

Validation of Automated Systems for Immuno-hematological Testing Before Implementation; Approved Guideline

This document provides guidance to the end user and laboratory for validation of automated systems used in immuno-hematological testing before implementation.

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



Validation of Automated Systems for Immunohematological Testing Before Implementation; Approved Guideline

Katharine Appleton Downes, MD
Melanie Champion, MBA, MT(ASCP), SBB, HP
Mary Kay Golisano, MPA, MT(ASCP), SBB
Kathie Goodwin, MBA, MT(ASCP)BB
Sheryl A. Kochman, MT(ASCP)
Michael E. Passwater, MT(ASCP)SBB
James W. Piper, PhD
Kathleen E. Puca, MD, MT(ASCP)SBB
Betty-Ann Vesala, MLT(CSMLS), CQM
Candace Williams, MT(ASCP)SBB
Raya D. Zerger, MT(ASCP) SBB

Abstract

Clinical and Laboratory Standards Institute document I/LA33-A—*Validation of Automated Systems for Immunohematological Testing Before Implementation; Approved Guideline* provides guidance to the user and laboratory for validating an automated system for immunohematological testing. Current automated system methodologies are discussed. This document addresses the development of a validation plan and the information required for its creation. It includes guidelines for elements and tasks of the validation process, including installation qualification, operational qualification, and performance qualification. For each of these qualifications, the purpose, prerequisites, responsibilities, considerations for and examples of test cases, and activities performed are included. The Appendix contains templates that may be used by the laboratory for development of test cases related to and for different aspects of installation qualification, operational qualification, and performance qualification.

Clinical and Laboratory Standards Institute (CLSI). *Validation of Automated Systems for Immunohematological Testing Before Implementation; Approved Guideline*. CLSI document I/LA33-A (ISBN 1-56238-714-6). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2009.

The Clinical and Laboratory Standards Institute consensus process, which is the mechanism for moving a document through two or more levels of review by the health care community, is an ongoing process. Users should expect revised editions of any given document. Because rapid changes in technology may affect the procedures, methods, and protocols in a standard or guideline, users should replace outdated editions with the current editions of CLSI/NCCLS documents. Current editions are listed in the CLSI catalog and posted on our website at www.clsi.org. If your organization is not a member and would like to become one, and to request a copy of the catalog, contact us at: Telephone: 610.688.0100; Fax: 610.688.0700; E-Mail: customerservice@clsi.org; Website: www.clsi.org



Copyright ©2009 Clinical and Laboratory Standards Institute. Except as stated below, neither this publication nor any portion thereof may be adapted, copied, or otherwise reproduced, by any means (electronic, mechanical, photocopying, recording, or otherwise) without prior written permission from Clinical and Laboratory Standards Institute (“CLSI”).

CLSI hereby grants permission to each individual member or purchaser to make a single reproduction of this publication for use in its laboratory procedure manual at a single site. To request permission to use this publication in any other manner, contact the Executive Vice President, Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA.

Suggested Citation

CLSI. *Validation of Automated Systems for Immunohematological Testing Before Implementation; Approved Guideline*. CLSI document I/LA33-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2009.

