

A decorative graphic consisting of a vertical blue line on the left side of the slide. A horizontal blue line extends from this vertical line to the left of the main title. A red dot is placed at the intersection of these two lines. Another red dot is located at the bottom of the vertical blue line, near the footer.

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

life
technologies

Thermo
SCIENTIFIC

F **Fisher**
Scientific

Unity Lab Services

Leverage Our Unique Customer Value Proposition

Thermo
SCIENTIFIC



Technology Innovation

Analytical Instruments
Laboratory Products
Specialty Diagnostics

Clinical Diagnostics

life
technologies



Life Science Research
Products
Genetic Analysis
Bioproduction
Molecular Diagnostics

F Fisher Scientific



Laboratory Channel

Industry-Leading Brands
Convenience
Logistics
Clinical Trial Services

Unity Lab Services

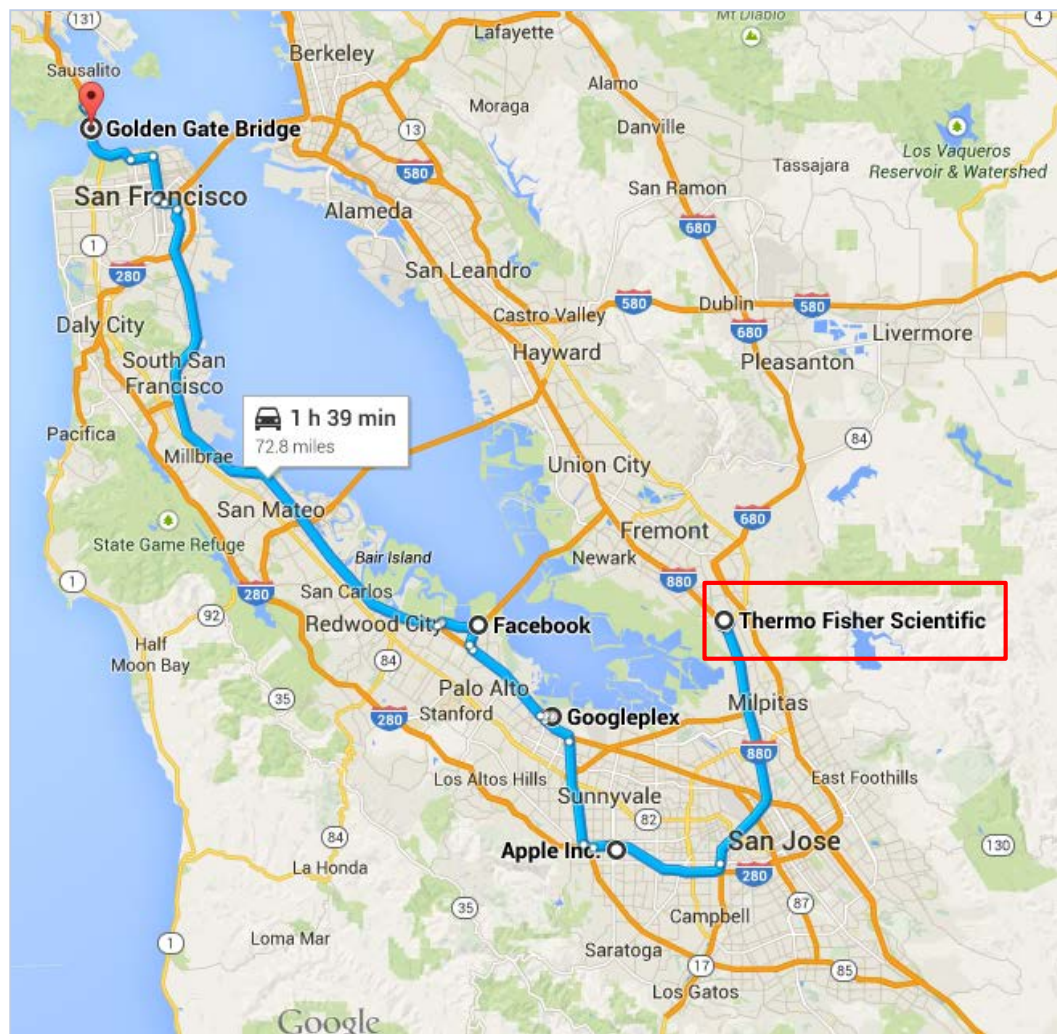


Enterprise Services

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*

Thermo Fisher Scientific FMT (10930)
46360 Fremont Blvd
Fremont, CA, United States, 94538

Lactic Acid (mmol/L)

Chemistry-H Unassayed 1 Lot# CHU100

Your Lab			
SIEMENS DIMENSION RXL - A			
Period	Mean	SD	
Jul	1.8	0.1	
LTD	1.8	0.1	
Test System Peer			
SIEMENS DIMENSION SYSTEM			
Period	Mean	SD	
Jul	1.8	0.1	
LTD	1.8	0.1	
Method Principle			
ENZYMATIC OXIDATION			
Period	Mean	SD	
Jul	1.8	0.1	
LTD	1.8	0.1	

Chemistry-H Unassayed 3 Lot# CHU100

Your Lab			
SIEMENS DIMENSION RXL - A			
Period	Mean	SD	
Jul	7.2	0.2	
LTD	7.4	0.2	
Test System Peer			
SIEMENS DIMENSION SYSTEM			
Period	Mean	SD	
Jul	7.5	0.2	
LTD	7.4	0.2	
Method Principle			
ENZYMATIC OXIDATION			
Period	Mean	SD	
Jul	7.5	0.2	
LTD	7.4	0.2	

Chemistry-H Unassayed 1 Lot# CHU100

Your Lab			
SIEMENS DIMENSION RXL - B			
Period	Mean	SD	
Jul	1.8	0.1	
LTD	1.8	0.1	
Test System Peer			
SIEMENS DIMENSION SYSTEM			
Period	Mean	SD	
Jul	1.8	0.1	
LTD	1.8	0.1	
Method Principle			
ENZYMATIC OXIDATION			
Period	Mean	SD	
Jul	1.8	0.1	
LTD	1.8	0.1	

Print Date & Time: 09/21/2009 3:45:42 PM

Monthly Summary Report

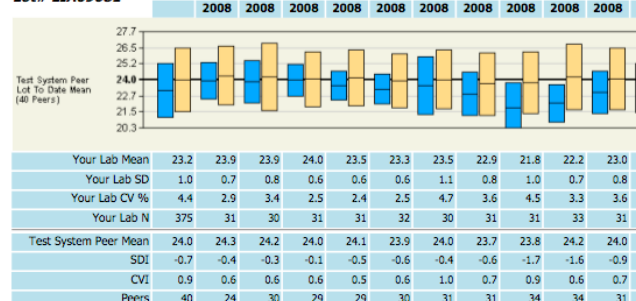
All Instruments, Immunoassay, Dec 2008

Thermo Fisher Scientific FMT (10930)
46360 Fremont Blvd.
Fremont, CA, United States, 94538

T3/T-Uptake % (%)

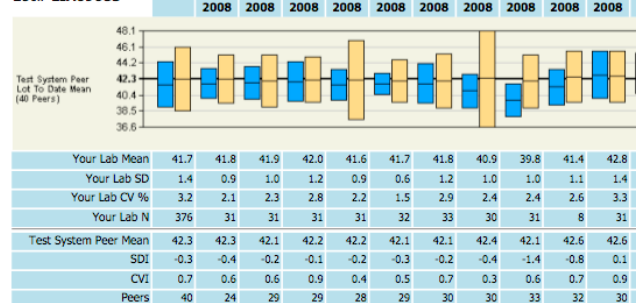
SIEMENS DIMENSION RXL - A

Lot# LIA09081



SIEMENS DIMENSION RXL - A

Lot# LIA09083



Print Date & Time: 06/05/2009 2:42:24 PM

Affiliated Lab Report

All Instruments, Chemistry-H Unassayed, Dec 2008

Thermo Fisher Scientific FMT (10930)
46360 Fremont Blvd.
Fremont, CA, United States, 94538

Digoxin (ng/mL) - All Shift, SIEMENS DIMENSION SYSTEMS, SIEMENS HEALTHCARE, MAGNETIC PARTICLE IMMUNOASSAY

Chemistry-H Unassayed 1 - Lot CHU10051										Comparison to...				Test System Peer		
										Test System Peer				Affiliate Peer		
Lab # / Name	S/N	Shift	Mean	SD	CV	N	SDI	CVI	SDI	CVI	-3SD	Mean	+3SD			
10935 Thermo Fisher Scientific AAA	1	All	0.98	0.04	4.51	21	-0.49	0.71	-0.21	0.60						
10935 Thermo Fisher Scientific AAA	2	All	1.00	0.06	5.48	24	-0.05	0.86	0.16	0.73						
10946 Thermo Fisher Scientific B88	1	All														
10946 Thermo Fisher Scientific B88	2	All														
10920 Thermo Fisher Scientific DDD	88	All	0.99	0.07	7.45	36	-0.22	1.17	0.01	0.99						
10920 Thermo Fisher Scientific DDD	91	All	0.93	0.07	7.13	42	-1.27	1.12	-0.88	0.95						
10929 Thermo Fisher Scientific EEE	1	All	1.03	0.06	6.20	24	0.40	0.97	0.55	0.82						
10929 Thermo Fisher Scientific EEE	2	All	1.09	0.06	5.33	25	1.28	0.84	1.30	0.71						
10930 Thermo Fisher Scientific PMT	C	All	1.0	0.0	4.8	32	0.5	0.8	0.6	0.6						
10930 Thermo Fisher Scientific PMT	A	All	0.9	0.1	5.4	32	-0.9	0.8	-0.6	0.7						
10930 Thermo Fisher Scientific PMT	B	All	1.0	0.0	4.8	34	-0.6	0.7	-0.3	0.6						
Affiliate Peer										1.0	0.1	7.5	9			
Test System Peer										1.0	0.1	6.4	62			

Chemistry-H Unassayed 2 - Lot CHU10052										Comparison to...				Test System Peer		
										Test System Peer				Affiliate Peer		
Lab # / Name	S/N	Shift	Mean	SD	CV	N	SDI	CVI	SDI	CVI	-3SD	Mean	+3SD			
10930 Thermo Fisher Scientific PMT	B	All														
10930 Thermo Fisher Scientific PMT	A	All														
10930 Thermo Fisher Scientific PMT	C	All														
Affiliate Peer										1.79	0.07	4.07	2			
Test System Peer										1.79	0.07	4.07	2			

Chemistry-H Unassayed 3 - Lot CHU10053										Comparison to...				Test System Peer		
										Test System Peer				Affiliate Peer		
Lab # / Name	S/N	Shift	Mean	SD	CV	N	SDI	CVI	SDI	CVI	-3SD	Mean	+3SD			
10935 Thermo Fisher Scientific AAA	2	All	2.45	0.08	3.31	26	-0.50	0.80	-0.40	0.81						
10935 Thermo Fisher Scientific AAA	1	All	2.44	0.08	3.33	20	-0.61	0.80	-0.51	0.81						
10946 Thermo Fisher Scientific B88	2	All														
10946 Thermo Fisher Scientific B88	1	All														
10920 Thermo Fisher Scientific DDD	91	All	2.43	0.11	4.36	32	-0.65	1.05	-0.55	1.06						
10920 Thermo Fisher Scientific DDD	88	All	2.50	0.09	3.40	33	0.02	0.82	0.13	0.83						
10929 Thermo Fisher Scientific EEE	2	All	2.57	0.06	2.34	31	0.69	0.56	0.81	0.57						
10929 Thermo Fisher Scientific EEE	1	All	2.56	0.08	3.04	29	0.62	0.74	0.74	0.74						
10930 Thermo Fisher Scientific PMT	C	All	2.6	0.1	2.7	32	0.7	0.6	0.8	0.6						
10930 Thermo Fisher Scientific PMT	A	All	2.5	0.1	3.2	31	-0.3	0.8	-0.2	0.8						
10930 Thermo Fisher Scientific PMT	B	All	2.4	0.1	2.7	34	-1.1	0.6	-1.0	0.7						
Affiliate Peer										2.5	0.1	4.1	9			
Test System Peer										2.5	0.1	4.1	61			

Print Date & Time: 06/02/2009 3:28:37 PM

Page 48 of 110

Exception Notes Report

All Instruments, Immunoassay, Jun 2009

Thermo Fisher Scientific FMT (10930)
46360 Fremont Blvd
Fremont, CA, United States, 94538

- 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

EMIT

Control Lot	Flag
Level 1 Lot# LIA09081	TOTAL ERROR
Reviewed By _____	
Action Taken _____	

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

Control Lot	Flag
Level 1 Lot# LIA09081	SDI >= 2.5
Reviewed By _____	
Action Taken _____	

Exception Notes Report

All Instruments, Immunoassay, Jun 2009

Thermo Fisher Scientific FMT (10930)
46360 Fremont Blvd
Fremont, CA, United States, 94538

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

FERRIC IRON COMPLEX

Control Lot	Value	Date & Time	LTD Mean	Shift
Level 1 Lot# LIA09081	7.8 L	06/19/2009 5:18 PM	6.7	All Shift

- Flag L

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

FERRIC IRON COMPLEX

Control Lot	Value	Date & Time	LTD Mean	Shift
Level 1 Lot# LIA09081	8 L	06/19/2009 10:04 PM	7	All Shift

Thermo Fisher Scientific OSG (80030)
46360 Fremont Blvd
Fremont, CA, United States, 94538

LIA09081 | LIA09082 | LIA09083

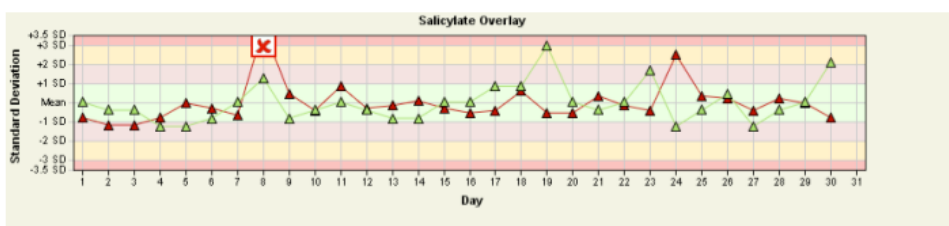
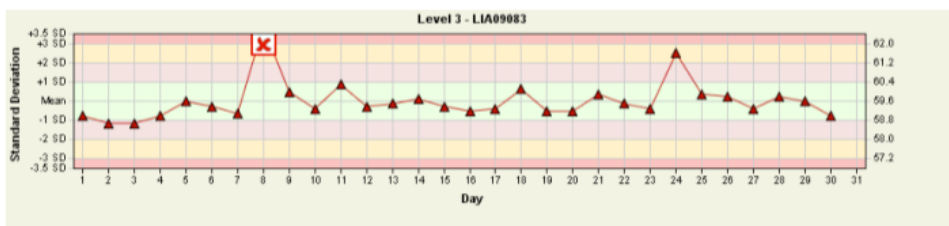
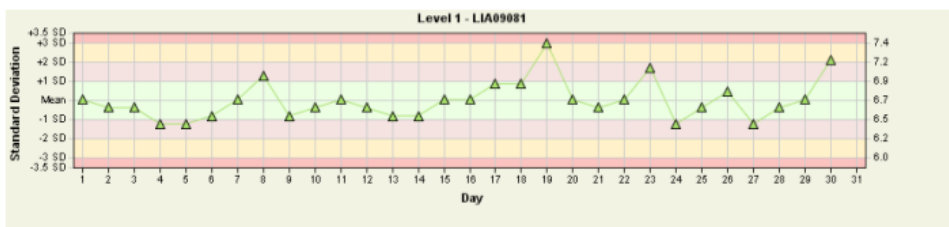
Test Instrument Reagent Method	Level	Your Lab Period: Dec 2008				Your Lab LTD				Test System Period: Dec 2008			
		Mean	SD	CV	N	Mean	SD	CV	N	Mean	CV	SD	
Digoxin (ng/mL)	L1	0.74	0.04	5.80	23	0.78	0.06	8.19	286	0.79	8.99	-0.3	
BECKMAN ACCESS 2 - 1	L2	1.69	0.09	5.27	20	1.80	0.13	7.35	243	1.81	9.75	-0.6	
BECKMAN COULTER	L3	2.53	0.09	3.72	22	2.71	0.18	6.74	287	2.69	8.26	-0.7	
CHEMILUMINESCENCE													
Human Chorionic Gonadotropin-Beta hCG (mIU/mL)	L1	7.40	0.26	3.45	25	7.27	0.42	5.80	294	7.34	7.97	0.0	
BECKMAN ACCESS 2 - 1	L2	130.81	4.49	3.44	21	128.12	5.34	4.17	248	130.79	10.43	0.0	
BECKMAN COULTER	L3	239.17	6.83	2.85	22	237.62	10.95	4.61	291	233.48	6.95	0.3	
CHEMILUMINESCENCE													
Prostatic Specific Antigen PSA (ng/mL)	L1	0.98	0.04	3.87	23	0.93	0.04	4.72	286	0.98	52.73	0.0	
BECKMAN ACCESS 2 - 1	L2	16.40	0.63	3.87	20	16.26	0.58	3.57	234	16.23	5.65	0.1	
BECKMAN COULTER	L3	32.02	1.12	3.50	22	31.69	1.16	3.66	281	31.30	7.20	0.3	
CHEMILUMINESCENCE													
Thyroid Stimulating Hormone TSH (uIU/mL)	L1	0.28	0.01	4.98	24	0.28	0.02	6.33	288	0.28	101.08	0.0	
BECKMAN ACCESS 2 - 1	L2	13.58	0.67	4.90	19	13.73	0.81	5.88	241	13.17	6.98	0.4	
BECKMAN COULTER	L3	25.77	1.58	6.13	22	26.19	1.68	6.42	286	25.33	7.49	0.2	
CHEMILUMINESCENCE													
Thyroxine, Free FT4 (ng/dL)	L1	0.29	0.04	13.79	23	0.34	0.04	11.41	287	0.36	15.07	-1.3	
BECKMAN ACCESS 2 - 1	L2	0.72	0.07	9.03	19	0.74	0.05	7.20	237	0.76	7.79	-0.7	
BECKMAN COULTER	L3	1.44	0.11	7.83	23	1.41	0.09	6.43	286	1.45	6.22	-0.0	
CHEMILUMINESCENCE													

Print Date & Time: 02/06/2009 15:00:32

Thermo Fisher Scientific FMT (10930)
46360 Fremont Blvd.
Fremont, CA, United States, 94538

Salicylate (mg/dL)

Lot Number	Level	Current				LTD			
		Mean	SD	CV	N	Mean	SD	CV	N
LIA09081	1	6.7	0.2	3.6	30	6.7	0.3	3.8	340
LIA09083	3	59.6	0.8	1.3	31	59.6	0.8	1.3	340



T3/T-Uptake % (%)

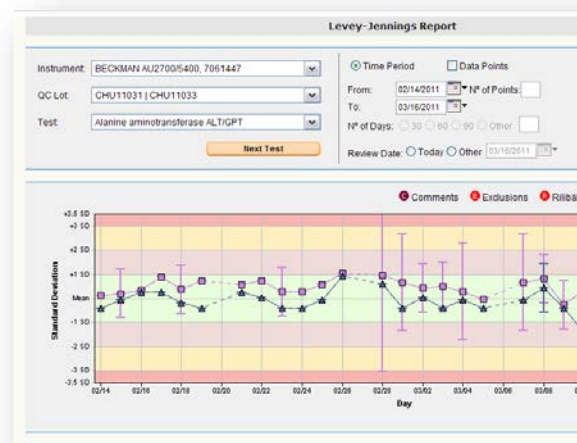
Lot Number	Level	Current				LTD			
		Mean	SD	CV	N	Mean	SD	CV	N
LIA09081	1	23.9	0.8	3.4	30	23.1	1.0	4.5	344

