Data Innovations CAP Webinar
5/17/2017
Before We Begin

• Background
  – Received MT in 1977 and MCLT in 1982
  – CompuNet Clinical Labs, Premier Health
    ▪ Joint Venture Lab in Dayton, OH 1986.
    ▪ CompuNet – Director of Chemistry, Premier Health – Chemistry Technical Systems Specialists
    ▪ Instrument Manager
      • Company Wide system (95 connection licenses over 16 locations, 3 LIS’s, Unity Real Time, CAP Driver, Moving Averages, Maintenance Manager, Lab Intel)
      • Worked with DI on: Hematology Workspace, Unity Real Time, Lab Intel, CAP Driver
    ▪ Data Innovations 2016

• CAP inspections since 1986, inspector for ~20 years
CAP Checklist

• Lab General – 8.17.16
• All Common – 8.17.16
• Hematology and Coagulation – 8.17.16
• Chemistry and Toxicology – 8.17.16

The follow are suggestions on how each of the covered standards might be answered using Instrument Manager. Each inspector may view compliance with the standards differently.
Objectives

• Understand how Instrument Manager can assist you during inspections.
• Control Security – User access.
• Use Specimen Event Logs for documentation of:
  – Auto-verification
  – Data review, delta checks, range checks etc.
  – Error Detection
Computer Access Codes

Computer access codes (security codes, user codes) are in place to confine individual’s access to those functions they are authorized to use, and the security of access codes is maintained (e.g. inactivated when employees leave, not posted on terminals).

- User Authentication
  - Instrument Manager Authentication – stored within Instrument Manager
  - Operating System Authentication – stored at the Operating System level
  - LDAP Authentication - stored on the LDAP server (e.g. Microsoft Active Directory)

- Password strength and expiration based on individual laboratory security polices.
Group Definition
1. Define group names
2. Define general actions
3. Define owner of the group
4. Define what SM data elements they can access
5. Define what menu items they can access
6. Define what connections they can access
Phase II

- User Definition

1. Define user ID and name
2. Enable the user
3. List of group(s) to which they belong
Welcome to Instrument Manager™ v8.14

Consulting and Training Resources
Data Innovations® offers complete support and training as well as consulting services for all your needs. Click a topic for more information.

Instrument Manager Consulting
Instrument Manager Training

Instrument Manager Online Documentation
Data Innovations offers a broad range of user’s guides that provide instructions for using the different features of Instrument Manager. This Help system contains the complete Help for Instrument manager and its features. You can print out individual topics from the Help. You can also view PDF copies from your installation DVD.

Archiving User’s Guide
Eliminate the stacks of paper records piling up in your lab. With Instrument Manager’s archiving feature, you can store your records electronically. Retrieve the data quickly and easily when needed.

ODBC User’s Guide
Learn how to access and examine data stored by Instrument Manager using an Open Database Connectivity interface, such as Crystal Reports, Access, or Excel. This feature can be used with any third-party tool that supports ODBC access.
Specimen Event Log (SEL)

- All transactions involving a Specimen are contained in the Specimen Event Log
- Can be viewed in three different prospective:
  - Specimen Tracking – Overview of major transactions
  - Audit Trail – Overview of Audit Events
  - Specimen Event Log View – Detailed view of all transactions.

For additional information on the Specimen Event Log, see the Instrument Manager Troubleshooting Guide located under Help from the main Instrument Manager Screen
How to find
## Specimen Tracking View

<table>
<thead>
<tr>
<th>Specimen ID</th>
<th>Event Date/Time</th>
<th>Origin Connection</th>
<th>Destination Connection</th>
<th>Message Type</th>
<th>Rack/Carrier ID/Y</th>
<th>Cup/Position/XX</th>
<th>Sequence Number</th>
<th>Instrument ID</th>
<th>Location 1</th>
<th>Location 2</th>
<th>Event Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>MISYS_ORDERS</td>
<td>11/22/2016 1:00</td>
<td>MISYS_ORDERS</td>
<td>CENT3 - MYH Ma</td>
<td>request</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MISYS_ORDERS</td>
<td>11/22/2016 1:10</td>
<td>MISYS_ORDERS</td>
<td>CENT3 - MYH Ma</td>
<td>request</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Misys</td>
<td>11/22/2016 2:10</td>
<td>Cobas 4</td>
<td>Cobas 4</td>
<td>query</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Misys</td>
<td>11/22/2016 2:20</td>
<td>Cobas 4</td>
<td>Cobas 4</td>
<td>status</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Misys</td>
<td>11/22/2016 2:30</td>
<td>Cobas 4</td>
<td>Cobas 4</td>
<td>status</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Misys</td>
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<td>Cobas 4</td>
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<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MISYS_ORDERS</td>
<td>11/22/2016 2:50</td>
<td>MISYS_ORDERS</td>
<td>CENT3 - MYH Ma</td>
<td>request</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MISYS_ORDERS</td>
<td>11/22/2016 3:00</td>
<td>MISYS_ORDERS</td>
<td>CENT3 - MYH Ma</td>
<td>request</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Misys</td>
<td>11/22/2016 3:10</td>
<td>Cobas 4</td>
<td>Cobas 4</td>
<td>query</td>
<td></td>
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<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

