Pharma&Biotech

WinKQCL™ 5 Endotoxin Detection Software – Using Trending and Other Advanced Features

Speaker: David Herbst, MS MBA

Moderator: Dr. Saskia Ihle

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60-Minute Agenda

- Part 1: Money-saving and Time-saving features
- Part 2: New security features that ensure compliance to 21 CFR Part 11 and internal security policies
- Part 3: How to effectively use the trending feature to support OOS/OOT investigations
- Questions and Answers

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Agenda

- Part 1: Money-saving and Time-saving features
- Part 2: New security features which ensure compliance to 21 CFR Part 11 and internal security policies
- Part 3: How to effectively use the trending feature to support OOS/OOT investigations
- Questions and Answers

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Part 1: Money and Time-Saving Ideas

- “The most expensive tests are the retests”
- Use WinKQCL™ Software to work smarter
- Reduce deviations and retests
- Features that save time and money:
  - Prevent retests where you have split pair/split replicate events
  - How to keep spot contamination from invalidating your standard curve
  - Barcode scanning and other data automation features to reduce manual entry errors

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Split Replicate Detection

- Problem:
  - A split pair or a split replicate is a case where one replicate reacts and one does not, resulting in a reaction time for one replicate and not the other
  - For duplicates this will result in an undefined %CV
  - Most companies will retest
- Solution:
  - Lonza's Kinetic SmartStop™ Feature
  - Demo video next slide

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Spot Contamination

- Problem:
  - When individual blanks, standards, or product replicates become contaminated, they cause a %CV failure or cause the blank and low standard to overlap.
  - In the case of invalid standard curves, the entire plate must be retested.
  - In the case of an invalid sample, the sample and PPC must be retested.
- Solution:
  - WinKQCL™ version 5 Software allows one to setup extra negative controls, standards, increase replicates, and/or mask hot wells

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Spot Contamination – Template Options

Template Manager -

	1	2	3	4	5	6	7	8	9	10	11	12
A	BLNK	BLNK	S3 Vacc LOT121	S3 Vacc LOT121	S11 WF Loop 1	S11 WF Loop 1	S19 WF Loop 2	S19 WF Loop 2				
B	STD1 0.0100	STD1 0.0100	S4+ Va LOT121	S4+ Va LOT121	S12+ W Loop 1	S12+ W Loop 1	S20+ W Loop 2	S20+ W Loop 2				
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Setup | Standards | Lot / Exp | Accessories | Parameters

Name

Assay Type: PYROGENT-5000

Test Type: Routine

Product Layout

Automatic Layout | Custom Layout

Replicates: 2

Replicate Direction: Horizontal

Sample Fill Direction: Vertical

PPC Fill Direction: Vertical

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A	BLNK	BLNK	BLNK	S3 Vacc LOT121	S3 Vacc LOT121	S3 Vacc LOT121	S11 WF Loop 1 [	S11 WF Loop 1 [	S11 WF Loop 1 [	S19 WF Loop 2 [	S19 WF Loop 2 [	S19 WF Loop 2 [
B	STD1 0.0100	STD1 0.0100	STD1 0.0100	S4+ Va LOT121	S4+ Va LOT121	S4+ Va LOT121	S12+ W Loop 1 [	S12+ W Loop 1 [	S12+ W Loop 1 [	S20+ W Loop 2 [	S20+ W Loop 2 [	S20+ W Loop 2 [
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STD2	0.100
STD3	1.00
STD4	10.0
STD5	100

Number of standards: 5

Units: EU

Enable separate Standards layout

Replicates: 2

Replicate Direction: Horizontal

Sample Fill Direction: Vertical

Preset Curve

PYROGENT5000 | Save | Delete

Stored Curve

Stored curve query not performed.

Search

Use

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Spot Contamination – Template Options

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Sample Fill Direction: Horizontal

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PYROGENT5000 | Save | Delete

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Standards Increasing
Standards Decreasing
Duplicate
Insert Blank Above
Insert Blank Below
Insert Empty Above
Insert Empty Below
Remove

Preset Curve
PYROGENT5000

Stored Curve
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C	STD1 0.0100	STD1 0.0100	S3 Vacc LOT121	S3 Vacc LOT121	S11 WF Loop 1	S11 WF Loop 1	S19 WF Loop 2	S19 WF Loop 2				
D	STD1 0.0100	STD1 0.0100	S4+ Va LOT121	S4+ Va LOT121	S12+ W Loop 1	S12+ W Loop 1	S20+ W Loop 2	S20+ W Loop 2				
E	STD2 0.100	STD2 0.100	S5 Vacc LOT121	S5 Vacc LOT121	S13 WF Loop 1	S13 WF Loop 1	S21 WF Loop 2	S21 WF Loop 2				
F	STD3 1.00	STD3 1.00	S6+ Va LOT121	S6+ Va LOT121	S14+ W Loop 1	S14+ W Loop 1	S22+ W Loop 2	S22+ W Loop 2				
G	STD4 10.0	STD4 10.0	S7 Devi LOT125	S7 Devi LOT125	S15 WF Loop 2	S15 WF Loop 2	S23 WF Loop 2	S23 WF Loop 2				
H	STD5 100	STD5 100	S8+ De LOT125	S8+ De LOT125	S16+ W Loop 2	S16+ W Loop 2	S24+ W Loop 2	S24+ W Loop 2				

Setup | Standards | Lot / Exp | Accessories | Parameters

BLNK	0
BLNK	0
STD1	0.0100
STD1	0.0100
STD2	0.100
STD3	1.00
STD4	10.0
STD5	100

Number of standards: 5

Units: EU

☑ Enable separate Standards layout

Replicates: 2

Replicate Direction: Horizontal

Sample Fill Direction: Vertical

Preset Curve

PYROGENT5000 | Save | Delete

Stored Curve

Stored curve query not performed.

Search

Use ☐

Lonza

Spot Contamination – Template Options

Template Manager -

	1	2	3	4	5	6	7	8	9	10	11	12
A	BLNK	BLNK	S1 Vacc LOT121	S1 Vacc LOT121	S9 WFI Loop 1	S9 WFI Loop 1	S17 WF Loop 2	S17 WF Loop 2	S25 WF Loop 2	S25 WF Loop 2		
B	BLNK	BLNK	S2+ Va LOT121	S2+ Va LOT121	S10+ W Loop 1	S10+ W Loop 1	S18+ W Loop 2	S18+ W Loop 2	S26+ W Loop 2	S26+ W Loop 2		
C	STD1 0.0100	STD1 0.0100	S3 Vacc LOT121	S3 Vacc LOT121	S11 WF Loop 1	S11 WF Loop 1	S19 WF Loop 2	S19 WF Loop 2				
D	STD1 0.0100	STD1 0.0100	S4+ Va LOT121	S4+ Va LOT121	S12+ W Loop 1	S12+ W Loop 1	S20+ W Loop 2	S20+ W Loop 2				
E	STD2 0.100	STD2 0.100	S5 Vacc LOT121	S5 Vacc LOT121	S13 WF Loop 1	S13 WF Loop 1	S21 WF Loop 2	S21 WF Loop 2				
F	STD3 1.00	STD3 1.00	S6+ Va LOT121	S6+ Va LOT121	S14+ W Loop 1	S14+ W Loop 1	S22+ W Loop 2	S22+ W Loop 2				
G	STD4 10.0	STD4 10.0	S7 Devi LOT125	S7 Devi LOT125	S15 WF Loop 2	S15 WF Loop 2	S23 WF Loop 2	S23 WF Loop 2				
H	STD5 100	STD5 100	S8+ De LOT125	S8+ De LOT125	S16+ W Loop 2	S16+ W Loop 2	S24+ W Loop 2	S24+ W Loop 2				

Setup | Standards | Lot / Exp | Accessories | Parameters

BLNK	0
BLNK	0
STD1	0.0100
STD1	0.0100
STD2	0.100
STD3	1.00
STD4	10.0
STD5	100

Number of standards: 5

Units: EU

☑ Enable separate Standards layout

Replicates: 2

Replicate Direction: Horizontal

Sample Fill Direction: Vertical

Preset Curve

My Standard Curve | Save | Delete

Stored Curve

Stored curve query not performed.

