Simplifying your Quality Controls with Thermo Scientific™ LabLink xL™ and Instrument Manager

Arjun Mehta
Software Product Manager
The World Leader in Serving Science

Global Scale
• 50,000 employees in 50 countries
• $17 billion in annual revenues
• Unparalleled commercial reach
• 10,000 employees working with customers every day

Unmatched Depth
• Innovative technologies
• Applications expertise
• Lab productivity partner

Premier Brands

Thermo Scientific

Fisher Scientific

Unity Lab Services
Leverage Our Unique Customer Value Proposition

Technology Innovation
- Analytical Instruments
- Laboratory Products
- Specialty Diagnostics
- Clinical Diagnostics

Laboratory Channel
- Life Science Research Products
- Genetic Analysis
- Bioproduction
- Molecular Diagnostics
- Industry-Leading Brands
- Convenience
- Logistics
- Clinical Trial Services

Enterprise Services
- Instrument Services
- Asset Management
- Supply Management
- Scientific Support

Enabling customer innovation and productivity
Clinical Diagnostics – Fremont, CA
Clinical Diagnostics – New Center of Excellence
A History of Innovation

- 40 years of dedicated QC manufacture
- Pioneers of QC liquid stabilization
- First to market with consolidated controls
  - ...MAS OmniCORE
  - ...MAS OmniIMMUNE + PRO
  - ...MAS OmniCARDIO
- First QC product with 5 year shelf life
- LabLink xL = Only fully real-time QAP
LabLink xL Quality Assurance Solution

- One integrated QC program
  peer to peer comparison + daily QC review

- 100% web-based

- Fully real-time
  ...real-time data transfer
  ...real-time data processing
  ...real-time reporting
  ...real-time peer comparison
  ...real-time data review
The Power of Real-time Data Processing

- Data can be submitted at *anytime*
  
  ...*no cutoff date for data submission*

- Data can be accessed at *anytime*

- Interlaboratory peer comparison at *anytime*
  
  ...*identify QC shifts and trends sooner*

  ...*reduce troubleshooting time*

- All reports can be generated *anytime* and on demand
  
  ...*13 different reports*
The flags below are based on the statistical analysis of your data compared to your test system peer and do not necessarily indicate a quality control problem. See Individual Lab Report for additional detail.

Decisions regarding these flags should be based both on analytical significance and also medical significance of your quality control data compared to test system peer data.

Q.C. Monitor Flags
This section flags SDI, CVI, and Total Error data from current month based on comparison with the worldwide Test System Peer (TSP).

### Immunoassay

**Thyroxine, TT4 (ug/dL) - SIEMENS DIMENSION RXL, B - SIEMENS HEALTHCARE**

<table>
<thead>
<tr>
<th>Control Lot</th>
<th>Flag</th>
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<tbody>
<tr>
<td>Level 1 Lot Z</td>
<td>TOTAL ERROR</td>
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Reviewed By: 
Action Taken: 

**Vitamin B12 (pg/ml) - SIEMENS ADVIA CENTAUR, 3527 - SIEMENS HEALTHCARE**

<table>
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<th>Control Lot</th>
<th>Flag</th>
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<tbody>
<tr>
<td>Level 1 Lot Z</td>
<td>SDI &gt;= 2.5</td>
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Reviewed By: 
Action Taken: 

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Data Review Flags
Data included in this section is showing a larger bias when compared to your laboratory or the Test System Peer. It is recommended that you check the data submitted to determine if exclusion or update of individual / group results is required.

