CLINICAL AND LABORATORY STANDARDS INSTITUTE®

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GP40-A4-AMD

Preparation and Testing of Reagent Water in the Clinical Laboratory; Approved Guideline—Fourth Edition

This document provides guidelines on water purified for clinical laboratory use; methods for monitoring water quality and testing for specific contaminants; and water system design considerations.

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

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Clinical and Laboratory Standards Institute
950 West Valley Road, Suite 2500
Wayne, PA 19087 USA
P: +1.610.688.0100
F: +1.610.688.0700
www.clsi.org
standard@clsi.org

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Preparation and Testing of Reagent Water in the Clinical Laboratory; Approved Guideline—Fourth Edition

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W. Gregory Miller, PhD, DABCC, FACB
Erich L. Gibbs, PhD
Dennis W. Jay, PhD, DABCC, FACB
Kenneth W. Pratt, PhD
Bruno Rossi, MS
Christine M. Vojt, MT(ASCP), MS
Paul Whitehead, PhD, CChem, FRSC

Abstract

CLSI document GP40-A4-AMD—*Preparation and Testing of Reagent Water in the Clinical Laboratory; Approved Guideline—Fourth Edition* provides information on water purity requirements for clinical laboratory testing, validation of specifications, technology available for water purification, and test procedures to monitor and trend water purity parameters.

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Committee Membership

The changes in this amendment were approved by the Consensus Committee on Clinical Chemistry and Toxicology as follows.

Consensus Committee on Clinical Chemistry and Toxicology

David G. Grenache, PhD, DABCC, FACB
Chairholder
University of Utah, ARUP Laboratories
Salt Lake City, Utah, USA

Loralie J. Langman, PhD
Vice-Chairholder
Mayo Clinic
Rochester, Minnesota, USA

Julianne Cook Botelho, PhD
Centers for Disease Control and Prevention
Atlanta, Georgia, USA

Yung W. Chan, MT(ASCP)
FDA Center for Devices and Radiological Health
Rockville, Maryland, USA

Corinne R.Fantz, PhD, DABCC
Emory University
Atlanta, Georgia, USA

T. Scott Isabell, PhD, DABCC, FACB
Nova Biomedical Corporation
Chicago, Illinois, USA

Jessie Shih, PhD
Abbott
Abbott Park, Illinois, USA

Graham Henderson White, PhD
Flinders Medical Centre
South Australia, Australia

Jack Zakowski, PhD, FACB
Beckman Coulter
Brea, California, USA

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CLSI and the Consensus Committee on Clinical Chemistry and Toxicology gratefully acknowledge the following individual for reviewing all data and providing all appropriate amendments to this document:

W. Gregory Miller, PhD
Virginia Commonwealth University
Richmond, Virginia, USA

Committee Membership

Area Committee on Clinical Chemistry and Toxicology

David A. Armbruster, PhD, DABCC, FACB
Chairholder
Abbott Laboratories
Abbott Park, Illinois

W. Gregory Miller, PhD
Vice-Chairholder
Virginia Commonwealth University
Richmond, Virginia

John Rex Astles, PhD, FACB
Centers for Disease Control and Prevention
Atlanta, Georgia

David M. Bunk, PhD
National Institute of Standards and Technology
Gaithersburg, Maryland

Neil Greenberg, PhD
Ortho-Clinical Diagnostics, Inc.
Rochester, New York

Christopher M. Lehman, MD
Univ. of Utah Health Sciences Center
Salt Lake City, Utah
Richard R. Miller, Jr.
Dade Behring Inc.
Newark, Delaware

Linda Thienpont, PhD
University of Ghent
Gent, Belgium

Hubert Vesper, PhD
Centers for Disease Control and Prevention
Atlanta, Georgia

Advisors

Mary F. Burritt, PhD
Mayo Clinic
Rochester, Minnesota

Paul D'Orazio, PhD
Instrumentation Laboratory
Lexington, Massachusetts

Carl C. Garber, PhD, FACB
Quest Diagnostics, Incorporated
Teterboro, New Jersey

Uttam Garg, PhD, DABCC
Children's Mercy Hospital
Kansas City, Missouri

Harvey W. Kaufman, MD
Quest Diagnostics, Incorporated
Lyndhurst, New Jersey

Gary L. Myers, PhD
Centers for Disease Control and Prevention
Atlanta, Georgia

David Sacks, MD
Brigham and Women's Hospital and Harvard Medical School
Boston, Massachusetts

