Non-Technical SOP **Approved draft for training**

Title	**Autoverification Policy for Hospital Based Labs**	
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Owner/BPT leader	Hospital Best Practice Team	

Laboratory Approval	**Effective Date:**	
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		

Review		
Print Name and Title	**Signature**	**Date**

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1. PURPOSE

The purpose of this document is to provide instruction and guidance for the implementation, utilization, and maintenance of autoverification functionality within the hospital based laboratory. Autoverification is a process whereby computer based algorithms automatically perform actions on laboratory results without the need for manual intervention by the technologist. Usually the computer-based action is the immediate verification of a result. Autoverification ensures that every result consistently receives the very same review process. By automatically performing actions on results that meet well-defined criteria, more time is made available for manual processing of those results that require special attention.

2. SCOPE

This procedure applies to all hospital based laboratories where autoverification has been approved for patient result reporting use by the laboratory medical director.

3. RESPONSIBILITY

The **Laboratory Director** is responsible for:

- The initial approval of the autoverification practice in his/her laboratory, as indicated by the approval of this policy.
- The selection of tests and corresponding autoverification rules as appropriate for his/her laboratory and annual approval of these tests and rules thereafter.
- Ensuring that each rule and revised rule is validated initially, prior to implementation and annually thereafter.
- Approval of this policy and subsequent revisions.
- Ensuring that proficiency testing is performed on instruments using autoverification and that specimens are treated identically to routine specimens.

- Ensuring that the test report released by autoverification contains all of the required elements for patient reports.
- Ensuring that an alternative method for report delivery is available when autoverification is not functioning.
- Ensuring that all test reports remain accessible for two years or longer, if required.

The **Laboratory Director** may delegate technical oversight of the autoverification process to the **Technical Supervisor**.

The **Laboratory Director or designee** is responsible for the recurring review of this policy.

The **Technical Supervisor** is responsible for:

- Implementing this policy.
- Ensuring compliance to all policy requirements.
- Ensuring that autoverification quality control measures are performed and documented periodically, (in addition to analytical controls).
- Ensuring that all laboratory staff involved in the autoverification process are appropriately trained.

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4. DEFINITIONS

Autoverification: The automated actions performed by a computer system related to the release of test results to the medical record using criteria and logic established, documented, and tested by the laboratory staff.

Logic: a set or sequence of rules that provides a consistent output based on a predefined set of input parameters.

LIS: laboratory information system

Rule or Rule Set: a method for applying a predefined set of input parameters to a test result to achieve a consistent action (usually release or hold).

Validation: the confirmation that requirements for a specific intended use have been fulfilled using objective evidence.

Validation Plan: a written document that describes the required validation activities and acceptance criteria. Plans must be customized for each type of analyzer and information system. Each plan must be approved by the laboratory director prior to initiation.

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5. PROTOCOL

Approval

The laboratory medical director must approve:

- The use of the autoverification process prior to implementation.
- The validation plan describing validation activities.
- The initial set of laboratory-specific rules used for the auto-release of each individual test performed on participating instruments, prior to implementation and annually thereafter. These parameters may include but are not limited to reference ranges, quality control results, patient demographics, moving averages, instrument flagging, delta checks, maintenance checks, lot checks, and critical limits.
- The initial validation of each rule, prior to implementation.
- Any change to a test specific rule, prior to implementation.
- The validation of a changed test specific rule, prior to implementation.

Requirements for an Autoverification System

- Initial set of validated autoverification rules for each test performed on participating instruments.
- The ability to suppress the process of auto-releasing results in the event of a system or instrument malfunction.
- Documentation of all validation activities and their remedial and corrective actions.
- Ongoing quality control of the autoverification process with periodic evaluation of the overall process.
- Subsequent validation of any revised rule.
- Annual re-validation of the autoverification process.

Rules

- Test result rules consist of laboratory defined criteria consistent with the same criteria technologists use when manually verifying a result for release.
- All reported test results must be evaluated for release criteria including calculated results.
- Rules must include all parameters that affect the accuracy of the result.
- Rules must include all parameters requiring additional manual action by the technologist.
- Possible rules may include (but are not limited to) the following parameters:
  - Instrument flags
  - Result flags
  - Patient demographics such as gender, age, etc.
  - Specimen age
  - Specimen source
  - Sample integrity (hemolyzed, icteric, lipemic, clotted)
  - Reference ranges
  - Delta checks
  - Critical values
  - AMR limits
  - Medical decision values

  - Therapeutic ranges
  - Setpoint for repeat analysis
  - Requirement for manual review
  - Moving averages
- Each set of test rules must be approved by the laboratory director, prior to implementation and annually thereafter.
- A Test Specific Criteria Template (Appendix A) provides guidelines for initial rule development but is not mandatory.

