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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.

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Autoverification of Medical Laboratory Results for Specific Disciplines

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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.

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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.

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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

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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.

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