CLINICAL AND LABORATORY STANDARDS INSTITUTE®

1st Edition

AUTO15

Autoverification of Medical Laboratory Results for Specific Disciplines

This guideline includes detailed information for design, testing, validation, implementation, and ongoing support of an autoverification algorithm system for use in the medical laboratory.

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

Clinical and Laboratory Standards Institute

Setting the standard for quality in medical laboratory testing around the world.

The Clinical and Laboratory Standards Institute (CLSI) is a not-for-profit membership organization that brings together the varied perspectives and expertise of the worldwide laboratory community for the advancement of a common cause: to foster excellence in laboratory medicine by developing and implementing medical laboratory standards and guidelines that help laboratories fulfill their responsibilities with efficiency, effectiveness, and global applicability.

Consensus Process

Consensus—the substantial agreement by materially affected, competent, and interested parties—is core to the development of all CLSI documents. It does not always connote unanimous agreement but does mean that the participants in the development of a consensus document have considered and resolved all relevant objections and accept the resulting agreement.

Commenting on Documents

CLSI documents undergo periodic evaluation and modification to keep pace with advances in technologies, procedures, methods, and protocols affecting the laboratory or health care.

CLSI's consensus process depends on experts who volunteer to serve as contributing authors and/or as participants in the reviewing and commenting process. At the end of each comment period, the committee that developed the document is obligated to review all comments, respond in writing to all substantive comments, and revise the draft document as appropriate.

Comments on published CLSI documents are equally essential and may be submitted by anyone, at any time, on any document. All comments are managed according to the consensus process by a committee of experts.

Appeal Process

When it is believed that an objection has not been adequately considered and responded to, the process for appeal, documented in the CLSI *Standards Development Policies and Processes,* is followed.

All comments and responses submitted on draft and published documents are retained on file at CLSI and are available upon request.

Get Involved—Volunteer!

Do you use CLSI documents in your workplace? Do you see room for improvement? Would you like to get involved in the revision process? Or maybe you see a need to develop a new document for an emerging technology? CLSI wants to hear from you. We are always looking for volunteers. By donating your time and talents to improve the standards that affect your own work, you will play an active role in improving public health across the globe.

For additional information on committee participation or to submit comments, contact CLSI.

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

AUTO15, 1st ed.
September 2019

Autoverification of Medical Laboratory Results for Specific Disciplines

William Marquardt, C(ASCP), MBA
Linda Stang, MLT
Jim Yakimec, BS
Jennifer A. Brown, PhD
William A. Coughlin
Pilar Fernandez-Calle, MD, PhD
Jonathan Foskett, MT(ASCP), PhD
Jay Jones, PhD, FACB
Martin H. Kroll, MD
Michael Novak
Arno Pieter Theron
Richard Y. Wang, DO
Diane M. Washburn, MT(ASCP) SH

Abstract

Clinical and Laboratory Standards Institute guideline AUTO15—*Autoverification of Medical Laboratory Results for Specific Disciplines* provides general guidance, as well as discipline-specific direction, on design and validation of an autoverification system. Autoverification is the process by which laboratory analyte results are accepted or rejected for automatic delivery to a patient data repository. This process uses a predetermined set of criteria applied at one or more points during the electronic flow of information. This guideline is provided for use by laboratorians, personnel responsible for information systems, and vendors for medical informatics and *in vitro* diagnostics.

Clinical and Laboratory Standards Institute (CLSI). *Autoverification of Medical Laboratory Results for Specific Disciplines*. 1st ed. CLSI guideline AUTO15 (ISBN 978-1-68440-056-0 [Print]; ISBN 978-1-68440-057-7 [Electronic]). Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2019.

Suggested Citation

CLSI. *Autoverification of Medical Laboratory Results for Specific Disciplines*. 1st ed. CLSI guideline AUTO15. Wayne, PA: Clinical and Laboratory Standards Institute; 2019.

ISBN 978-1-68440-056-0 (Print)
ISBN 978-1-68440-057-7 (Electronic)
ISSN 1558-6502 (Print)
ISSN 2162-2914 (Electronic) Volume 39, Number 11

Committee Membership

Consensus Council

Dennis J. Ernst, MT(ASCP), NCPT(NCCT)
Chairholder
Center for Phlebotomy Education
USA

