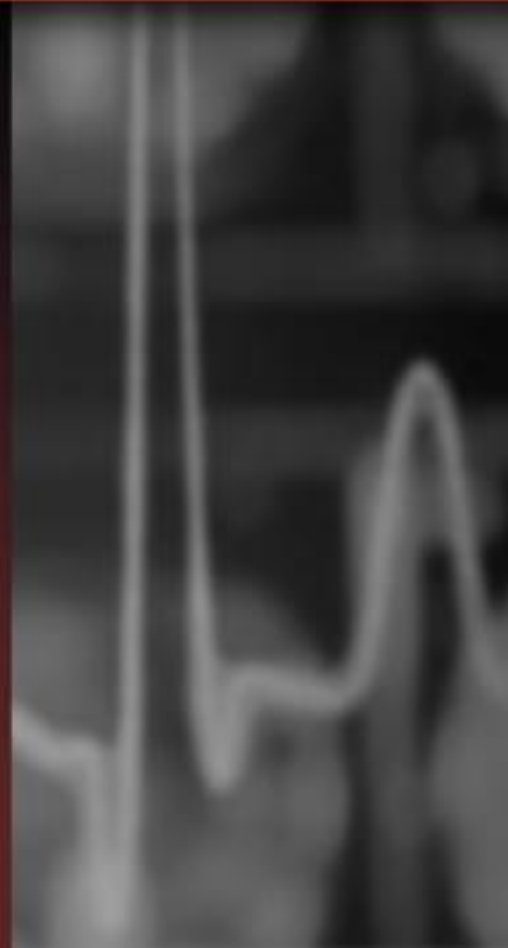


Autoverification, Reference Ranges, and Critical Results

Suzanne Duncan, MT(ASCP)

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Session Objectives

- Describe the key benefits of autoverification of Laboratory results
- Understand regulatory and patient safety issues related to autoverification and the reporting of critical laboratory results
- Understand how reference ranges and result flags can be used to drive autoverification processes

What is Autoverification?

- Autoverification (automated result verification): 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 medical staff of the laboratory.*
- The end process of a set of rules or algorithms, invoked by specific instrument data, ranges, and/or flags that trigger...the release of results to the patient record.**

