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Data Innovations CAP Webinar

5/17/2017

Data Innovations®
Delivering Tomorrow's Lab, Today

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
      - Original Install 2003. Live with first set of autoverification rules in 2006.
      - 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).

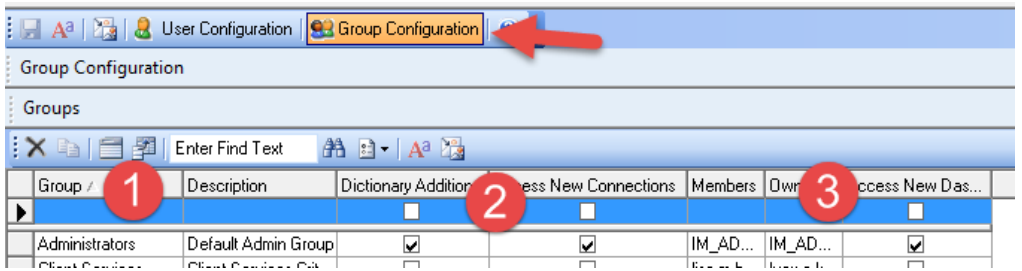
- User Authentication
  - Instrument Manager Authentication – stored within Instrument Manager
  - Operating System Authentication – stored at the Operating System level
  - LDAP Authentication - stored on the LDAP server (e.g. Microsoft Active Directory)

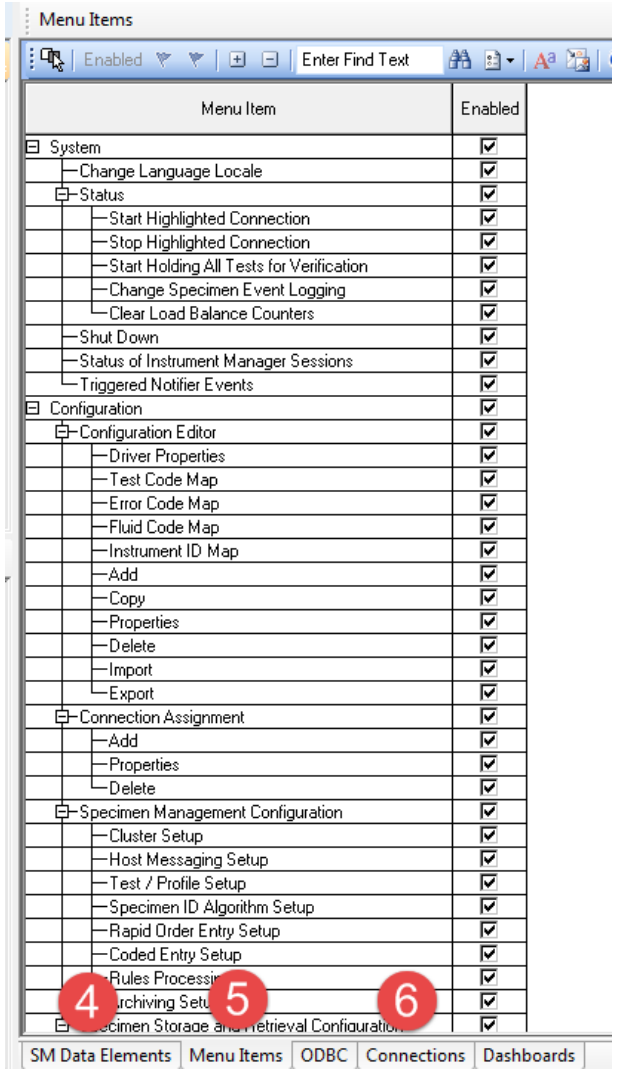
- Password strength and expiration based on individual laboratory security polices.

CAP - GEN 43200 (cont.) Phase II

Group Definition

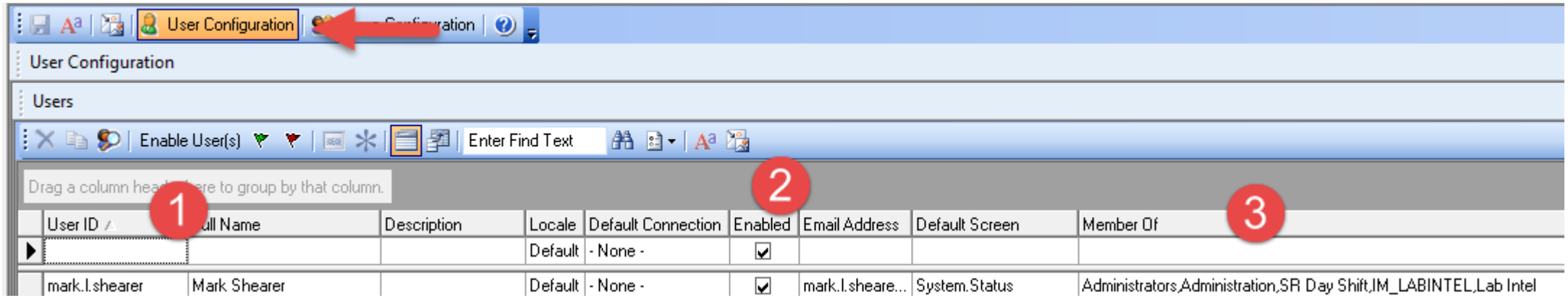
1. Define group names
2. Define general actions
3. Define owner of the group
4. Define what SM data elements they can access
5. Define what menu items they can access
6. Define what connections they can access



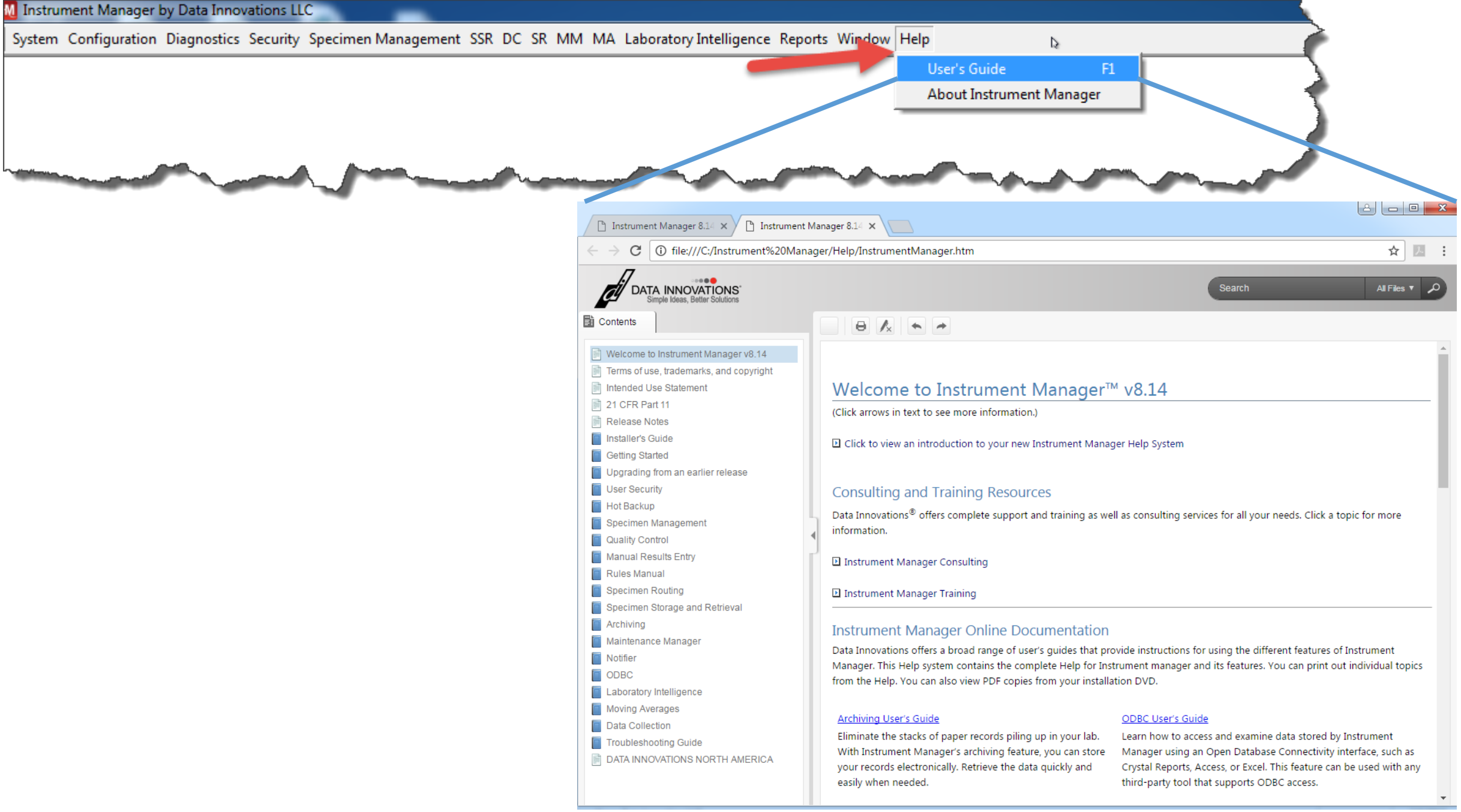


CAP - GEN 43200 (cont.) Phase II

- User Definition



1. Define user ID and name
2. Enable the user
3. List of group(s) to which they belong

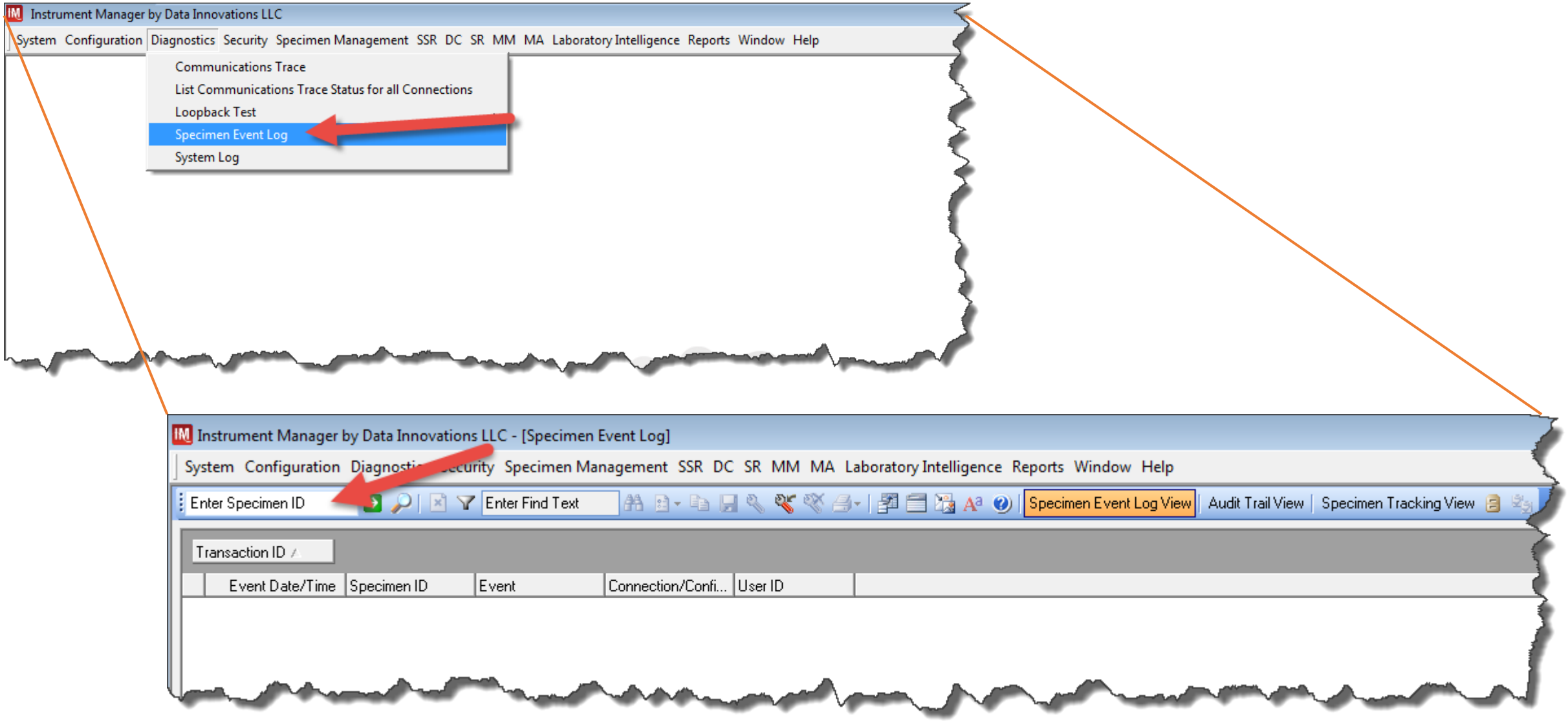

Instrument Manager by Data Innovations LLC
System Configuration Diagnostics Security Specimen Management SSR DC SR MM MA Laboratory Intelligence Reports Window Help
User's Guide F1
About Instrument Manager
Instrument Manager 8.14
Instrument Manager 8.14
file:///C:/Instrument%20Manager/Help/InstrumentManager.htm
DATA INNOVATIONS
Simple Ideas, Better Solutions
Search
All Files
Contents
Welcome to Instrument Manager v8.14
Terms of use, trademarks, and copyright
Intended Use Statement
21 CFR Part 11
Release Notes
Installer's Guide
Getting Started
Upgrading from an earlier release
User Security
Hot Backup
Specimen Management
Quality Control
Manual Results Entry
Rules Manual
Specimen Routing
Specimen Storage and Retrieval
Archiving
Maintenance Manager
Notifier
ODBC
Laboratory Intelligence
Moving Averages
Data Collection
Troubleshooting Guide
DATA INNOVATIONS NORTH AMERICA
Welcome to Instrument Manager™ v8.14
(Click arrows in text to see more information.)
Click to view an introduction to your new Instrument Manager Help System
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)

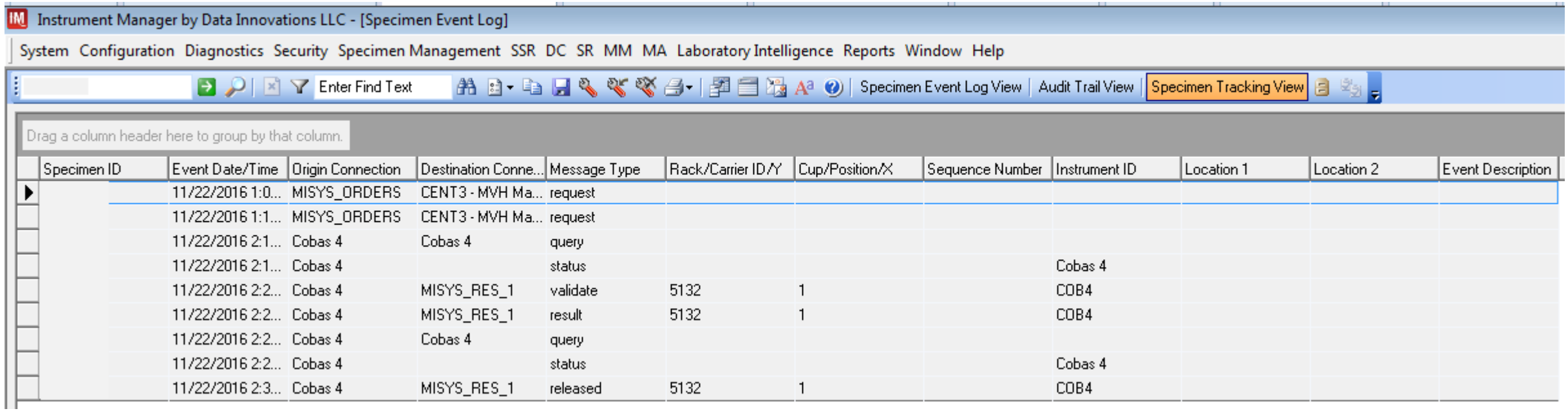
- All transactions involving a Specimen are contained in the Specimen Event Log
- Can be viewed in three different prospective.
  - Specimen Tracking – Overview of major transactions
  - Audit Trail – Overview of Audit Events
  - Specimen Event Log View – Detailed view of all transactions.

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

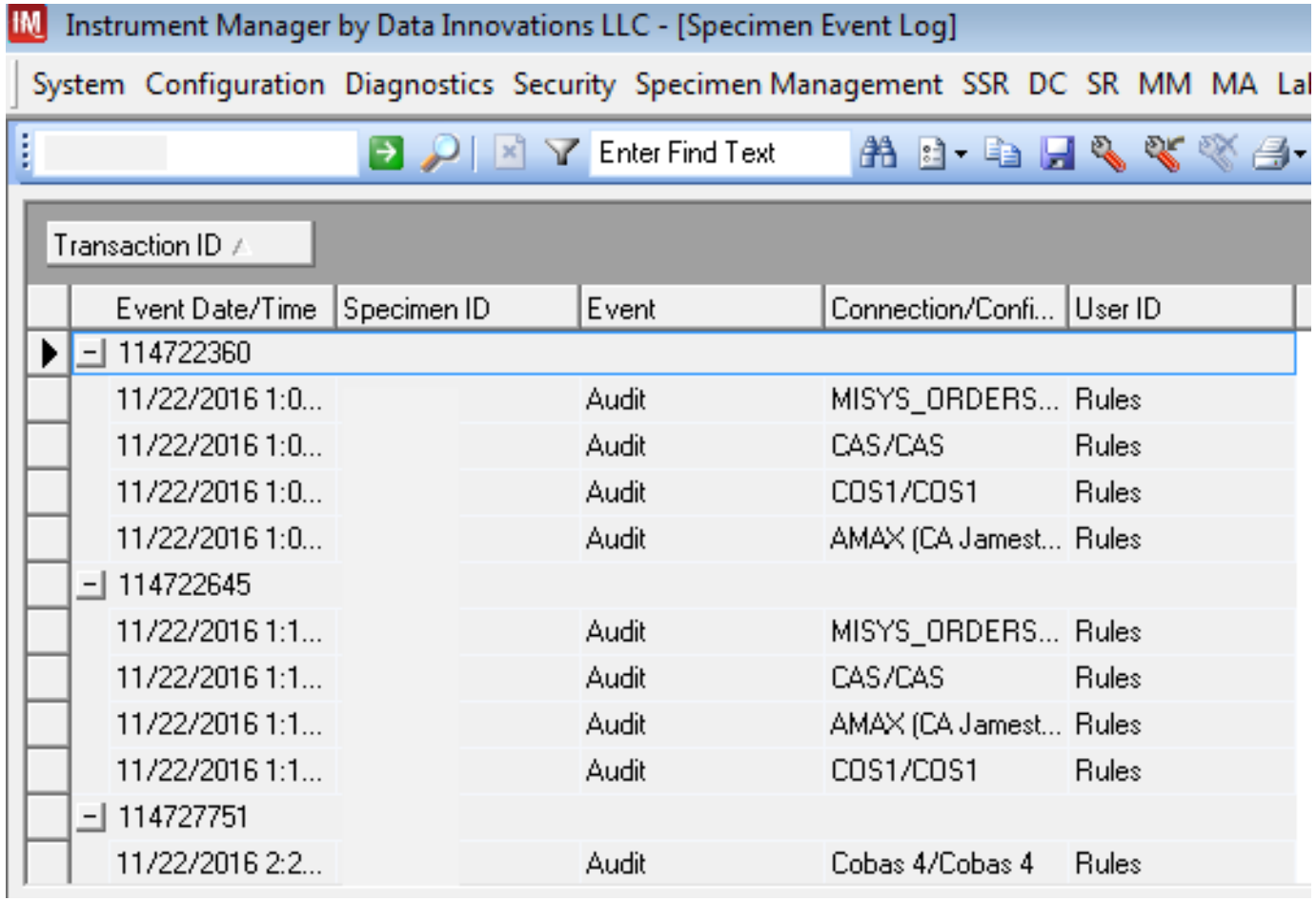

Instrument Manager by Data Innovations LLC
System Configuration Diagnostics Security Specimen Management SSR DC SR MM MA Laboratory Intelligence Reports Window Help
Communications Trace
List Communications Trace Status for all Connections
Loopback Test
Specimen Event Log
System Log
Instrument Manager by Data Innovations LLC - [Specimen Event Log]
System Configuration Diagnostics Security Specimen Management SSR DC SR MM MA Laboratory Intelligence Reports Window Help
Enter Specimen ID
Enter Find Text
Specimen Event Log View
Audit Trail View
Specimen Tracking View
Transaction ID
Event Date/Time
Specimen ID
Event
Connection/Confi...
User ID

Specimen Tracking View

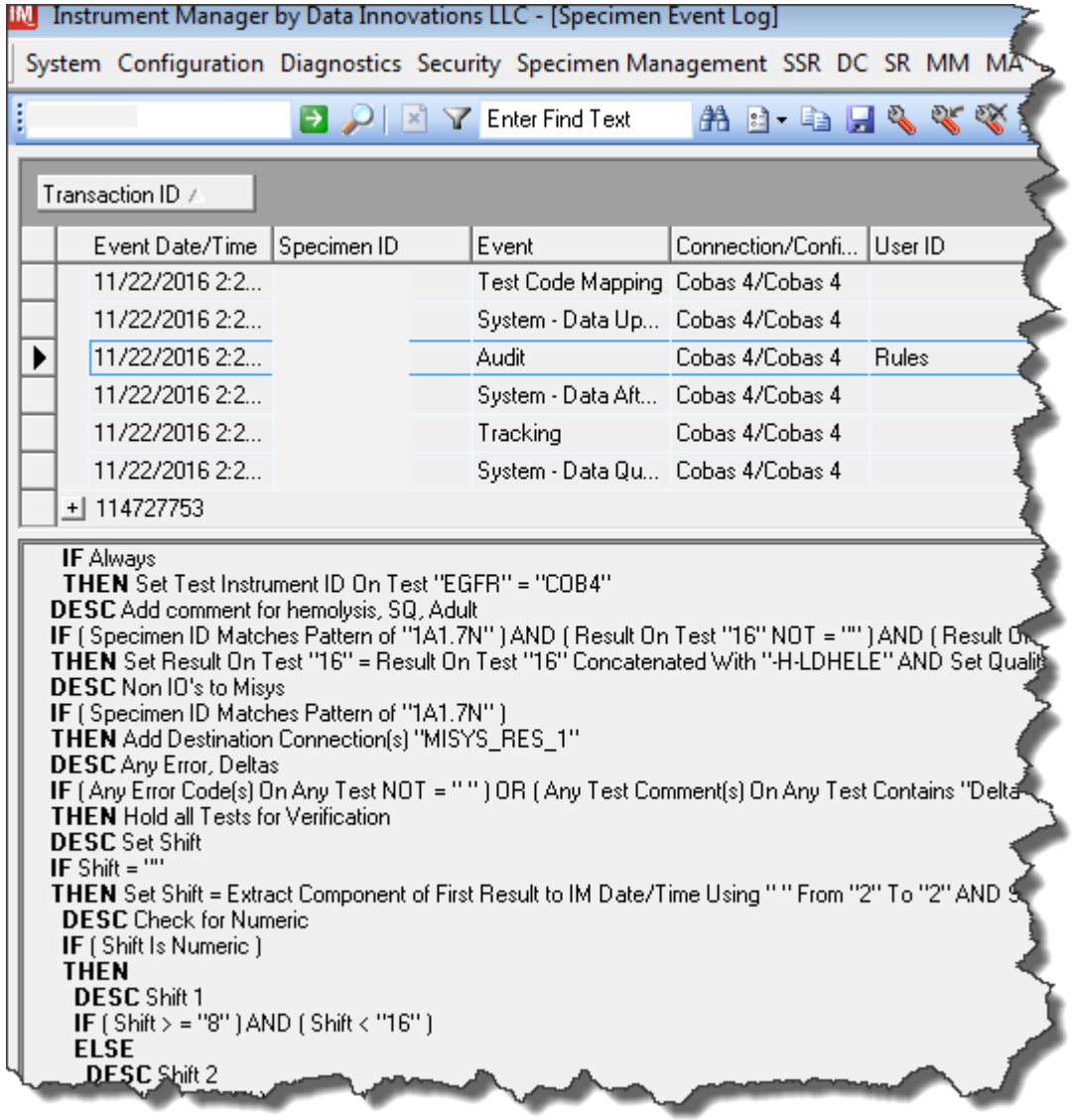


Specimen ID	Event Date/Time	Origin Connection	Destination Conne...	Message Type	Rack/Carrier ID/Y	Cup/Position/X	Sequence Number	Instrument ID	Location 1	Location 2	Event Description
	11/22/2016 1:0...	MISYS_ORDERS	CENT3 - MVH Ma...	request							
	11/22/2016 1:1...	MISYS_ORDERS	CENT3 - MVH Ma...	request							
	11/22/2016 2:1...	Cobas 4	Cobas 4	query							
	11/22/2016 2:1...	Cobas 4		status				Cobas 4			
	11/22/2016 2:2...	Cobas 4	MISYS_RES_1	validate	5132	1		COB4			
	11/22/2016 2:2...	Cobas 4	MISYS_RES_1	result	5132	1		COB4			
	11/22/2016 2:2...	Cobas 4	Cobas 4	query							
	11/22/2016 2:2...	Cobas 4		status				Cobas 4			
	11/22/2016 2:3...	Cobas 4	MISYS_RES_1	released	5132	1		COB4			

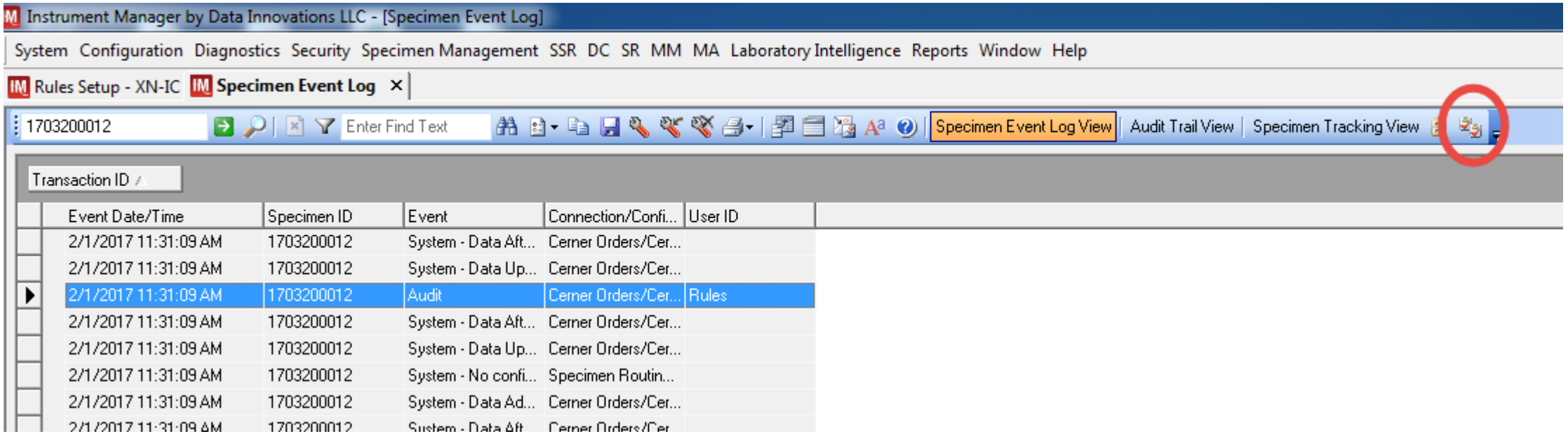
Audit Trail


Instrument Manager by Data Innovations LLC - [Specimen Event Log]
System Configuration Diagnostics Security Specimen Management SSR DC SR MM MA La
Enter Find Text
Transaction ID
Event Date/Time | Specimen ID | Event | Connection/Confi... | User ID
114722360
11/22/2016 1:0... | Audit | MISYS_ORDERS... | Rules
11/22/2016 1:0... | Audit | CAS/CAS | Rules
11/22/2016 1:0... | Audit | COS1/COS1 | Rules
11/22/2016 1:0... | Audit | AMAX (CA Jamest... | Rules
114722645
11/22/2016 1:1... | Audit | MISYS_ORDERS... | Rules
11/22/2016 1:1... | Audit | CAS/CAS | Rules
11/22/2016 1:1... | Audit | AMAX (CA Jamest... | Rules
11/22/2016 1:1... | Audit | COS1/COS1 | Rules
114727751
11/22/2016 2:2... | Audit | Cobas 4/Cobas 4 | Rules

Specimen Event Log View



Using Patient Data in Rules Testing



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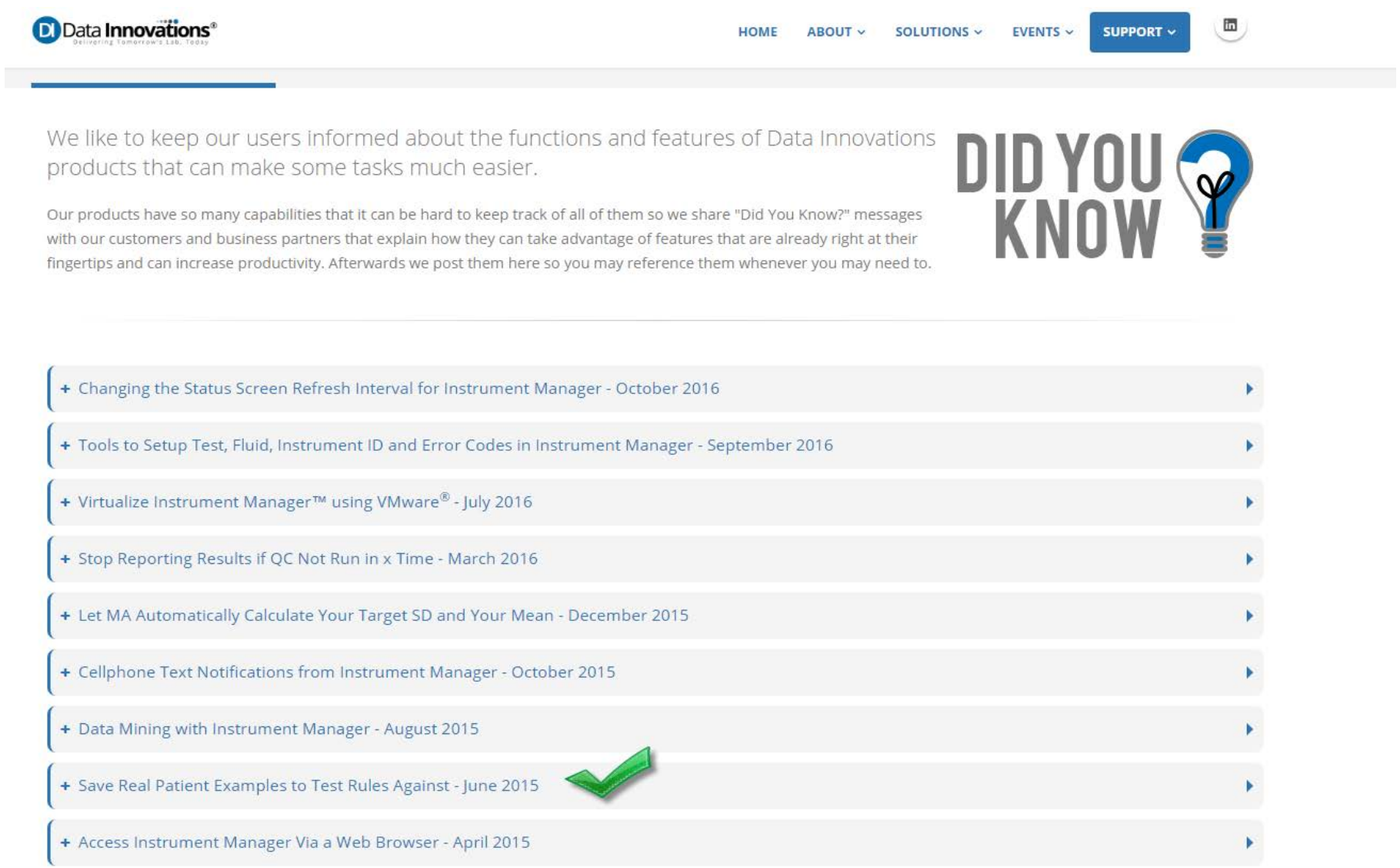
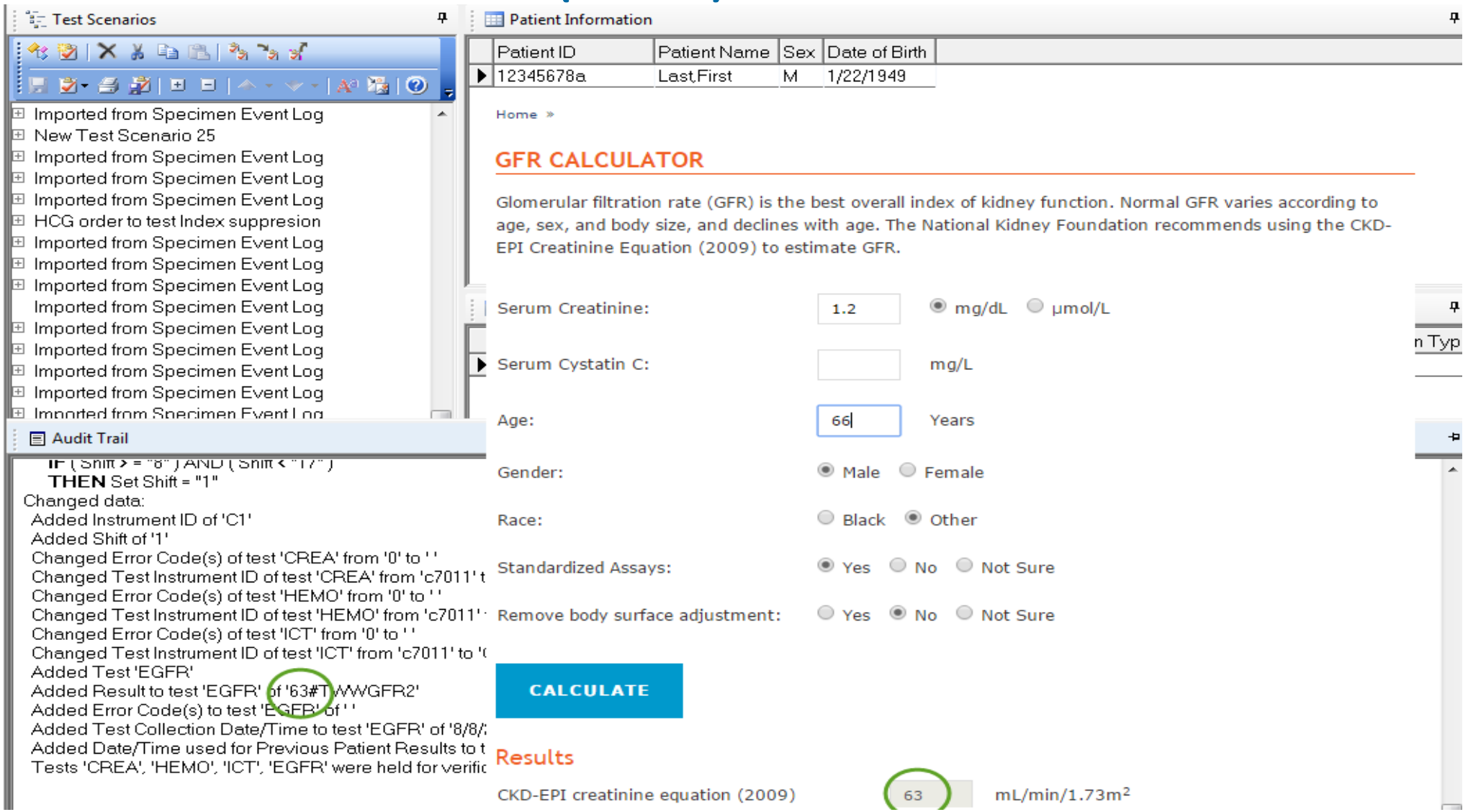


Calculated Patient Data Verification

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.

CAP - GEN 43450 (cont.)

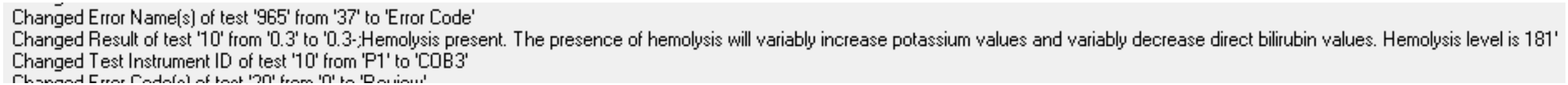
Phase II



CAP - GEN 43750 Phase II

Specimen Quality Comment

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

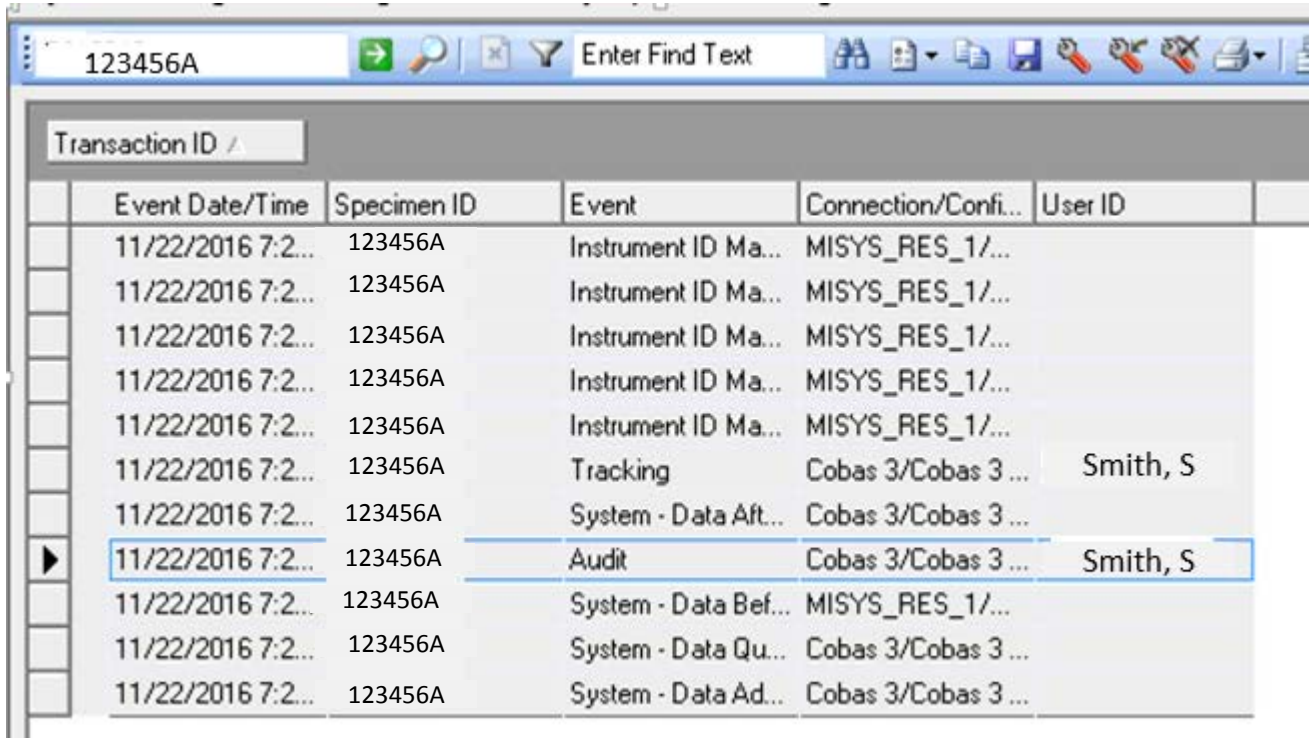


The Specimen Event Log (SEL) can be used to show rules that are used to evaluate hemolysis and then add message to the result or hold the specimen for recollection

Data Input ID

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

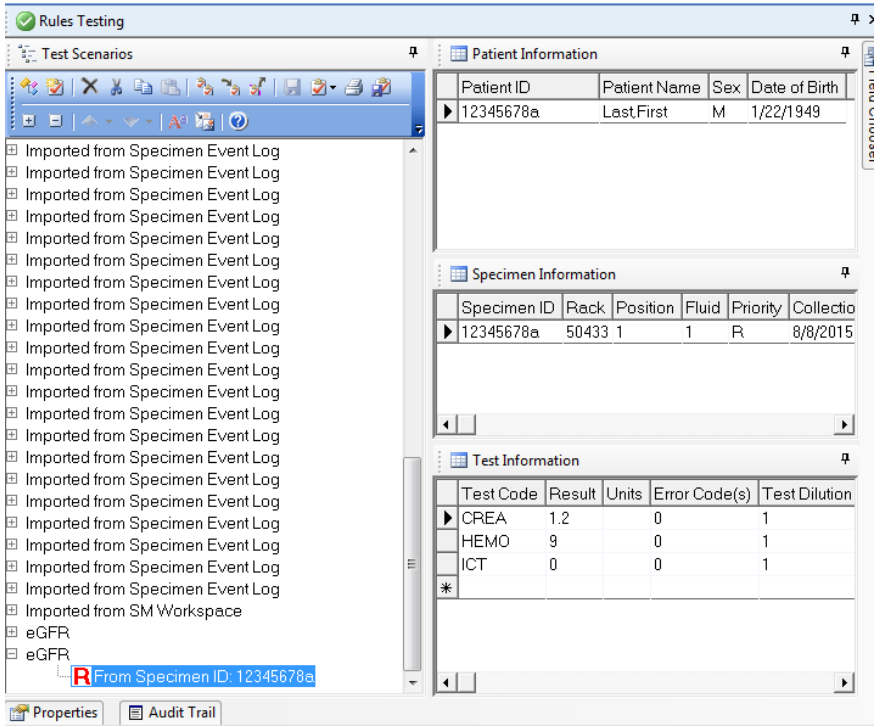
The SEL can also be used to demonstrate this as the user that reviewed or modified is clearly documented.



Autoverification Validation

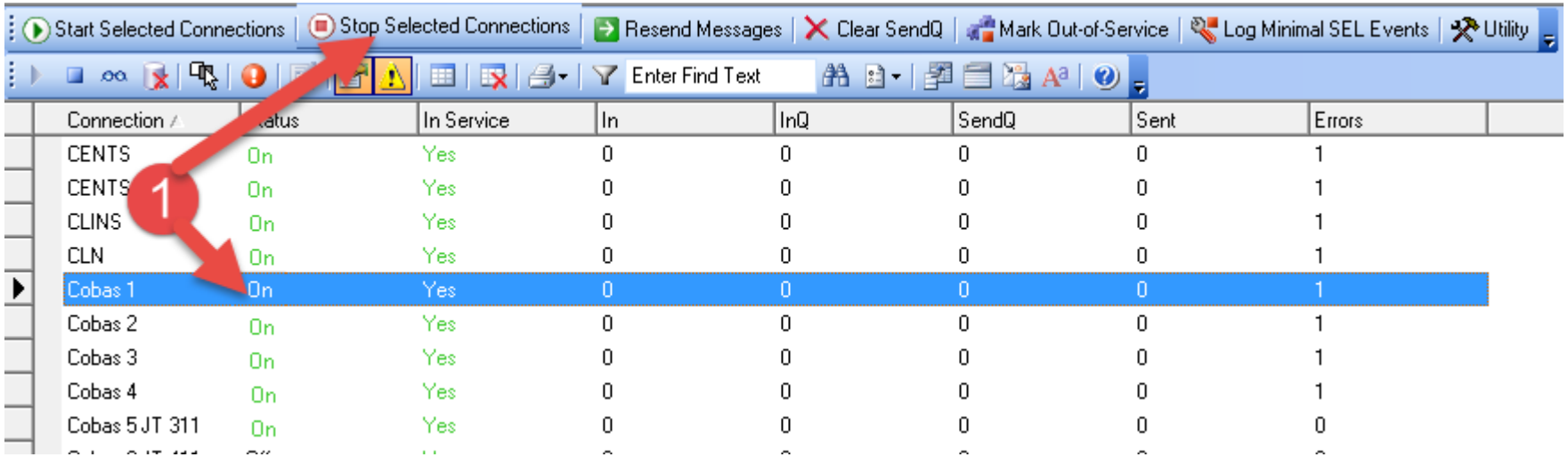
There is documentation that the autoverification process was validated initially, and is tested at least annually and whenever there is a change to the system that could affect the autoverification logic.

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.



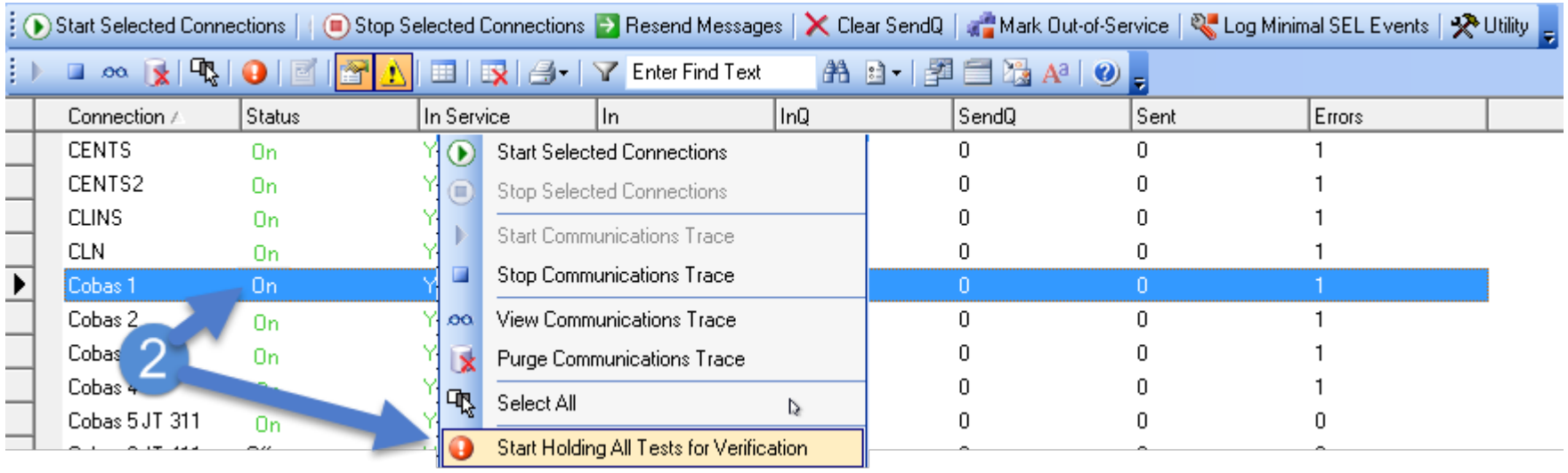
Autoverification Can Be Turned Off

1. Stop the Connection



Connection	Status	In Service	In	InQ	SendQ	Sent	Errors
CENTS	On	Yes	0	0	0	0	1
CENTS	On	Yes	0	0	0	0	1
CLINS	On	Yes	0	0	0	0	1
CLN	On	Yes	0	0	0	0	1
Cobas 1	On	Yes	0	0	0	0	1
Cobas 2	On	Yes	0	0	0	0	1
Cobas 3	On	Yes	0	0	0	0	1
Cobas 4	On	Yes	0	0	0	0	1
Cobas 5 JT 311	On	Yes	0	0	0	0	0

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.

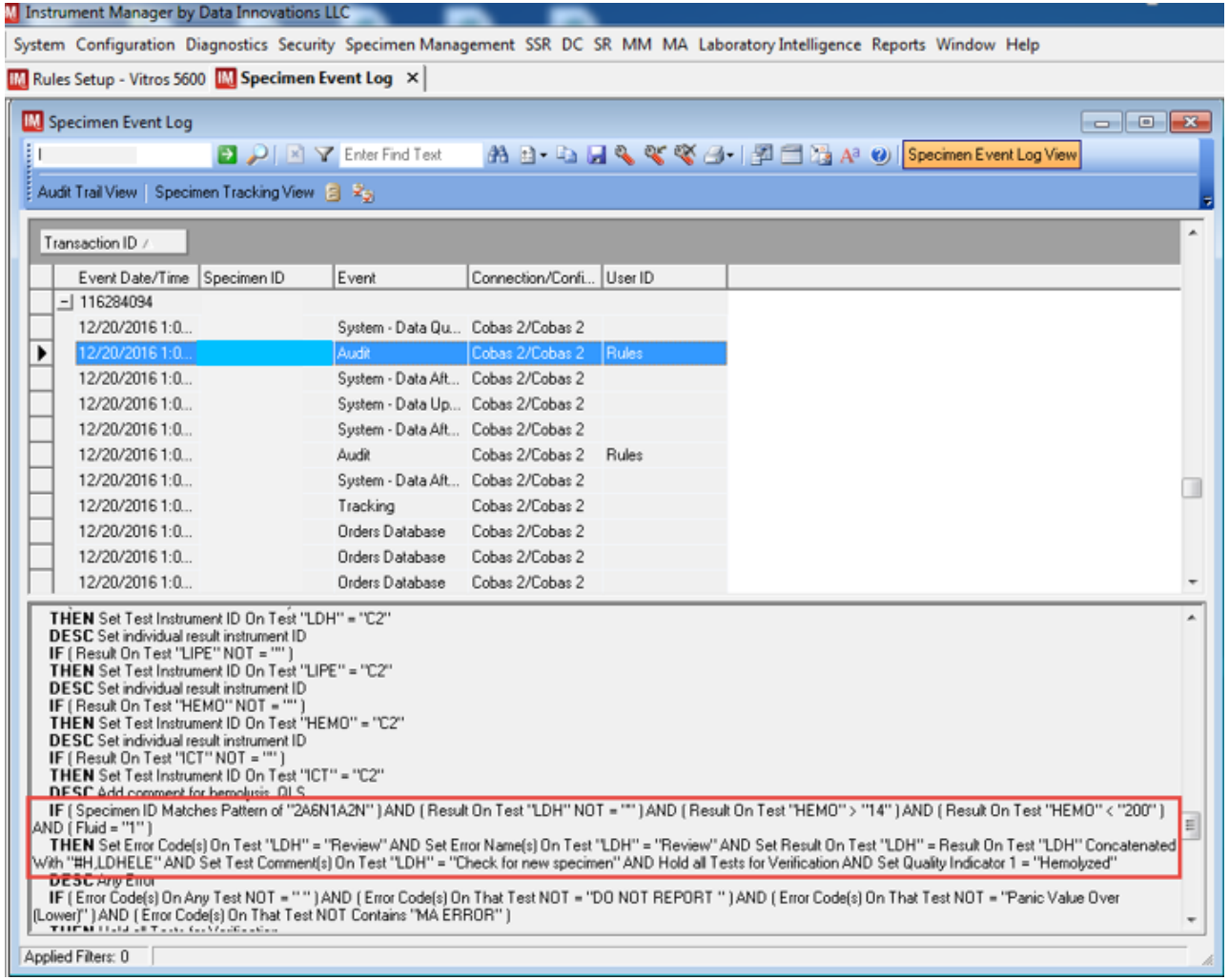
CAP - GEN 43881

Phase II

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.



CAP - GEN 43881 (cont.)

Phase II

Autoverification Results

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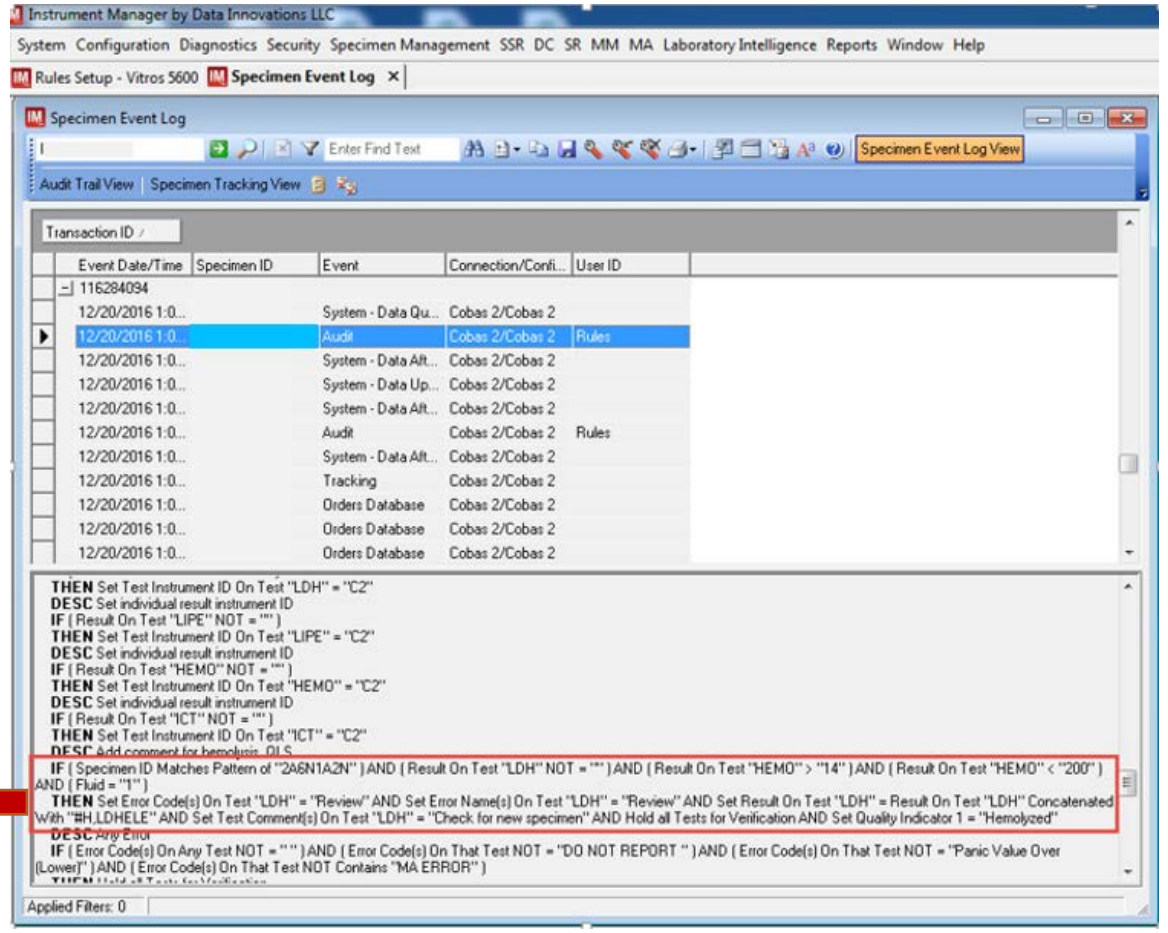
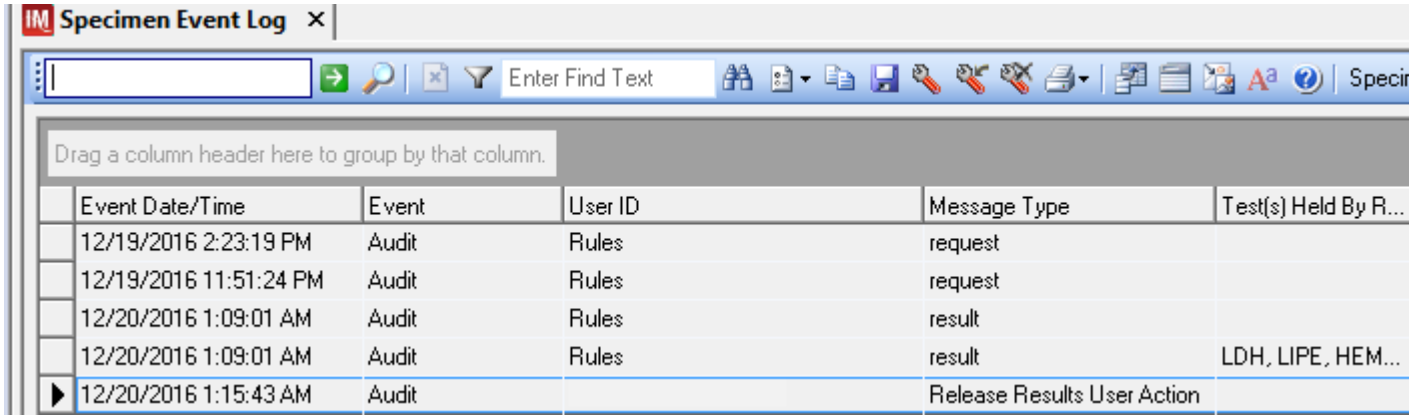



```
IF ( Specimen ID Matches Pattern of "2A6N1A2N" ) AND ( Result On Test "LDH" NOT = "" ) AND ( Result On Test "HEMO" > "14" ) AND ( Result On Test "HEMO" < "200" ) AND ( Fluid = "1" )
THEN Set Error Code(s) On Test "LDH" = "Review" AND Set Error Name(s) On Test "LDH" = "Review" AND Set Result On Test "LDH" = Result On Test "LDH" Concatenated With "#H,LDHELE" AND Set Test Comment(s) On Test "LDH" = "Check for new specimen" AND Hold all Tests for Verification AND Set Quality Indicator 1 = "Hemolyzed"
```

Autoverification Audit Trail

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

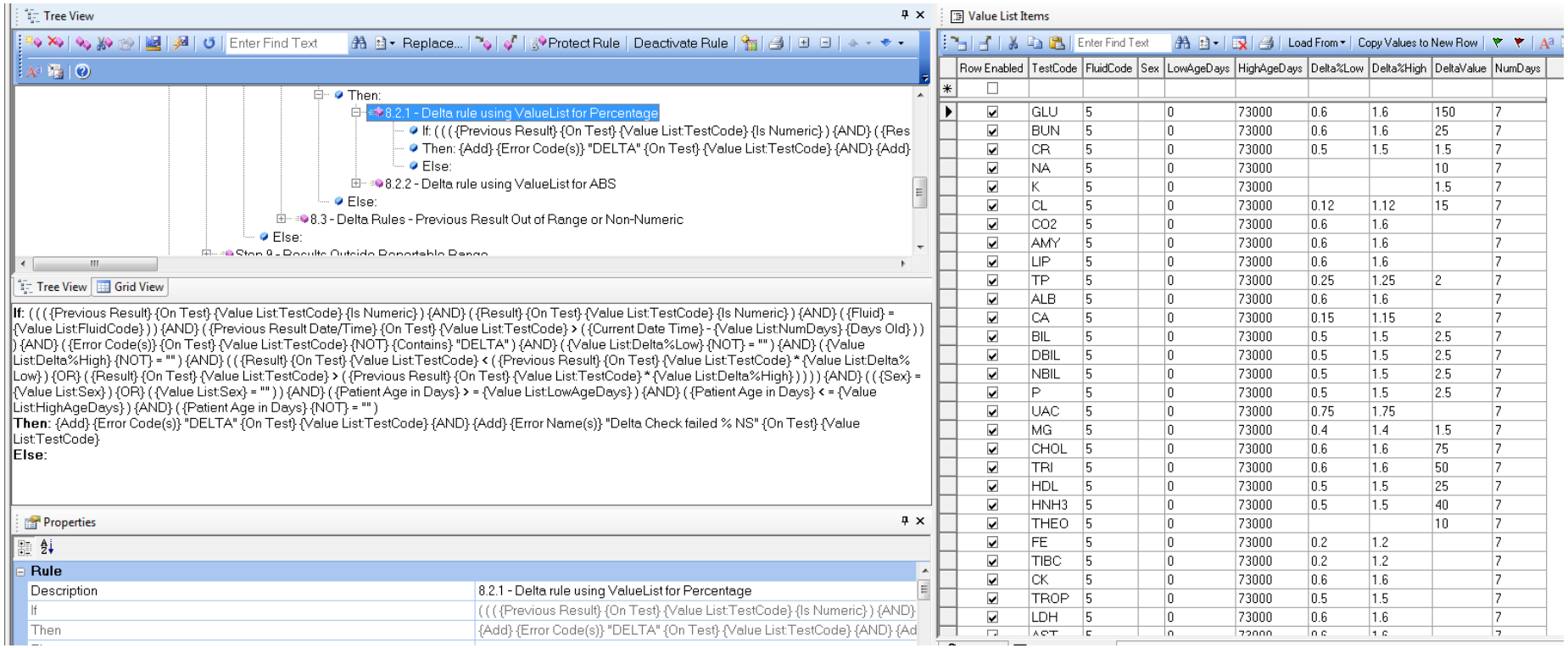
Specimen Event Log (SEL) has an audit trail view which documents the exact date and time of each event. The User ID (blocked out on this example) would show who released the result.



Autoverification Delta Checks

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

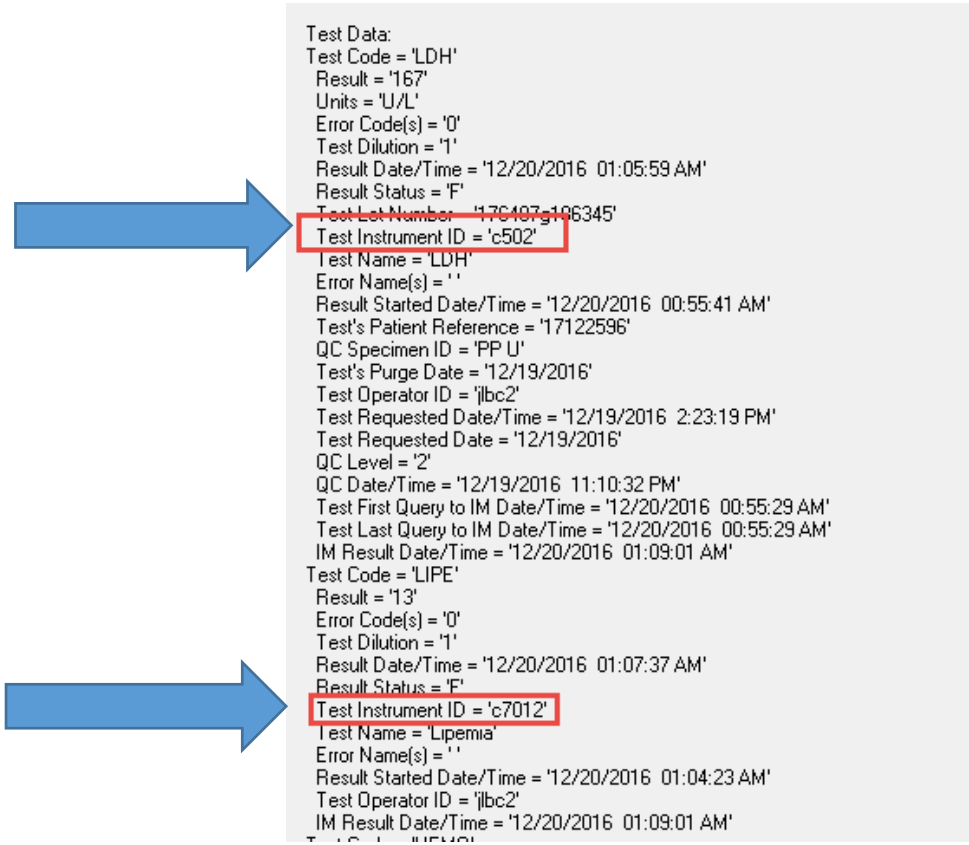
Delta rules can be constructed to cover any number of parameters, values, timeframes, as well as patient demographics and even location. Specimen Event Log can demonstrate when a rule has fired. Remember all rules are reviewed on all samples to see if the results qualifies for that rule.



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.

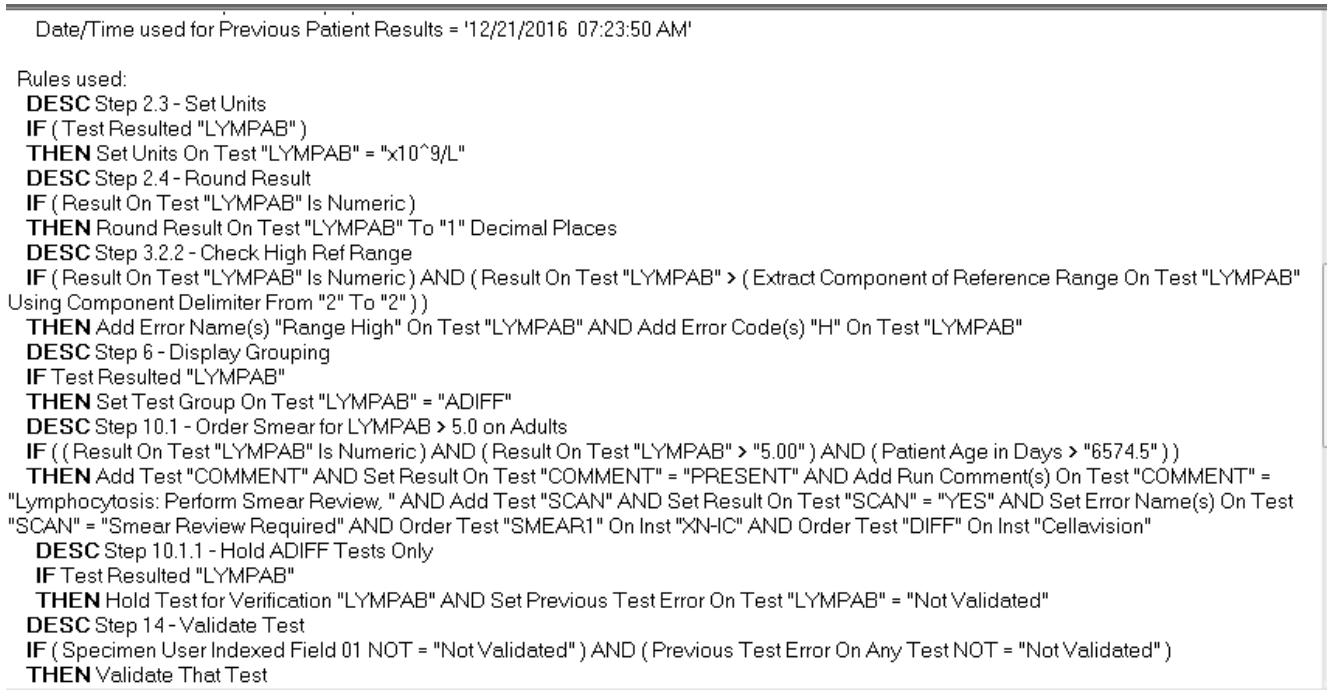
The Specimen Event Log shows the details of each result including the instrument that generated the result. If the instrument includes multiple modules then the individual module is identified.



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.



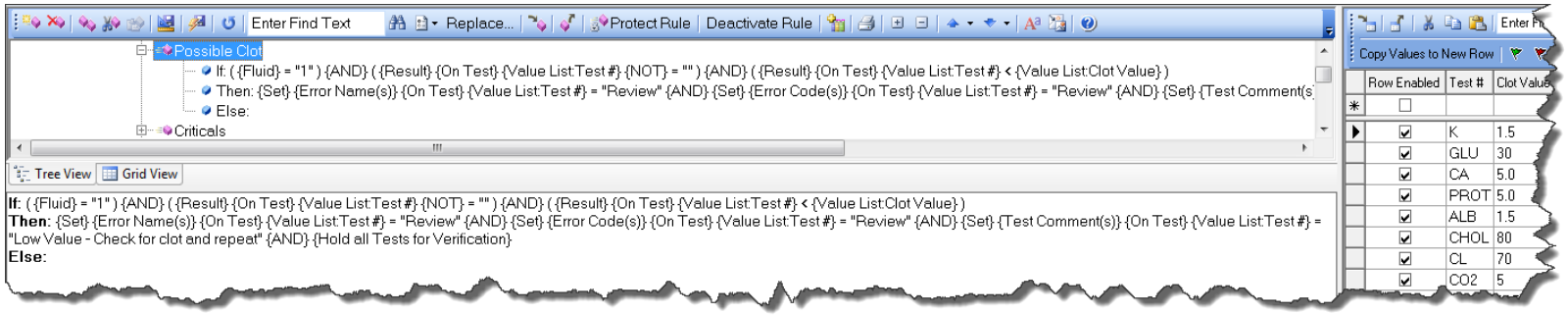
```
Date/Time used for Previous Patient Results = '12/21/2016  07:23:50 AM'

Rules used:
  DESC Step 2.3 - Set Units
  IF ( Test Resulted "LYMPAB" )
  THEN Set Units On Test "LYMPAB" = "x10^9/L"
  DESC Step 2.4 - Round Result
  IF ( Result On Test "LYMPAB" Is Numeric )
  THEN Round Result On Test "LYMPAB" To "1" Decimal Places
  DESC Step 3.2.2 - Check High Ref Range
  IF ( Result On Test "LYMPAB" Is Numeric ) AND ( Result On Test "LYMPAB" > ( Extract Component of Reference Range On Test "LYMPAB"
Using Component Delimiter From "2" To "2" ) )
  THEN Add Error Name(s) "Range High" On Test "LYMPAB" AND Add Error Code(s) "H" On Test "LYMPAB"
  DESC Step 6 - Display Grouping
  IF Test Resulted "LYMPAB"
  THEN Set Test Group On Test "LYMPAB" = "ADIFF"
  DESC Step 10.1 - Order Smear for LYMPAB > 5.0 on Adults
  IF ( ( Result On Test "LYMPAB" Is Numeric ) AND ( Result On Test "LYMPAB" > "5.00" ) AND ( Patient Age in Days > "6574.5" ) )
  THEN Add Test "COMMENT" AND Set Result On Test "COMMENT" = "PRESENT" AND Add Run Comment(s) On Test "COMMENT" =
"Lymphocytosis: Perform Smear Review, " AND Add Test "SCAN" AND Set Result On Test "SCAN" = "YES" AND Set Error Name(s) On Test
"SCAN" = "Smear Review Required" AND Order Test "SMEAR1" On Inst "XN-IC" AND Order Test "DIFF" On Inst "Cellavision"
    DESC Step 10.1.1 - Hold ADIFF Tests Only
    IF Test Resulted "LYMPAB"
    THEN Hold Test for Verification "LYMPAB" AND Set Previous Test Error On Test "LYMPAB" = "Not Validated"
  DESC Step 14 - Validate Test
  IF ( Specimen User Indexed Field 01 NOT = "Not Validated" ) AND ( Previous Test Error On Any Test NOT = "Not Validated" )
  THEN Validate That Test
```

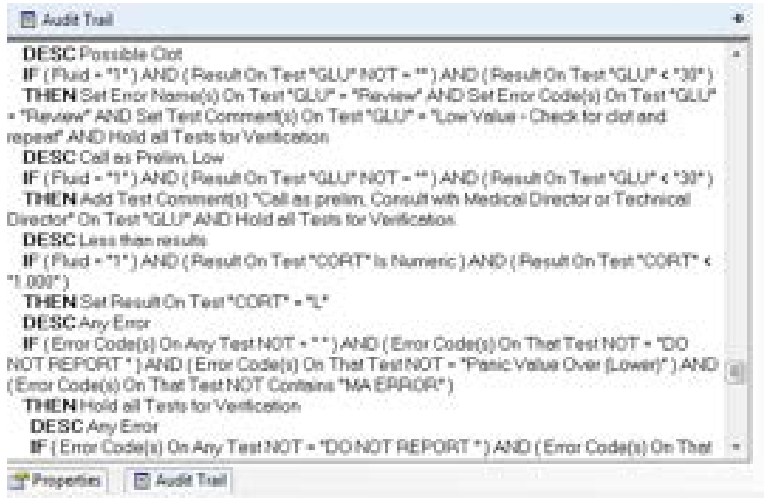
Error Detection and Correction

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.

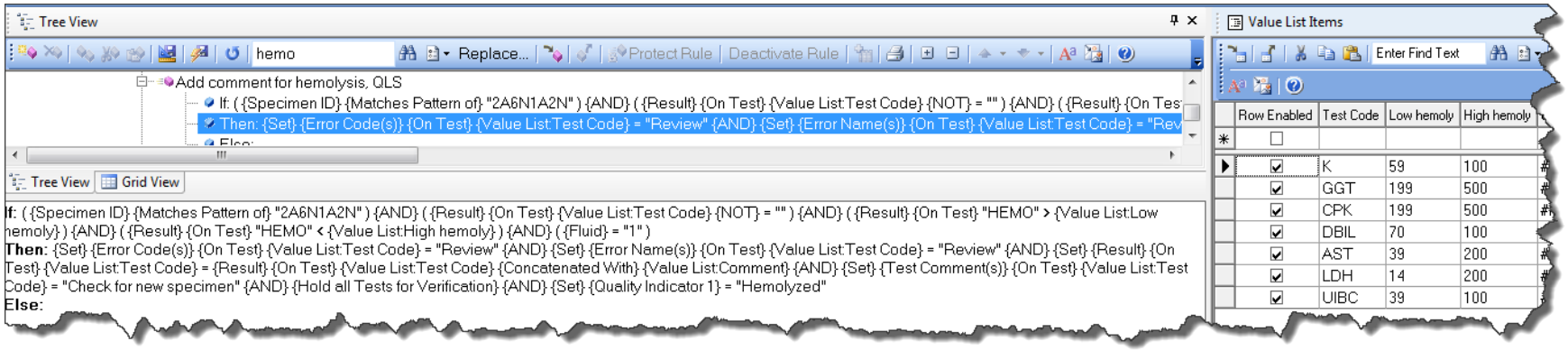
Rules can set-up to require secondary review before the release of results. This can be based on Instrument, Date or Time, Reviewing Tech, etc.

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



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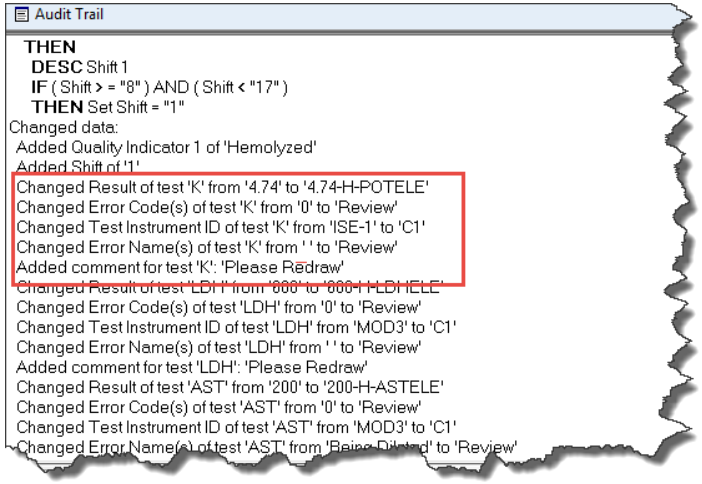


CAP – COM.30000 Phase II

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.

CAP – COM.30100

Phase I

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.

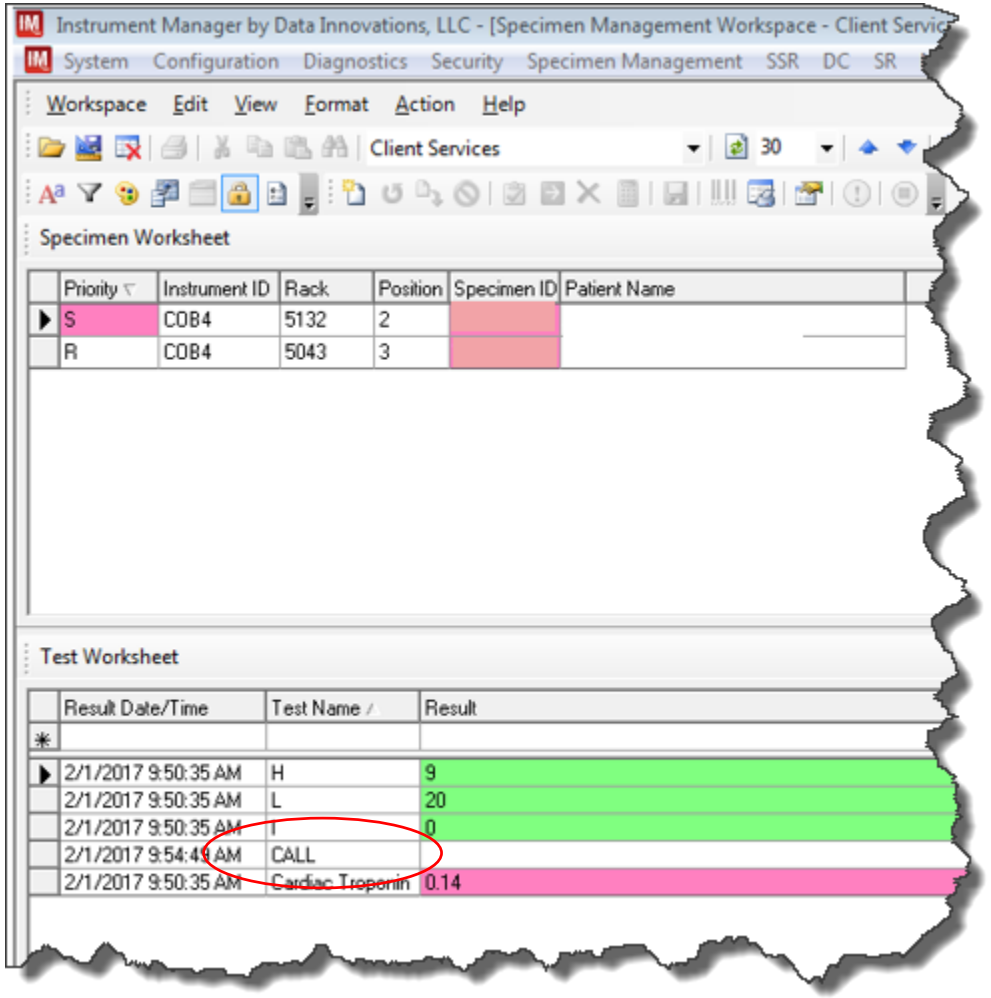
If: ((({Patient Age in Days} > = {Value List:AgeDyLow}) {OR} ({Value List:AgeDyLow} = "")) {AND} (({Patient Age in Days} < {Value List:AgeDyHigh}) {OR} ({Value List:AgeDyHigh} = ""))) {AND} ({Value List:CritLow} {NOT} = "") {AND} ((({Result} {On Test} {Value List:TestCode} {Is Numeric}) {AND} ({Result} {On Test} {Value List:TestCode} < = {Value List:CritLow})) {OR} ({Result} {On Test} {Value List:TestCode} {Contains} "<") {AND} ({Location - Facility} = {Value List:Location}))
Then: {Hold all Tests for Verification} {AND} {Set} {Error Name(s)} {On Test} {Value List:TestCode} = "CRITICAL LOW " {Concatenated With} {Value List:TestCode} {AND} {Add} {Run Comment(s)} {On Test} "COMMENT" = "Perform Clot Check, Follow Critical Callback SOP" {AND} {Set} {Error Code(s)} {On Test} {Value List:TestCode} = "cL" {AND} {Add} {Test Comment(s)} "Critical Value called to: at: by: on: " {On Test} {Value List:TestCode}
Else:

The Specimen Event Log maintains this documentation in addition to the LIS.

CAP – COM.30100 (cont)

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 as 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!