TITLE: Autoverification Validation

PURPOSE: Autoverification is the process by which patient results are generated from interfaced instruments and sent to the LIS. The results are compared by the computer system against laboratory defined acceptance parameters. Results that fall within these defined parameters will be automatically released. Results that fall outside of these predefined parameters will be reviewed by laboratory staff before releasing. Parameters that will be evaluated by the computer system include, but are not limited to reference ranges, critical values, delta checks, and technical ranges.

SCOPE: This procedure is intended for all ARMC laboratories, ARMC main lab, ARMC Cancer Center lab and MedCenter Mebane laboratory.

POLICY:

1. Assays selected for autoverification must be approved by the site director and the facility medical director.
2. Autoverification process is tested before institution and annually thereafter
3. Autoverification revalidation is also performed when a problem is identified, and when there is a change to the system.
4. Appropriate quality control must be verified before patients are placed on the instrument.
5. Any changes to autoverification rules will require a re-validation of the autoverification process.
6. If a technologist discovers a problem during the autoverification process, the process will be suspended immediately (see below) and the Laboratory Information Department contacted.

Chemistry: The assays selected for autoverification must meet all criteria established to ensure only appropriate results will be accepted and reported. Current criteria for autoverification include the following:

* Results must be within the technical range of the analyzer (see CCIS for technical range of analyzer).
* Serum indices are within acceptable range for each analyte tested.
* Calculated anion gap must be >2 and <20.
* Results must not be in the critical range (see critical value chart)
* Results must meet delta check criteria (see delta check policy)

Hematology: The assays selected for autoverification must meet all criteria established to ensure only appropriate results will be accepted and reported. Criteria for autoverification include the following:

* Results must be within the technical range of the analyzer
* Results must not be in the critical range (see critical value chart)
* Instrument printouts that contain instrument flags, will not autoverify.
* Results must meet delta check criteria (see delta check policy)

Microbiology: The assays selected for autoverification must meet all criteria established to ensure only appropriate results will be accepted and reported. Current criteria for autoverification include the following:

* PCR testing must be negative/not detected
* Delta checks, where applicable

Coagulation: The assays selected for autoverification must meet all criteria established to ensure only appropriate results will be accepted and reported. Current criteria for autoverification include the following:

* Results must be within the technical range of the analyzer (see Stago Information Sheet for technical range of analyzer).
* Results with error messages will not autoverify (<min, >max, value in primary units skewed)
* Results must not be in the critical range (see critical value chart).

PROCEDURE:

Autoverification Validation Procedure:

1. Select the instrument and assays for autoverification. Obtain approval of site director and facility medical director.
2. Medical director will determine the acceptable criteria for autoverification and document.
3. In the testing environment, define the autoverification guidelines. Test a minimum of twenty samples per instrument.
	1. Include samples that will test the autoverification algorithm decision rules such as samples above the acceptable technical limits and samples below the acceptable technical limits. Include specimens with delta checks, critical values and samples with multiple failures.
4. Move the criteria to the live environment. Test for a minimum of one day or a minimum of fifty auto-verified results. Assure that results that do not meet the test criteria are not auto-verified.
5. The autoverification process must be 100% effective before approval. Any non-agreement of expected to actual results must be investigated and resolved.
6. As samples are complete on the analyzer, samples that meet the autoverification criteria will automatically file to the patient’s record. In Laboratory Inquiry, results will appear as finalized for the appropriate instrument for autofiling.
7. Samples that do not meet the auto-release criteria will remain in pending status for technologist review.
8. If any failure to meet the criteria is discovered (held when should auto-release, released when it should have held), autoverification will be suspended immediately until additional testing is completed in the testing environment of the LIS.
9. Save documentation of validation process (screen shots, printouts, etc.) for review.
10. Records of autoverification validation studies must be reviewed and approved by the medical director with the following statement:

*The range of results obtained during the autverification process challenged the algorithm and has confirmed that the autoverification algorithm decision rules are functioning properly.*

1. Autoverification validation data must be retained as long as the assay is in use and for two years beyond the date of discontinuing the test.

Autoverification Revalidation Procedure:

Compare one day’s work or at least fifty samples of accepted results to actual results per interface/method type. Take samples from each interface/method type across the system. If 100% is not achieved, suspend autoverification and indicate the corrective action taken. Problem must be resolved before autoverification can be used.