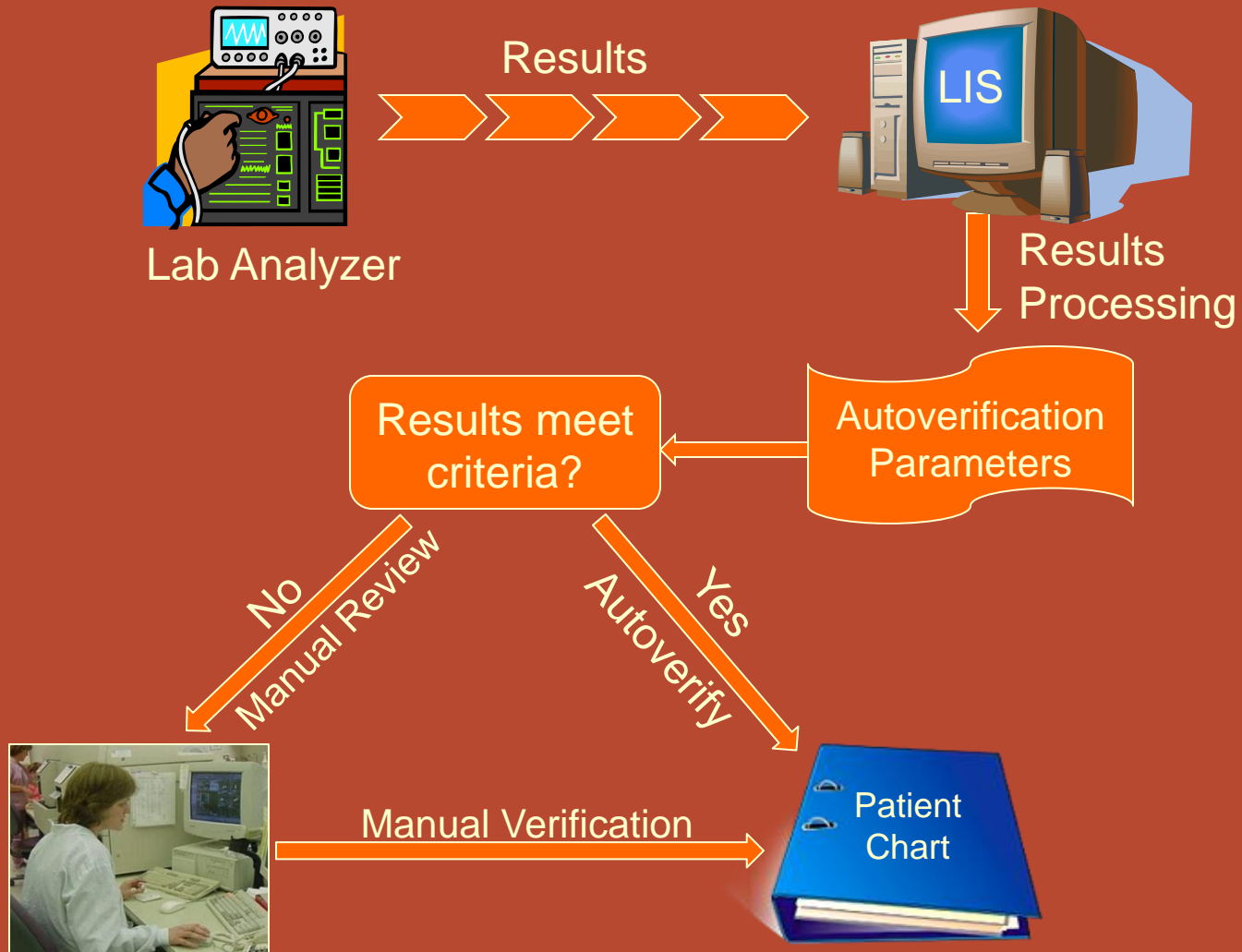
*Clinical Laboratory Standards Institute (CLSI). *Autoverification of Clinical Laboratory Test Results*, Document AUTO10-A

**Duca, Dale J. *Autoverification in a Laboratory Information System*, Laboratory Medicine, January 2002, Vol. 33.

CAP Checklist Definition

- Autoverification is the process by which patient results are generated from interfaced instruments and sent to the LIS, where they are compared against laboratory-defined acceptance parameters. If the results fall within these defined parameters, the results are automatically released to patient reporting formats without any additional laboratory staff intervention. Any data that fall outside the defined parameters is reviewed by laboratory staff prior to reporting.

Autoverification Process



Autoverification Requirements

Two Basic Requirements:

1. Analyzer interfaced with...

2. Rules-based software

- Interfaced analyzers require software that can release results directly to the patient record
- Software requires instruments that can produce specific flags, error messages and data to be evaluated by its autoverification algorithms

CAP Requirements for Autoverification

- Formal policy signed by the Lab Director
- Documentation of initial validation
- Re-validation at least annually or when a system change could affect autoverification logic
- QC has been run and is in control
- Results are checked against appropriate range of values prior to autoverification
- Results are checked for flags or warnings
- Audit trail in the system identifying all autoverified results with the date/time of autoverification

Why Autoverify?

- Improve TAT for result reporting
- Faster notification of critical values
- Reduce error rate
- Staffing shortages
- Align costs with reduced revenue



- Total Lab Automation
 - Integration of pre-analytical and post-analytical processes

Risks of Autoverification

- Major risk – releasing erroneous results
 - Caused by poor planning, inadequate validation of algorithms, or failure to follow established protocols
 - Process needs to minimize user error
- Minor risk – delay of results that could be autoverified
 - Negatively impacts TAT and workflow
- Mitigate risk by thorough testing
 - All combinations of result flags, instrument errors, and ranges
 - Periodic revalidation of autoverification algorithms

Critical Lab Results

- 1970's – George D. Lundberg, MD introduced the concept of critical lab results
- Suggestive of a potentially life-threatening condition warranting prompt clinical intervention

Regulatory Considerations

– CLIA '88

- Mandated caregiver notification of critical results
- “The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values.”

