Università degli Studi di Padova
Scuola di Specializzazione in Biochimica Clinica (A.A. 2005-2006)
INDIRIZZI: DIAGNOSTICO E ANALITICO TECNOLOGICO

Biochimica Clinica e Biologia Molecolare Clinica:
automazione ed informatica in Biochimica Clinica
area D SSD BIO/12 ex E05C ore 20 anno IV
-OBIETTIVO FORMATIVO: Acquisire le conoscenze informatiche per la gestione del laboratorio

correzione, verifica e validazione dei risultati

Marco Pradella
Castelfranco Veneto

correzione, verifica e validazione

- ciclo, cicli e deragliamenti
- verifica e validazione nel flusso operativo diagnostico
- verifiche e algoritmi
- middleware, autoverifica

AACC's Middleware Library

- **What is Middleware?**
  Middleware is software that sits strategically between your instruments and LIS. Through rule-based decision processing it helps you to better manage your test result generation. It allows you to optimize your autoverification, track samples, delta checking, and customize your processes and information based on your lab's specific needs and populations and much more.
- **What is the Middleware Library?**
  The Middleware Library is where laboratorians can share rules they have found helpful with others and where they can search for rules that other labs have found effective. You can add comments about rules, rate them and search for rules in specific areas

http://www.aacc.org/labrules/index.cfm

AACC's Middleware library

Rules-based detection of discrepancies between TSH and Free T4 results
Mitchell DR, Parvin CA, Gronowski AM.
Feb 06, 2006 Ann Gronowski

Consensus Hematology Rule 33
Identifies a specimen requiring manual slide revie ...
Oct 05, 2005 William Coughlin

Consensus Hematology Rule 10
This rule will identify specimens requiring manual ...
Oct 05, 2005 William Coughlin

Double Sided Delta Check
This rule will hold for verification any ASP resul ...
Oct 05, 2005 William Coughlin

correzione, verifica e validazione

- flusso, ciclo, cicli e deragliamenti
- verifiche e algoritmi
- autoverifica

AUTOVERIFICATION in (CAP) Checklists

- *****NEW** 10/06/2005***
- *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; Implementation Schemes Instrument System, or LIS

Richard S. Seaberg, MT(ASCP)
Administrative Director North Shore
University Hospital Long Island Jewish
Medical Center

Definition of Autoverification

- "The end process of a set of rules or Algorithms, invoked by specific instrument data, ranges and/or flags, that trigger an action by the LIS."1
- Release of results to the user
- Hold results for intervention
- "Reflex" to additional testing while releasing results
- According to CAP: "The process by which the computer (LIS or instrument system) performs initial verification of results."

Regulations Governing System

CAP

- **GEN.43360 – "If the laboratory employs autoverification procedures for tests performed on any instrumentation, is there a signed policy by the Laboratory Director approving this action."**
- **GEN.43370 – "Is there documentation that the laboratory has validated the autoverification process against the rules prescribed by the laboratory director before implementation."**
- **GEN.43380 – "Is there documentation that the autoverification process has been tested at least annually, and whenever there has been a change to the system."**
- **GEN.43450 – "Is there documentation that calculations performed on patient data by the computer are periodically reviewed?"**
- **GEN.43600 – "Are result entries checked against a defined range of expected results to detect absurd values before reporting?"**
- **NCCLS – Auto3P, GP19-A2 (Design of User Interfaces)**

FDA

- **External PC based systems may require 510K approval**
- **Commercially Available Products**
- **Other State and/or Local Regulatory Agencies**

Richard S. Seaberg, MT(ASCP) Administrative Director North Shore University Hospital Long Island Jewish Medical Center

Richard S. Seaberg, MT(ASCP) Administrative Director North Shore University Hospital Long Island Jewish Medical Center

Benefits of Autoverification

- **Mitigate Pressures Caused by Staffing Shortages**
  - Currently 15% - 20% in NYC Metro area
    - Aug 04 G2 Report – Shortage Eased in 2003 Due to Mergers – Long Term Issues Persist
- **Can Provide Mechanism to Further "Outreach Market" Expansion By:**
  - ? Daily Technical Workload on FTE's
    - TLA - Leads to ? # Tests/FTE
  - ? Productivity
- **Enables Service Expansion to New Markets**
- **Allows for Further Professional Development of Staff**
- **Cross Train in other Depts**
- **Improved Overall Departmental TAT (Lab Sections Implemented)**
- **Improved Consistency of Result Reporting**
  - Enables Technical Staff to Focus on Problem Samples (Sample That Fail Autoverification Rule Processing)
- **Quality Improvements – QC, QA and PI**
- **Reduction in Staff Fatigue due to Routine Releasing Tasks**