1. Ensure that all appropriate quality control has been verified before any samples are loaded onto the instrument.
2. As with the initial validation, select samples that will test the decision rules
	1. Include samples with anlyte concentrations within the normal range, above the reference limit, above or below the AMR, in the critical range, and specimens with known interference
3. Samples that the tech does not wish to autofile should be manually programmed with an identifier other than the accession number. Below are examples of samples that should not be programmed with the accession number.
* Samples that may have inadequate volume for analysis.
* Samples that have been diluted and does not include an instrument dilution factor.
* Samples placed on the instrument pending QC review.
1. As samples are complete on the analyzer, samples that meet the autoverification criteria will automatically file to the patient’s record. In Laboratory Inquiry, results will appear as finalized for the appropriate instrument for autofiling.
2. Samples that do not meet the criteria will remain in pending status for technologist review.
	1. The technologist should handle the results that do not autofile according to the individual instrument procedures.
3. Save documentation of revalidation process (screen shots, printouts, etc.) for review.
4. Records of annual autoverification revalidation studies must be reviewed and approved at a minimum by a technical supervisor with the following statement:

*The range of results obtained during the autverification process challenged the algorithm and has confirmed that the autoverification algorithm decision rules are functioning properly.*

Suspending Autofiling:

1. If a problem arises during the autoverification process, it can be immediately suspended by the technologist.
2. To suspend autovalidation, Log in to the Putty/Roll and Scroll side of Sunquest
3. At the function prompt, type SAF.
4. A prompt will appear to enter the method code.
5. Enter method code of instrument that needs to be stopped.
6. Press Y to stop autofiling.
7. Enter A to accept.
8. Enter additional method code or press ENTER.
9. Enter Y for yes.
10. Wait for computer message “Reset Complete….”
11. Press ENTER.
12. Report problems immediately to LIS department.

Activation of Autofiling:

1. When problem has been resolved, Log in to the Putty/Roll and Scroll side of Sunquest
2. Type SAF at the function prompt.
3. A prompt will appear to enter the method code.
4. Enter method code of instrument that needs to be resumed.
5. Press Y to resume autofiling.
6. Enter additional method code or press ENTER.
7. Enter Y for yes.
8. Wait for computer message “Reset Complete….”
9. Press ENTER

References:

“Autofiling: Basic Maintenance”, August 5, 2008, Sunquest Information Systems,

Tucson, AZ 85711.

“Autofiling: On-Line Calculations”, August 5, 2008, Sunquest Information Systems,

Tucson, AZ 85711.

Beckman Coulter Newsletter. The Art of Autovalidation: Doing It Right and Making It

Work for your Lab. Beckman Coulter. February 28, 2008.

College of American Pathologists. Laboratory General Checklist. Current Version.

Johnson, J MT(ASCP)SH & Stelmach, D MT(ASCP), MS. September 2007 Clinical

Laboratory News: Autoverification of Test Results.

www.aacc.org/AACC/publications/cln/2007/series.

|  |  |
| --- | --- |
|  |  Signature Date |
| Medical Director Approval – ARMC Cancer CenterARMC Main Lab |  |  |
| Medical Director Approval – MedCenter Mebane |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| Review Date | Signature | Mgmt. | Director |
|   |   |   |   |
|   |   |   |   |
|   |   |   |   |
|   |   |   |   |
|   |   |   |   |
|   |   |   |   |
|   |   |   |   |
|   |   |   |   |
|   |   |   |   |
|   |   |   |   |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|   |   |   |   |
|   |   |   |   |
|   |   |   |   |
|   |   |   |   |
|   |   |   |   |

HISTORY PAGE

SOP Number: LIS-109-CH

SOP Title: Autoverification Validation

Written By: Paula Hamlett, Wendy Turner

Manual in which Hard Copy of this SOP is located: LIS/IT Manual

Distribution: no other locations

Supersedes Procedure:

SOP CHANGE CONTROL

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|   | Approvals |   | Action | In |
| Mgmt. | Date |  Director | Date |   | Effect |
|   |   |   |   |   |   |
|   |   |   |   |   |   |
|   |   |   |   |   |   |
|   |   |   |   |   |   |
|   |   |   |   |   |   |
|   |   |   |   |   |   |
|   |   |   |   |   |   |
|   |   |   |   |   |   |
|   |   |   |   |   |   |
|   |   |   |   |   |   |
|  |  |  |  |  |  |
| Date archived: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |
| Reason: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Initials:\_\_\_\_\_\_\_\_\_\_ |  |
|  |  |  |  |  |  |