CAP Requirements

- Does the laboratory have procedures for immediate notification of a physician (or other clinical personnel responsible for patient care) when results of certain tests fall within established 'alert' or 'critical' ranges? (GEN.41320 Phase II)
 - *NOTE: Alert or critical results are those results that may require rapid clinical attention to avert significant patient morbidity or mortality. These results should be defined by the laboratory director, in consultation with the clinicians served.*
 - *Allowing clinicians to "opt out" of receiving critical results is strongly discouraged.*
 - *Checklist applies specifically to critical results, not to critical tests as defined by The Joint Commission.*

CAP Requirements

- **Is there documentation of notification of the appropriate clinical individual of all critical results? (GEN.41330 Phase II)**
- **When critical results are communicated verbally or by phone, is there a policy that laboratory personnel ask for a verification “read-back” of the results? (GEN.41340 Phase I)**

Joint Commission 2010 National Patient Safety Goals

Goal 2 – Improve the effectiveness of communication among caregivers.

- NPSG.02.03.01 Timely Reporting of Critical Tests and Critical Results
- Collaborate with organization leaders to develop written procedures for managing the critical results of tests and diagnostic procedures that address the following:
 - The definition of critical results of tests and diagnostic procedures
 - By whom and to whom critical results are reported
 - The acceptable length of time between the availability and reporting of critical results
- Implement procedures for managing critical results
- Evaluate the timeliness of reporting critical results

*Joint Commission 2010 National Patient Safety Goals, Pre-publication version.

Critical Tests

- Tests that are always reported to the clinician immediately regardless of the result value
- May be indicated by priority
 - Stat or Critical
- May be designated test orders
 - Example: Code blue Blood Gas
- Typically a small subset of your order catalog

Critical Result Notification

- Legal responsibility
 - Policies must be enforced
- Design your critical result notification and autoverification policies for patient safety
 - Policies should not be based on personal preference, the convenience of the clinician, or the convenience of the Lab staff
- Critical reporting is crucial to patient safety & quality patient care



Autoverification – Where do I start?

- Start small – pilot one instrument
 - Select an instrument with few error flags and high acceptance rate
 - Chemistry or Coag instruments
- Review your current policy for release of results
 - Follow your established criteria for result review
 - What result flags trigger follow-up?
 - What is your criteria for acceptable quality control?
 - What are your policies for reporting critical results?