Search

Use ☐

Spot Contamination – Data Analysis

WinKQCL 5 - [Endotoxin Test Results (1 of 50): Medtronic Water 2 #0 01/27/2014 11:01:57 AM]

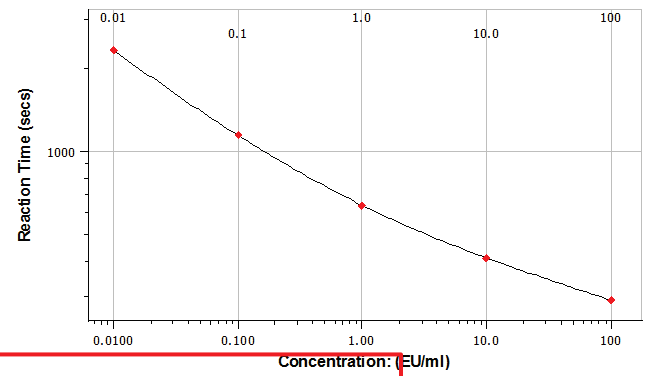
Lonza - Scientific Support
SST BioTek ELx-808 Reader A
Lonza - WinKQCL Version 5.1.2

Page 1 of 2

Performed By : TWALLACE (VA)	LAL Lot No.	: NL046EVHVY	Exp : 05/14/2015	Time : 11:01:57AM (UTC-5)
PYROGENT-5000 - Routine Test	Water Lot No.	: 0000362370	Exp : 06/12/2015	Date : 01/27/2014
Template : Medtronic Water 2	Endotoxin Lot No.	: 0000368802	Exp : 08/05/2017	ELx808
Temperature : 36.9°C - 37.0°C	Recon. Buffer Lot No.	: 0000348623	Exp : 05/08/2015	S/N 1305225

Linear Regression : Correlation Coefficient = -0.990 Slope = -0.225 Y-Intercept = 2.862

PowerCurve : A = 2.8062 B = -0.2198 C = 0.0323 D = -0.0015 E = -0.0013



Standards Results

Standards	Conc./Dil.	Well	Reaction Time (sec)	Average Reaction Time (sec)	Back Prediction (Power Curve)
Blank	Blank	A 1	4440	4375	< 0.0100
		A 2	4555		
		A 3	4130		
Std. 1	0.01	B 1	2340	2325	0.00998
		B 2	2395		
		B 3	2240		
Std. 2	0.1	C 1	1140	1144	0.100

Lonza

Spot Contamination – Data Analysis

Standards Results

Standards	Conc./Dil.	Well	Reaction Time (sec)	Average Reaction Time (sec)
Blank	Blank	A 1	4440	4375
		A 2	4555	
		A 3	4130	
Std. 1	0.01	B 1	2340	2325
		B 2	2395	
		B 3	2240	
Std. 2	0.1	C 1	1140	1144
		C 2	1145	

Current Page No.: 1 | Total Page No.: 2 | Zoom

View Template | View Raw Data | Linear Regression | Temperature | Next Test >>

Analyze | Export to LIMS | PowerCurve | Close | << Previous Test

03/03/2014 11:30:22 AM

Lonza

Spot Contamination – Data Analysis

Standards Results

Standards	Conc./Dil.	Well	Reaction Time (sec)	Average Reaction Time (sec)
Blank	Blank	A 1	4440	4375
		A 2	4555	
		A 3	4130	
Std. 1	0.01	B 1	2340	2325
		B 2	2395	
		B 3	2240	
Std. 2	0.1	C 1	1140	1144
		C 2	1145	

Current Page No.: 1 | Total Page No.: 2 | Zoom

View Template | View Raw Data | Linear Regression | Temperature | Next Test >>

Analyze | Export to LIMS | PowerCurve | Close | << Previous Test

03/03/2014 11:30:22 AM

Lonza

Spot Contamination – Data Analysis

To mask or unmask points double click on a row

Row	Col	React. Time	Masked
A	1	4440	
A	2	4555	
A	3	4130	
B	1	2340	
B	2	2395	
B	3	2240	
C	1	1140	
C	2	1145	
C	3	1147	
D	1	636	
D	2	646	
D	3	637	
E	1	406	
E	2	420	

- Linear Regression
- PowerCurve

!! Masked
***** UnReacted
????? Atypical
>>>>> High OD

OK Cancel

Lonza

Spot Contamination – Data Analysis

To mask or unmask points double click on a row

Row	Col	React. Time	Masked
A	1	4440	
A	2	4555	
A	3	4130	!!
B	1	2340	
B	2	2395	
B	3	2240	
C	1	1140	
C	2	1145	
C	3	1147	
D	1	636	
D	2	646	
D	3	637	
E	1	406	
E	2	420	

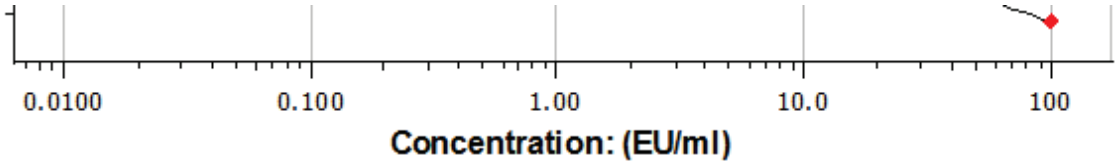
- Linear Regression
- PowerCurve

!! Masked
***** UnReacted
????? Atypical
>>>>> High OD

OK Cancel

Lonza

Spot Contamination – Data Analysis



Standards Results

Standards	Conc./Dil.	Well	Reaction Time (sec)	Average Reaction Time (sec)	Back Prediction (Power Curve)
Blank	Blank	A 1	4440	4498	< 0.0100
		A 2	4555		
		A 3	4130 !!		
Std. 1	0.01	B 1	2340	2325	0.00998
		B 2	2395		
		B 3	2240		
Std. 2	0.1	C 1	1140	1144	0.100
		C 2	1145		

urrent Page No.: 1 | Total Page No.: 3 | Zoom Factor: Page Width

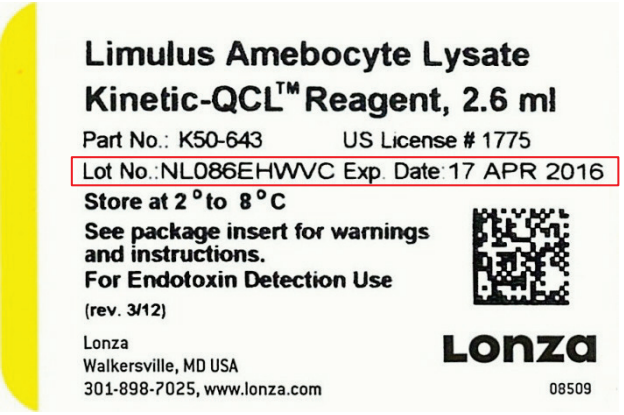
Lonza

Barcode Scanning/Data Import

- Problem:
  - Labels are difficult to read
  - Manual data entry is error prone
- Solutions:
  - Scan in data via a handheld barcode scanner (Lonza P/N: 25-507)
  - New data import feature
  - Lonza's PyroTec™ Solution allows automatic import of sample barcodes

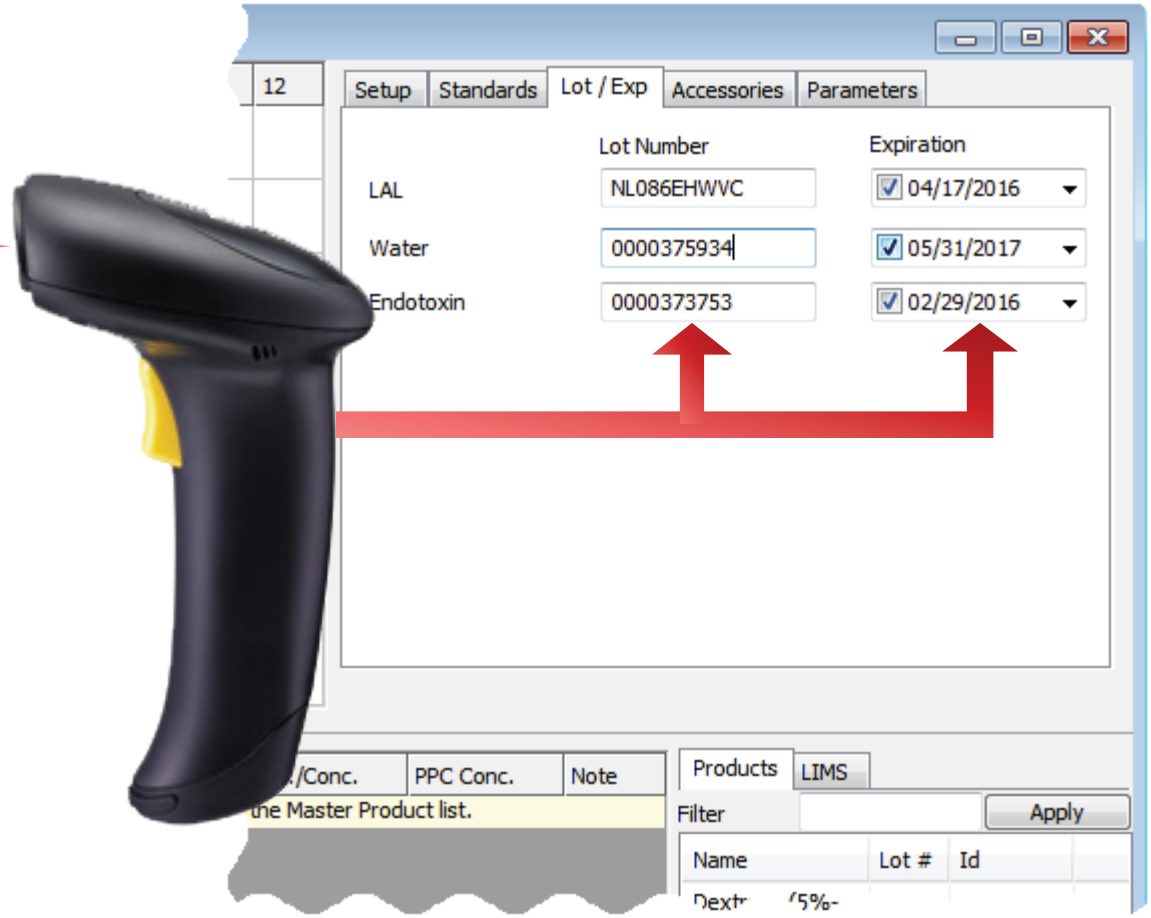
Barcode Scanning

- Starting with version 4.0.3, the WinKQCL™ Software supports scanning reagent data directly into the template using the 2D barcode printed on our vials