Mary Lou Gantzer, PhD, FACB
Vice-Chairholder
USA

Julia H. Appleton, MT(ASCP), MBA
Centers for Medicare & Medicaid Services
USA

J. Rex Astles, PhD, FACB, DABCC
Centers for Disease Control and Prevention
USA

Thomas R. Fritsche, MD, PhD, FCAP, FIDSA
Marshfield Clinic
USA

Loralie J. Langman, PhD, DABCC, FACB, F-ABFT
Mayo Clinic
USA

Tania Motschman, MS, MT(ASCP)SBB
Laboratory Corporation of America
USA

James R. Petisce, PhD
BD Diagnostic Systems
USA

Andrew Quintenz
Bio-Rad Laboratories, Inc.
USA

Robert Rej, PhD
New York State Department of Health – Wadsworth Center
USA

Zivana Tezak, PhD
FDA Center for Devices and Radiological Health
USA

Document Development Committee on Autoverification

William Marquardt, C(ASCP), MBA
Chairholder
LABSCO
USA

Linda Stang, MLT
Vice-Chairholder
University of Alberta Hospital
Canada

Jim Yakimec, BS
Committee Secretary
Vancouver Coastal Health Authority
Canada

Jennifer A. Brown, PhD
Regions Hospital
USA

William A. Coughlin
Data Innovations LLC
USA

Pilar Fernandez-Calle, MD, PhD
La Paz University Hospital
Spain

Jonathan Foskett, MT(ASCP), PhD
Siemens Healthcare
USA

Jay Jones, PhD, FACB
USA

Richard Y. Wang, DO
Centers for Disease Control and Prevention
USA

Diane M. Washburn, MT(ASCP) SH
Sentara Healthcare
USA

Staff

Clinical and Laboratory Standards Institute
USA

David E. Sterry, MT(ASCP)
Project Manager

Kunal Hivale
Project Manager

Megan L. Tertel, MA, ELS
Editorial Manager

Catherine E.M. Jenkins
Editor

Kristy L. Leirer, MS
Editor

Laura Martin
Editor

Acknowledgment for the Expert Panel on Automation and Informatics

CLSI, the Consensus Council, and the Document Development Committee on Autoverification gratefully acknowledge the Expert Panel on Automation and Informatics for serving as technical advisors and subject matter experts during the development of this guideline.

Expert Panel on Automation and Informatics

Ed Heierman, PhD
Chairholder
Abbott
USA

Jyh-Ching Yaur
Vice-Chairholder
Siemens Healthcare Diagnostics Inc.
USA

Ulysses J. Balis, MD
University of Michigan
USA

Ettore Cavallaro, PhD
Ortho Clinical Diagnostics
France

David Chou, MD
University of Washington Medical Center
USA

Andrzej J. Knafel, PhD, CISA, CISSP, CCSP
Roche Diagnostics International Ltd.
Switzerland

Elizabeth Kenimer Leibach, EdD, MS, MLS(ASCP)cm, SBBcm
Rutgers University
USA

Manjula Gama Ralalage, MBBS, MSc
Centers for Disease Control and Prevention
USA

Richard S. Seaberg, MT(ASCP)
NSLIJ HS & Long Island Jewish Medical Center
USA

Li You, PhD
FDA Center for Devices and Radiological Health
USA

Acknowledgment

CLSI, the Consensus Council, and the Document Development Committee on Autoverification gratefully acknowledge the following volunteers for their important contributions to the development of this guideline:

Martin H. Kroll, MD
Quest Diagnostics
USA

Michael Novak
Roche Diagnostics Corporation
USA

Arno Pieter Theron
PathCare Pathology Laboratory
South Africa

Contents

Foreword

This guideline is an extension of CLSI document AUTO10,[1] published in 2006. CLSI document AUTO10[1] discusses general Boolean logic principles and autoverification algorithm design and briefly covers preexamination, examination, and postexamination elements that might be included at decision points in an autoverification system. It explains the definition and principle behind delta checks and compares the use of various numerical limits, such as reference intervals, critical-risk results, and medical decision values. CLSI document AUTO10[1] also provides details on repeat analysis, follow-up, and the possibility of using health care provider profiles in algorithm design. Additionally, general information on regulatory and accreditation compliance and validation of algorithms is included.

Logistics and technical ability (through LIS), instrument software, or middleware (MW) to autoverify medical laboratory results have been available for some time. However, many North American laboratories are not using autoverification for some (or all) of the laboratory's key areas where it is a plausible option.[2] The need for autoverification in medical laboratories stems from many contributing factors. Currently, there are three major concerns in the medical laboratory: laboratorian shortages,[3] quality requirements, and a demand for shorter turnaround times.[4,5] Autoverification covers all these issues. However, implementing an autoverification system in the average laboratory is challenging because of the same issues it manages. When an autoverification system is designed from current manual review processes, multiple rules and interactions occur. At each stage, information that would otherwise come from laboratorian intervention should be captured. This information includes:

- What detail is being reviewed or sought out?
- What is the follow-up to that detail and is it a manual process (eg, repeat, reflex another test, make a dilution, investigate for X)?
- Is it possible that one (or more) software programs that interact with this information can detect that detail and possibly start, complete, or provide an alert to the desired follow-up? If not, is there a hybrid automated/manual solution that could provide the same function?