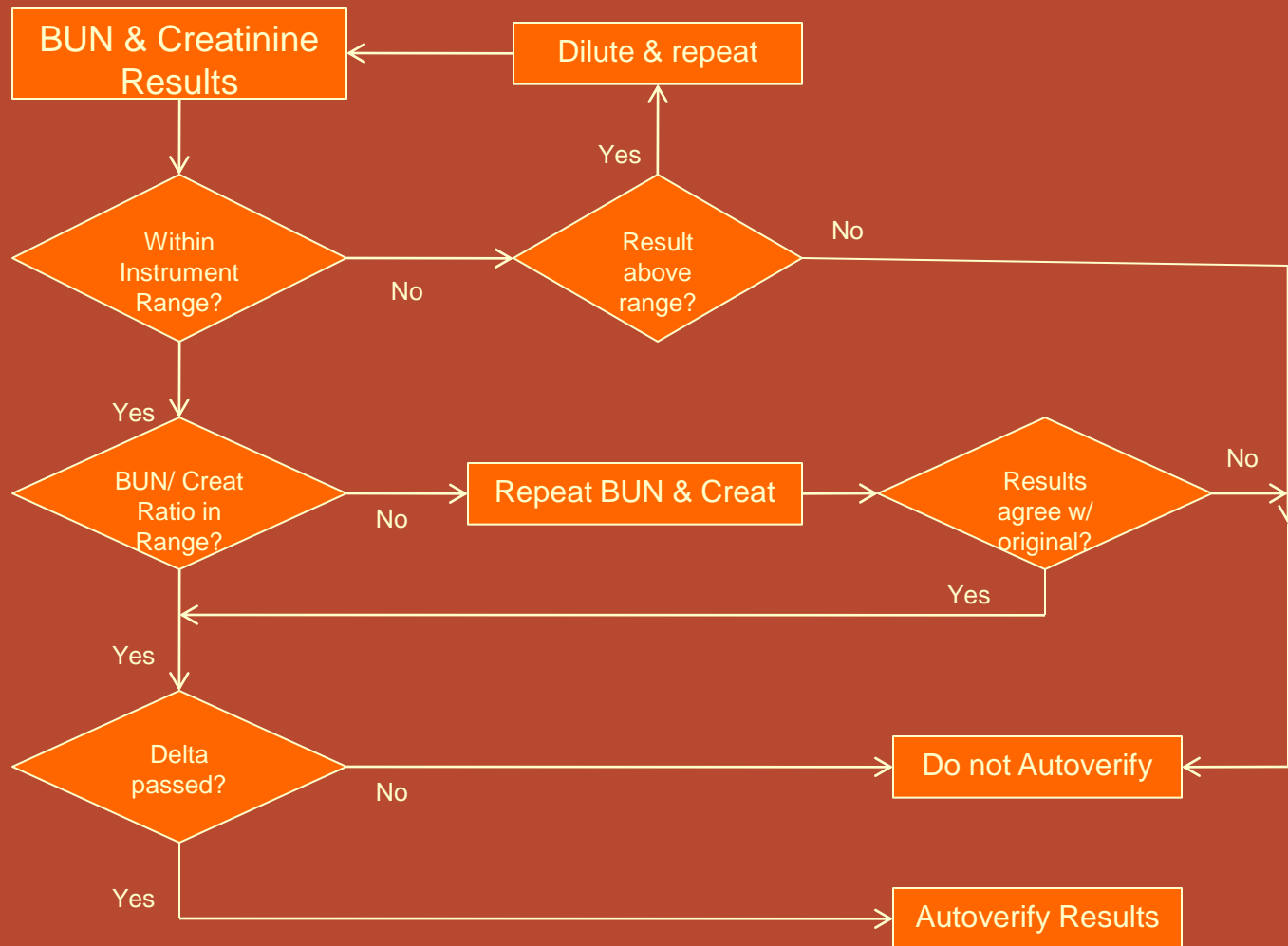
Where do I start?

- Review regulatory requirements
- Most regulatory agencies provide high level guidelines
 - CAP: Criteria must be defined, documented, and adhered
 - FDA: No alteration of LIS or instrument software
 - JCAHO: No standards specific to autoverification, but quality control standards indirectly apply
- State and country regulations vary

What can your LIS do?

- Automatically verify results based on site-defined parameters
- Criteria are defined by instrument, orderable item, and assay
- Numeric, calculation, and alpha result types can be autoverified
- QC results can be autoverified based on expected ranges and QC rule evaluation
- In-control QC can be required to autoverify patient results

Algorithm Example



Instrument Parameters

- Parameters are built for each performing instrument
- Multiplexor – build parameters for each individual instrument
- QC can be required to autoverify patient results
 - If QC has not been run, or is not in control, patient results will not be autoverified
 - If QC is out of control (QC rule failure), then autoverification of patient results should be automatically turned off

Instrument Parameters

- QC can be required to be in control for all assays in the interface transaction, or each assay can be evaluated separately
- QC schedules define the required time intervals for running QC

Instrument Parameters

- QC results themselves can be autoverified
- You define if each result is validated independently or if all QC results must be in control to be autoverified
- Results that fail autoverification are posted as Performed and must be reviewed and released manually, just as they are without autoverification

Orderable Item Parameters

- Defined for each performing instrument
- When a result fails autoverification, you can also fail all results for the orderable item that are received in the same interface message
 - May not be an option if results are transmitted separately by the instrument

Orderable Item Parameters

- Orderable items can be identified that should never be autoverified
- Associated orderable items can be identified so that if a result in one orderable item fails autoverification, then results for the associated orderable items are not autoverified

Reference Ranges

- Provide relevance or context for a result value
- May be differentiated by:
 - Specimen Type
 - Age
 - Gender
 - Species
 - Race or ethnicity
 - Test Methodology or Instrumentation
- Determine the flags that are applied to a result