Lonza

Barcode Scanning



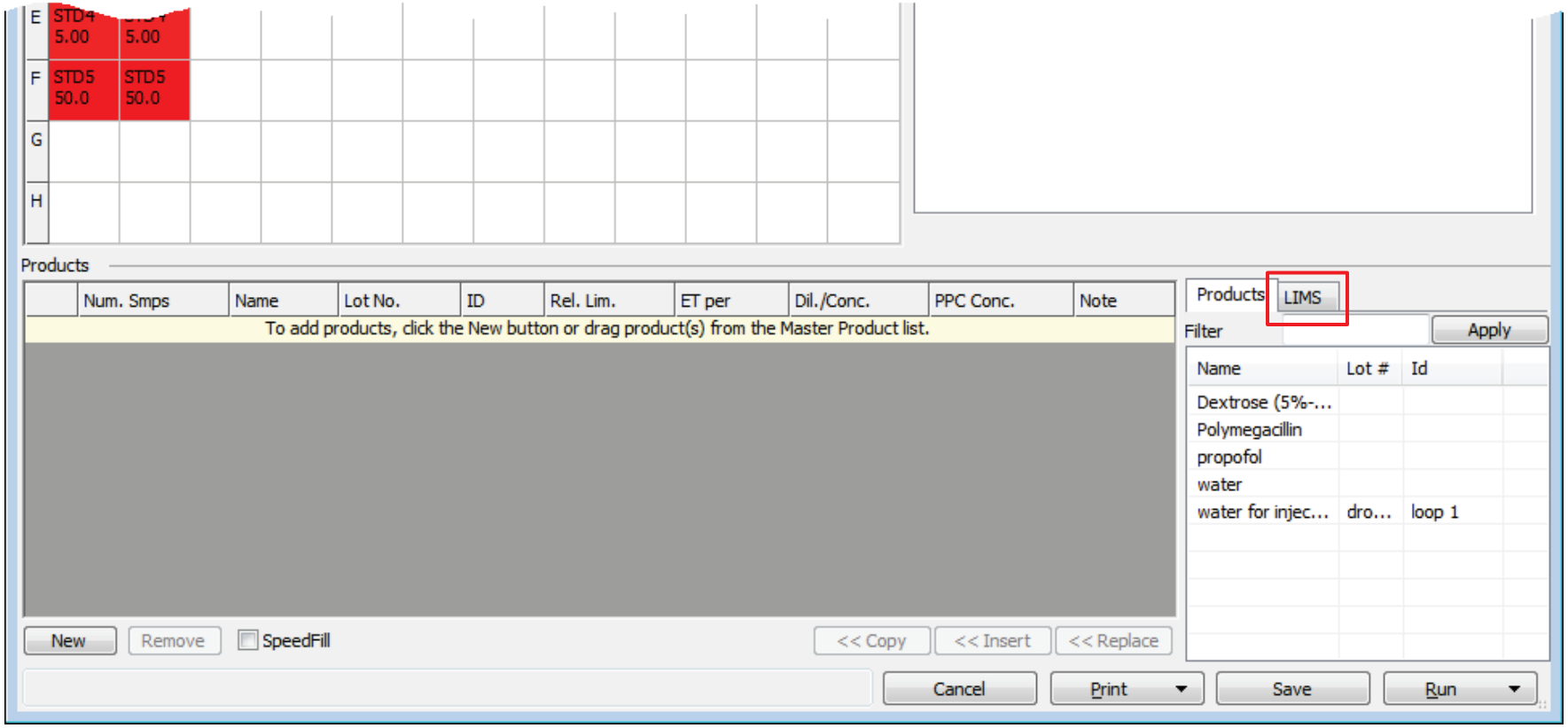
Lonza

Data Import

- WinKQCL™ Software now supports bi-directional interfaces with 3rd party sample tracking systems
- These 3rd party systems include Lonza's MODA™ Environmental Monitoring system, commercially available LIMS, LIS and custom-made sample tracking systems
- WinKQCL™ Software will automatically import sample testing worklists and display this information in the template manager.

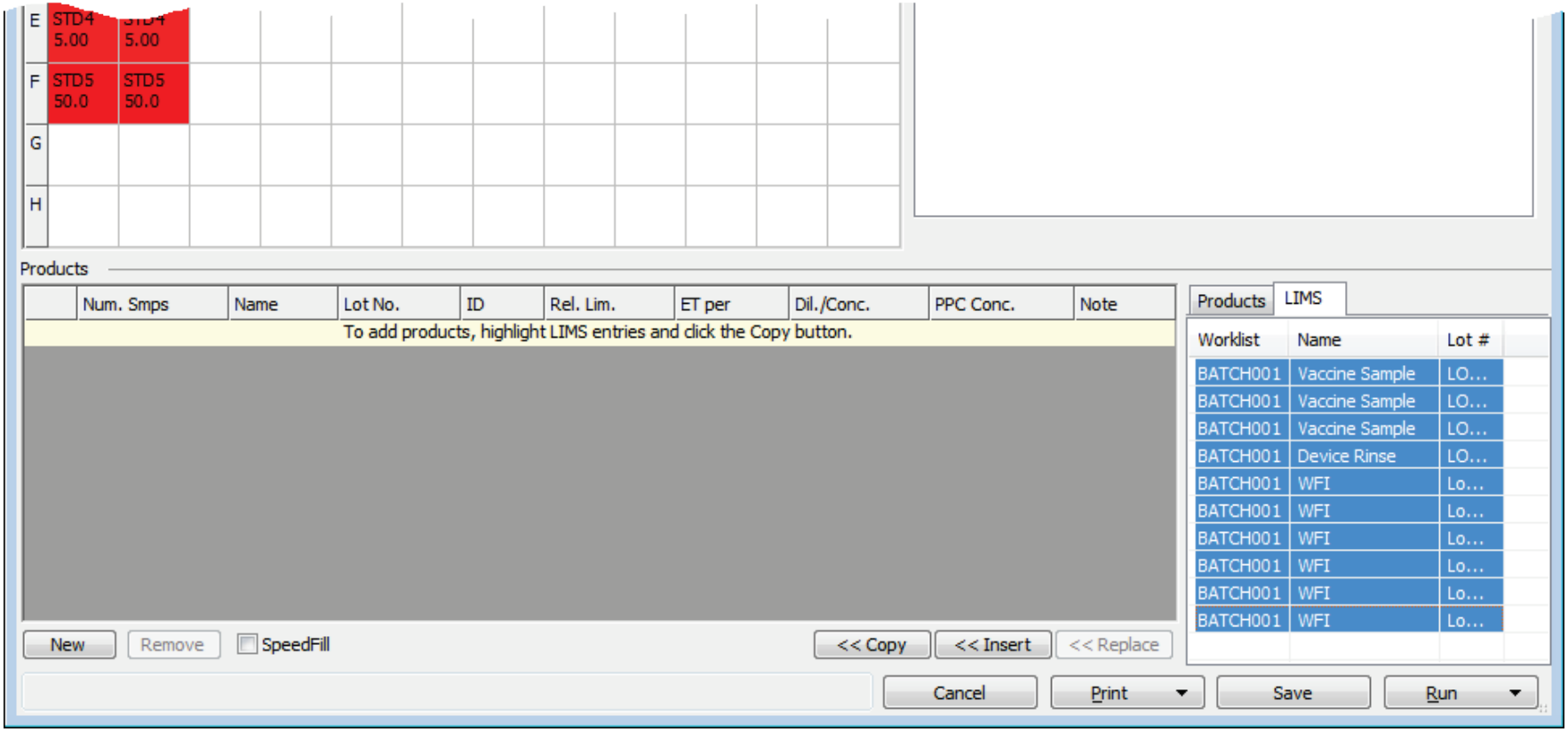
Lonza

Data Import



Lonza

Data Import



Lonza

Template Manager - test template

	1	2	3	4	5	6	7	8	9	10	11	12
A	BLNK	BLNK	S3 Vacci LOT121	S3 Vacci LOT121	S11 WFI Loop 1 D	S11 WFI Loop 1 D	S19 WFI Loop 2 D	S19 WFI Loop 2 D				
B	STD1 0.00500	STD1 0.00500	S4+ Vac LOT121	S4+ Vac LOT121	S12+ W Loop 1 D	S12+ W Loop 1 D	S20+ W Loop 2 D	S20+ W Loop 2 D				
C	STD2 0.0500	STD2 0.0500	S5 Vacci LOT121	S5 Vacci LOT121	S13 WFI Loop 1 D	S13 WFI Loop 1 D						
D	STD3 0.500	STD3 0.500	S6+ Vac LOT121	S6+ Vac LOT121	S14+ W Loop 1 D	S14+ W Loop 1 D						
E	STD4 5.00	STD4 5.00	S7 Devic LOT125	S7 Devic LOT125	S15 WFI Loop 2 D	S15 WFI Loop 2 D						
F	STD5 50.0	STD5 50.0	S8+ Dev LOT125	S8+ Dev LOT125	S16+ W Loop 2 D	S16+ W Loop 2 D						
G	S1 Vacci LOT121	S1 Vacci LOT121	S9 WFI Loop 1 D	S9 WFI Loop 1 D	S17 WFI Loop 2 D	S17 WFI Loop 2 D						
H	S2+ Vac LOT121	S2+ Vac LOT121	S10+ W Loop 1 D	S10+ W Loop 1 D	S18+ W Loop 2 D	S18+ W Loop 2 D						

Setup | Standards | Lot / Exp | Accessories | Parameters

	Lot Number	Expiration
LAL	NL086EHWVC	☑ 04/17/2016
Water	000375934	☐ 02/28/2014
Endotoxin	000373753	☐ 02/28/2014

Products

	Num. Smps	Name	Lot No.	ID	Rel. Lim.	ET per	Dil./Conc.	PPC Conc.	Num. Devs	Extr. Vol.	Note
	1	Vaccine Sample	LOT12114	LIMS003784790	≤ 1.000	ml	10.00	☑ 0.500	N/A	N/A	middle
	1	Vaccine Sample	LOT12114	LIMS003784791	≤ 1.000	ml	10.00	☑ 0.500	N/A	N/A	end
	1	Device Rinse	LOT12514	LIMS003784796	< 5.000	device	1.0	☑ 1.000	10	100.00	
	1	WFI	Loop 1 Drop 2	MODA013413	< 0.250	ml	1.0	☑ 0.500	N/A	N/A	
	1	WFI	Loop 1 Drop 3	MODA013414	< 0.250	ml	1.0	☑ 0.500	N/A	N/A	
	1	WFI	Loop 1 Drop 4	MODA013415	< 0.250	ml	1.0	☑ 0.500	N/A	N/A	
	1	WFI	Loop 2 Drop 1	MODA013416	< 0.250	ml	1.0	☑ 0.500	N/A	N/A	
	1	WFI	Loop 2 Drop 2	MODA013417	< 0.250	ml	1.0	☑ 0.500	N/A	N/A	
	1	WFI	Loop 2 Drop 3	MODA013418	< 0.250	ml	1.0	☑ 0.500	N/A	N/A	

Products | LIMS

Worklist	Name	Lot #
BATCH001	Vaccine Sample	LO...
BATCH001	Vaccine Sample	LO...
BATCH001	Vaccine Sample	LO...
BATCH001	Device Rinse	LO...
BATCH001	WFI	Lo...
BATCH001	WFI	Lo...
BATCH001	WFI	Lo...
BATCH001	WFI	Lo...
BATCH001	WFI	Lo...
BATCH001	WFI	Lo...

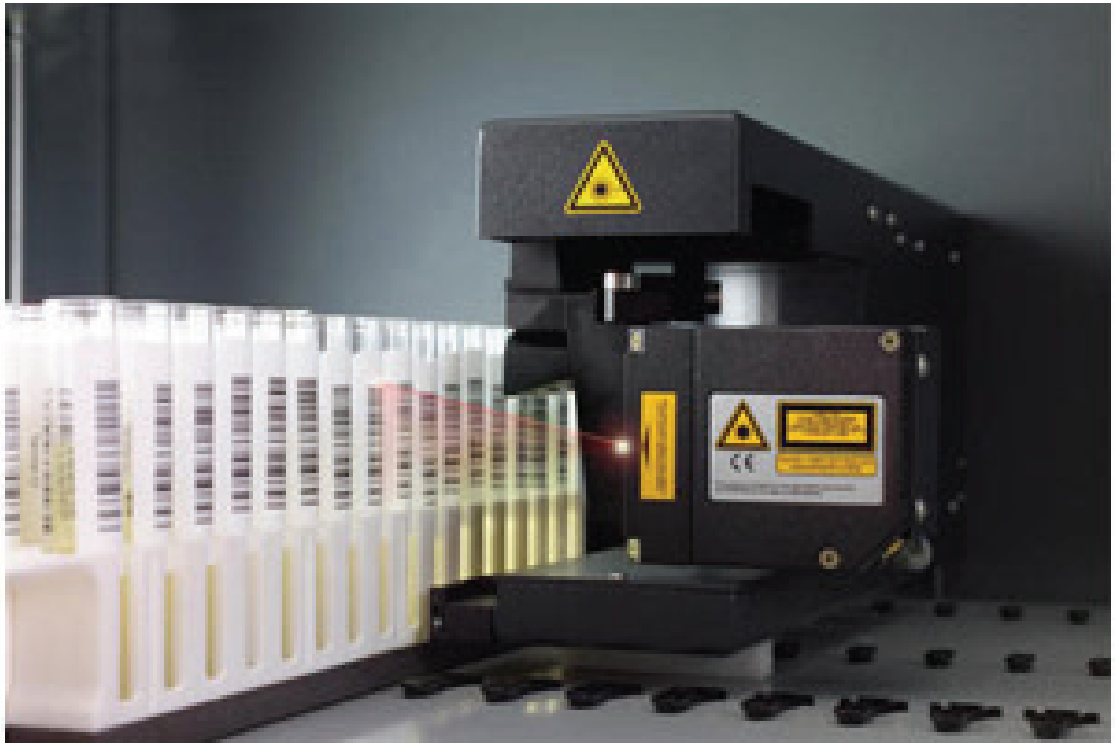
New | Remove | SpeedFill | << Copy | << Insert | << Replace

Cancel | Print | Save | Run

Lonza

PyroTec™ Robot Barcode Scanning

- WinKQCL™ Software is also fully integrated with Tecan's EVOware® Software
- Lonza's PyroTec™ Solution can be integrated to automatically import barcode information from the sample tubes using the built-in scanner



Lonza

Agenda

- Part 1: Money-saving and Time-saving features
- Part 2: New security features which ensure compliance to 21 CFR Part 11 and internal security policies
- Part 3: How to effectively use the trending feature to support OOS/OOT investigations
- Questions and Answers

Lonza

Part 2: New Security Features

- Problem:
  - Software must comply with regulatory, industry, and company security requirements
  - Software must still be flexible and easy to use
- Solutions:
  - WinKQCL™ 5 Software introduces many new security enhancements which improve both compliance and ease-of-use

Lonza

New Security Features

- WinKQCL™ Software continues to meet the technical requirements for 21 CFR Part 11 and support the European Annex 11 guidance
- New features enable flexibility and easier adherence
- WinKQCL™ 5 Software and higher now support:
  - IT initiatives to secure all data under one central database and segregate data into laboratory workgroups
  - Restriction of user access to individual laboratory workgroup data
  - The use of your Windows® password
  - Activity timer settings to allow WinKQCL™ Software to match company policies
  - Flexible, user-specific access rights configuration

Lonza

New Security Features – Data Security

- Data Storage:
  - Endotoxin data is GMP data!
  - Do not store it on your laboratory computer!
  - If you are storing your data on a laboratory computer and not backing it up daily, have your IT department contact scientific support, we can assist in securing your data

Lonza

New Security Features – Data Security

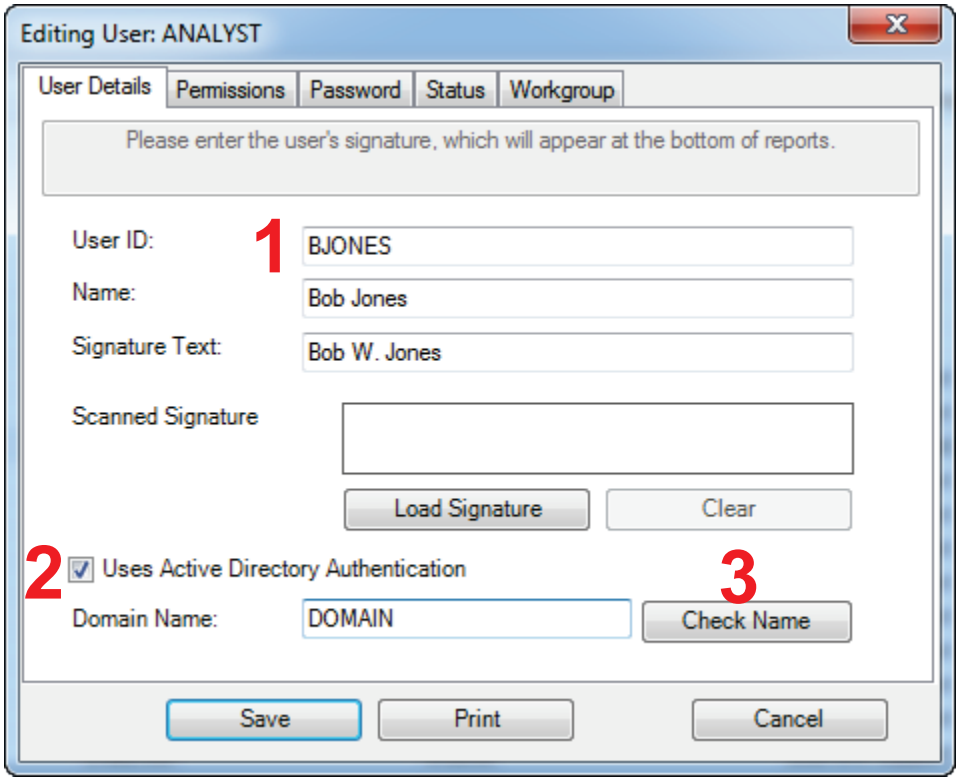
- Lonza has supported a true client-server network since 2004
- Starting with WinKQCL™ 5 Software, data can be centralized and shared across sites, even if these sites are in different countries

- Steps to securing your data:
  - Work with IT to identify an existing database server that can be used
  - WinKQCL™ Software has tools that can import and merge existing data
  - Install the client software on all lab and office computers

Lonza

New Security Features – Passwords

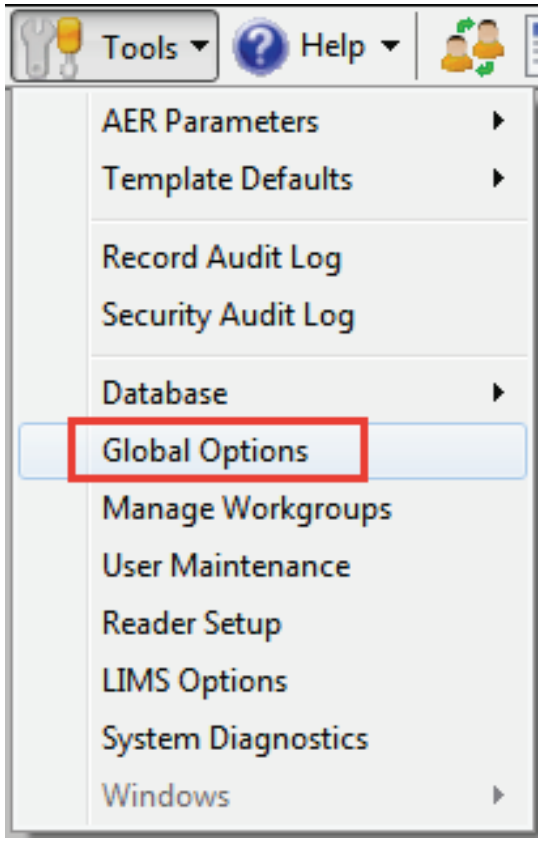
- Starting with the WinKQCL™ 5 Software, you can use the same password you use to log in to Windows®



Lonza

New Security Features – Password Rules

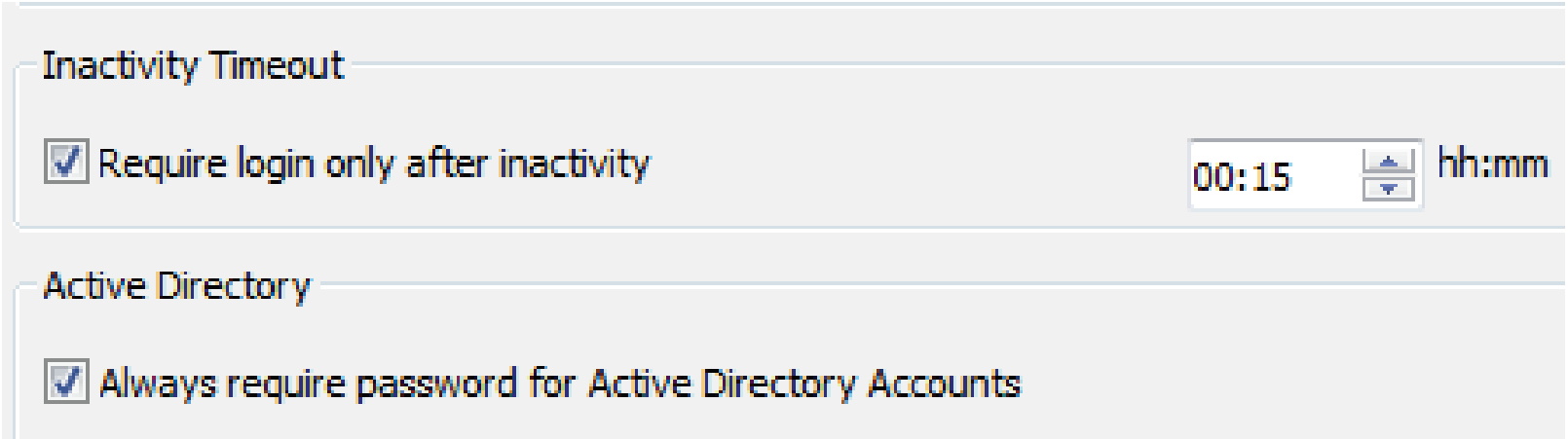
- Set the WinKQCL™ Software password rules to match company policy:



Lonza

New Security Features – Password Rules

- Set the WinKQCL™ Software password rules to match company policy:
  - Set the inactivity timer
  - Enable/disable active directory “single sign-on” (SSO) feature. SSO allows WinKQCL™ Software to automatically log you in with the password you used to log in to Windows®.



Lonza

New Security Features – Password Rules

- Set the WinKQCL™ Software password rules to match company policy:
  - Set the inactivity timer
  - Enable/disable active directory “single sign-on” (SSO) feature. SSO allows WinKQCL™ Software to automatically log you in with the password you used to log in to Windows®.
  - **When applying e-signatures and cancelling tests, the WinKQCL™ Software will always require passwords**

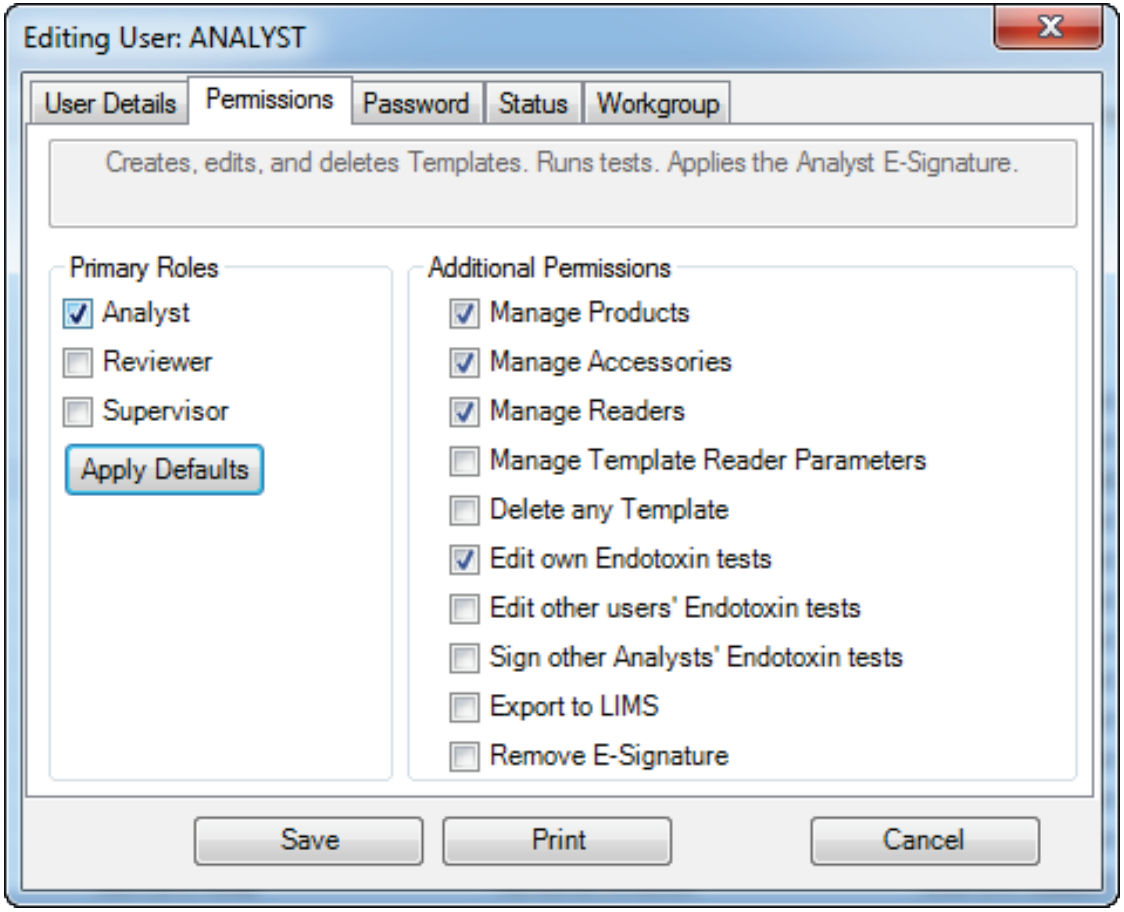
Lonza

New Security Features – User Access

- WinKQCL™ 5 Software adds user access flexibility:
  - Per 21 CFR Part 11, assign access according to the user's training/role in the company
  - Use these features to restrict access of non-QC or less experienced QC personnel or increase it for experienced personnel/managers
  - Allow/restrict access to specific workgroups

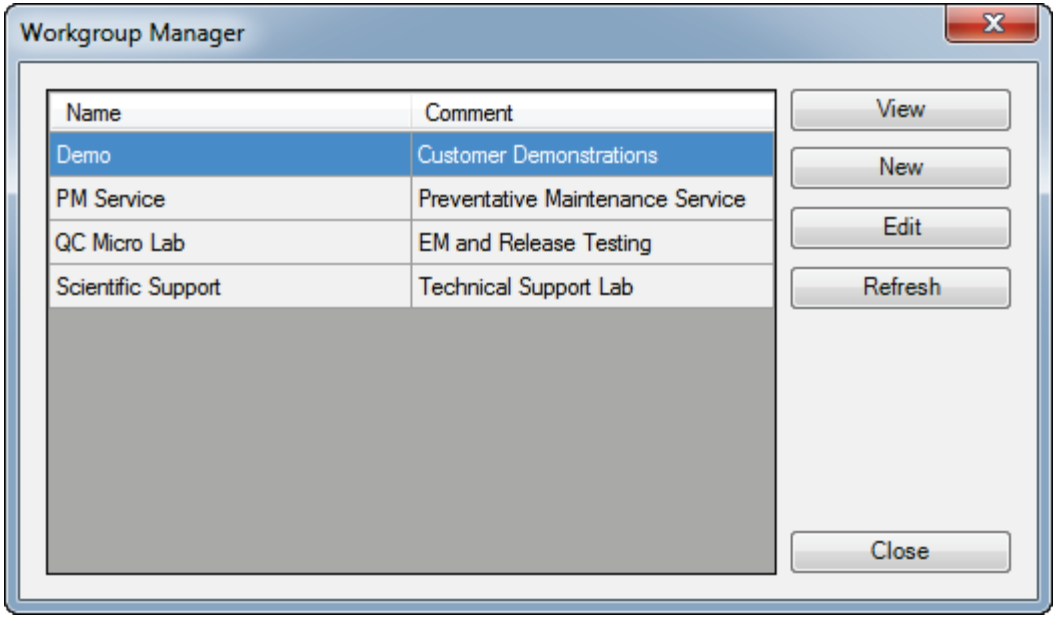
Lonza

New Security Features – User Access



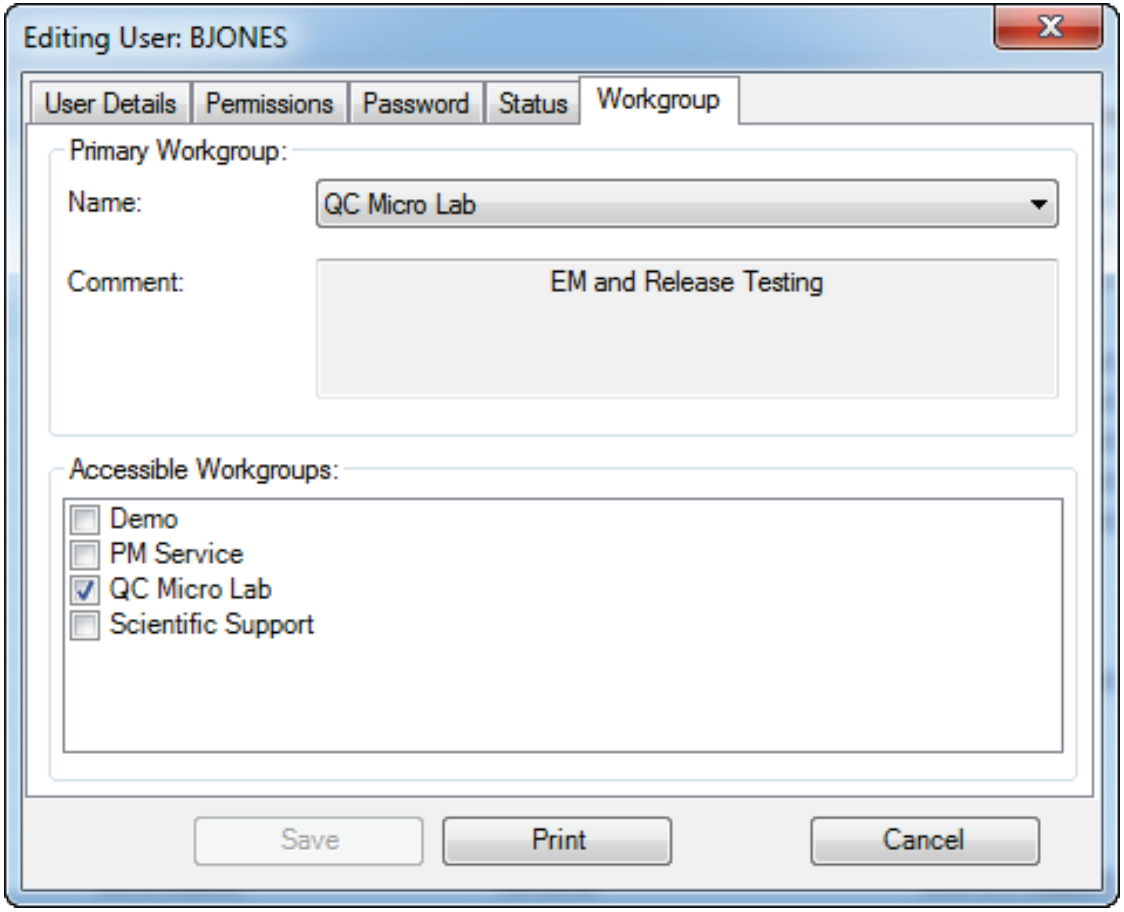
Lonza

New Security Features – User Access



Lonza

New Security Features – User Access



Lonza

Agenda

- Part 1: WinKQCL™ Money/Time saving software features
- Part 2: New security features which ensure compliance to 21 CFR Part 11 and internal security policies
- Part 3: How to effectively use the trending feature to support OOS/OOT investigations
- Questions and Answers

Lonza

Part 3: How to Effectively Use Trending

- Problem:
  - Customers need an easy way to review and monitor data
- Solutions:
  - WinKQCL™ 4 Software and higher introduce a new generation of integrated trending and data analysis capability
  - WinKQCL™ 5 Software adds additional standards data analysis capability
  - How to use trending…

Lonza

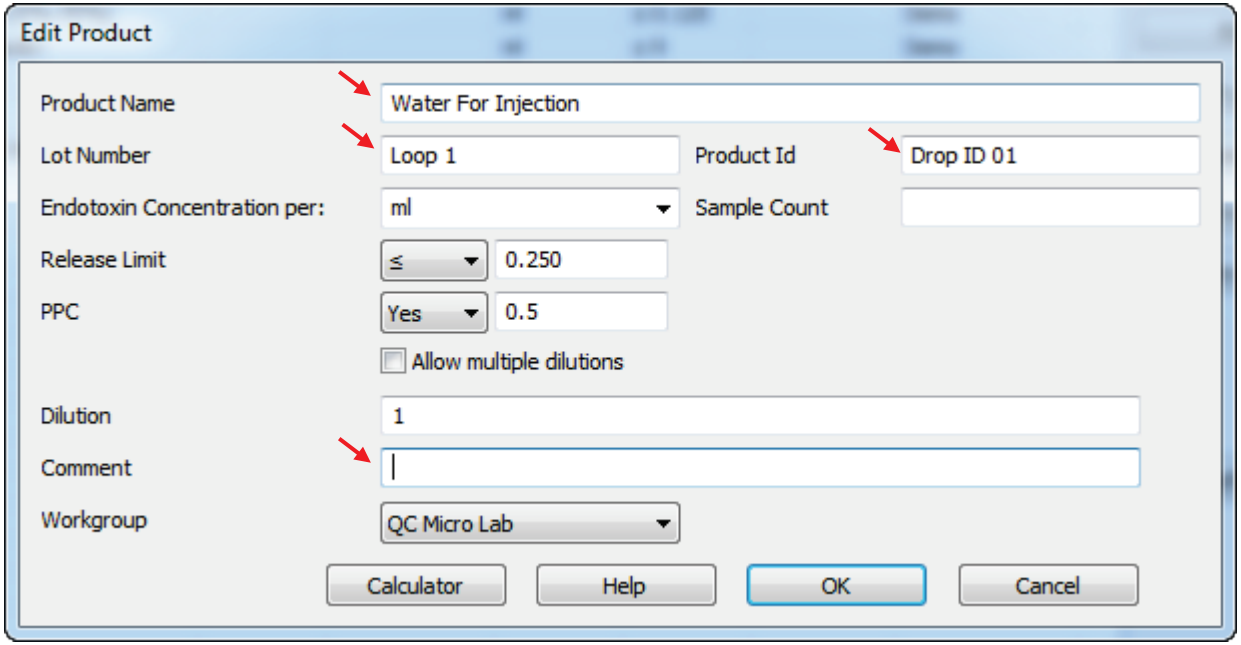
How to Effectively Use Trending

- First, and most importantly, users in the lab must get into the habit of inputting all data consistently and accurately
- Examples of inconsistent data:
  - Water ≠ WFI ≠ Water for Injection
  - P20 Pipette ≠ 20ul Pipette
- Examples of poorly entered data:
  - “0.9% Sodium Chloride Injection 26MAR2014”
  - “Eppendorf® 20ul Pipetter”
  - Data elements need to be separated into appropriate fields