CLSI AUTO10-P

- Autoverification engine

Collegamento a selAUTO10PE.pdf.lnk

policy of autoverification in (CAP) Checklists

- **GEN.43850**
- **Is there a policy signed by the laboratory director approving the use of autoverification procedures?**
  - REFERENCES: 1) Davis GM. Autoverification of the peripheral blood count. *Lab Med.* 1994;25:528-531; 2) Davis GM. Autoverification of macroscopic urinalysis. *Lab Med.* 1999;30:56-60; 3) Nicoli M, *et al.* The use of the Sysmex Co. data processing software program (PC-DPS) for the automatic validation of haematological data. *Clin Chem.* 2000;46:A133; 4) NCCLS. Laboratory automation: communications with automated clinical laboratory systems, instruments, devices, and information systems; proposed standard AUTO3-P. Wayne, PA: NCCLS, 1998; 5) Duco DJ. Autoverification in a laboratory information system. *Lab Med.* 2002;33:21-25.

autoverification validation in (CAP) Checklists

- **GEN.43875**
- **Is there documentation that the autoverification process was validated initially, and is tested at least annually and whenever there is a change to the system that could affect the autoverification logic?**
  - *NOTE: The range of results for which autoverification is acceptable must be defined for all patient tests subject to autoverification.*
  -

Autoverification & quality control in (CAP) Checklists

- **GEN.43878**
- **For all test results subject to autoverification, does the laboratory ensure that applicable quality control samples have been run within an appropriate time period, with acceptable results?**
  - *NOTE: This requirement may be met by, 1) the computer system automatically checking quality control status prior to autoverification, or, 2) manually disabling autoverification after any unacceptable QC result, or when QC has not been run within the required time interval.*
  -

acceptable values & autoverification in (CAP) Checklists

- **GEN.43881 Are results compared with an appropriate range of acceptable values prior to autoverification?**
  - *NOTE: Appropriate comparisons include checking patient results against absurd and critical values requiring manual intervention (repeat testing, dilution, telephone notification of results, etc.)*
  -

flags or warnings & autoverification in (CAP) Checklists

- **GEN.43884**
- **Are results checked for flags or warnings prior to autoverification?**
  - *NOTE: The mere presence of a flag may not disqualify a result from autoverification, but any flag that is not specifically recognized by the autoverification program must cause the flagged result to be held for manual review.*
  -

audit trail, autoverification & date/time in (CAP) Checklists

- **GEN.43887**
- **Does the audit trail in the computer system identify all test results that were autoverified, and the date/time of autoverification?**
-

delta checks & autoverification in (CAP) Checklists

- **GEN.43890**
- **Does the autoverification process include all delta checks that the laboratory performs prior to manual release of test results?**
  - *NOTE: This question does not require delta-checking for all autoverified results, but the laboratory's delta-checking procedures should be the same for manually released and autoverified test results.*
  -

suspension of autoverification in (CAP) Checklists

- **GEN.43893**
- **Does the laboratory have a procedure for rapid suspension of autoverification?**
  - *NOTE: Laboratory personnel should be able to suspend autoverification in the event of a problem with a test method, analytic instrument, or the autoverification program.*
  -

Overall Autoverification Considerations

- **Can Present with Some Limited Capabilities**
  - Usually in the hands of the LIS Vendor – Third Party IT Contractor
- **Rules Can be Difficult to Change/Implement/Maintain**
- **Complex Algorithms Usually Cannot be Implemented**
  - Special Testing Laboratories; Chem / Coag / Hema / Molecular Biology
  - Microbiology
  - Anatomic Pathology
- **May Allow Sample Results with Problems to Pass to LIS**
  - Corrective Actions Required
  - Extensive Notification of Corrections
  - QA, Nursing, Outreach MD's

Richard S. Seaberg, MT(ASCP) Administrative Director North Shore University Hospital Long Island Jewish Medical Center

Reflex Testing vs. Autoverification

- **Reflex Testing Involves Application of "Expert Rules"**
  - Based Upon One Result or Serial Results – Another Test is Ordered
    - If Urine Chemistry Positive – Reflexive order Urine Microscopic
    - If Urine Chemistry Negative & Micro has been ordered – Reflexively cancel Urine Microscopic
    - If CPK > 225 U/L – Reflexive order CK-MB
- **Autoverification Involves Application of Multiple Rules That Enable the Release of Results**
  - Usually Autoverification Occurs Before Application of Reflex Rules
    - If Delta Passed and High CK – Can Release CK and Reflexively order MB
- **Things to Consider When Occurs**
  - Need Mechanism to Notify Operator/s
  - Want to Maintain TAT
    - Printed Notification – Preferred Method
    - Generation of Testing Site Worklist
    - Verbally

Richard S. Seaberg, MT(ASCP) Administrative Director North Shore University Hospital Long Island Jewish Medical Center

What/Where/When to Autoverify

- What Part of the Testing Process
  - Pre-Analytical
  - Clinician Based Rules
  - Draw vs. Analysis Times
  - Analytical
- Where to "Do It"
  - LIS
  - Instrument or Workstation Based
  - Stand Alone Buffer
  - Hybrid Approach – Part Instrument / Part LIS
- Should Consider When You Have a Clear Benefit

Richard S. Seaberg, MT(ASCP) Administrative Director North Shore University Hospital Long Island Jewish Medical Center

Autoverification Questions to Consider – Part 1

When You Should NOT Verify Results?