For AUTO15, consideration has been taken to make the autoverification approach scalable and actionable and thus suitable across laboratories, patient types, and acuity. Different approaches to implementing autoverification range from using basic minimum ranges to complex cascading Boolean rule sets; AUTO15 provides direction along this continuum.

Some vendors offer predefined rule sets that can be purchased for autoverification. However, laboratory staff should understand the variables that exist from both a laboratory (instrument, MW, LIS) and clinical perspective and that these variables can make those rule sets ineffective and potentially dangerous. There are currently no autoverification standards for many departments in the medical laboratory. AUTO15 helps laboratories develop their own standards based on their needs and pathologist (or director) requirements.

This guideline contains discipline-specific algorithmic design concepts; assay-specific preexamination, examination, and postexamination concerns; and result-specific suggestions for definable numerical limits that can be considered when local algorithms are developed. Defined numbers (eg, 28 to 38 seconds) do not apply to all instrument-reagent-population combinations for a given assay. However, terms such as "reference interval" and "critical-risk results," which are applicable in most assays, are used. Where possible, guidance for specific intervention from a laboratorian, because of the algorithm, is included in this guideline.

In addition to the information provided in this guideline, other permutations may be added to these guidelines based on local patient populations, health care provider, instrumentation, reagents, conditions, etc. Local statistics and/or studies may be used to define criteria. For example, if clotted samples are found to be a high percentage of samples with a result below reference interval for a given test, values below reference interval may be held back from autoverification to verify sample integrity. Each chapter contains discipline- or test-specific validation guidelines to aid the user in confirming that the algorithms or rules perform as expected. Additional validation may be needed, depending on the exact steps used in the autoverification system's design.

The laboratory should follow regulatory and accreditation requirements for autoverification (including validation and postvalidation follow-up) where applicable. Awareness of regulatory and accreditation requirements is the laboratory's or user's responsibility. Current existing regulatory and accreditation requirement details are included where relevant. Because AUTO15 is intended for global use, including a comprehensive list of regulatory and accreditation requirements is not feasible.

Various subchapters contain some material that appears more than once. Basic information for all users is found in Subchapter 2.3, whereas specific information relating to the same concepts are found in subchapters pertaining to certain laboratory areas. This redundancy provides more specific information, examples, or levels of detail that could not be cohesively included in the basic subchapter.

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

Algorithm design, autoverification, Boolean logic, implementation, laboratory information system, middleware, rules, validation

Autoverification of Medical Laboratory Results for Specific Disciplines

Chapter 1: Introduction

This chapter includes:

- Guideline's scope and applicable exclusions
- Background information pertinent to the guideline's content
- "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 recommendations for designing autoverification algorithms for specific disciplines and types of testing in the medical laboratory (eg, chemistry, coagulation, hematology, immunochemistry, infectious diseases, toxicology, and urinalysis), as well as guidance for human intervention, whether results are generated from an automated system or manual result entry. Additionally, it provides recommendations for the creation of scalable algorithms that provide levels of adaptation from simple to more complex criteria and the actionable implementation of autoverification in the medical laboratory.

The intended users of this guideline are clinical pathologists, medical directors, and medical technology staff responsible for the timely delivery of actionable health care information provided by medical laboratories. Additionally, laboratory personnel responsible for the information systems, medical informatics vendors, and *in vitro* diagnostics vendors should ensure their products and services comply with the recommendations provided in this guideline.

This guideline is not intended to provide a specific programming language, vendor-specific implementations for autoverification for a discipline, or analyte-specific autoverification algorithms. This guideline is not applicable to all possible medical permutations that are present in the medical laboratory respective to a specific discipline. These recommendations are not applicable to transfusion medicine, microbiology, molecular medicine, anatomic pathology, or point-of-care testing.

1.2 Background

From large laboratories where tracks carry specimens onto centrifuges and to analyzers, to small laboratories where one analyzer is used to measure over 100 different analytes, automation is widely used. Even small point-of-care instruments are becoming more complex and automated. However, review and release of results continues to be a primarily manual process that can take up a great deal of a laboratorian's time. With increasing labor shortages and demand for quality improvement and shorter turnaround time (TAT) requirements, implementing an autoverification system is a recommended solution.