Lonza

Maintaining Products Lists

- Break each piece of information about the test article into separate fields



Lonza

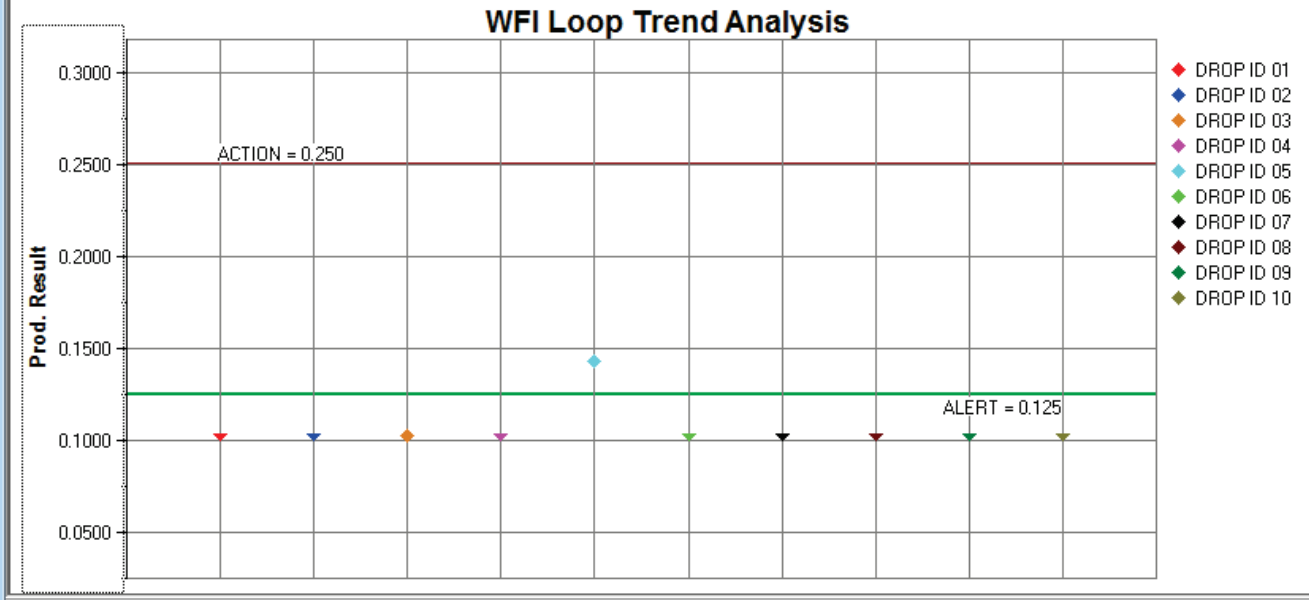
WinKQCL 5 - [Trend View (Records: 10)]

Templates | Products | Accessories | Endotoxin Tests | Trending | Other Tests | Robotics | Tools | Help

Saved Queries: Water Loop | Queries | Run | Trend Unsigned Tests | Print | Close

Qualifier	Operator	Value
Product Name	=	WATER FOR INJECTION
Product Lot Number		
Product Result		

R#	Hide	Run Date	Template Name	#	Product Name	P#	Product Lot #	S#	Dil./Conc.	Prod. Result	Product ID
5		05/09/2007 2:08 PM	SAH Sat #6 B	0	Water For Injection	6	Loop 1	1	1	0.143	Drop ID 05
6		05/09/2007 2:08 PM	SAH Sat #6 B	0	Water For Injection	7	Loop 2	1	1	< 0.100	Drop ID 06
7		05/09/2007 2:08 PM	SAH Sat #6 B	0	Water For Injection	8	Loop 2	1	1	< 0.100	Drop ID 07
8		05/09/2007 2:08 PM	SAH Sat #6 B	0	Water For Injection	9	Loop 2	1	1	< 0.100	Drop ID 08



Channels
Variable: Prod. Result
Series: Product ID
Reset Graph
DROP ID 02
DROP ID 03
DROP ID 04
DROP ID 05
Show Trace Lines
Show Invalid Tests

Y-Axis
ACTION 0.250
ALERT 0.125
-σx 3.0 0.1430

X-Axis
Plot By Run Number
Plot In Parallel
Plot By Run Date

DHERBST logged into localhost\WinKQCL since 02/28/2014 3:52:31 PM | NUM | 02/28/2014

Lonza

Maintaining Your Accessories

- Just like with products, it is important to associate an accurate and consistent list of accessories used with each test to allow for effective trending and investigations
- WinKQCL™ Software allows maintenance of a global list of accessories used for each laboratory
- Each user can create their own default list from this global list to save time when setting up their template
- It is possible to assign a calibration technician or a specific analyst with the responsibility of maintaining this list, while locking out all other users

Lonza

Maintaining Your Accessories

Accessories

User Template Defaults: 4

Accessory Name	Lot Num.
13mm Dilution Tubes	123D
MP200 Multipettor	PIP 375
P20 Pipettor	PIP 008
P200 Pipettor	PIP 489

Master List: 74

Accessory Name	Lot Num.	Workgroup
13mm Dilution Tubes	123D	QC Micro Lab
MP200 Multipettor	PIP 375	QC Micro Lab
P20 Pipettor	PIP 008	QC Micro Lab
P200 Pipettor	PIP 489	QC Micro Lab
PIPETTOR 1	12631253	QC Micro Lab
10 uL pipette	591R511	Scientific Support - Europe
100 ul pipette	N24314	Scientific Support - Europe
1000µl tips	B146262H	Scientific Support - Europe
1000uL pipette	N01753	Scientific Support - Europe
1000ul tips Biopur	W130167Q	Scientific Support - Europe
200 ul Pipette	N24313	Scientific Support - Europe
200 uL pipette	T46026	Scientific Support - Europe
200-1000 ul pipette	U588904500	Scientific Support - Europe
200-1000ul Pipette	U58868	Scientific Support - Europe
200ul tips Biopur	Z140510N	Scientific Support - Europe
20-200 uL pipette	T46007	Scientific Support - Europe
2-200µl ep biopur	0000299555	Scientific Support - Europe
2-20ul Pipette	CQ26383	Scientific Support - Europe
50-1000µl ep biopur	0000300665	Scientific Support - Europe
8 channel pipette	A18684	Scientific Support - Europe
8-channel Eppendorf	355698A	Scientific Support - Europe
96 wellplate	0000260275	Scientific Support - Europe

New
Delete
Edit
View Only
Refresh

Print User List
<<
>>
Print Master List
Close

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Maintaining Your Accessories

Accessories

User Template Defaults: 4

Accessory Name	Lot Num.
13mm Dilution Tubes	123D
MP200 Multipettor	PIP 375
P20 Pipettor	PIP 008
P200 Pipettor	PIP 489

Master List: 74

Accessory Name	Lot Num.	Workgroup
13mm Dilution Tubes	123D	QC Micro Lab
MP200 Multipettor	PIP 375	QC Micro Lab
P20 Pipettor	PIP 008	QC Micro Lab
P200 Pipettor	PIP 489	QC Micro Lab
PIPETTOR 1	12631253	QC Micro Lab
10 uL pipette	591R511	Scientific Support - Europe
100 ul pipette	N24314	Scientific Support - Europe
1000µl tips	B146262H	Scientific Support - Europe
1000uL pipette	N01753	Scientific Support - Europe
1000ul tips Biopur	W130167Q	Scientific Support - Europe
200 ul Pipette	N24313	Scientific Support - Europe
200 uL pipette	T46026	Scientific Support - Europe
200-1000 ul pipette	U588904500	Scientific Support - Europe
200-1000ul Pipette	U58868	Scientific Support - Europe
200ul tips Biopur	Z140510N	Scientific Support - Europe
20-200 uL pipette	T46007	Scientific Support - Europe
2-200µl ep biopur	0000299555	Scientific Support - Europe
2-20ul Pipette	CQ26383	Scientific Support - Europe
50-1000µl ep biopur	0000300665	Scientific Support - Europe
8 channel pipette	A18684	Scientific Support - Europe
8-channel Eppendorf	355698A	Scientific Support - Europe
96 wellplate	0000260275	Scientific Support - Europe

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View Only
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Print User List
<<
>>
Print Master List
Close

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Using Trending

- Once you have started collecting data consistently, it is just a matter of determining what you want to see and selecting the matching qualifiers
- WinKQCL™ Software allows selection of any data associated with the test, including the following:
  - General endotoxin test data, including the date range, analysts, reader serial numbers, workgroups, reagent lot numbers, and more.
  - All Product and Accessory data
  - Standard curve parameter data and raw data