- **Critical Values**
- **Delta Checks – Which to Consider**
  - Percentage Based / Absolute / Both
- **QC Range Failures**
  - Westgard Rule Failures
  - Patient Averages
  - Bull's Algorithm
- **Repetitive Instrument Results**
  - Due to Instrument Clots
- **Sample Characteristics/Flags**
  - Instrument Flags, (L, H, I)
- **Specimen Receipt Time to Analysis Failures**
- **Client/Physician Special Requests**

Richard S. Seaberg, MT(ASCP) Administrative Director North Shore University Hospital Long Island Jewish Medical Center

Autoverification Questions to Consider – Part 2

- "Algorithm Turnoff" Button (Auto or Manual)
  - System "downtime"
- Instrument Requirements
  - Barcode Capabilities
  - Sampling system
  - Instrument Linear Limits
  - Data Streams – Especially in Hematology
  - Results Usually Dependent Upon One Another

Richard S. Seaberg, MT(ASCP) Administrative Director North Shore University Hospital Long Island Jewish Medical Center

Determine Specific System Limitations

- **Information Systems**
  - **Instrument/Host Interface Limitations**
    - **HL7, ASCII, ASTM**
  - **What Will The IS system Accept From The Instrument**
    - **Instrument Flags or Combination of Flags**
    - **Instrument Errors**
    - **Can the IS Utilize the QC Files on the Instrument or Processed in the Host**
- **Instrument Manager**
  - **What Information is Needed and Available**
    - **Instrument Flags**
    - **QC; Patient Averages**
  - **How Robust is the Database?**
    - **Client/Physician Rule Application**
- **Standalone PC – "Home Brew" or Purchased Software**
    - **Same as Instrument Manager**
- **Hybrid System**
  - **Some Rules Evaluated in the Instrument Mgr or "Home Brew System" Remainder in the Host**
    - **Applicable Pharmacy Data**
    - **Client/Physician Rule Application**
    - **Other Interfaced Data; i.e. "Hemocare Data"**
  - **Complete evaluation in the IS system**

Richard S. Seaberg, MT(ASCP) Administrative Director North Shore University Hospital Long Island Jewish Medical Center

detect and correct errors in (CAP) Checklists

- **CHM.10800**
- **Is there a documented system in operation to detect and correct significant clerical and analytical errors, and unusual laboratory results, and does the system provide for timely correction?**
  - COMMENTARY: The laboratory must have a documented system in operation to detect and correct significant clerical and analytical errors, and unusual laboratory results. One common method is review of results by a qualified person (technologist, supervisor, pathologist) before release from the laboratory, but there is no requirement for supervisory review of all reported data. The selective use of delta checks also may be useful in detecting clerical errors in consecutive samples from the same patient/client. In computerized laboratories, there should be automatic "traps" for improbable results. The system for detecting clerical errors, significant analytical errors, and unusual laboratory results must provide for timely correction of errors, *i.e.*, before results become available for clinical decision making. For suspected errors detected by the end user after reporting, corrections must be promptly made if such errors are confirmed by the laboratory.
    - REFERENCE: Dufour D, *et al*. The clinical significance of delta checks. *Am J Clin Pathol*. 1998;110:531.
    -

autoverification in AACC EXPERT ACCESS: live on line

March 08, 2005

Developing a Patient Safety Culture in the Clinical Laboratory

Michael Astion, MD, PhD

An overview of patient safety issues related to laboratory testing and addresses how any laboratory can perform quality improvement projects to reduce patient harm related to errors in laboratory testing.

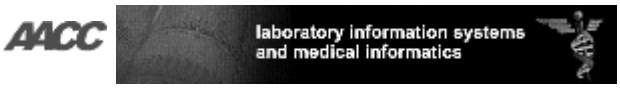
January 06, 2004

Laboratory Reporting for the Future: Linking Autoverification to the Electronic Medical Record

Robin Felder, PhD

Laboratory professionals must learn how medical decision making can be enhanced by the use of next-generation information systems that manage both automation and process-control software. Following the appearance of chronic and acute conditions, point-of-care systems may be used to enhance the diagnostic process. Once professional medical intervention is necessary, esoteric testing can then be performed in more traditional laboratory settings. Through the use of process management tools, the laboratory can become an efficient medical partner that contributes substantial interpretive value to clinical care.

