EDUCATIONAL COMMENTARY – NEW INSTRUMENT IMPLEMENTATION: FOCUS ON AUTOMATED BLOOD BANKING SYSTEMS

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Learning Objectives

On completion of this exercise, the participant should be able to

- identify at least two resources for developing a validation plan for an automated blood bank testing platform;
- define and differentiate between Installation, Operational, and Performance Qualification; and
- identify a critical control point that requires a risk analysis.

Introduction

Laboratories are under pressure to improve patient care and outcomes while decreasing the cost of operations. Advancing technology in the form of automated, interfaced instruments is one of the most common solutions to this challenge. Acquiring a new instrument and bringing it into production can be a daunting task. If the instrument is an automated blood bank unit, it is possible that you are entering entirely new territory. Although automated chemistry and hematology analyzers have been commonly employed for many years, blood bank instruments are a more recent addition to most laboratories, and they are rapidly becoming commonplace. In a recent College of American Pathologists (CAP) survey, 45% of respondents used an automated unit for at least typing and screening.¹

Blood bank testing historically relied on the manual tube method to identify antigen-antibody reactions. The development of solid-phase gel columns and hemagglutination in microplate wells has enhanced standardization of reaction strengths and provided methodologies that can be automated. Using photometric and/or digital analysis of the results, the images can be read as positive (+), negative (0), or indeterminate (?). Those results are recorded by the system, and tables, computer logic, and/or algorithms are used to produce an interpretation that can be reported electronically (Table 1).
This discussion focuses on the basic steps and considerations in implementing a new automated immunohematologic instrument after it has been purchased. How do you know what to do?

Before you start, ensure that you have historic data available to benchmark any changes to turnaround times, error rates, supply costs, etc. Any new process should be controlled and benchmarked against previous control markers.

Determine Which Regulations Apply to Your Laboratory

Federal, state, and accreditation bodies define specific requirements. It is the responsibility of the laboratory to research and identify which regulations and standards will apply.

Federal

According to CLIA § 493.1253 Standard: Establishment and verification of performance specifications: “… Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (A) Accuracy. (B) Precision. (C) Reportable range of test results for the test system. (ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory’s patient population …”

State

Refer to your state Department of Health Laboratory Guidelines; many follow the CLIA guidelines very closely.
Laboratory Accreditation Agencies

The CAP (All Common Checklist),³ AABB (Technical Manual⁴ and Standards for Blood Banks and Transfusion Services⁵), International Organization for Standardization (ISO 15189),⁶ and The Joint Commission (Laboratory Accreditation Program)⁷ each provide steps and processes to meet CLIA guidelines in slightly different formats. Although you are likely to be accredited through only one agency, you may choose to review several sets of standards to find helpful tips or ways to implement your new system. They all provide detailed expectations and guidelines for implementing your new system.

Other Resources

Clinical and Laboratory Standards Institute (CLSI) documents I/LA33-A⁸ and GP31-A⁹ provide guidance for implementing automated systems. Additional reference materials specific to each element of a validation plan can be found at the CLSI website.

Ask the Vendor

Verify what the vendor supplies in terms of support, documentation, validation plan development, test cases, templates, and supplies.

After compiling the regulatory/accreditation requirements and the vendor information, you are ready to perform the risk assessment and begin developing your validation plan. Once the plan is complete and approved, you are ready to start the series of tasks that make up the plan. Each step or task must be documented for review and approval by the laboratory’s medical director. Thoroughly review each step and ensure that it has been completely vetted before moving to the next level.

Requirements for Validation

Definitions

Critical Control Point (CCP): A point or step at which controls can be applied to prevent, eliminate, or reduce risk to acceptable levels. If the CCP is omitted or not performed adequately, the process is at risk for failure.

Installation Qualification (IQ): Confirmation that each component of the automated system has been installed according to the vendor’s specification and that the functional tests have been performed and documented with expected results.

Operational Qualification (OQ): Confirmation that the automated system is capable of operating within established limits and tolerances.
Performance Qualification (PQ): Confirmation that the automated system produces an acceptable outcome under normal operating conditions and functions according to the laboratory, regulatory, and accrediting agency requirements.

Perform Risk Assessment
There are a number of areas to evaluate in the risk assessment.

- CCPs in the automated testing functions
- CCPs in the software, including a focus on confidentiality and data integrity
- Any step where there could be harm to the patient, employee, or the laboratory if a failure were to occur

Each area that is identified as a risk should be clearly delineated and followed back to a trigger, event, or cause. Information is then collected, analyzed, and the level of risk rated. Based on that level, the risk should be mitigated or eliminated. The risk assessment is used in developing a validation plan and included in each test scenario. CCPs could include the instrument’s ability to link the correct bar code to the correct patient, to identify QC failures and prevent subsequent release of patient results, to identify inadequate or outdated reagent or compromised sample integrity, and so on.