Using Trending

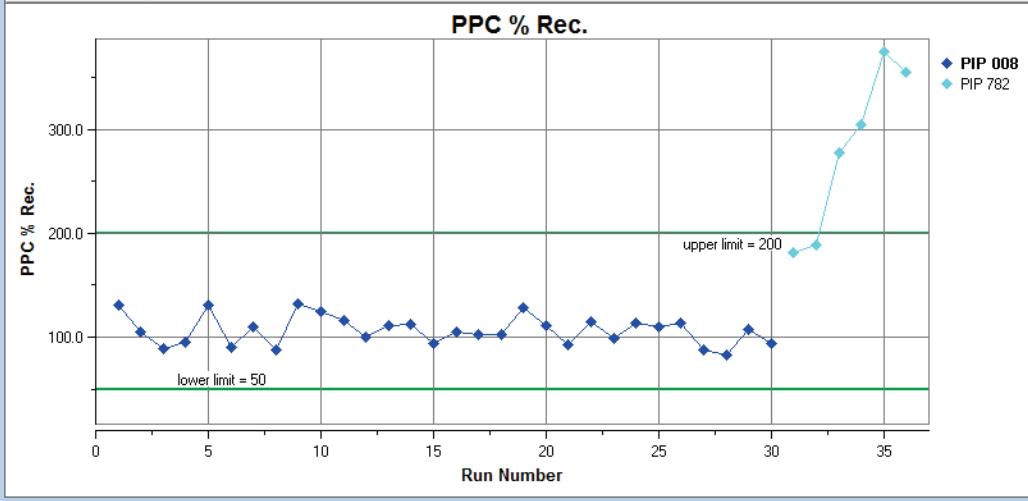
- User can query based on any number of Qualifiers

Trend View (Records: 36)

Saved Queries: PPC%,Acc lots, analyst ids | Queries | Run | Trend Unsigned Tests | Print | Close

Qualifier	Operator	Value
Product PPC % Rec.		
Accessory Name	=	P20 PIPETTOR
Accessory Lot Number	=	PIP 008 or PIP 782
Analyst ID	=	CLANE or JSMITH or LKENT or MPARKER or PJONES

R#	Hide	Run Date	Template Name	#	PPC % Rec.	Accessory Name	Acc. Lot #	Analyst ID
33		6/21/2002 3:30 PM	PMC Release Test PJ	2	277.6	P20 Pipettor	PIP 782	PJONES
34		6/21/2002 3:30 PM	PMC Release Test PJ	3	304.4	P20 Pipettor	PIP 782	PJONES



Channels
Variable: PPC % Rec.
Series: Acc. Lot #
Reset Graph
PIP 008
PIP 375 (no data)
PIP 489 (no data)
PIP 782
Show Trace Lines
Show Invalid Tests
Y-Axis
Mean 106.4
upper limit 200
lower limit 50
X-Axis
Plot By Run Number
Plot In Parallel
Plot By Run Date

Using Trending

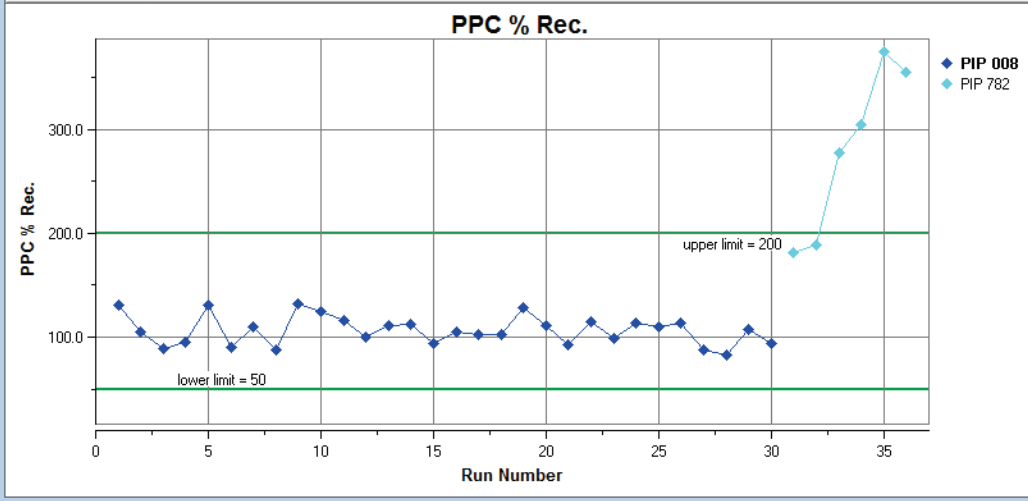
- One window shows query, results table, and graph.

Trend View (Records: 36)

Saved Queries: PPC%,Acc lots, analyst ids | Queries | Run | Trend Unsigned Tests | Print | Close

Qualifier	Operator	Value
Product PPC % Rec.		
Accessory Name	=	P20 PIPETTOR
Accessory Lot Number	=	PIP 008 or PIP 782
Analyst ID	=	CLANE or JSMITH or LKENT or MPARKER or PJONES

R#	Hide	Run Date	Template Name	#	PPC % Rec.	Accessory Name	Acc. Lot #	Analyst ID
33		6/21/2002 3:30 PM	PMC Release Test PJ	2	277.6	P20 Pipettor	PIP 782	PJONES
34		6/21/2002 3:30 PM	PMC Release Test PJ	3	304.4	P20 Pipettor	PIP 782	PJONES



Channels
Variable: PPC % Rec.
Series: Acc. Lot #
Reset Graph
PIP 008
PIP 375 (no data)
PIP 489 (no data)
PIP 782
Show Trace Lines
Show Invalid Tests
Y-Axis
Mean 106.4
upper limit 200
lower limit 50
X-Axis
Plot By Run Number
Plot In Parallel
Plot By Run Date

Using Trending

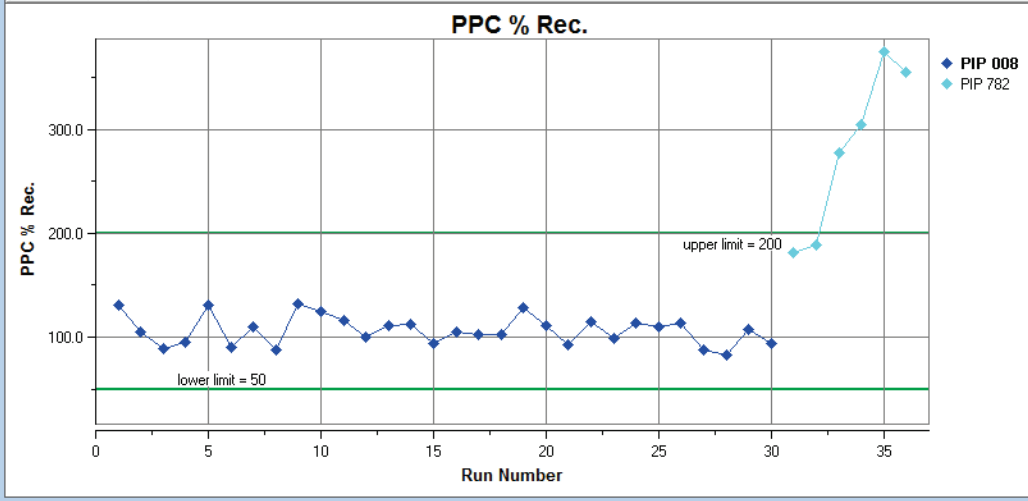
- Ability to mask outliers

Trend View (Records: 36)

Saved Queries: PPC%,Acc lots, analyst ids | Queries | Run | Trend Unsigned Tests | Print | Close

Qualifier	Operator	Value
Product PPC % Rec.		
Accessory Name	=	P20 PIPETTOR
Accessory Lot Number	=	PIP 008 or PIP 782
Analyst ID	=	CLANE or JSMITH or LKENT or MPARKER or PJONES

R#	Hide	Run Date	Template Name	#	PPC % Rec.	Accessory Name	Acc. Lot #	Analyst ID
33		6/21/2002 3:30 PM	PMC Release Test PJ	2	277.6	P20 Pipettor	PIP 782	PJONES
34		6/21/2002 3:30 PM	PMC Release Test PJ	3	304.4	P20 Pipettor	PIP 782	PJONES



Channels
Variable: PPC % Rec.
Series: Acc. Lot #
Reset Graph
PIP 008
PIP 375 (no data)
PIP 489 (no data)
PIP 782
Show Trace Lines
Show Invalid Tests
Y-Axis
Mean 106.4
upper limit 200
lower limit 50
X-Axis
Plot By Run Number
Plot In Parallel
Plot By Run Date

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Using Trending

- Examples of questions you may wish to answer using the trending feature:
  - Does my water loop show an increase in endotoxin over time?
  - Does any specific drop show positive results more often than another, and if so, at what frequency?
  - Is the % PPC Recovery on my product consistent from lot to lot? Do I see a trend that should be investigated, before a failure occurs?
  - I am using a new accessory, reader, or analyst in my lab, let me compare performance of one vs. another using quality indicators, such as %CV, R-Value, or blank/low standard separation

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Agenda

- Part 1: Money-saving and Time-saving features
- Part 2: New security features which ensure compliance to 21 CFR Part 11 and internal security policies
- Part 3: How to effectively use the trending feature to support OOS/OOT investigations
- Questions and Answers

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Do You Have More Questions?

- Contact our Scientific Support

  scientific.support.eu@lonza.com

  scientific.support@lonza.com

- Join our upcoming webinar on June 3rd and 4th:

  Endotoxin Testing and Regulatory Requirements

- Register at:

  http://www.lonza.com/qcwebinars