AUTOVERIFICATION IN AACC LIS DIVISION



October 2004 *http://www.aacc.org/divisions/lis/lismidnew.stm*

- Autoverification: an Example Implementation Scheme

Richard S. Seaberg, MT(ASCP), Administrative Director
North Shore University Hospital, Long Island Jewish Medical Center
(Online Presentation)

- Developing Autoverification Strategies in Clinical Chemistry
- Autoverification: Process And Practice
- Autoverification:The How

Michael W. Fowler, Ph.D.
Distinguished Professor of Chemistry and Biology
Oklahoma Christian University, Oklahoma City, OK

History of Verification

Stage I (SMA and Manual Testing)

–Conditions

- **Staffing with Medical Technologists**
- **Lower volume of testing**
- **Little referral testing done by hospital laboratories**
- **Little or no instrument operation flags**

–Abnormal Pattern Recognition (SMA)

–Manual Previous Result/Delta Checks

–Manual Ratio Checks

–Manual Assay-to-assay Comparisons

–Individual Technologists Response to Verification Failures

http://www.aacc.org/divisions/lis/m_fowler3_files/frame.htm

History of Verification

Stage II – Automation of Most Testing

–Conditions

- •Staffing with Medical Technologists
- •Some Medical Laboratory Technicians
- •Increased volume of testing
- •Some referral testing done by hospital laboratories
- •Some instrument operation flags

–Manual Previous Result/Delta Checks

–Manual Ratio Checks

–Manual Assay-to-assay Comparisons

–Individual Technologists Response to Verification Failures

http://www.aacc.org/divisions/lis/m_fowler3_files/frame.htm

History of Verification

Stage III Automated Testing with LIS/HIS Interfaces

–Conditions
- •Fewer Medical Technologists
- •More Medical Laboratory Technicians
- •Some non-MT and MLT workers
- •Increased volume of testing
- •Increasing Referral testing done by hospital laboratories
- •Extensive instrument operation flags

–Computerized Previous Result/Delta Checks

–Some Autoverification by Instrument or Middleware

–Some Prescribed Technologists Response to Verification Failures

http://www.aacc.org/divisions/lis/m_fowler3_files/frame.htm

Why Autoverification?

- •Improve Quality and Consistency
- •Improve Productivity
  - –Cost Issues (Staffing)
  - –Turn-around Issues

http://www.aacc.org/divisions/lis/m_fowler3_files/frame.htm

Issues with Autoverification

- Staff Issues
  - –Loss of Jobs
  - –What to do when Autoverifcation Fails
  - –Will result in Incorrect Result
  - –Can't be as good as I am
- Information Technology Issues
  - –Cooperative Process Necessary
  - –Schedules
  - –Expertise
- Vendor Issues
  - –Instrument Vendor Cooperation
  - –Middleware Vendor Cooperation
  - –LIS/HIS Vendor Cooperation
- Regulatory Issues
  - –CAP
  - –CLIA
  - –NCCLS

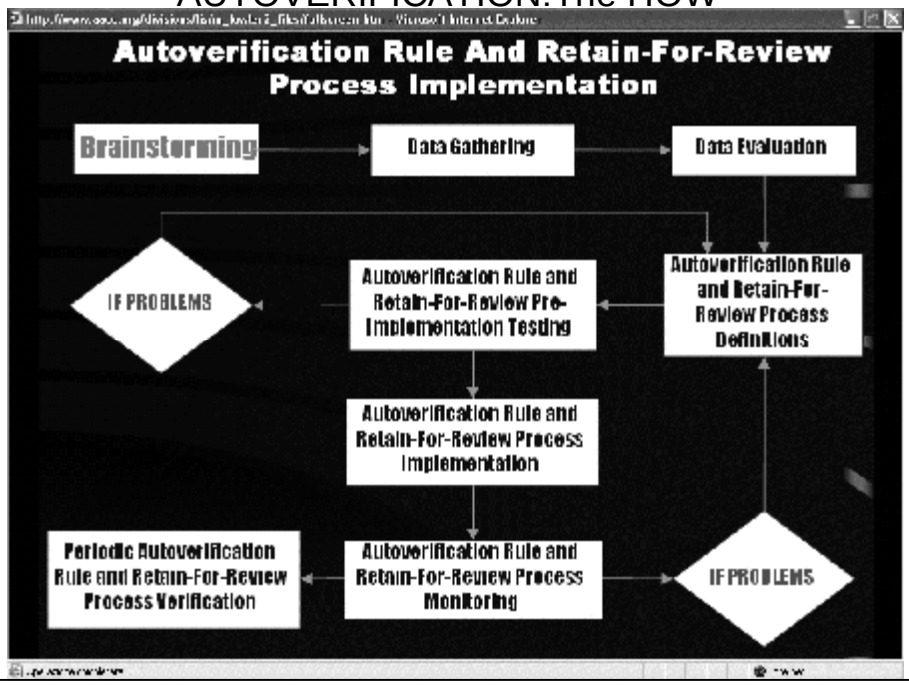
http://www.aacc.org/divisions/lis/m_fowler3_files/frame.htm

AUTOVERIFICATION: PROCESS AND PRACTICE

- Autoverification of Single Test
- Autoverification of Panel
  - – Work on Individual Tests Separately
  - – Test in Groups
  - – Combine Groups

http://www.aacc.org/divisions/lis/m_fowler1_files/frame.htm

AUTOVERIFICATION:The HOW



BRAINSTORMING

- Involve Staff
- Bench Technologists
- Lead Technologists/Technical Specialists
- Managers/Coordinators
- Scientific/Technical and Medical Directors
- IS&T
- Make list of all necessary information – specimen types, instrument error messages, etc.