Validation

- All autoverification rules must be validated prior to implementation and whenever there is a possible change to the computer system that could affect the autoverification logic.
- Every rule revision must be validated.
- Validation must confirm that every rule or set of rules generates the expected outcome. For example, if a rule for glucose includes holding a result greater than the upper critical value, then the outcome of the autoverification process for a critically high glucose result must be that the result is "held" or "not released."
- Validation can be performed in two phases.
  - The first phase involves the use of simulated results to trace the logic of the rule or rule set and to verify any calculations that may be performed.
    - Simulated testing can be performed in a test environment.
    - Testing must include results with all possible parameters.
    - Testing must include results falling in all decision points. For example, if there are two decision points for a test analyte, simulated data must include: below the lower decision point, exactly on the lower decision point, between the two points, exactly on the upper decision point and above the upper decision point.
    - Every simulated test must confirm the expected outcome desired: hold the result or release the result.
  - The second phase involves the use of clinical specimens and actual test results to verify performance of the rule or rule set.
    - Clinical testing involves the use of previously assayed patient specimens that challenge the rule or rule set.
    - The individual performing the validation must confirm that the specimen results undergoing autoverification were appropriately held or released.
    - Patient specimens can be supplemented with the analyte being tested or with interfering substances to adequately challenge the rule or rule set, if native specimens with the appropriate characteristics are hard to obtain.
    - The laboratory director or designee must determine the number and type of patient specimens needed to confirm the operation of the autoverification process.
    - Specimens that may be required for validation depend of the test specific rules, for example:
    - Specimens with analyte concentrations within the reference range of the assay,
    - Specimens with analyte concentrations greater than the upper reference limit,

- Specimens with analyte concentrations less than the lower reference limit,
- Specimens with analyte concentrations that are in the critical range, if one exists for that analyte,
- Specimens with analyte concentrations both less than and greater than the AMR of the assay,
- Specimens with interferent indices, if measured for that analyte, above the level that can cause interference for the assay,
- Specimens that require calculations to be reported.

- Results generated by the instrument must be compared to the final patient results that appear in the LIS to confirm that data integrity has been maintained.
- A Test Validation Template (Appendix B) provides guidelines for validation documentation but is not mandatory.

Documentation

- A validation plan must be created that describes the required validation activities and acceptance criteria.
- The individual(s) responsible for building the rule set must be identified, as well as any individual who makes subsequent changes to the rule set.
- All steps in the validation process must be documented indicating the expected outcome, the actual outcome, and the results of any investigation or changes made if the actual outcome was not as expected.
- All remedial and corrective actions must be recorded as part of ongoing quality assurance.
- The test record audit trail provides documentation of how and when results are released. Each result must be traceable to specific technologists for all manual steps performed and if results are auto-released.

Validation Plan:

1. Determine the rules for release/hold for each assay.
2. Obtain laboratory director approval of rules.
3. Build rules in the information system database.
4. If possible, test all rules under all possible conditions using a simulated computer program.
5. Train staff on new hold/release computer process. Training must include how to rapidly suspend the autoverification process.
6. Save patient samples with a variety of conditions (elevated values, low or zero values, critical values, dilutions needed, specific patient age or sex, icterus, hemolysis, other instrument flags, etc.) for each assay.
7. Run patient samples in succession to ensure delta check functionality.
8. Run test samples (in a test environment, if possible) and verify that the appropriate response (hold or release) occurs for each assay based upon the test result and accompanying flags and other sample specific parameters. Make corrections as needed, documenting all results.
9. **On the go-live day**, activate autoverification on one analyzer (if more than one is in use) for validation purposes. NOTE: Be sure no patients are run until final testing is performed.
10. Run test patients and verify expected outcome. Document results using screen shots through all interfaces to the final patient report.

11. Follow the first 5 or more real patients using the same method of documentation.
12. Repeat steps 8-10 for other analyzers.
13. Collect all documentation with the attestation cover page and deliver for technical supervisor and laboratory director approval.

Rapid Suspension of Autoverification

- Laboratory personnel must be able to suspend autoverification whenever a problem is detected.
  - With the test method / reagent
  - With the analytic instrument
  - With the autoverification process
- All analytical quality control samples must be run within the appropriate time period and be acceptable. This can be accomplished by:
  - The computer system automatically checking quality control status prior to autoverification
  - Manually disabling autoverification after any unacceptable QC result
  - Manually disabling autoverification when QC has not been run within the required time interval,
- An alternate system for the timely release of results must be available when autoverification is not in use.

Re-validation and Compliance

- Ongoing challenges of the rules (test specific criteria) must be performed to ensure proper functioning of the autoverification process.
  - Challenges must represent the various types of rules used (reference range limits, delta checks, critical values, etc.). There is no requirement to re-validate every test specific rule.
  - Selective challenge specimens must be inserted into testing batches periodically to ensure "hold" criteria are being detected. This can also be performed retrospectively as an auditing process.
  - Autoverification challenges must be documented.
  - Results of these challenges must be evaluated along with any other corrective actions to assure continuous process improvement.
- Proficiency testing must be analyzed using autoverification if patient samples are analyzed using autoverification.
- All problems must be corrected, thoroughly documented with evidence that the system is working properly, before autoverification is resumed.

6. RELATED DOCUMENTS

None

7. REFERENCES

Clinical and Laboratory Standards Institute (CLSI). Autoverification of Clinical Laboratory Test Results: Approved Guideline. CLSI document AUTO10A (ISBN 1-56238-620-4).
College of American Pathologists. Laboratory General Checklist 2011

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
1.0	7/20/12	Header: add row for site Footer: add local version Section 8: add Approver column Section 9: templates placed in landscape format	L Barrett	R SanLuis, J Buss

9. ADDENDA/ APPENDICES

A. Test Specific Criteria Template
B. Test Validation Template

APPENDIX A

TEST SPECIFIC CRITERIA TEMPLATE

DATE:

INSTRUMENT:

Hold results for the following Instrument Flags:

Test Code	UOM	Sex	Age Day Low	Age Day High	Ref Low	Ref High	Crit Low	Crit High	Delta (days)	AMR Low	AMR High	CRR Low	CRR High	Hold Criteria

APPENDIX B:

TEST VALIDATION TEMPLATE

INSTRUMENT:

Date	Accession Number	Rule	Expected Outcome	Outcome	Acceptable?