Bette Seamonds, PhD
Mercy Health Laboratory
Swarthmore, Pennsylvania

Dietmar Stöckl, PhD
University of Ghent
Gent, Belgium

Thomas L. Williams, MD
Nebraska Methodist Hospital
Omaha, Nebraska

Jack Zakowski, PhD, FACB
Beckman Coulter, Inc.
Brea, California

Working Group on Reagent Water

W. Gregory Miller, PhD, **Chairholder**
Virginia Commonwealth University
Richmond, Virginia

Erich L. Gibbs, PhD
High-Q, Inc.
Wilmette, Illinois

Dennis W. Jay, PhD, DABCC, FACB
St. Jude Children's Research Hospital
Memphis, Tennessee

Kenneth W. Pratt, PhD
National Institute of Standards and Technology
Gaithersburg, Maryland

Bruno Rossi, MS
Millipore SAS
Guyancourt, France

Christine M. Vojt, MT(ASCP), MS
Ortho-Clinical Diagnostics, Inc.
Rochester, New York

Paul Whitehead, PhD, CChem, FRSC
ELGA LabWater, Lane End, Bucks, United Kingdom

Advisors

Kelli Buckingham-Meyer
Montana State University
Bozeman, Montana

Darla M. Goeres, MS
Montana State University
Bozeman, Montana

Marilyn J. Gould, PhD
Falmouth, Massachusetts

Zenaida Maicas, PharmD
Cape Neddick, Maine

Stephane Mabic
Millipore SAS
Guyancourt, France

Alan Mortimer, CChem, FRSC
ELGA LabWater, Lane End, Bucks, United Kingdom

Keith W. Richardson
Associates of Cape Cod, Inc.
Woods Hole, Massachusetts

Staff

Clinical and Laboratory Standards Institute
Wayne, Pennsylvania

John J. Zlockie, MBA
Vice President, Standards

Tracy A. Dooley, BS, MLT(ASCP)
Staff Liaison

Staff (Continued)

Donna M. Wilhelm
Editor

Melissa A. Lewis
Assistant Editor

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Ellen Jo Baron, PhD, Stanford University Hospital and Medical School
Anita Highsmith, Highsmith Environmental Consultants, Inc.
Gary A. O'Neill, PhD, Selective Micro Technologies
Bette Seamonds, PhD, DABCC, Mercy Health Laboratories

Contents

Contents (Continued)

Summary of Changes in GP40 Amendment

Foreword

- For clarification, added the statement "In situations in which the CLRW purity may not be satisfactory, or may not be required, a specified type of purified water can be validated as fit-for-purpose and used by a laboratory as a special reagent water."

Sections 4 and 4.1

- Identification of where frequency advice is discussed, with the addition of the title **Section 4.1, Frequency of Monitoring Water Purity Parameters.**

- Added "Making more frequent measurements" to the statement "Setting an alert threshold for a measured parameter at a more stringent level than the validated water purity can reduce the risk from gradual drift; however, this strategy does not protect against abrupt changes."

Section 4.2.2.2 (formerly Section 4.1.2.2)

- Corrected "<" to "≤"

Section 4.3.1 (formerly Section 4.2.1)

- For clarification, added the statement, "Note that the 10 MΩ·cm specification is not intended to be used as an indicator when ion-exchange resin tanks need to be replaced; manufacturers' instructions should be followed for specific purification systems."

Section 4.4 (formerly Section 4.3)

- For clarification, added the statement "CLRW is intended to meet the purity requirements for many clinical laboratory procedures. However, some laboratory procedures may require water of greater or lesser purity than that of CLRW."

Section 7.2.1.3

- Corrected "less than" to "≤"

Summary of Consensus and Delegate Comments and Working Group Responses

- The Summary of Consensus and Delegate Comments and Working Group Responses was removed as part of this amendment. This summary is on file at the CLSI office and available upon request by contacting CLSI at 610.688.0100 or standard@clsi.org.

Foreword

This edition of the guideline includes updated information regarding the preparation and testing of reagent water in clinical laboratories. Specifications are based on measuring parameters that serve as indicators for the total ionic, organic, and microbial contamination. Emphasis is placed on the value of trending these parameters as an effective way to control the quality and consistency of purified laboratory water, as well as the importance of validating that a given type of laboratory water is fit for its intended purpose. A new section provides guidelines for water purification system validation, ongoing maintenance, and revalidation on a recurring schedule.