DATA GATHERING

- Specimen Parameters
- Instrument Flags
- Analytical Performance and Quality Control Information
- Reference Range Considerations
- Reference Change Values and Delta Checks
- Look-back Interval
- Clinical Practice Guidelines and Information
- Concurrent Test Information

Specimen Parameters
Instrument Parameters

- Specimen Type, Acceptability and Analysis Bias
- Serum
- Plasma (EDTA, heparin, other)
- Whole Blood
- Specimen Stability

- Specimen Validity Flags, Indices Flags and/or Quantification
- Hemolysis
- Lipemia
- Icterus
- Others
- Performance Flags
- Abnormal Absorbance
- Range Limits
- Insufficient Sampling
- Clots

Analytical and Quality Control Information
Reference Range Considerations
Clinical Practice GuidelinesPublished

- Method Imprecision
- Method Interferences
- Method Bias
- Automated QC monitoring

- Age-related Issues - ALKP
- Gender-related issues – hormones, tumor markers
- Ethnic-related issues
- Collection Issues
- AM vs PM - hormones
- Recumbant vs ambulatory – albumin
- Concurrent therapy (e.g. IV, K+)
- Inpatient vs outpatient

- Thyroid (2002)
- Diabetes Mellitus (2002)
- Cardiac Markers (1999)
- Hepatic Injury (2000)
- Interviews with client physicians

Delta Checks: How to Determine?
Delta Checks and Reference Change

- Technologist Experience
- Data Review
- Clinician Input
- Literature
- Reference Change Values

- ValuesCalculation of RCV (Significant Change)
- Necessary Data
- Analytical Variation (Imprecision)
- Local, historical CV near decision points
- Biologic Variation
- Literature Sources
  - *Fraser CG, Biologic Variation: From Principles To Practice, AACC Press, 2001*
  - *Ricos C, et.el., Current databases on biologic variation: pros, cons, and progress. Scand J Clin Lab Invest 1999;59:491-500*
  - *www.westgard.com/guest17.htm*
- Experimental Data – hard to obtain locally

Calculation of Reference Change Values

$RCV = 2^{1/2} \times Z \times (CVA^2 + CVI^2)^{1/2}$

Z – Probability or Degree of Significance
Z= 2.58 at 99% Probability (Highly Significant)
Z = 1.96 at 95% Probability (Significant)
*Other Z values available in statistics tables

CVA – Analytical Variation
CVI – Biological Variation (within-subject)

Significant Change

$RCVsig(95\%) = 2^{1/2} \times 1.96 \times (CVA^2 + CVI^2)^{1/2}$

Highly Significant Change

$RCV\ high\ sig(99\%) = 2^{1/2} \times 2.58 \times (CVA^2 + CVI^2)^{1/2}$

DATA EVALUATION

- Use acquired data and workgroup experience to formulate rule
- Decide where to implement each part of the rule
  - Instrument System
  - Middleware
  - LIS
  - HIS

AUTOVERIFY RULE DEFINITION

Define Autoverify Rules in proper form

- IF statements e.g. IF result > or < Ref Range
  - Evaluate True or False or Then
- Multiple IF statements linked
  - IF result > or < Ref Range and IF Delta Value > X%
  - Evaluate True or False or Then

RETAIN-FOR-REVIEW PROCESS

Clearly define what to do when Autoverification Rule Fails (Retain-for –Review Process)

Use Brainstorming Group to Formulate Retain-for-Review Process

Example: If K+ > 5.5-6.0 mEq/L check for hemolysis; if not hemolyzed report; if hemolyzed report with comment or redraw

Do while developing Autoverification Rule (Linked Process)

AUTOVERIFY RULE and RETAIN-FOR-REVIEW PRE-IMPLEMENTATION TESTING

- Use computer test system to test Autoverify Rule against database
- Use database downloaded to spreadsheet to test Autoverify Rule
- Use manual testing of recently processed data
- Make necessary changes in the Autoverify Rule and Retain-for-Review Processes based on results of pre-implementation testing
- Retest modified Rule and Retain-for-Review Process