Result Flags

- Numeric results:
 - Normal (Low and High)
 - Review
 - Critical
 - Linear
 - Feasible
 - Delta
- Alphabetic results:
 - Abnormal
 - Review
 - Critical
 - Delta
- Some flags are published with results while others may be internal to the laboratory

Autoverification Parameters based on Result Flags

- Results can be required to be repeated based on a result flag such as High, Low, or Critical
 - Parameters may require a repeat of one assay or all assays for the entire orderable
 - Logic can trigger the LIS to send a new download to the instrument
 - LIS can tell the robotics system to send the specimen back to the instrument

Autoverification Parameters based on Result Flags

- Consistency checking
 - Compares the result flag to the previous result's result flag
 - Enables you to autoverify critical results if the previous result was also critical
 - Comment or note can be automatically appended
 - Includes time interval and result variance (absolute or percent)

Delta Checking

- Autoverification parameters can be based on delta checking pass, fail, or not applied
- Delta flag not applied when:
 - Delta parameters are not defined for the assay & instrument
 - There is no previous result
 - The time difference between the current and previous result exceeds the time interval defined for the delta check

Assay Parameters

- Parameters can be defined to not autoverify a repeated result
- LIS looks for a repeated result for the same assay on the same specimen
 - Ex: the first result failed autoverification and you don't want the system to autoverify the repeated result, even if it meets other criteria for autoverification.

Assay Parameters

- Duplicate assay or equivalent assay
 - Look for the same or equivalent assay on the same specimen, and if found then fail AV
- Check for instrument error codes
 - Error codes must be configured to post with the results
 - Autoverification fails if any error code is received with the result

QC Result Autoverification

- QC results are evaluated using the expected ranges and QC rules defined for the assay, instrument, and control lot
- QC results can be autoverified if they pass the QC rule evaluation in the LIS
- Results failing QC rules are not autoverified

QC Result Autoverification

- Autoverification of patient results can be automatically stopped when a QC result is out-of-control
 - Autoverification of QC results continues
 - LIS should validate that the out of control situation has been resolved and all required QC is in control before AV can be restarted

QC Result Parameters

- System should enable you to bypass QC validation for assays that don't have QC results
 - Example: assays used to capture certain instrument messages
- Equivalent assay for QC validation
 - When QC validation is required, the system can check for QC results on equivalent assays if a QC result is not found for the assay being evaluated

QC Validation

- When autoverification fails due to out of control or expired QC, results posted during this time should be reviewed and evaluated for verification
- The LIS should provide an audit trail of results that were autoverified and error codes for results that fail autoverification

What can't be autoverified?

- Freetext, date, interpretation or textual results cannot be autoverified
 - Not typically posted by an interfaced instrument
 - No result flags to determine acceptability
- Converted results
 - Ex: a numeric result where the instrument posts “No Result”
- Calculations that contain optional components

Autoverification Testing

- After setting up rules & algorithms – perform testing and validation
- Ensure that results that should be held are held & results that should be released are released
- Test every rule for each assay & instrument, and for all order combinations
- Document your testing evidence
- Laboratory Director review and sign off is required

Autoverification Training

- Train & educate your staff concurrently during your testing process
- Involve your technical staff in the testing process
 - Enhances learning
 - Builds troubleshooting skills
 - Helps you create content for FAQ & troubleshooting documentation

User Documentation

- Create an autoverification troubleshooting guide for your lab
- Include the autoverification codes, flags, or status messages that exist in your LIS autoverification audit tool
- Identify FAQs and troubleshooting tips & tricks



Ongoing Maintenance

- Revalidation of autoverification is required at least once a year AND when...
 - New software is installed
 - New instruments are implemented
 - New tests are added to an instrument
 - Autoverification parameters are modified
- Revalidation is recommended when reference ranges are modified

Sample Autoverification Percentages

- 95% Urine Macroscopics
- 45% CBCs
- 85% PT and PTTs
- 65% BMP and CMP
- 50% ABG

Autoverification Benefits

- Personnel savings – FTE reduction
- Improved TAT for routine results
- Improved TAT for STAT orders
- Decrease in the number of STAT orders
- Reduction in result review errors
- Reduction in overall error rates

References

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Email: sduncan@cerner.com