Develop a Validation Plan
A written validation plan must comply with applicable regulatory and accreditation requirements. This plan contains a number of required elements and will be a large document.

1. **Title:** Include the name of the automated system being validated.
2. **Laboratory and Vendor Information:** Names, addresses, key contact people.
3. **Purpose of the Validation:** State the reason for the validation. Include confirmation that the policies, processes, and procedures have been written and that the completion of the plan will provide proof that the system will consistently meet the laboratory requirements.
4. **Description of the Automated System:** Include a detailed overview; intended use according to labeling; technical specifications; all versions of hardware and software; serial numbers; list of reagents, diluents and kits; and a reference to the user’s manual.
5. **Responsibilities:** Clearly delineate individual responsibility for the development of the plan, the review and acceptance of the plan, execution of the validation tasks, and acceptance of the final validation, including results.
6. **Qualifications:** IQ, OQ, and PQ
7. **Vendor Protocols:** Use these as an aid to develop the validation system; however, they cannot replace the laboratory’s internal validation plan.
8. **Limitations of the Automated System:** Identify any system limitations and determine how to handle them. These may include, but are not limited to duplicate bar codes, missing or damaged bar codes on specimens and reagent/cards/plates, compromised specimens (e.g., clotted, hemolyzed, icteric, fibrin, underfilled tubes), unexpected results, use of expired products, missing QC, and incorporating urgent testing into the workflow.

9. **Templates for Test Cases:** Refer to CLSI I/LA 33-A for examples of test templates. Templates should include the following:
   a. what is being validated
   b. prerequisites that should be completed before the test case can be carried out
   c. how the test will be documented (e.g., handwritten, screen capture, printed report)
   d. list of CCPs or tasks as a procedural guide for the test case
   e. expected results
   f. acceptance criteria for the test case
   g. space to record results and any discrepancies
   h. pass/fail for result of the test case
   i. references
   j. documentation of who performed the test, when it was performed, and who reviewed the test, with date reviewed

10. **Acceptance criteria for review of test cases**

11. **Timeline for validation**

12. **Reviews and approvals**

After completing the plan and receiving approval from the laboratory’s medical director, you can begin to compile information and complete the specific tasks that have been outlined.

**Write Procedures**

Procedures for operating the new instrument will need to be established or modified according to CLIA regulations and/or accreditation requirements. System operations, appropriate reporting of patient results, quality control procedures, and maintenance procedures are examples of what should be included. Follow your internal policy/procedure for developing and controlling procedures. Establishing new standard operating procedures is an opportunity to share knowledge with others in your laboratory system. It may also be a good opportunity to develop consistency in procedures within a laboratory system.
Establish Training/Competency

Follow your internal policy/procedure to develop the training program, documents, checklists, and manuals required. The training plan should include validation training and operator training.

Installation Qualification

Installation Qualification (IQ) provides validation that the instrument, with all its components, is placed correctly in the laboratory and validated for performance according to the manufacturer’s guidelines. Successful installation relies heavily on the vendor for support, direction, and definitive limitations / expectations for the platform operation. IQ should be successfully completed and documented before moving on to the OQ process.

Operational Qualification

Operational Qualification (OQ) challenges the automated system and process operating parameters to ensure that they will result in an outcome that meets all defined user requirements under all anticipated conditions of testing, including worst-case testing. To perform OQ validation, the user requirements must already have been defined. These requirements are usually built on the regulatory agencies’ requirements and standards for blood banking, as well as on the laboratory’s own business rules. OQ validation proves that the facility can do business and comply with the rules and regulations for which the transfusion service is responsible and is mandated to follow.

Performance Qualification

Performance Qualification (PQ) demonstrates that the computerized/automated system will consistently produce an acceptable product/output under normal operating conditions. It establishes confidence that accurate, reproducible results are generated using simulated real-world conditions and is performed after the IQ and OQ have been successfully completed. The system should be challenged with a variety of test samples that include both routine and non-routine sample types. Challenges should include very weakly or very strongly positive specimens that prove the repeatability near the limits of detection, antibody detection and identification, compatibility testing, mixed field reactions, hemolyzed or lipemic specimens, and all combinations of testing that may be performed in this environment.

Documentation

Each task or step in the validation process should be documented and included in the final validation plan or implementation testing document. This should include any discrepancies identified during the process.
Final Review and Conclusion

The final validation documentation should include a conclusion that summarizes successful completion of IQ, OQ, and PQ and identifies any discrepancies or limitations to the system. After the summary and documentation of testing is reviewed and approval signatures are collected, the document should be stored per regulatory and laboratory requirements.

This discussion focuses on the basic steps and considerations in implementing a new automated immunohematologic instrument. A full risk assessment and validation is required to ensure the system is utilized to improve patient care and reduce cost.

References


Additional Resources


*Transfusion Medicine* Journal


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