AUTOVERIFY RULE and RETAIN-FOR-REVIEW PROCESS MONITORING REVISION VERIFICATION

- Have Back Out Plan to remove rule
- Monitor intensely for 24 – 48 hours!!
- Monitor carefully for 1 – 2 weeks!
- Monitor for 1 month
- Make necessary changes in the Autoverify Rule and Retain-for-Review Processes based on results of monitoring
- Retest
- Implement
- Monitor

- Include Autoverify Rule Description, Retain-for-Review Process and Periodic Verification Process in SOP
- Design Periodic Verification Process to meet regulatory requirements

DATA GATHERING

- Specimen Parameters
- Instrument Flags
- Analytical Performance and Quality Control Information
- Reference Range Considerations
- Reference Change Values and Delta Checks
- Look-back Interval
- Clinical Practice Guidelines and Information
- Concurrent Test InformationInstrument Manual

Autoverification of Panel

EP1 – Na, K, Cl, CO_2, Urea N, Creatinine, Ca, Glucose

Work on Individual Tests Separately

- –Data Gathering/Evaluation
- –Write AV Rule and RfR Rules for Each Analyte
- –Test each analyte for frequency of failure against appropriate database(s)

Test in Groups e.g Na, K, Cl, CO_2 and Anion Gap or Urea N and Creatinine

- –Look for Analyte-to-analyte Relationships
- –Look for Ratio Checks
- –Decide Order of Checks
- –Test Group Against Database(s) n

Combine Groups

- –Decide Order of Checks
- –Test Against Database(s)
- –Implement
- –Modify

http://www.aacc.org/divisions/lis/m_fowler1_files/frame.htm

Begin the Process

- Brainstorm the Protocol
  - Involve Technical Staff, Pathologists, Clinicians, Marketing, IS Staff
- Determine the Algorithms to be Considered
  - Ranges, Instrument Flags or IS Flags
  - Delta Checking, QC, Patient Averages
    - Analyte dependencies - Hierarchy
  - Specimen/Client/Clinician Requests
  - "Home Brew" Buffer rules
  - Instrument Rules
  - Hybrid PC Rules
- My Opinion; Start Small With One Analyte - "Chem or Coag"
- Develop the Autoverification Workflow Diagram and Autoverification Table – "Key Component"
  - Determine the Rules Required for Each Analyte

Richard S. Seaberg, MT(ASCP) Administrative Director North Shore University Hospital Long Island Jewish Medical Center

Second Step

- **Write the Protocol & Develop the Procedure**
  - **Be as Detailed as Possible**
  - **Develop Workflow Diagram**
  - **Consider Resulting Possibilities**
  - **Consider Ongoing Regulatory/QA Policies Involving Autoverification**
  - **"Willing To Settle - While Yielding the Largest Bang for the Buck"**
- **Develop a Table to Document Process – Implementation and Ongoing Validation**
- **Get Medical Directors Written Approval**

Richard S. Seaberg, MT(ASCP) Administrative Director North Shore University Hospital Long Island Jewish Medical Center

Conclusioni Long Island

- Esempio: flusso del sodio
- Esperienza concreta

Collegamento (2) a SodiumWorkflow.pdf.lnk

Collegamento a SodiumExampleSeaberg.pdf.lnk

Collegamento a SeabergExperience.pdf.lnk

Richard S. Seaberg, MT(ASCP) Administrative Director North Shore University Hospital Long Island Jewish Medical Center

correzione, verifica e validazione

- flusso, ciclo, cicli e deragliamenti
- verifiche e algoritmi
- autoverifica

- The Next Generation of Autoverification: Looking Beyond the Horizon
  - *William E. Neeley, MD, Medical Director, DMC University Laboratories, Detroit Medical Center/Wayne State University, Detroit, MI*
    - Complex algorithms to manage an almost infinite number of variables
    - User configurations that meet specific requirements
    - Development of algorithms that allow the user to emulate and reflect their medical knowledge and thought processes
    - New autoverification systems will be closely integrated with lab automation and instruments
    - How to improve quality of results, reduce errors and increase the percentage of results automatically released

AUTO10-P
Vol. 26 No. 4

Autoverification of Clinical Laboratory Test Results; Proposed Guideline

PLEASE

This proposed document is published for wide and thorough review in the new, accelerated Clinical and Laboratory Standards Institute consensus-review process. The document will undergo concurrent consensus review, Board review, and delegate voting (i.e., candidate for advancement) for 90 days.

Please send your comments on scope, approach, and technical and editorial content to CLSI.

Comment period ends

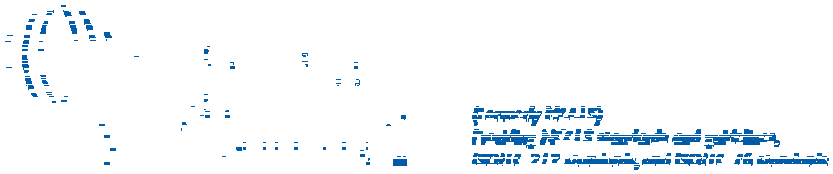
18 April 2006

The subcommittee responsible for this document will assess all comments received by the end of the comment period. Based on this assessment, a new version of the document will be issued. Readers are encouraged to send their comments to Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA; Fax: +610.688.0700; or to the following e-mail address: customerservice@clsi.org.

COMMENT

This document provides a general framework that will allow each laboratory to easily design, implement, validate, and customize rules for autoverification (automated verification) based on the needs of its own patient population.

A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process.



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Autoverification can be achieved through the use of information technology (IT) tools, but the laboratory is ultimately responsible for defining the criteria that are implemented with the IT tools to make autoverification decisions. This document provides guidelines for developing criteria that may be used in autoverification algorithms.

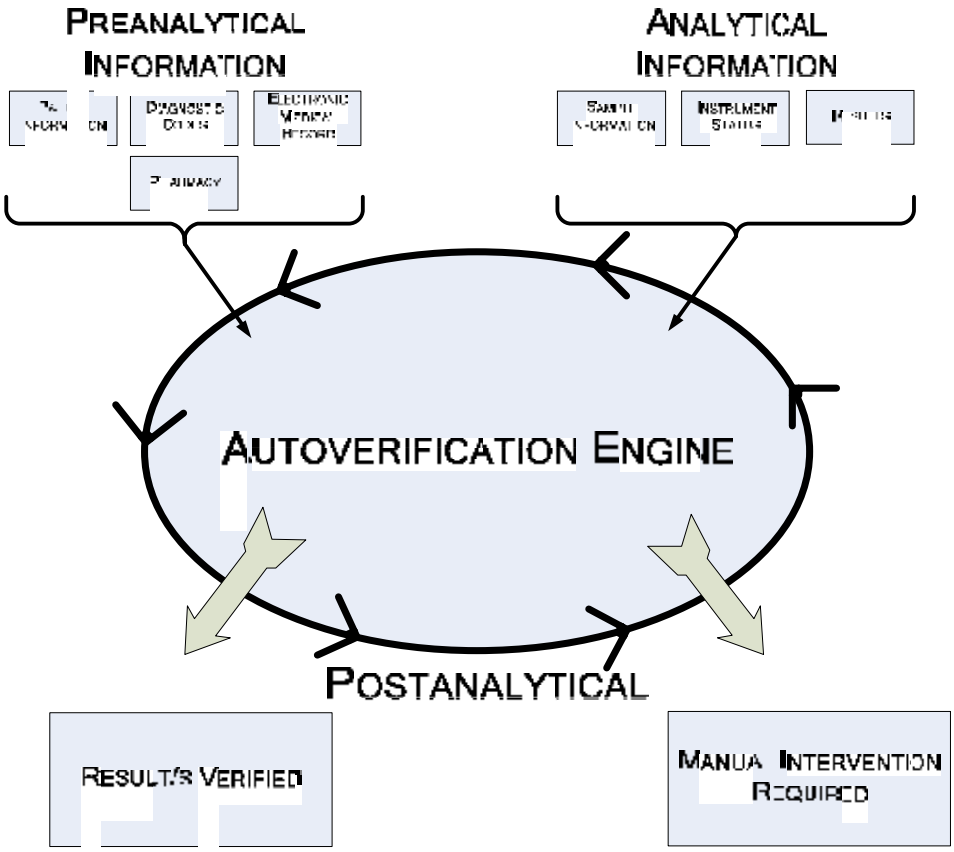

Figure 3. Autoverification Process

Invitation for Participation in the Consensus Process

An important aspect of the development of this and all Clinical and Laboratory Standards Institute (CLSI) documents should be emphasized, and that is the consensus process. Within the context and operation of CLSI, the term “consensus” means more than agreement. In the context of document development, “consensus” is a process by which CLSI, its members, and interested parties (1) have the opportunity to review and to comment on any CLSI publication; and (2) are assured that their comments will be given serious, competent consideration. Any CLSI document will evolve as will technology affecting laboratory or healthcare procedures, methods, and protocols; and therefore, is expected to undergo cycles of evaluation and modification.

The Area Committee on Automation and Informatics has attempted to engage the broadest possible worldwide representation in committee deliberations. Consequently, it is reasonable to expect that issues remain unresolved at the time of publication at the proposed level. The review and comment process is the mechanism for resolving such issues.