**Note:** The table above shows a view of specimen tracking with various columns including Specimen ID, Event Date/Time, Origin Connection, Destination Connection, Message Type, Rack/Carrier ID/Y, Cup/Position/XX, Sequence Number, Instrument ID, Location 1, Location 2, and Event Description.
# Audit Trail

<table>
<thead>
<tr>
<th>Transaction ID</th>
<th>Event Date/Time</th>
<th>Specimen ID</th>
<th>Event</th>
<th>Connection/Configuration</th>
<th>User ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>114722360</td>
<td>11/22/2016 1:0...</td>
<td>Audit</td>
<td>MISYS_ORDERS...</td>
<td>Rules</td>
<td></td>
</tr>
<tr>
<td>114722645</td>
<td>11/22/2016 1:1...</td>
<td>Audit</td>
<td>MISYS_ORDERS...</td>
<td>Rules</td>
<td></td>
</tr>
<tr>
<td>114727751</td>
<td>11/22/2016 2:2...</td>
<td>Audit</td>
<td>Cobas 4/Cobas 4</td>
<td>Rules</td>
<td></td>
</tr>
</tbody>
</table>

*Note: The image shows a screenshot of a software interface displaying an audit trail with event logs.*
Specimen Event Log View

<table>
<thead>
<tr>
<th>Transaction ID</th>
<th>Event Date/Time</th>
<th>Specimen ID</th>
<th>Event</th>
<th>Connections/Configuration</th>
<th>User ID</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>11/22/2016 22..</td>
<td></td>
<td>Test Code Mapping</td>
<td>Cobas 4/Cobas 4</td>
<td></td>
</tr>
<tr>
<td></td>
<td>11/22/2016 22..</td>
<td></td>
<td>System - Data Up.</td>
<td>Cobas 4/Cobas 4</td>
<td></td>
</tr>
<tr>
<td></td>
<td>11/22/2016 22..</td>
<td></td>
<td>Audit</td>
<td>Cobas 4/Cobas 4</td>
<td>Rules</td>
</tr>
<tr>
<td></td>
<td>11/22/2016 22..</td>
<td></td>
<td>System - Data Up.</td>
<td>Cobas 4/Cobas 4</td>
<td></td>
</tr>
<tr>
<td></td>
<td>11/22/2016 22..</td>
<td></td>
<td>Tracking</td>
<td>Cobas 4/Cobas 4</td>
<td></td>
</tr>
<tr>
<td></td>
<td>11/22/2016 22..</td>
<td></td>
<td>System - Data Up.</td>
<td>Cobas 4/Cobas 4</td>
<td></td>
</tr>
<tr>
<td></td>
<td>11/22/2016 22..</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>11/22/2016 22..</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

IF Always
THEN Set Test Instrument ID On Test "EGFR" = "C094"
DESC Add comments for handling, SQ, ADME
IF (Specimen ID Matches Pattern of "NA1.70") AND (Result On Test "16" NOT = "0") AND (Result On Test "18" NOT = "0") AND (Result On Test "19" NOT = "0")
THEN Set Result On Test "16" = Result On Test "18" Concatenated With "H-LDHELE" AND Set Quality
DESC Non ID's to Max:
IF (Specimen ID Matches Pattern of "NA1.70")
THEN Add Destination Connection(s) "WHYSRES1"
DESC Any Error, Delay
IF (Any Error Code(s) On Any Test NOT = "0") OR (Any Test Common(s) On Any Test Contains "Data"
THEN Hold all Tests for Verification
DESC Set Shift
IF Shift = "0"
THEN Set Shift = Extract Component of First Result to IM Date/Time Using "0\" From "12\" To "24\" AND Set DESC Check for Numeric
IF (Shift Is Numeric)
THEN
DESC Shift 1
IF (Shift >= "0") AND (Shift < "16")
ELSE
DESC Shift 2
# Using Patient Data in Rules Testing

![Image of Instrument Manager interface](image.png)

<table>
<thead>
<tr>
<th>Transaction ID</th>
<th>Specimen ID</th>
<th>Event</th>
<th>Connection/Confidential</th>
<th>User ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>21703200012</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2/1/2017 11:31:09 AM</td>
<td>1703200012</td>
<td>System - Data A...</td>
<td>Corner Orders/Conf...</td>
<td></td>
</tr>
<tr>
<td>2/1/2017 11:31:09 AM</td>
<td>1703200012</td>
<td>System - Data U...</td>
<td>Corner Orders/Conf...</td>
<td></td>
</tr>
<tr>
<td>2/1/2017 11:31:09 AM</td>
<td>1703200012</td>
<td>Audit</td>
<td>Corner Orders/Conf...</td>
<td>Rules</td>
</tr>
<tr>
<td>21703200012</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2/1/2017 11:31:09 AM</td>
<td>1703200012</td>
<td>System - Data A...</td>
<td>Corner Orders/Conf...</td>
<td></td>
</tr>
<tr>
<td>2/1/2017 11:31:09 AM</td>
<td>1703200012</td>
<td>System - Data U...</td>
<td>Corner Orders/Conf...</td>
<td></td>
</tr>
<tr>
<td>2/1/2017 11:31:09 AM</td>
<td>1703200012</td>
<td>System - No conf...</td>
<td>Specimen Rulin...</td>
<td></td>
</tr>
<tr>
<td>2/1/2017 11:31:09 AM</td>
<td>1703200012</td>
<td>System - Data A...</td>
<td>Corner Orders/Conf...</td>
<td></td>
</tr>
<tr>
<td>2/1/2017 11:31:09 AM</td>
<td>1703200012</td>
<td>System - Data A...</td>
<td>Corner Orders/Conf...</td>
<td></td>
</tr>
</tbody>
</table>
We like to keep our users informed about the functions and features of Data Innovations products that can make some tasks much easier.

Our products have so many capabilities that it can be hard to keep track of all of them so we share “Did You Know?” messages with our customers and business partners that explain how they can take advantage of features that are already right at their fingertips and can increase productivity. Afterwards we post them here so you may reference them whenever you may need to.

- Changing the Status Screen Refresh Interval for Instrument Manager - October 2016
- Tools to Setup Test, Fluid, Instrument ID and Error Codes in Instrument Manager - September 2016
- Virtualize Instrument Manager™ using VMware® - July 2016
- Stop Reporting Results if QC Not Run in x Time - March 2016
- Let MA Automatically Calculate Your Target SD and Your Mean - December 2015
- Cellphone Text Notifications from Instrument Manager - October 2015
- Data Mining with Instrument Manager - August 2015
- Save Real Patient Examples to Test Rules Against - June 2015
- Access Instrument Manager Via a Web Browser - April 2015
Calculated Patient Data Verification

Calculated values reported with patient results are reviewed every two years or when a system change is made that may affect the calculations. NOTE: This checklist requirement applies only to calculations based on formulas modifiable by the user.
Phase II

GFR CALCULATOR

Glomerular filtration rate (GFR) is the best overall index of kidney function. Normal GFR varies according to age, sex, and body size, and declines with age. The National Kidney Foundation recommends using the CKD-EPI Creatinine Equation (2009) to estimate GFR.

Serum Creatinine: 1.2 mg/dL  1.2 μmol/L
Serum Cystatin C:       mg/L
Age:                   64 Years
Gender:                Male
Race:                  Black
Standardized Assays:
Yes          No  Not Sure
Remain body surface adjustment: Yes  No  Not Sure

Added Test EGFR
Added Result to test 'EGFR' in 'EVENT/CHFR2'
Added Error Code(s) to test 'EGFR'
Added Test Collection Date/Time to test 'EGFR' of '0/0/0'
Added Date/Time used for previous Patient Results to 'a'
Tests 'CREA', 'HEMO', 'ICT', 'EGFR' were held for vertic
Specimen Quality Comment

The system provides for comments on specimen quality that might compromise the accuracy of analytic results (e.g. hemolyzed, lipemic).

The Specimen Event Log (SEL) can be used to show rules that are used to evaluate hemolysis and then add message to the result or hold the specimen for recollection.
Data Input ID

There is an adequate system to identify all individuals who have entered and/or modified patient data or control files.

The SEL can also be used to demonstrate this as the user that reviewed or modified is clearly documented.
Autoverification Validation

There is 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.

The rules testing area can be used to store samples that trigger various rules and then use the audit trail to confirm that the appropriate rule(s) fired and the correct action took place. Audit trails can be stored or printed for inspection ready documentation.
Autoverification Can Be Turned Off

1. Stop the Connection

2. Start Holding All Tests for Verification
Autoverification QC Samples

For all test results subject to autoverification, the laboratory ensures that applicable quality control samples have been run within an appropriate time period, with acceptable results.

- QC module can be used to upload QC results in real time and provide immediate feedback to the staff if QC passed or failed.
- Upon QC Failure IM can automatically stop the release of that analyte.
- Can be demonstrated via rules testing module or via real life situation.
CAP - GEN 43881
Autoverification Results

Results are compared with an appropriate range of acceptable values and flags or warnings reviewed prior to autoverification.

Specimen Event Log (SEL) can be used to show the rules that fired on any given sample. This will include warnings and flags as appropriate.
Autoverification Results

Results are compared with an appropriate range of acceptable values and flags or warnings reviewed prior to autoverification.

Specimen Event Log (SEL) can be used to show the rules that fired on any given sample. This will include warnings and flags as appropriate.
Autoverification Audit Trail

The audit trail in the computer system identifies all test results that were autoverified, and the date/time of autoverification.

Specimen Event Log (SEL) has an audit trail view which documents the exact date and time of each event. The User ID (blocked out on this example) would show who released the result.
Autoverification Delta Checks

The autoverification process includes all delta checks that the laboratory performs prior to manual release of test results.

Delta rules can be constructed to cover any number of parameters, values, timeframes, as well as patient demographics and even location. Specimen Event Log can demonstrate when a rule has fired. Remember all rules are reviewed on all samples to see if the results qualifies for that rule.
Multiple Analyzer ID

When multiple identical analyzers are used, they are uniquely identified such that a test result may be appropriately traced back to the instrument performing the test.

The Specimen Event Log shows the details of each result including the instrument that generated the result. If the instrument includes multiple modules then the individual module is identified.
PT Integration Routine Workload

The laboratory integrates all proficiency testing samples within the routine laboratory workload, and those samples are analyzed by personnel who routinely test patient/client samples, using the same primary method systems as for patient/client/donor samples.

When logged in like any patient sample, the Instrument Manager rules will apply exactly like with patient samples. This can be demonstrated via use of the Specimen Event Log.
Error Detection and Correction

There is a written procedure for the detection and correction of significant clerical and analytical errors, and unusual laboratory results, in a timely manner.

While a written procedure is required by this standard rules can be constructed to provide much of this review.

You can then use the Specimen Event Log or Rules Testing to demonstrate rules that do this type of check.
Supervisory Result Review

In the absence of on-site supervisors, high complexity testing performed by trained high school graduates qualifying as high complexity testing personnel is reviewed by the laboratory director or supervisor/general supervisor within 24 hours.

Rules can set-up to require secondary review before the release of results. This can be based on Instrument, Date or Time, Reviewing Tech, etc.

If: (Test Results Reviewed by) {On Any Test} = {Value List:Tech}
Then: (Set) {Second Level Review Required} {On That Test} = "1"
Else:
Specimen Rejection Criteria

There are written criteria for the rejection of unacceptable specimens, instructions for the special handling of sub-optimal specimens, and records of disposition of all unacceptable specimens in the patient/client report and/or quality management records.

Rules can be constructed to review for suboptimal specimens (hemolysis, lipemia, icterus) and add messages, reject or take other actions based on written policy.

You can then use the Specimen Event Log or Rules Testing to demonstrate rules that do this type of check.
Critical Result Notification

The laboratory has written procedures for immediate notification of a physician (or other clinical personnel responsible for the patient's care) when results of designated tests exceed established "critical" values that are important for prompt patient management decisions. Records of notification are maintained.
Critical Result Read-Back

When critical results are communicated by phone, “read-back” of the results is requested and recorded.

Rules can be written that prompt for the documentation of the read-back.

The Specimen Event Log maintains this documentation in addition to the LIS.
Can also be handled as Second Level Review which allows the call to be made by alternate individuals.

The “Call” result is answered with the name of the person who was called along with the date and time. IM then puts together the message “Critical Result Called to and read back by J. Doe 02012017, 9:55:15.” and attaches the message to the critical result for documentation within the LIS.
Questions?

Thank you for your time!