### Immunoassay

**Salicylate (mg/dL) - SIEMENS DIMENSION RXL, A - SIEMENS HEALTHCARE**

<table>
<thead>
<tr>
<th>Control Lot</th>
<th>Value</th>
<th>Date &amp; Time</th>
<th>LTD Mean</th>
<th>Shift</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1 Lot Z</td>
<td>7.8 L</td>
<td>06/19/2009 5:18 PM</td>
<td>6.7</td>
<td>All Shift</td>
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</table>

Flag 1

**Salicylate (mg/dL) - SIEMENS DIMENSION RXL, B - SIEMENS HEALTHCARE**

<table>
<thead>
<tr>
<th>Control Lot</th>
<th>Value</th>
<th>Date &amp; Time</th>
<th>LTD Mean</th>
<th>Shift</th>
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</thead>
<tbody>
<tr>
<td>Level 1 Lot Z</td>
<td>8 L</td>
<td>06/19/2009 10:04 PM</td>
<td>7</td>
<td>All Shift</td>
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</table>
### SDI Summary Report

**Thermo Fisher Scientific CSG (80830)**

43360 Fremont Blvd

Fremont, CA, United States, 94538

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### Levey-Jennings Report

**Thermo Fisher Scientific FMT (10930)**

43360 Fremont Blvd

Fremont, CA, United States, 94538

#### Salicylate (mg/dL)

<table>
<thead>
<tr>
<th>Lot Number</th>
<th>Level</th>
<th>Mean</th>
<th>SD</th>
<th>CV</th>
<th>N</th>
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<tr>
<td>LIA09081</td>
<td>1</td>
<td>6.7</td>
<td>0.2</td>
<td>3.6</td>
<td>30</td>
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<tr>
<td>LIA09081</td>
<td>3</td>
<td>59.6</td>
<td>0.8</td>
<td>1.3</td>
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#### Thyroid Stimulating Hormone (TSH) (mIU/mL)

<table>
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<th>SD</th>
<th>CV</th>
<th>N</th>
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<tr>
<td>LIA09081</td>
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<td>0.28</td>
<td>0.1</td>
<td>3.9</td>
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<td>LIA09081</td>
<td>3</td>
<td>15.16</td>
<td>4.7</td>
<td>3.1</td>
<td>31</td>
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#### T3/T-Uptake % (%)

<table>
<thead>
<tr>
<th>Lot Number</th>
<th>Level</th>
<th>Mean</th>
<th>SD</th>
<th>CV</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>LIA09081</td>
<td>1</td>
<td>23.9</td>
<td>0.8</td>
<td>3.6</td>
<td>30</td>
</tr>
</tbody>
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**Proprietary & Confidential**

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**Print Date & Time:** 01/03/2009 15:00:32

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**Print Date & Time:** 01/04/2009 12:00:00
LabLink xL Quality Assurance Solution

- Easy to use and quick to setup
- Setup Westgard QC rules for QC performance tracking
  - setup QC ranges
  - QC rules violation alerts
  - manual and automatic exclusion of data
- Input free-text or canned comments
- Side by side L-J instrument comparison
- Setup non-MAS QC products
- Comparison of QC data across affiliated laboratories
Automated Real-time Data Transfer To LabLink xL

*via* Data Innovations Instrument Manager
Bi-Directional Feedback to Instrument Manager

- QC rule violation in LabLink xL
  - ...Triggers communication back to Instrument Manager
  - ...In real-time
- Notifier configured in Instrument Manager
  - ...E-mail
  - ...Network Message (dialog box)
  - ...Text
  - ...Light pole

![Graph showing 1s rule violation with data points within the ±3s range.](image)
## Use Case: No QC Performed in x Hours

| Use Case: | Creates a QC failure if no QC is performed for a test in specified period |
| IF:       | {QC Failed for Specimen ID} “QCSample01” {on Test} “GLU” {within} “8” {Hour(s)} |
| THEN:     | {Holding Test for Verification} “GLU” |
| Note(s):  | • Substitute “QCSample01” with identification of QC sample  
           • Duration between QC events is user-defined |

*Note: Instrument Manager rules provided as an example. Customer is responsible for testing and validation of any rules in their system.*
### Use Case: QC Warning and Actions

**Notification:** Notification to a technologist if a user-defined QC warning is detected

- Notification sent via email, text, network message and/or light pole
- Event time and day or week determines whom and how to notify

