CLINICAL AND LABORATORY STANDARDS INSTITUTE®

3rd Edition

C52

Toxicology and Drug Testing in the Medical Laboratory

This guideline provides an overview of drug testing by medical laboratories, including testing for drugs of abuse. It discussed the preexamination, examination, and postexamination considerations for specimen collection, methods of analysis, and the reporting and interpretation of results.

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 Medical Laboratory

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Abstract

Clinical and Laboratory Standards Institute guideline C52— *Toxicology and Drug Testing in the Medical Laboratory* helps medical laboratories develop procedures for analyzing drugs of abuse and other compounds. C52 provides guidance on clinical toxicology testing from the initial consultation through final result reporting and interpretation, and includes a variety of specimen types, analytical procedures, and instrumentation.

This guideline discusses the most common purposes for clinical toxicology testing, including the support of emergency medicine, obstetrics and gynecology, neonatology, pediatrics, psychiatry, pain management, and addiction medicine. The primary objective is to ensure high-quality standards are maintained throughout the entire testing process, from specimen collection, processing, and analysis, through results reporting and interpretation.

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Foreword

For the purposes of this guideline, it is necessary to initially define "drug." In the broadest sense, a drug is any chemical or compound administered to produce a physiological effect. From a legal perspective, "drug" often refers to substances for which the manufacture, possession, and use are regulated by government mandates, including drugs of abuse and prescription drugs. This guideline provides an overview of the analysis of scheduled drugs, nonprescription drugs, synthetic designer drugs, and other nonscheduled compounds. Substances medical laboratories do not typically analyze, such as solvents and anabolic steroids, are beyond this guideline's scope.

This guideline discusses the detection and quantitation of drugs and compounds in biological specimens for medical purposes. Readers should be aware that clinical toxicology and drug testing results may be used in a court of law as part of the medical record and, inadvertently, become medico-legal results. However, formal forensic testing is also outside this guideline's scope.

This guideline provides helpful information about preexamination, examination, and postexamination procedures for both screening and definitive testing that meet clinical needs. Each laboratory needs to determine medical staff's and patients' expectations and support the relevant extent of testing. Every laboratory cannot reasonably be expected to test for the same drugs or offer analyses for all drugs for which analytical procedures are available. In fact, laboratories should not offer drug tests simply because the measurement procedures are readily available. Laboratory directors need to determine the appropriate offering for drug testing.

Toxicology testing has traditionally been performed in medical laboratories, and this continues to be the case for most testing. However, many point-of-care testing devices, especially screening devices for drugs of abuse, are now available.[1,2]

Many sources provide 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. Readers need to use discretion when adapting this guideline's recommendations to suit specific purposes and circumstances.

Clinical drug testing is readily distinguished from forensic drug testing because clinical specimens are not collected using a documented chain of custody. Clinical toxicology specimens are collected and processed following the same procedures used for other clinical specimens. Many clinical toxicology measurement procedures are quantitative, but qualitative screening tests may also be used. The results of rapid screening tests may be clinically useful but their results may not always be confirmed by more specific methods.

Forensic testing is not usually conducted in most medical laboratories or only takes place infrequently and under unusual circumstances. However, there is the potential for situations in which the distinction between clinical and forensic testing becomes blurred. For example, a pregnant woman who undergoes drug testing as a patient but who screens positive for a drug of abuse could be referred to the authorities for prosecution for use or endangering the fetus. Testing of emergency room patients for ethanol may have forensic implications, eg, in the case of a motor vehicle accident with fatalities. It may not be possible for a laboratory to foresee all potential scenarios that can arise, and it may not have a standard operating procedure that covers all eventualities.

Guidelines for conducting drug testing in medical laboratories are presented using any number of organizational schemes. The approach in this guideline follows laboratory preexamination, examination, and postexamination workflow processes for both screening and definitive toxicology testing. This approach is consistent with other guidance documents that seek to ensure the entire laboratory testing process's quality, from the time a test is ordered until a result is reported.

Clinical and analytical toxicology are rapidly changing sciences. Although efforts have been made to include the most common issues, not all measurands, instruments, or scenarios could be included in this guideline. Therefore, these recommendations may not be applicable to all circumstances, analytical methods, or scenarios.

Overview of Changes

This guideline replaces the previous edition of the approved guideline, C52-A2, published in 2007. Several changes were made in this edition, including:

- Focusing the guideline exclusively on clinical toxicology testing (in contrast to previous editions of C52, which focused extensively on clinical and forensic testing for drugs of abuse)

- Removing forensic testing, to avoid redundancy with forensic testing recommendations published by forensic organizations

NOTE: The content of this guideline is supported by the CLSI consensus process, and does not necessarily reflect the views of any single individual or organization.

Key Words

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

Toxicology and Drug Testing in the Medical Laboratory

Chapter 1: Introduction

This chapter includes:

- Guideline's scope and applicable exclusions
- Background information pertinent to the guideline's content
- Standard precautions information
- "Note on Terminology" that highlights particular use and/or variation in use of terms and/or definitions
- Terms and definitions used in the guideline
- Abbreviations and acronyms used in the guideline

1.1 Scope

This guideline provides laboratories with basic and general toxicology testing information for medical purposes. The guideline discusses the most common specimen types used for toxicology testing, which include urine, serum, plasma, blood, oral fluid, hair, meconium, sweat, and breath. Other matrixes that can be used for toxicology testing include, but are not limited to, gastric contents, umbilical cord and cord blood, amniotic fluid, breast milk, nails, dried blood spots, and placental tissue. However, these other matrixes are not discussed in this guideline.

The measurands considered in this guideline include drugs of abuse, therapeutic drugs, over-the-counter (OTC) medications, ethanol, and miscellaneous substances. Test methodologies include rapid screening measurement procedures designed to produce only positive or negative results (qualitative tests), routine semiquantitative and quantitative tests, and more complex definitive measurement procedures.

C52 also provides useful guidance when performing drug testing for measurands other than those specifically included and for purposes and situations not covered.

This guideline is primarily applicable to drug testing performed in medical 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 in other testing venues, such as large specialized reference laboratories, dedicated forensic laboratories, and the various sites in which point-of-care "field testing" may occur.

1.2 Background

1.2.1 Purposes of Clinical Toxicology Testing

Clinical toxicology testing is performed for medical reasons. The specimens are collected from patients to diagnose, monitor, and treat pathological conditions. Clinical toxicology testing often involves the following situations: