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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
 - 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).

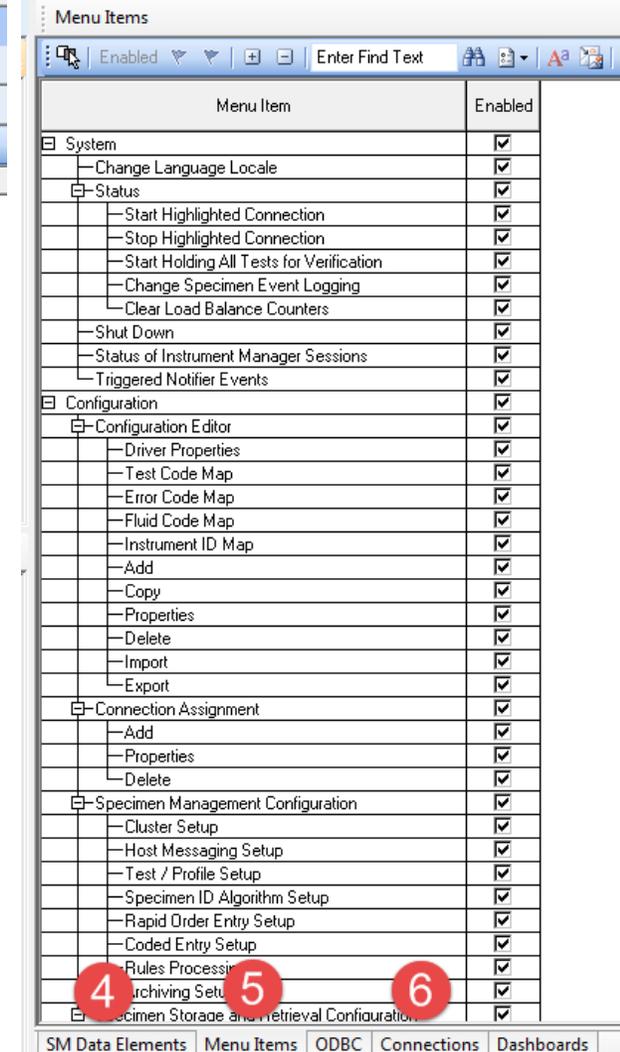
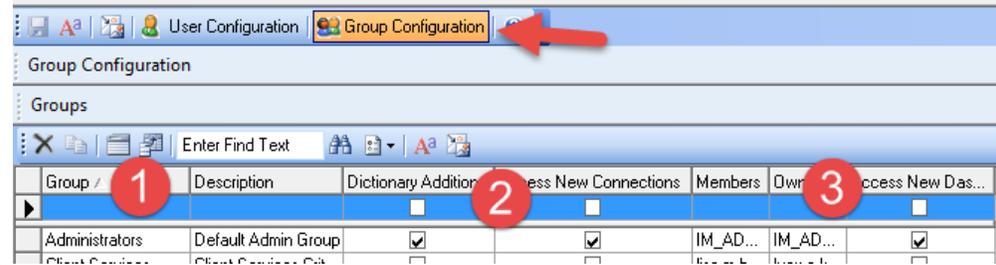
– User Authentication

- 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.

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



- User Definition

Drag a column header here to group by that column.

User ID /	Full Name	Description	Locale	Default Connection	Enabled	Email Address	Default Screen	Member Of
			Default	- None -	<input checked="" type="checkbox"/>			
mark.l.shearer	Mark Shearer		Default	- None -	<input checked="" type="checkbox"/>	mark.l.sheare...	System.Status	Administrators,Administration,SR Day Shift,IM_LABINTEL,Lab Intel

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



User's Guide F1
About Instrument Manager

Instrument Manager 8.14 x Instrument Manager 8.14 x

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.

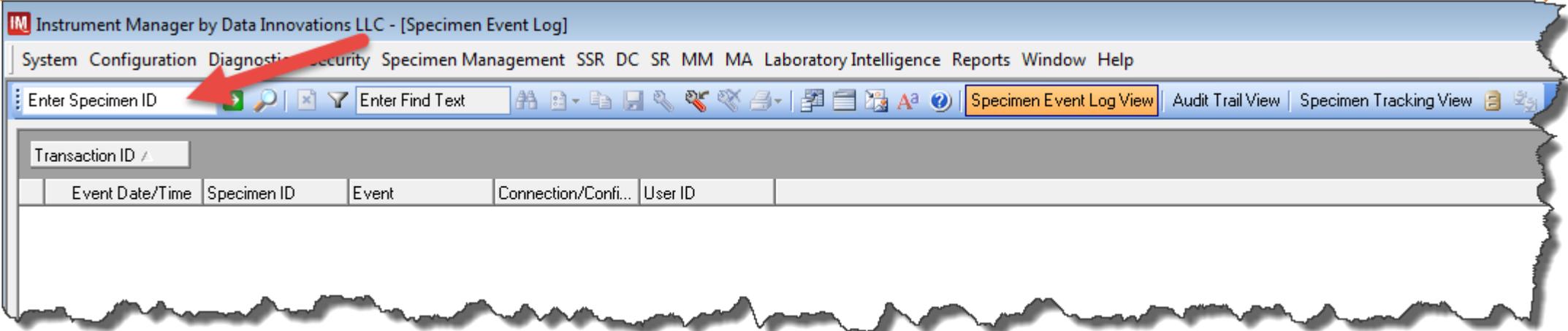
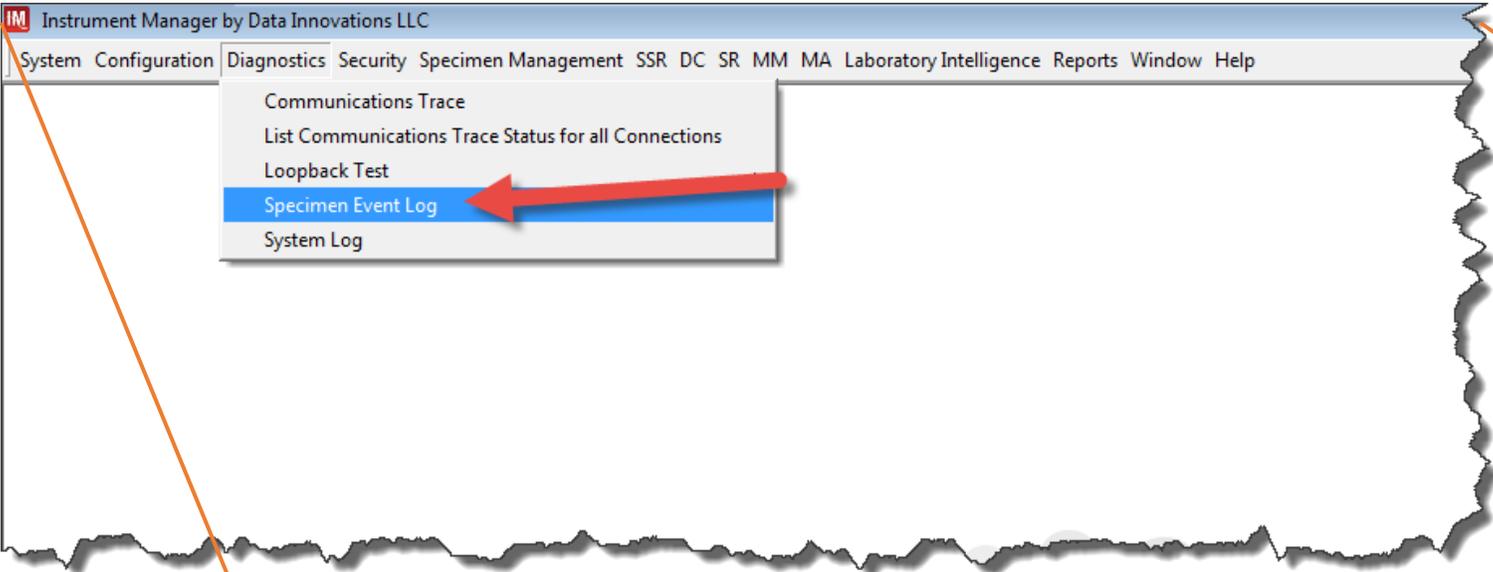
- [Archiving User's Guide](#)
Eliminate the stacks of paper records piling up in your lab. With Instrument Manager's archiving feature, you can store your records electronically. Retrieve the data quickly and easily when needed.
- [ODBC User's Guide](#)
Learn how to access and examine data stored by 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



Specimen Tracking View

IM 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 Find Text Specimen Event Log View Audit Trail View Specimen Tracking View

Drag a column header here to group by that column.

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

IM Instrument Manager by Data Innovations LLC - [Specimen Event Log]

System Configuration Diagnostics Security Specimen Management SSR DC SR MM MA Lal

Enter Find Text

Transaction ID

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

IM Instrument Manager by Data Innovations LLC - [Specimen Event Log]

System Configuration Diagnostics Security Specimen Management SSR DC SR MM MA

Enter Find Text

Transaction ID /

Event Date/Time	Specimen ID	Event	Connection/Conf...	User ID
11/22/2016 2:2...		Test Code Mapping	Cobas 4/Cobas 4	
11/22/2016 2:2...		System - Data Up...	Cobas 4/Cobas 4	
11/22/2016 2:2...		Audit	Cobas 4/Cobas 4	Rules
11/22/2016 2:2...		System - Data Aft...	Cobas 4/Cobas 4	
11/22/2016 2:2...		Tracking	Cobas 4/Cobas 4	
11/22/2016 2:2...		System - Data Qu...	Cobas 4/Cobas 4	

+ 114727753

```
IF Always
THEN Set Test Instrument ID On Test "EGFR" = "COB4"
DESC Add comment for hemolysis, SQ, Adult
IF ( Specimen ID Matches Pattern of "1A1.7N" ) AND ( Result On Test "16" NOT = "" ) AND ( Result On Test "16" NOT = "" )
THEN Set Result On Test "16" = Result On Test "16" Concatenated With "H-LDHELE" AND Set Quality Code to "H"
DESC Non ID's to Misys
IF ( Specimen ID Matches Pattern of "1A1.7N" )
THEN Add Destination Connection(s) "MISYS_RES_1"
DESC Any Error, Deltas
IF ( Any Error Code(s) On Any Test NOT = "" ) OR ( Any Test Comment(s) On Any Test Contains "Delta" )
THEN Hold all Tests for Verification
DESC Set Shift
IF Shift = ""
THEN Set Shift = Extract Component of First Result to IM Date/Time Using "" From "2" To "2" AND Set Quality Code to "H"
DESC Check for Numeric
IF ( Shift Is Numeric )
THEN
DESC Shift 1
IF ( Shift >= "8" ) AND ( Shift < "16" )
ELSE
DESC Shift 2
```

Using Patient Data in Rules Testing

The screenshot shows the Instrument Manager interface. At the top, there is a menu bar with options: System, Configuration, Diagnostics, Security, Specimen Management, SSR, DC, SR, MM, MA, Laboratory Intelligence, Reports, Window, and Help. Below the menu bar, there are tabs for 'Rules Setup - XN-IC' and 'Specimen Event Log'. A search bar contains the text '1703200012'. To the right of the search bar, there are view options: 'Specimen Event Log View' (highlighted), 'Audit Trail View', and 'Specimen Tracking View'. A red circle highlights a small icon in the top right corner of the interface. Below the search bar is a table with the following columns: Transaction ID, Event Date/Time, Specimen ID, Event, Connection/Confi..., and User ID. The table contains several rows of event data, with the third row highlighted in blue.

Transaction ID	Event Date/Time	Specimen ID	Event	Connection/Confi...	User ID
	2/1/2017 11:31:09 AM	1703200012	System - Data Aft...	Cerner Orders/Cer...	
	2/1/2017 11:31:09 AM	1703200012	System - Data Up...	Cerner Orders/Cer...	
	2/1/2017 11:31:09 AM	1703200012	Audit	Cerner Orders/Cer...	Rules
	2/1/2017 11:31:09 AM	1703200012	System - Data Aft...	Cerner Orders/Cer...	
	2/1/2017 11:31:09 AM	1703200012	System - Data Up...	Cerner Orders/Cer...	
	2/1/2017 11:31:09 AM	1703200012	System - No confi...	Specimen Routin...	
	2/1/2017 11:31:09 AM	1703200012	System - Data Ad...	Cerner Orders/Cer...	
	2/1/2017 11:31:09 AM	1703200012	System - Data Aft...	Cerner Orders/Cer...	

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.

Test Scenarios

- Imported from Specimen Event Log
- New Test Scenario 25
- Imported from Specimen Event Log
- Imported from Specimen Event Log
- Imported from Specimen Event Log
- HCG order to test Index suppression
- Imported from Specimen Event Log

Audit Trail

```
IF (Shift >= "8") AND (Shift < "17")  
THEN Set Shift = "1"  
Changed data:  
Added Instrument ID of 'C1'  
Added Shift of '1'  
Changed Error Code(s) of test 'CREA' from '0' to ''  
Changed Test Instrument ID of test 'CREA' from 'c7011' to ''  
Changed Error Code(s) of test 'HEMO' from '0' to ''  
Changed Test Instrument ID of test 'HEMO' from 'c7011' to ''  
Changed Error Code(s) of test 'ICT' from '0' to ''  
Changed Test Instrument ID of test 'ICT' from 'c7011' to ''  
Added Test 'EGFR'  
Added Result to test 'EGFR' of '63#T\\W\\GFR2'  
Added Error Code(s) to test 'EGFR' of ''  
Added Test Collection Date/Time to test 'EGFR' of '8/8/  
Added Date/Time used for Previous Patient Results to t  
Tests 'CREA', 'HEMO', 'ICT', 'EGFR' were held for verific
```

Patient Information

Patient ID	Patient Name	Sex	Date of Birth
12345678a	Last,First	M	1/22/1949

Home >

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: mg/dL µmol/L

Serum Cystatin C: mg/L

Age: Years

Gender: Male Female

Race: Black Other

Standardized Assays: Yes No Not Sure

Remove body surface adjustment: Yes No Not Sure

CALCULATE

Results

CKD-EPI creatinine equation (2009) **63** mL/min/1.73m²

Specimen Quality Comment

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

Changed Error Name(s) of test '965' from '37' to 'Error Code'
Changed Result of test '10' from '0.3' to '0.3;Hemolysis present. The presence of hemolysis will variably increase potassium values and variably decrease direct bilirubin values. Hemolysis level is 181'
Changed Test Instrument ID of test '10' from 'P1' to 'COB3'
Changed Error Code(s) of test '20' from '0' to 'Review'

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.

Transaction ID	Event Date/Time	Specimen ID	Event	Connection/Conf...	User ID
	11/22/2016 7:2...	123456A	Instrument ID Ma...	MISYS_RES_1/...	
	11/22/2016 7:2...	123456A	Instrument ID Ma...	MISYS_RES_1/...	
	11/22/2016 7:2...	123456A	Instrument ID Ma...	MISYS_RES_1/...	
	11/22/2016 7:2...	123456A	Instrument ID Ma...	MISYS_RES_1/...	
	11/22/2016 7:2...	123456A	Instrument ID Ma...	MISYS_RES_1/...	
	11/22/2016 7:2...	123456A	Tracking	Cobas 3/Cobas 3 ...	Smith, S
	11/22/2016 7:2...	123456A	System - Data Aft...	Cobas 3/Cobas 3 ...	
	11/22/2016 7:2...	123456A	Audit	Cobas 3/Cobas 3 ...	Smith, S
	11/22/2016 7:2...	123456A	System - Data Bef...	MISYS_RES_1/...	
	11/22/2016 7:2...	123456A	System - Data Qu...	Cobas 3/Cobas 3 ...	
	11/22/2016 7:2...	123456A	System - Data Ad...	Cobas 3/Cobas 3 ...	

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.

The screenshot displays the 'Rules Testing' application window. The interface is divided into several panes:

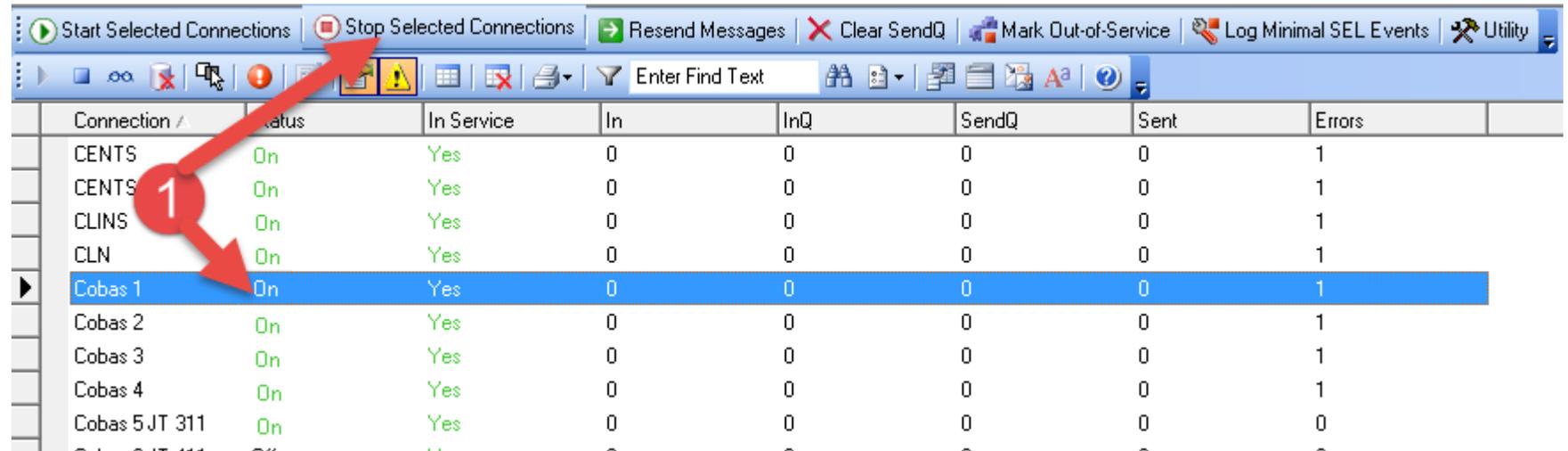
- Test Scenarios:** A list of 20 entries, all labeled 'Imported from Specimen Event Log'. At the bottom, there is a red icon and the text 'From Specimen ID: 12345678a'.
- Patient Information:** A table with columns: Patient ID, Patient Name, Sex, Date of Birth. The data row shows: 12345678a, LastFirst, M, 1/22/1949.
- Specimen Information:** A table with columns: Specimen ID, Rack, Position, Fluid, Priority, Collectio. The data row shows: 12345678a, 50433, 1, 1, R, 8/8/2015.
- Test Information:** A table with columns: Test Code, Result, Units, Error Code(s), Test Dilution. The data rows are:

Test Code	Result	Units	Error Code(s)	Test Dilution
CREA	1.2	0	1	
HEMO	9	0	1	
ICT	0	0	1	
*				

At the bottom of the window, there are buttons for 'Properties' and 'Audit Trail'.

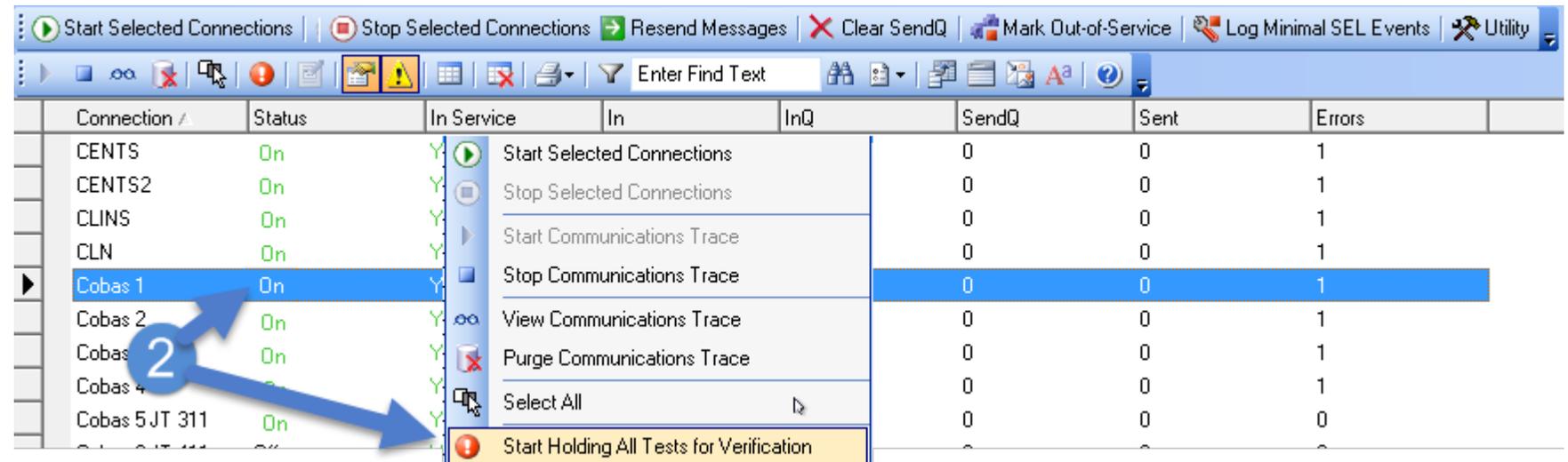
Autoverification Can Be Turned Off

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 5JT 311	On	Yes	0	0	0	0	0

2. Start Holding All Tests for Verification



Connection /	Status	In Service	In	InQ	SendQ	Sent	Errors
CENTS	On	Y	0	0	0	0	1
CENTS2	On	Y	0	0	0	0	1
CLINS	On	Y	0	0	0	0	1
CLN	On	Y	0	0	0	0	1
Cobas 1	On	Y	0	0	0	0	1
Cobas 2	On	Y	0	0	0	0	1
Cobas 3	On	Y	0	0	0	0	1
Cobas 4	On	Y	0	0	0	0	1
Cobas 5JT 311	On	Y	0	0	0	0	0

- Start Selected Connections
- Stop Selected Connections
- Start Communications Trace
- Stop Communications Trace
- View Communications Trace
- Purge Communications Trace
- Select All
- 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.

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.

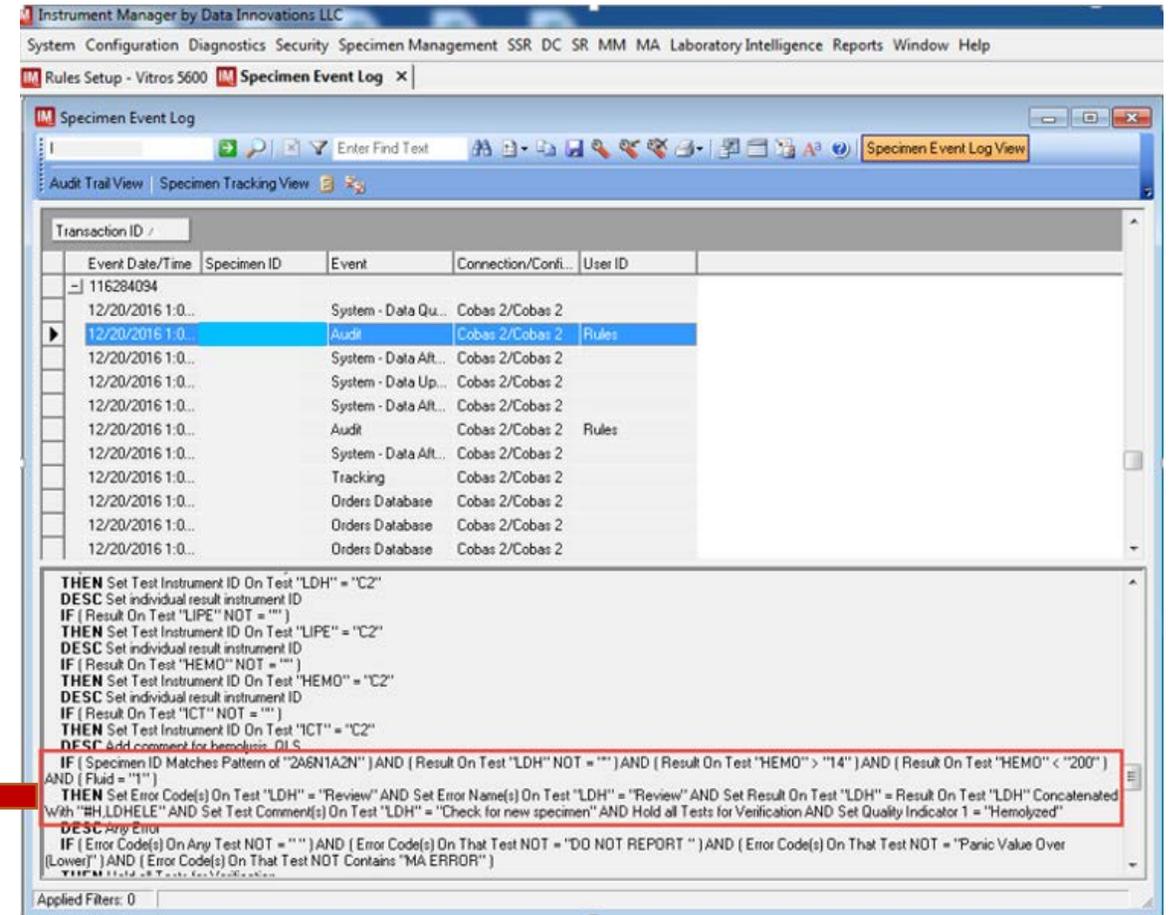
The screenshot shows the 'Specimen Event Log' window in the Instrument Manager software. The window title is 'IM Specimen Event Log'. It has a menu bar with 'System Configuration', 'Diagnostics', 'Security', 'Specimen Management', 'SSR', 'DC', 'SR', 'MM', 'MA', 'Laboratory Intelligence', 'Reports', 'Window', and 'Help'. Below the menu bar is a toolbar with various icons and a search box labeled 'Enter Find Text'. The main area is divided into two tabs: 'Audit Trail View' and 'Specimen Tracking View'. The 'Audit Trail View' is active, showing a table with columns: 'Transaction ID /', 'Event Date/Time', 'Specimen ID', 'Event', 'Connection/Conf...', and 'User ID'. The table contains several rows of data, with the second row highlighted in blue. Below the table is a text area containing a rule definition. The rule is highlighted with a red box and reads:

```
THEN Set Test Instrument ID On Test "LDH" = "C2"
DESC Set individual result instrument ID
IF ( Result On Test "LIPE" NOT = "" )
THEN Set Test Instrument ID On Test "LIPE" = "C2"
DESC Set individual result instrument ID
IF ( Result On Test "HEMO" NOT = "" )
THEN Set Test Instrument ID On Test "HEMO" = "C2"
DESC Set individual result instrument ID
IF ( Result On Test "ICT" NOT = "" )
THEN Set Test Instrument ID On Test "ICT" = "C2"
DESC Add comment for hemolysis: DLS
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 "HH.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"
DESC Any Error
IF ( Error Code(s) On Any Test NOT = "" ) AND ( Error Code(s) On That Test NOT = "DO NOT REPORT " ) AND ( Error Code(s) On That Test NOT = "Panic Value Over
(Lower)" ) AND ( Error Code(s) On That Test NOT Contains "MA ERROR" )
```

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.



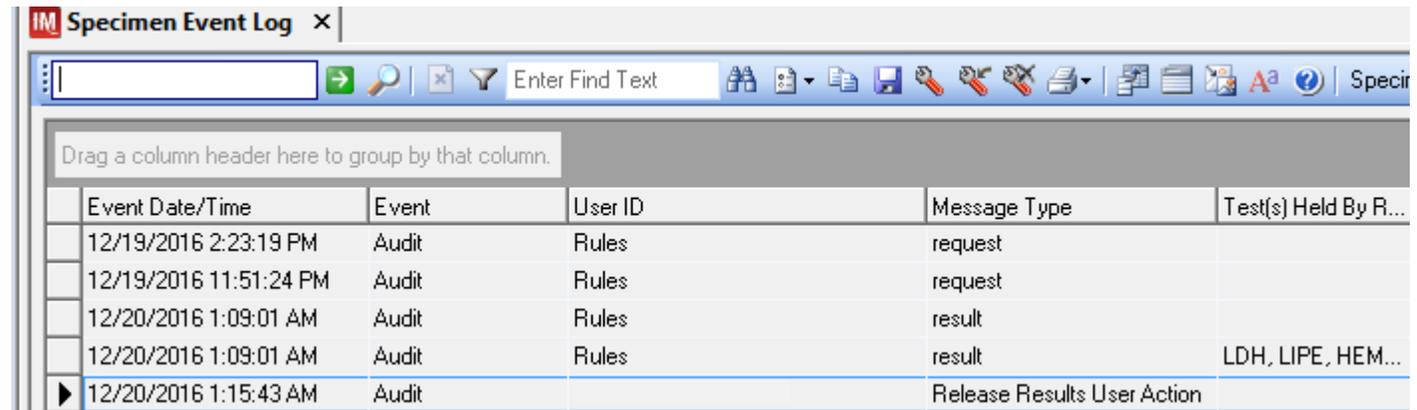
```

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.



The screenshot shows a web application window titled "Specimen Event Log". It features a search bar with the text "Enter Find Text" and a toolbar with various icons. Below the search bar is a table with the following columns: "Event Date/Time", "Event", "User ID", "Message Type", and "Test(s) Held By R...". The table contains five rows of audit data.

Event Date/Time	Event	User ID	Message Type	Test(s) Held By R...
12/19/2016 2:23:19 PM	Audit	Rules	request	
12/19/2016 11:51:24 PM	Audit	Rules	request	
12/20/2016 1:09:01 AM	Audit	Rules	result	
12/20/2016 1:09:01 AM	Audit	Rules	result	LDH, LIPE, HEM...
12/20/2016 1:15:43 AM	Audit		Release Results User Action	

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.

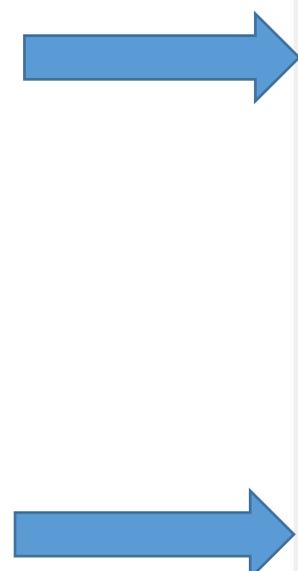
The screenshot displays a software interface for configuring delta rules. On the left, a 'Tree View' shows a hierarchy of rules, including '8.2.1 - Delta rule using ValueList for Percentage' and '8.2.2 - Delta rule using ValueList for ABS'. The main window shows the configuration for rule 8.2.1, with an 'If' condition that checks for numerical results and compares them to previous results based on age and time. The 'Then' clause adds an error code 'DELTA' to the test result. Below the rule configuration, a 'Properties' pane shows the rule's description and logic. On the right, a 'Value List Items' table lists various test codes and their associated parameters.

Row Enabled	TestCode	FluidCode	Sex	LowAgeDays	HighAgeDays	Delta%Low	Delta%High	DeltaValue	NumDays
<input type="checkbox"/>									
<input checked="" type="checkbox"/>	GLU	5		0	73000	0.6	1.6	150	7
<input checked="" type="checkbox"/>	BUN	5		0	73000	0.6	1.6	25	7
<input checked="" type="checkbox"/>	CR	5		0	73000	0.5	1.5	1.5	7
<input checked="" type="checkbox"/>	NA	5		0	73000			10	7
<input checked="" type="checkbox"/>	K	5		0	73000			1.5	7
<input checked="" type="checkbox"/>	CL	5		0	73000	0.12	1.12	15	7
<input checked="" type="checkbox"/>	CO2	5		0	73000	0.6	1.6		7
<input checked="" type="checkbox"/>	AMY	5		0	73000	0.6	1.6		7
<input checked="" type="checkbox"/>	LIP	5		0	73000	0.6	1.6		7
<input checked="" type="checkbox"/>	TP	5		0	73000	0.25	1.25	2	7
<input checked="" type="checkbox"/>	ALB	5		0	73000	0.6	1.6		7
<input checked="" type="checkbox"/>	CA	5		0	73000	0.15	1.15	2	7
<input checked="" type="checkbox"/>	BIL	5		0	73000	0.5	1.5	2.5	7
<input checked="" type="checkbox"/>	DBIL	5		0	73000	0.5	1.5	2.5	7
<input checked="" type="checkbox"/>	NBIL	5		0	73000	0.5	1.5	2.5	7
<input checked="" type="checkbox"/>	P	5		0	73000	0.5	1.5	2.5	7
<input checked="" type="checkbox"/>	UAC	5		0	73000	0.75	1.75		7
<input checked="" type="checkbox"/>	MG	5		0	73000	0.4	1.4	1.5	7
<input checked="" type="checkbox"/>	CHOL	5		0	73000	0.6	1.6	75	7
<input checked="" type="checkbox"/>	TRI	5		0	73000	0.6	1.6	50	7
<input checked="" type="checkbox"/>	HDL	5		0	73000	0.5	1.5	25	7
<input checked="" type="checkbox"/>	HNH3	5		0	73000	0.5	1.5	40	7
<input checked="" type="checkbox"/>	THEO	5		0	73000			10	7
<input checked="" type="checkbox"/>	FE	5		0	73000	0.2	1.2		7
<input checked="" type="checkbox"/>	TIBC	5		0	73000	0.2	1.2		7
<input checked="" type="checkbox"/>	CK	5		0	73000	0.6	1.6		7
<input checked="" type="checkbox"/>	TROP	5		0	73000	0.5	1.5		7
<input checked="" type="checkbox"/>	LDH	5		0	73000	0.6	1.6		7
<input checked="" type="checkbox"/>	AST	5		0	73000	0.6	1.6		7

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.



```
Test Data:  
Test Code = 'LDH'  
Result = '167'  
Units = 'U/L'  
Error Code(s) = '0'  
Test Dilution = '1'  
Result Date/Time = '12/20/2016 01:05:59 AM'  
Result Status = 'F'  
Test Lot Number = '176107g106345'  
Test Instrument ID = 'c502'  
Test Name = 'LDH'  
Error Name(s) = ''  
Result Started Date/Time = '12/20/2016 00:55:41 AM'  
Test's Patient Reference = '17122596'  
QC Specimen ID = 'PP U'  
Test's Purge Date = '12/19/2016'  
Test Operator ID = 'jbc2'  
Test Requested Date/Time = '12/19/2016 2:23:19 PM'  
Test Requested Date = '12/19/2016'  
QC Level = '2'  
QC Date/Time = '12/19/2016 11:10:32 PM'  
Test First Query to IM Date/Time = '12/20/2016 00:55:29 AM'  
Test Last Query to IM Date/Time = '12/20/2016 00:55:29 AM'  
IM Result Date/Time = '12/20/2016 01:09:01 AM'  
Test Code = 'LIPE'  
Result = '13'  
Error Code(s) = '0'  
Test Dilution = '1'  
Result Date/Time = '12/20/2016 01:07:37 AM'  
Result Status = 'F'  
Test Instrument ID = 'c7012'  
Test Name = 'Lipemia'  
Error Name(s) = ''  
Result Started Date/Time = '12/20/2016 01:04:23 AM'  
Test Operator ID = 'jbc2'  
IM Result Date/Time = '12/20/2016 01:09:01 AM'
```

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.

The screenshot shows a rules engine interface with a tree view on the left and a main pane on the right. The tree view shows a rule named "Possible Clot" under a "Criticals" category. The main pane displays the rule's logic:

```
IF ( {Fluid} = "1" ) {AND} ( {Result} {On Test} {Value List:Test #} {NOT} = "" ) {AND} ( {Result} {On Test} {Value List:Test #} < {Value List:Clot Value} )  
Then: {Set} {Error Name(s)} {On Test} {Value List:Test #} = "Review" {AND} {Set} {Error Code(s)} {On Test} {Value List:Test #} = "Review" {AND} {Set} {Test Comment(s)} {On Test} {Value List:Test #} = "Low Value - Check for clot and repeat" {AND} {Hold all Tests for Verification}  
Else:
```

Below the rule logic is a table with columns "Row Enabled", "Test #", and "Clot Value". The table contains the following data:

Row Enabled	Test #	Clot Value
<input type="checkbox"/>	K	1.5
<input checked="" type="checkbox"/>	GLU	30
<input checked="" type="checkbox"/>	CA	5.0
<input checked="" type="checkbox"/>	PROT	5.0
<input checked="" type="checkbox"/>	ALB	1.5
<input checked="" type="checkbox"/>	CHOL	80
<input checked="" type="checkbox"/>	CL	70
<input checked="" type="checkbox"/>	CO2	5

The screenshot shows an "Audit Trail" window with the following text:

```
DESC Possible Clot  
IF ( Fluid = "1" ) AND ( Result On Test "GLU" NOT = "" ) AND ( Result On Test "GLU" < "30" )  
THEN Set Error Name(s) On Test "GLU" = "Review" AND Set Error Code(s) On Test "GLU"  
= "Review" AND Set Test Comment(s) On Test "GLU" = "Low Value - Check for clot and  
repeat" AND Hold all Tests for Verification  
DESC Call as Prelim. Low  
IF ( Fluid = "1" ) AND ( Result On Test "GLU" NOT = "" ) AND ( Result On Test "GLU" < "30" )  
THEN Add Test Comment(s) "Call as prelim. Consult with Medical Director or Technical  
Director" On Test "GLU" AND Hold all Tests for Verification.  
DESC Less than results  
IF ( Fluid = "1" ) AND ( Result On Test "CORT" Is Numeric ) AND ( Result On Test "CORT" <  
"1.000" )  
THEN Set Result On Test "CORT" = "L"  
DESC Any Error  
IF ( Error Code(s) On Any Test NOT = "" ) AND ( Error Code(s) On That Test NOT = "DO  
NOT REPORT " ) AND ( Error Code(s) On That Test NOT = "Panic Value Over (Lower)" ) AND  
( Error Code(s) On That Test NOT Contains "MA ERROR" )  
THEN Hold all Tests for Verification  
DESC Any Error  
IF ( Error Code(s) On Any Test NOT = "DO NOT REPORT " ) AND ( Error Code(s) On That
```

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



Tree View

hemo

Replace... Protect Rule Deactivate Rule

Add comment for hemolysis, QLS

- If: ({Specimen ID} {Matches Pattern of} "2A6N1A2N") {AND} ({Result} {On Test} {Value List Test Code} {NOT} = "") {AND} ({Result} {On Test} {Value List Test Code} = "HEMO") {AND} ({Fluid} = "1")
- Then: {Set} {Error Code(s)} {On Test} {Value List Test Code} = "Review" {AND} {Set} {Error Name(s)} {On Test} {Value List Test Code} = "Review"
- Else:

Value List Items

Row Enabled	Test Code	Low hemoly	High hemoly
<input type="checkbox"/>			
<input checked="" type="checkbox"/>	K	59	100
<input checked="" type="checkbox"/>	GGT	199	500
<input checked="" type="checkbox"/>	CPK	199	500
<input checked="" type="checkbox"/>	DBIL	70	100
<input checked="" type="checkbox"/>	AST	39	200
<input checked="" type="checkbox"/>	LDH	14	200
<input checked="" type="checkbox"/>	UIBC	39	100

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



Audit Trail

THEN
DESC Shift 1
IF (Shift >= "8") AND (Shift < "17")
THEN Set Shift = "1"

Changed data:
Added Quality Indicator 1 of 'Hemolyzed'
Added Shift of '1'

Changed Result of test 'K' from '4.74' to '4.74-H-POTELE'
Changed Error Code(s) of test 'K' from '0' to 'Review'
Changed Test Instrument ID of test 'K' from 'ISE-1' to 'C1'
Changed Error Name(s) of test 'K' from '' to 'Review'
Added comment for test 'K': 'Please Redraw'

Changed Result of test 'LDH' from '800' to '800-H-HELE'
Changed Error Code(s) of test 'LDH' from '0' to 'Review'
Changed Test Instrument ID of test 'LDH' from 'MOD3' to 'C1'
Changed Error Name(s) of test 'LDH' from '' to 'Review'
Added comment for test 'LDH': 'Please Redraw'

Changed Result of test 'AST' from '200' to '200-H-ASTELE'
Changed Error Code(s) of test 'AST' from '0' to 'Review'
Changed Test Instrument ID of test 'AST' from 'MOD3' to 'C1'
Changed Error Name(s) of test 'AST' from 'Reine Diluted' to 'Review'

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.

```

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.

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.

The screenshot displays the Instrument Manager (IM) software interface. The title bar reads "Instrument Manager by Data Innovations, LLC - [Specimen Management Workspace - Client Services]". The menu bar includes "System", "Configuration", "Diagnostics", "Security", "Specimen Management", "SSR", "DC", and "SR". The main window is titled "Specimen Worksheet" and contains a table with the following data:

Priority	Instrument ID	Rack	Position	Specimen ID	Patient Name
S	COB4	5132	2		
R	COB4	5043	3		

Below the Specimen Worksheet is the "Test Worksheet" section, which contains a table with the following data:

Result Date/Time	Test Name /	Result
2/1/2017 9:50:35 AM	H	9
2/1/2017 9:50:35 AM	L	20
2/1/2017 9:50:35 AM	T	0
2/1/2017 9:54:49 AM	CALL	
2/1/2017 9:50:35 AM	Cardiac Troponin	0.14

A red circle highlights the "CALL" entry in the Test Worksheet table.

Questions?

Thank you for your time!