**Driver:**

1. Notifier Event to file on QC Warning
   - Critical Result
   - Moving Average Error - High
   - Moving Average Error - Low
   - Moving Average Warning - High
   - Moving Average Warning - Low
   - QC Error

2. Hold Tests on QC Error
   - QC Warning
   - Reagent Low

**Light Pole:**
Use Case: QC Warning and Actions - continued

**Actions:** Based on QC warning detection from LabLink xL, define actions to take:

- Do not hold tests or,
- Hold this test *from this instrument or module*
- Hold all tests *from this instrument or module*

**Driver:**

![Screenshot of the user interface for QC warning actions]

3. **Hold Tests on QC Warning**

4. **Select action** from the list:
   - Do not hold tests
   - Hold this test
   - Hold all tests
Use Case: QC Error and Actions

**Notification:** Notification to a technologist if a user-defined QC warning is detected
- Notification sent via email, text, network message and/or light pole
- Event time and day or week determines whom and how to notify

**Driver:**

1. Notifier Event to file on QC Error
2. Hold Tests on QC Error

**Light Pole:**

![Light Pole Image]
Use Case: QC Error and Actions - continued

**Actions:**
Based on QC error detection from LabLink xL, define actions to take:

- Do not hold tests or,
- Hold this test *from this instrument or module* or,
- Hold all tests *from this instrument or module*

**Driver:**

![Image of software interface showing options for QC error actions]
Multiple Labs, One QC Program

Data Innovations

Lab A
- Instrument 1
- Instrument 2

Lab B
- Instrument 1
- Instrument 2

Instrument Manager
- LabLink Driver

Thermo Scientific
- LabLink xL
- Cloud Communicator
One Instrument Manager, Multiple QC Vendors

Lab A
- Instrument 1
- Instrument 2

Lab B
- Instrument 1
- Instrument 2

Data Innovations

Instrument Manager
- LabLink Driver
- Other Driver

Thermo Scientific
- LabLink xL
- Cloud Communicator
- Other QC Vendor
Multiple Instrument Managers, One QC Program

Lab A
- Instrument 1
- Instrument 2

Lab B
- Instrument 1
- Instrument 2

Data Innovations
- IM
- LabLink Driver

Thermo Scientific
- LabLink xL
- Cloud Communicator

LabLink Driver
Simplifying Your QC

- Easy installation
- Hands free data transfer
  
  ...no manual data entry is required
- Bidirectional feedback to Instrument Manager
- Instant access to your QC data
  
  ...for interlaboratory peer comparison
  
  ...for daily QC review
Next Steps…

- Contact your Thermo Scientific MAS sales representative
  You will receive an installation checklist:
    - Data Innovations Instrument Manager
    - An open connection on the Instrument Manager
    - LabLink Driver (downloaded from DI website)
    - 24/7 Access to the internet
    - A LabLink xL account configured for your laboratory

  Thermo Scientific LabLink Technical Service Representative assigned to your lab
    - Configure the driver
    - Ensure data is transferring to your LabLink account
    - Provide training and ongoing support
Thermo Scientific QC Sales Representatives

- Andie Price
- Kristen Cavalieri
- John Hennell
- Open
- Phil Warmington
- Susan Brown
- Michelle Hardman
- Drew Burke
- Patrick McDermott
- Ernie Hobbs
- Bob Brister
- Rich Adler
- Charlotte Jones

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# Thermo Scientific QC Sales Representatives

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<th>Territory</th>
<th>Cell Phone</th>
<th>Email</th>
</tr>
</thead>
<tbody>
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</tr>
</tbody>
</table>

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| Richard Adler   | East  | (203) 592-9289 | richard.adler@thermofisher.com |

**Global Sales Manager**

| Chris Rapcan | US | (815) 572-1198 | chris.rapcan@thermofisher.com |
Questions…

LabLink Technical Support
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Option 2, then 1
lablink.QAP@thermofisher.com