Proposed Guideline

April 2009

Approved Guideline

December 2009

ISBN 1-56238-714-6

ISSN 0273-3099

Contents

Abstract.....	i
Committee Membership.....	iii
Foreword.....	vii
1 Scope.....	1
2 Standard Precautions.....	1
3 Terminology.....	1
3.1 Note on Terminology.....	1
3.2 Definitions.....	2
3.3 Abbreviations and Acronyms.....	9
4 Immunohematology Tests and Automated Systems.....	9
4.1 Blood Typing.....	9
4.2 Red Cell Alloantibody Detection.....	11
4.3 Red Cell Antibody Identification Testing.....	11
4.4 Crossmatch.....	11
4.5 Direct Antiglobulin Testing.....	12
4.6 Other Testing.....	12
4.7 Automated Methods.....	12
5 Validation Process.....	16
5.1 Requirements for Validation.....	17
6 Materials (Reagents, Equipment, and Supplies).....	26
6.1 Samples.....	27
6.2 Controls.....	28
6.3 Labels.....	29
6.4 Reagents.....	29
7 Installation Qualification.....	29
7.1 Purpose.....	29
7.2 Prerequisites.....	30
7.3 Responsibilities.....	30
7.4 Considerations for Test Cases.....	30
7.5 Examples of Test Cases and/or Checklists.....	31
7.6 Activities Performed.....	31
8 Operational Qualification.....	34
8.1 Purpose.....	34
8.2 Prerequisites.....	34
8.3 Responsibilities.....	34
8.4 Considerations for Test Cases.....	34
8.5 Examples of Test Cases and/or Checklists.....	34
8.6 Activities Performed.....	35
9 Performance Qualification.....	38
9.1 Purpose.....	38

Contents (Continued)

9.2 Prerequisites.....38

9.3 Responsibilities.....38

9.4 General Considerations for Performance of Test Cases and/or Checklists.....38

9.5 Examples of Test Cases and/or Checklists42

9.6 General Considerations for Acceptance Criteria43

References.....49

Appendix. Sample Templates and Test Cases51

Summary of Delegate Comments and Subcommittee Responses.....75

The Quality Management System Approach86

Related CLSI Reference Materials87

Foreword

Immunohematological laboratory testing has evolved from test tube–based methods to automated systems that employ a variety of techniques and methods. Automated systems for such testing may bring potential advantages to a laboratory, such as improvements in turnaround time, standardized interpretation of reactions, and positive sample identification using bar-code technology. Increasing use of automated systems in immunohematological testing necessitates the development of a guideline for laboratories for validation of these automated systems.

Before a laboratory can implement an automated system for immunohematological testing, the system should be validated. First, the laboratory should specify the required performance for the automated system. Performance specifications may be defined by local and/or national regulatory requirements and/or medical usefulness requirements. It is the responsibility of the laboratory to determine the applicable requirements. Second, the laboratory should select a system whose vendor’s claims meet the required performance specifications. Finally, the laboratory should verify that it can achieve the vendor’s claimed results. If the validation steps are successful, the automated system is then introduced into routine use for testing.

The subcommittee had the following principal goals during the development of this guideline:

- To develop a validation protocol that is applicable to all currently available immunohematological automated systems independent of the method employed
- To create a guideline that is simple enough to be applicable in laboratories with a wide variety of experience in automated systems and resources, from the small laboratory to the blood donor center
- To develop a protocol that is sufficiently rigorous to address all elements of validation studies
- To develop simplified templates or worksheets as examples for use in data gathering, statistical calculations, and testing of materials

Key Words

Automated system, immunohematological testing, installation qualification, operational qualification, performance qualification, test case, validation

Validation of Automated Systems for Immunohematological Testing Before Implementation; Approved Guideline

1 Scope

This guideline focuses on the validation of automated systems for immunohematological testing in the laboratory. This document assumes that the vendor of the immunohematological automated system (or systems) developed and validated performance claims using protocols in accordance with regulatory requirements. The elements of this document include immunohematology tests and automated systems, validation process, materials, installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ). The intended audience of this guideline is any laboratory that performs immunohematological testing.

This document addresses the validation of automated systems for immunohematological testing before implementation. It is applicable to situations in which validation should be performed before implementation; for example, when changing from a manual platform for immunohematological testing to an automated system, adding an automated system, or changing from one automated system to another automated system. Although this guideline focuses on preimplementation validation, it may also provide useful information for validation postimplementation, such as when adding new intended uses or tests, relocating equipment, or changing reagents and critical materials; when upgrading an existing automated system (eg, new software, hardware, firmware); when a component is modified; when new quality control (QC) material or new or revised software is implemented; or when the laboratory acquires a new laboratory information system (LIS) or Blood Establishment Computer Software (BECS).

