis, quality assurance, and the reporting and interpretation of results.

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

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Toxicology and Drug Testing in the Clinical Laboratory; Approved Guideline—Second Edition

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Abstract

Clinical and Laboratory Standards Institute document C52-A2—*Toxicology and Drug Testing in the Clinical Laboratory; Approved Guideline—Second Edition* is designed to aid the clinical laboratorian in developing procedures for the efficient and reliable analysis of clinical and forensic specimens to qualitatively and/or quantitatively determine the presence of drugs of abuse and other commonly encountered drugs. This guideline addresses forensic drug testing applications, such as workplace, criminal justice system, and rehabilitation settings, and clinical drug testing as typically undertaken for the diagnosis and treatment of emergency room patients. Its primary objective is to ensure that high quality standards are maintained within both of these important areas of clinical laboratory analysis.

This document conforms to the objective by addressing specimen collection and processing, methods of analysis, quality assurance, and the reporting and interpretation of results. Because the results of forensic analyses have obvious potential for use as evidence in legal proceedings, information is provided relating to forensic procedures used to safeguard the identity of the specimen, document the chain of custody, and ensure proper use of analytical results.

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Foreword

For the purposes of this guideline, it is necessary to initially define what is meant by the term “drug.” In this context, the term “drug” refers to substances whose manufacture, possession, and usage are regulated by government mandates, including drugs of abuse and prescription drugs. In addition, some nonprescription drugs are included, such as ethanol, acetaminophen, and salicylates. Substances such as tobacco, organic nitrites, solvents, and anabolic steroids that are not typically analyzed by clinical laboratories, are beyond the scope of this document, and will not be addressed.

This guideline addresses clinical (medical) testing encompassing the typical drugs of abuse and therapeutic drugs for which urine and blood specimens are tested from emergency room patients to diagnose drug overdoses, but it also includes forensic (nonmedical) testing performed on urine and blood specimens.

The previous and initial editions of this guideline focused extensively on forensic testing conducted to detect drug abuse. The guideline has been expanded to include drug testing for clinical purposes. Forensic testing is now a secondary consideration, as most typical hospital laboratories perform only a small amount of forensic testing, and perhaps none at all; but most hospital laboratories are expected to provide some level of clinical drug testing, at least to support the emergency department.

This guideline provides helpful information about preanalytical, analytical, and postanalytical procedures that meet forensic and clinical requirements. Each laboratory must determine its need to perform forensic and clinical drug testing and the extent of the testing required to support the needs of the medical staff and patients. Every laboratory cannot reasonably be expected to test for the same drugs or to offer the analyses for all of the drugs for which analytical procedures may be available. In fact, there is no reason for laboratories to offer drug tests because the assays are readily available. Laboratory directors must determine the appropriate extent of drug testing to be offered. It is critical that laboratories understand the distinction between forensic and clinical drug testing. Laboratories should be aware that clinically intended toxicology and drug testing results may be used in a court of law as part of the medical records and, inadvertently, become medicolegal results.

The working group developed this guideline in response to the frequently expressed need for information that addresses issues related to clinical and forensic drug testing. Comments and suggestions for future editions of this guideline are welcomed.

Key Words

Abused drugs, alcohol, clinical toxicology, controlled substances, DOA, drug abuse, drug screen, drug testing, drugs, emergency toxicology, forensic toxicology, intoxication, overdose, serum drug testing, substance abuse, therapeutic drugs, toxicology, urine drug testing

Toxicology and Drug Testing in the Clinical Laboratory; Approved Guideline—Second Edition

1 Scope

This guideline is intended to provide clinical laboratories with basic and general drug testing information for both clinical and forensic purposes. A reader of this document must recognize the difference between clinical and forensic drug testing and make a conscious decision about the type of testing that is conducted. Clinical laboratories may perform both types of drug testing as they are by no means mutually exclusive. However, the types of analytes tested, the way in which specimens are collected and maintained, the specifics of the analytical process, and the manner in which results are reported differ between clinical and forensic testing. The reader should recognize the legal standard required to perform forensic testing. While the analytical procedures for clinical and forensic drug testing are very similar, many nonanalytical details must be observed to conduct legally acceptable forensic analysis. Indeed, a clinical laboratory may find the documentation and laboratory security requirements so onerous that it will decide not to perform forensic testing. Ironically, while this guideline is intended to assist laboratories conducting forensic procedures, it will also serve its purpose if it dissuades laboratories that are ill prepared to meet the stringent mandates of forensic testing from entering that arena.

This guideline addresses the most common specimen types used for toxicology testing, including serum and plasma, whole blood, and urine. A wide variety of other specimen types are suitable for toxicological analysis, but they are not typically tested in routine clinical laboratories and are beyond the scope of this document.

Three general types of analytes are considered in this guideline: drugs of abuse, therapeutic drugs, and miscellaneous substances. Test methodologies include rapid screening assays designed to produce only positive or negative results (qualitative tests), routine semiquantitative and quantitative tests, and more complex confirmatory assays.

Toxicology testing has traditionally been performed in central laboratories, and this continues to be the case for the majority of testing. However, a wide variety of point-of-care testing (POCT) devices, especially screening devices for drugs of abuse, are now available. These POCT methods can be used in emergency room situations or the laboratory for clinical testing and in a variety of forensic testing situations. Hence, this guideline addresses POCT methods.

This document is intended to be general enough to provide useful guidance when performing drug testing for analytes other than those specifically included and for purposes and situations not covered. Obviously, users will need to exercise discretion to adapt these recommendations to suit their specific purposes and circumstances.

2 Introduction

There are many sources providing information about how to conduct drug testing. After extracting general information from this guideline, users should consult more specific and detailed textbooks, peer-reviewed professional journal papers, websites, and other sources.

This guideline is intended to be primarily applicable to drug testing being performed in clinical laboratories. The information is likely applicable for drug testing performed in physician office laboratories, clinics, satellite laboratories, and other facilities, but may be less applicable to some other testing venues, such as large specialized reference laboratories, dedicated forensic laboratories, drug