PURPOSE

Autoverification by the Meditech Laboratory Information System is a process that uses defined filters in the Remisol middleware interfaces on Hematology and Coagulation analyzers to evaluate patient results for eligibility (or ineligibility) for autoverification. Those samples that are autovalidated or pass all of the rule evaluations or algorithms in the Remisol middleware are deemed eligible for autoverification and are automatically sent to the LIS and autoverified without CLS intervention.

Rule evaluations include comparisons to reference intervals, reportable ranges, panic values, delta checks and medical decision values. Once the algorithms are determined and written, they must be validated to verify that the rules follow the expected logic and produce the expected outcome. Once validated initially the algorithms must be revalidated at least annually or when any changes are made (software upgrades etc.) that may be involved in the autovalidation process. This validation can be accomplished by using fresh samples real or contrived, a saved patient sample data base of samples that evaluate each active rule in the Remisol Test system, or a combination of both. In the test system, a report is generated for each saved sample tested that shows which rules were triggered, and which were not, to hold a sample from autovalidating. For live samples a Remisol printout of each applicable rule is saved.

The laboratory director or technical director reviews and approves each test algorithm initially, after changes, and annually thereafter.

PROCEDURE

# Appropriate quality controls must be performed and be in control on all instrumentation before running samples to assure proper instrument function. See individual instrument procedures for proper quality controls.

# Autoverification is turned on in Beaker at all times unless suspended manually. It is suspended at the analyzer level not the batch level as in Meditech.

# It is not necessary to suspend all analyzers at one time as in the past.

# The Operator may suspend autoverification at the interface level in the LIS, at the instrument level in the Remisol and at the instrument level if applicable.

## Autoverification is suspended in Beaker as follows:

### Under Actions button choose Autoverification Status

### Choose Department ML Hematology

### Click on Suspend button for analyzer you wish to suspend autoverification for.

### Fill in pop up box with reason for suspension

### Click Accept and Autoverification is suspended.

## To resume Autoverification in Beaker:

### Repeat the above actions to enter Autoverification Status.

### Click Resume button.

### Fill in pop up box with reason for resumption and click Accept.

## Autoverification is suspended at the instrument level in Remisol by clicking on the Gold STOP circle on the Remisol screen and unchecking the enable download button for the particular instrument in question.

### Bypass the problem instrument at the line controller so no patient samples are delivered to that instrument until the problem is resolved properly.

# Critical values will not autoverify and must be manually documented and verified.

# Priority One samples will autoverify and comments are to be added to specimen comments after the autoverification process occurs.

REFERENCES

# CAP General Checklist, 6/17/2010 revision, Autoverification GEN.43850- GEN.43893.

# CLSI Guideline, Autoverification of Clinical Laboratory Test Results; Approved Guideline (AUTO10-A), 2006

# Setting Up auto-validation with REMISOL Advance\* Data manager, Paul Reischmann, Beckman Coulter, 2009.

# Duco, DJ, Autoverification in the Laboratory Information System, Lab Med, 2002:33:21-25

# The Art of Autovalidation, Diagnostics Today, Winter 2008 edition, Beckman Coulter

# Crolla, Laerance and Westgard, James O, Evaluation of Rule-Based Autoverification Protocols, Clinical Leadership and Management Review, Sept/Oct 2003, 268-272

PROCEDURE HISTORY

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| --- | --- | --- | --- | --- |
| Date | Written Revised By | Revision | Approved Date | Approved By |
| 9/28/11 | L Freeman | new | 10/17/2011 | D Dwyre MD |
|  |  | Annual Review | 8/24/12 | D Dwyre MD |
|  |  | Biannual Review | 10/2/2014 | D Dwyre MD |
| 07/2017 | L Freeman | Revised for Beaker |  |  |
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