The exclusions and limitations of this document include selection of automated systems, prevalidation, manual immunohematological testing, validation of LIS or BECS (refer to CLSI document AUTO08),¹ implementation or postimplementation of automated systems, validation of off-label usage, and validation of a bar-code system (refer to CLSI document AUTO02).²

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 infectious agents and thus are more comprehensive than universal precautions, which are intended to apply only to transmission of blood-borne pathogens. Standard and universal precaution guidelines are available from the US Centers for Disease Control and Prevention.³ For specific precautions for preventing the laboratory transmission of all infectious agents from laboratory instruments and materials and for recommendations for the management of exposure to all infectious diseases, refer to CLSI document M29.⁴

3 Terminology

3.1 Note on Terminology

CLSI, as a global leader in standardization, is firmly committed to achieving global harmonization wherever possible. Harmonization is a process of recognizing, understanding, and explaining differences while taking steps to achieve uniformity. CLSI recognizes that medical conventions in the global metrological community have evolved differently in the United States, Europe, and elsewhere; that these differences are reflected in CLSI, International Organization for Standardization (ISO), and European Committee for Standardization (CEN) documents; and that legally required use of terms, regional usage, and different consensus timelines are all important considerations in the harmonization process. In light of

Related CLSI Reference Materials*

- AUTO02-A2** **Laboratory Automation: Bar Codes for Specimen Container Identification; Approved Standard—Second Edition (2005).** This document provides specifications for use of linear bar codes on specimen container tubes in the clinical laboratory and for use on laboratory automation systems.
- AUTO08-A** **Managing and Validating Laboratory Information Systems; Approved Guideline (2006).** This document provides guidance for developing a protocol for validation of the laboratory information system (LIS), as well as protocols for assessing the dependability of the LIS when storing, retrieving, and transmitting data.
- EP07-A2** **Interference Testing in Clinical Chemistry; Approved Guideline—Second Edition (2005).** This document provides background information, guidance, and experimental procedures for investigating, identifying, and characterizing the effects of interfering substances on clinical chemistry test results.
- EP14-A2** **Evaluation of Matrix Effects; Approved Guideline—Second Edition (2005).** This document provides guidance for evaluating the bias in analyte measurements that is due to the sample matrix (physiological or artificial) when two measurement procedures are compared.
- EP18-A2** **Risk Management Techniques to Identify and Control Laboratory Error Sources; Approved Guideline—Second Edition (2009).** This guideline describes risk management techniques that will aid in identifying, understanding, and managing sources of failure (potential failure modes) and help to ensure correct results. Although intended primarily for *in vitro* diagnostics, this document will also serve as a reference for clinical laboratory managers and supervisors who wish to learn about risk management techniques and processes.
- GP02-A5** **Laboratory Documents: Development and Control; Approved Guideline—Fifth Edition (2006).** This document provides guidance on development, review, approval, management, and use of policy, process, and procedure documents in the medical laboratory community.
- GP21-A3** **Training and Competence Assessment; Approved Guideline—Third Edition (2009).** This document provides background information and recommended processes for the development of training and competence assessment programs that meet quality and regulatory objectives.
- H57-A** **Protocol for the Evaluation, Validation, and Implementation of Coagulometers; Approved Guideline (2008).** This document provides guidance and procedures to the end user and manufacturer for the selection, evaluation, validation, and implementation of a laboratory coagulometer.
- M29-A3** **Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Third Edition (2005).** Based on US regulations, this document provides guidance on the risk of transmission of infectious agents by aerosols, droplets, blood, and body substances in a laboratory setting; specific precautions for preventing the laboratory transmission of microbial infection from laboratory instruments and materials; and recommendations for the management of exposure to infectious agents.

* CLSI documents are continually reviewed and revised through the CLSI consensus process; therefore, readers should refer to the most current editions.

940 West Valley Road ▼ Suite 1400 ▼ Wayne, PA 19087 ▼ USA ▼ PHONE 610.688.0100
FAX 610.688.0700 ▼ E-MAIL: customerservice@clsi.org ▼ WEBSITE: www.clsi.org ▼ ISBN 1-56238-714-6