The Type I, II, III designations for types of purified laboratory water, used in the previous edition, have been replaced with purity types that provide more meaningful specifications for clinical laboratory testing. Clinical laboratory reagent water (CLRW) can be used in place of Type I and Type II water for most applications. In situations in which the CLRW purity may not be satisfactory, or may not be required, a specified type of purified water can be validated as fit-for-purpose and used by a laboratory as a special reagent water. Autoclave and wash water will generally be a satisfactory replacement for Type III water. The definitions of the new types of water include parameters that were not used in previous editions and some of the parameters that were used in previous editions.

Resistivity measurement has been retained to monitor inorganic impurities. The previous edition recommended that water purification systems include a stage to reduce organic contamination, but required no control. This edition recognizes that organic contamination can be difficult to remove from feed water, can be introduced by components of water purification systems or biofilms, and must be controlled. Therefore, a total organic carbon (TOC) parameter has been added. Note that on-line or in-house measurements of TOC are not required. It is acceptable to send CLRW samples to a referral laboratory for TOC measurement. (See Section 7.5 for additional information on contamination risks when TOC is at low levels.)

Plate counting of colonies is a widely used method for monitoring the level of microorganisms in purified laboratory water, and this edition continues to specify this approach. However, epifluorescence and endotoxin testing have been added as optional tests, because they provide additional information and results can be determined quickly.

Specifications and methods for measuring pH and silicates, as SiO_2, have not been carried forward from the previous edition. Resistivity is more sensitive than pH to H^+ and OH^- contamination. Resistivity is not a sensitive indicator of weakly ionized contaminants, which may elute as concentrated pulses from ion-exchange beds when they approach depletion. However, the release of weakly ionized contaminants (silica being but one example) can be avoided by appropriate design and regular maintenance of ion-exchange components.

A parameter for sterility of general-purpose purified laboratory water has not been included in this edition of the guideline, because most clinical laboratory applications do not require sterile water. Water can be sterilized as necessary for some applications; however, the method of sterilization may degrade the purity of the water.

Key Words

Autoclave and wash water, bottled water, clinical laboratory reagent water, high-purity water, instrument feed water, purified water, reagent water, special reagent water, water purification

Preparation and Testing of Reagent Water in the Clinical Laboratory; Approved Guideline—Fourth Edition

1 Scope

A number of types of purified water for use in clinical laboratory testing procedures are specified:

- clinical laboratory reagent water (CLRW);
- special reagent water (SRW);
- instrument feed water;
- water supplied by a method manufacturer;
- autoclave and wash water; and
- commercially bottled, purified water.

Procedures are provided for measuring parameters that monitor ionic, organic, and microbial contamination in purified laboratory water. These parameters should be monitored over time to identify trends in performance so corrective action can be taken before a parameter exceeds specified limits. Recommendations are provided to control particulate and colloidal contamination. The guideline includes validation by the laboratory that a selected type of water is fit for its intended purpose. Suggested approaches for validation of water purification systems are included.

It is beyond the scope of this guideline to recommend specific types of water purification systems. Instead, the guideline provides information about discrete purification technologies and monitoring strategies that can be applied in various combinations to achieve and maintain the required water purity.

2 Introduction

The goal of every clinical laboratory is to produce accurate results. Purified water constitutes the major component of many reagents, buffers, and diluents used in clinical laboratory testing. It can also become an indirect component of tests when it is used for washing and sanitizing instruments and laboratory ware, generating autoclave steam, etc. Inadequate control of contamination in purified water is an important potential cause of laboratory error.

This guideline recommends measuring certain parameters of purified water used in clinical laboratory applications as a means of quality control for purification systems. The parameters are: *resistivity*, an indicator of ionic contamination; *total organic carbon*, an indicator of organic contamination; and *viable plate counts*, an indicator of microorganism contamination. Epifluorescence and endotoxin testing are included as optional approaches for measuring contamination from microbial sources. Particulate contamination is controlled by including appropriate filtration, or distillation, in the purification system. The guideline is not intended to assure the adequacy of purified water for a given laboratory application; rather, water of a specified purity must be validated as fit for use in a particular laboratory application. Any parameters used to specify a type of purified water, or to monitor the performance of a purification system, must be measured frequently enough to detect potential changes in the system, and the measurement results should be monitored for trends to anticipate maintenance before the water quality degrades to a point that will cause problems with laboratory testing.

Other organizations have published guidelines and specifications for purified water intended for various applications. Water conforming to the guidelines and specifications of these organizations may or may not be equivalent to the types of purified water described in this CLSI guideline. Any type of purified water should be validated as fit for purpose before being used in clinical laboratory testing.