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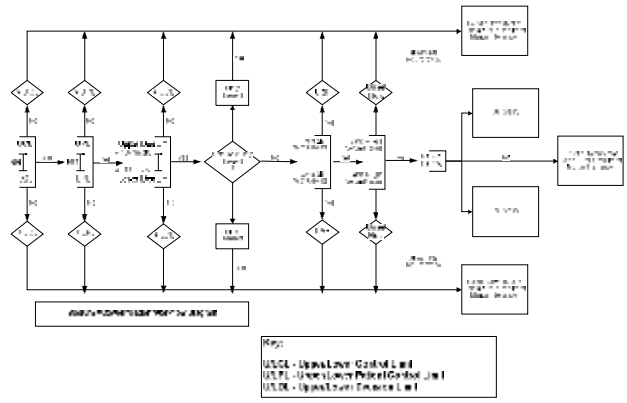
Sodium Workflow Diagram; An Example



Sodium Example

Autoverification Documentation									
Analyte:	Sodium		Site:	Core Lab	Method:	ISE			
Evaluator:									
Analyte Flag Evaluated	Accession Number	Results	Problems Encountered	Changes	Testing Performed By:				
QC Passed									
Patient Averages									
Medical Decision Levels									
• 155mmol/L									
• 115 mmol/L									
Instrument Flags - H, L, I,									
Check - % or Abs # (Rev New Pts)									
Sample Type; (Serum of Plasma)									
Fail if Urine or Fluid									
All New Patients Require Review									
Na > 125 mmol/L									
Na < 150 mmol/L									
If any fails encountered - hold group									

Implementation/Approval Documentation

- **Always Begin in the Certification Environment**
- **First – Run At Least 50 Samples ("Can Be Hard to Get")**
  - Previous run Patient Samples or "Spiked Samples"
    - Ensure that you test each entered rule
    - Document the process
- **If a "Group is Ordered" – CMP/Metabolic/CBC**
  - Ensure that any failed analyte will limit the process
    - "Better to manually verify than to retrospectively correct"
  - Use "Autoverification Form" to Document Process
    - Retain Information for Any Inspector Review
- **Once Completed – Ensure That Any "Rule Changes" are Documented In The Procedure, and Approved By The Medical Director**
- **Continue To Randomly Check The System - Frequently**
- **Perform Yearly Checks on All Analytes and Rules**

Types of Systems Available

- **Growing Number of Vendor Supplied Software to Accomplish**
  - HemaLink™ - ABX
  - Orchard™ Software – Beckman/Coulter
  - Middleware™ - Roche (? Third Quarter Release)
    - Additional Packages under Development
- **“Home Brew” System**
  - Simple or Sophisticated
    - Usually requires computer programming

Home Brew System

- **Usually Non-Invasive to the LIS**
  - Uses PC's Between Instrument Platform and LIS – "Post Analytical System"
    - Non – Interfering with Bi-Directional Instrument Interfaces
  - Takes Results from Instrument
    - Evaluates using External Program
      - Microsoft Visual Basic™
  - PC Evaluates Results and Communicates to Host over "Dumb Terminal Port"
- **Benefits of the "Home Brew System"**
  - Allows for Extensive Rule Base – Previous results, Δ's, QC, Special Requests of MD's etc.
  - Evaluation of Rules Produce an "Action Message" for Technologist Defining Problem and Failed Rule/s

Table & Description Courtesy of William Neely MD – Detroit Medical Center – Medical Director

My Experience to Date
LIS System – Cerner Classic

- **Done by the LIS**
  - Based upon 9915 Table & 0071 Testing Site Table – Instrument Interface
  - Workcenter/Testing Site
- **Dynamics & Rule Issues**
  - Results Assigned by Posting Manager to Lab Activity File
  - Cannot Utilize QC Data as a Rule
  - Instrument Flags NOT Sent to Cerner
- **Current Methodology**
  - Autoverify Results That are Within “Critical Limits”
  - ∆ Failures will Limit the Process
  - “IIM W/I ORD PROC” Field – Determine If One Analyte Fails Then Group Should Fail
- **Limitations**
  - Some Results Auto-Verify
    - Leads to Corrected Reports

Other LIS Systems - Example

- **Places Data into “Temporary Holding” Files**
  - Requires Instrument Capability of Interfacing Accession Number
  - QA, QC, Specimen Grouping
- **Reports to:**
  - Hold File
    - Evaluates Rules then Posts to Patient File
- **Rules not Applicable under Manual Entry**
- **Different LIS Vendors have Different Capabilities**

Our Experience

- **Any Changes will Require The System to Be Re-Verified**
- **Difficult to Maintain**
  - Keep System as Generic As Possible
- **Primarily LIS Based**
  - Only Considers IS rules
  - Cannot Utilize QC – Must Be run First
    - Concerns with New CLIA QC rule Changes
  - Lacks the ability to Use Instrument or Sample Flags
  - Cannot Utilize any Pre-Analytical variables
    - Example; Collection Time to Analysis Time
- **We are now Considering a "Hybrid" System**
  - Vendor Supplied Software Enabling more "Robust" Environment

Our Experience – Advantages

- **Noted Savings of Approximately 80hrs/Bi-Weekly**
- **Provides for Consistent Release of Results**
- **Removes Approximately 40% of Total Specimen Testing Volume for Normal Results**