CLINICAL AND LABORATORY STANDARDS INSTITUTE®

2nd Edition

C49

Analysis of Body Fluids in Clinical Chemistry

This guideline provides information for the medical laboratory for evaluating measurement procedures, as well as a strategy to characterize assay performance, when applied to body fluid matrixes. Key concepts that apply to the entire test cycle, including preexamination, examination, and postexamination phases of body fluid testing, are discussed.

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

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C49, 2nd ed.
November 2018
Replaces C49-A

Analysis of Body Fluids in Clinical Chemistry

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Abstract

Clinical and Laboratory Standards Institute guideline C49—*Analysis of Body Fluids in Clinical Chemistry* provides guidance to the medical laboratory for evaluating measurement procedures, as well as a strategy to characterize assay performance, when applied to body fluid matrixes. Key concepts that apply to the entire test cycle, including preexamination, examination, and postexamination phases of body fluid testing are discussed. This guideline does not consider serum, plasma, whole blood, or fluids for which measurement procedures typically have performance claims in the measurement procedure documentation. Appendix A provides didactic content on the anatomy, physiology, and pathophysiology of fluid accumulation. Appendix B provides the medical rationale for quantifying measurands in body fluids and the interpretation of results in the context of disease. Appendix C provides the user with a quick reference guide to the suggested utility of fluid and measurand combinations.

Clinical and Laboratory Standards Institute (CLSI). *Analysis of Body Fluids in Clinical Chemistry*. 2nd ed. CLSI guideline C49 (ISBN 978-1-68440-023-2 [Print]; ISBN 978-1-68440-024-9 [Electronic]). Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2018.

CLINICAL AND LABORATORY STANDARDS INSTITUTE®

Suggested Citation

CLSI. *Analysis of Body Fluids in Clinical Chemistry.* 2nd ed. CLSI guideline C49. Wayne, PA: Clinical and Laboratory Standards Institute; 2018.

Previous Editions:
June 2006, April 2007

ISBN 978-1-68440-023-2 (Print)
ISBN 978-1-68440-024-9 (Electronic)
ISSN 1558-6502 (Print)
ISSN 2162-2914 (Electronic) Volume 38, Number 20

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Acknowledgment for the Expert Panel on Clinical Chemistry and Toxicology

CLSI, the Consensus Council, and the Document Development Committee on Analysis of Body Fluids in Clinical Chemistry gratefully acknowledge the Expert Panel on Clinical Chemistry and Toxicology for serving as technical advisors and subject matter experts during the development of this guideline.

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Acknowledgment

CLSI, the Consensus Council, and the Document Development Committee on Analysis of Body Fluids in Clinical Chemistry gratefully acknowledge the following volunteers for their important contributions to the development of this guideline:

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Foreword

Since C49's original publication, regulatory requirements for laboratories performing body fluid testing have changed. In addition, the number of publications in peer-reviewed journals as well as single case studies documenting the diagnostic need to test a number of measurands in body fluids has increased substantially. To comply with regulatory requirements when choosing to offer body fluid testing, medical laboratories should determine which fluid types are appropriate to accept for testing through collaborating with the requesting clinical areas, characterizing measurement procedure suitability, and understanding performance limitations of methods not designated for use on body fluids by *in vitro* diagnostics manufacturers. This information is critical to ensure the accuracy of reported results, because physicians use these data for patient management.

Overview of Changes

This guideline replaces the previous edition of the approved guideline, C49-A, published in April 2007. This second edition of C49 provides medical laboratories with a strategy to evaluate method performance, as well as guidance on which measurands have clinical relevance when measured in body fluid matrixes. Several changes were made in this edition, including:

- Providing medical laboratories with a workflow that:
  - Outlines important preexamination conditions to consider when validating and performing body fluid testing (see Chapter 3)
  - Discusses key concepts for body fluid matrix considerations and measurement procedure selection (see Chapter 4)
  - Offers strategies for developing a measurement procedure validation plan to provide meaningful and accurate results for appropriate and timely patient management (see Chapter 5)
  - Offers recommendations for reporting body fluid tests to aid in the diagnostic interpretation of results (see Chapter 6)
  - Covers general laboratory QA activities to support ongoing body fluid testing (see Chapter 7)
- Assisting laboratories in minimizing patient risk and maximizing diagnostic return by:
  - Providing general information related to body fluid composition and pathogenic processes that lead to accumulation of body fluids (see Appendix A)
  - Defining the measurands and their expected concentrations that have diagnostic utility when measured in body fluids (see Appendix B)

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

Body fluid, exudate, matrix effect, measurement procedure validation, organ injury, serous fluid, synovial fluid, transudate

Analysis of Body Fluids in Clinical Chemistry

Chapter 1: Introduction

This chapter includes:

- Guideline's scope and applicable exclusions
- 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

C49 provides guidance to medical laboratories for the appropriate application of measurement procedures for body fluid testing and for reporting results. This guideline primarily focuses on the recommended practice for verification of measurement procedures for measurands in body fluids and is applicable for laboratory testing requests on body fluids that do not have performance claims in the manufacturer's package insert or an equivalent validated laboratory-developed test. C49 does not cover serum, plasma, whole blood, urine, or fluids (eg, CSF) for which measurement procedures typically have performance claims in the manufacturer's package insert.

1.2 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. Published guidelines are available that discuss the daily operations of diagnostic medicine in humans and animals while encouraging a culture of safety in the laboratory.[1] 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.[2]

1.3 Terminology

1.3.1 A Note on Terminology

CLSI, as a global leader in standardization, is firmly committed to achieving global harmonization whenever 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 different countries and regions and that legally required use of terms, regional usage, and different consensus timelines are all important considerations in the harmonization process. CLSI recognizes its important role in these efforts, and its consensus process