Print Date & Time: 06/05/2009 2:39:05 PM

Page 2 of 15

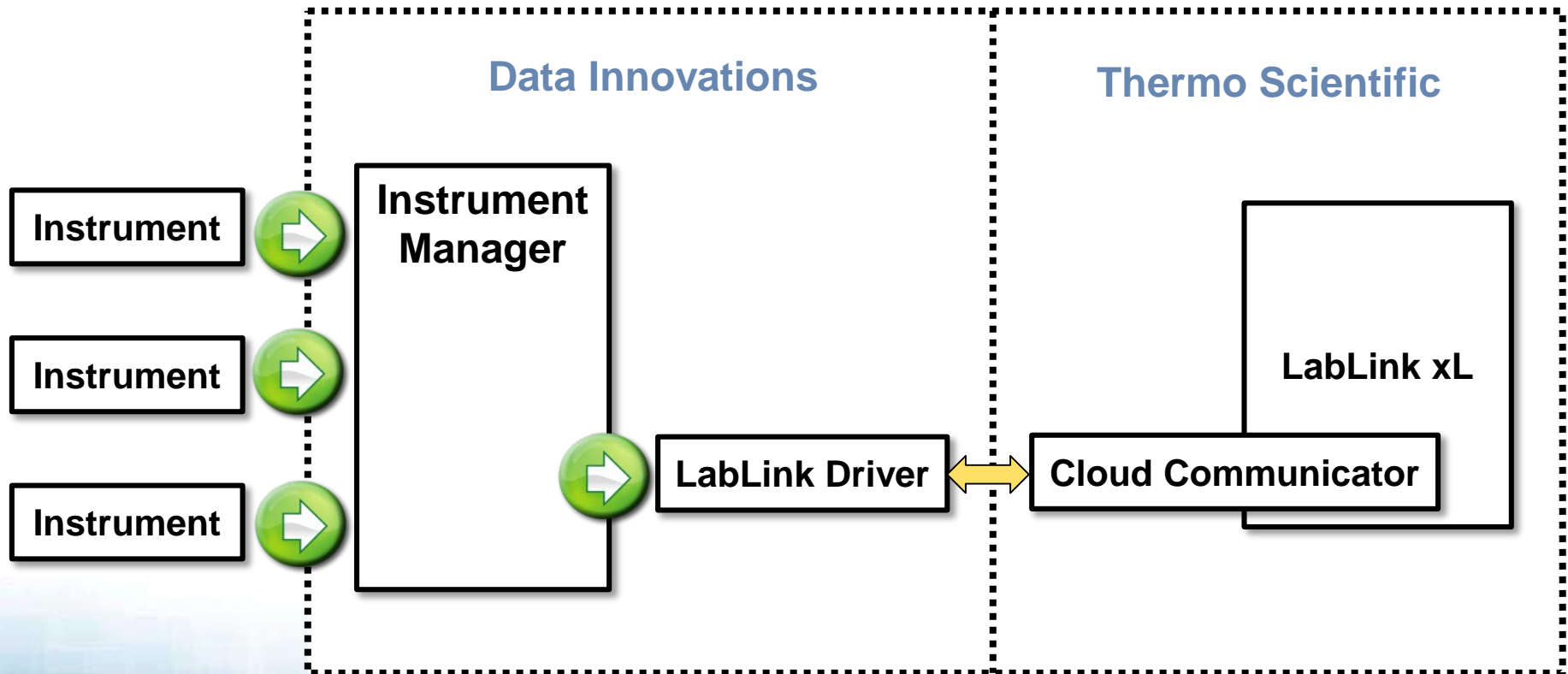
LabLink xL Quality Assurance Solution

- 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



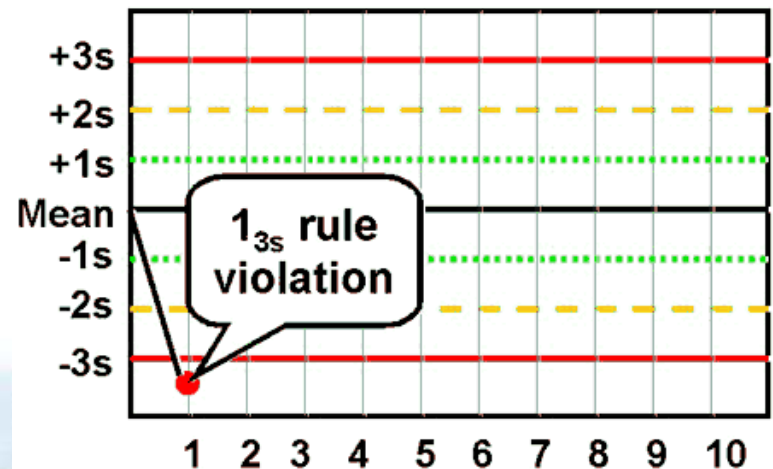
Automated Real-time Data Transfer To LabLink xL

- *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*



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):	<ul style="list-style-type: none">• <i>Substitute “QCSample01” with identification of QC sample</i>• <i>Duration between QC events is user-defined</i>

* **Note:** Instrument Manager rules provided as an example. Customer is responsible for testing and validation of any rules in their system.

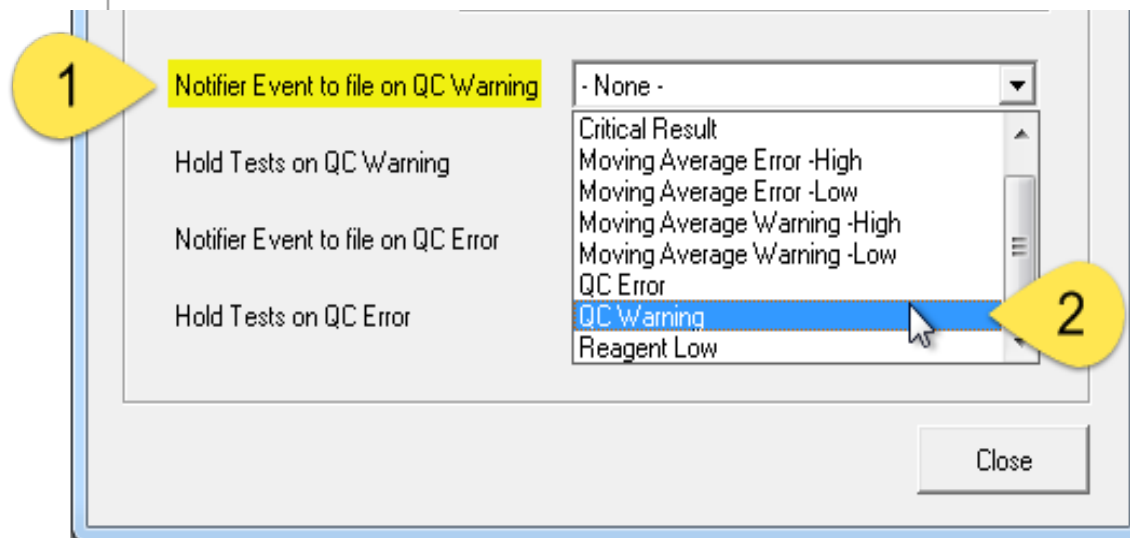
Use Case: QC Warning and Actions

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:



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:

The screenshot shows a configuration window for QC Warning actions. It contains three rows of settings, each with a label on the left and a dropdown menu on the right. A yellow callout bubble with the number '3' points to the 'Hold Tests on QC Warning' label. A yellow callout bubble with the number '4' points to the 'Do not hold tests' option in the second dropdown menu, which is currently selected and highlighted in blue. A mouse cursor is visible over the 'Do not hold tests' option.

Notifier Event to file on QC Warning	QC Warning
Hold Tests on QC Warning	Do not hold tests
Notifier Event to file on QC Error	Do not hold tests
Hold Tests on QC Error	Do not hold tests

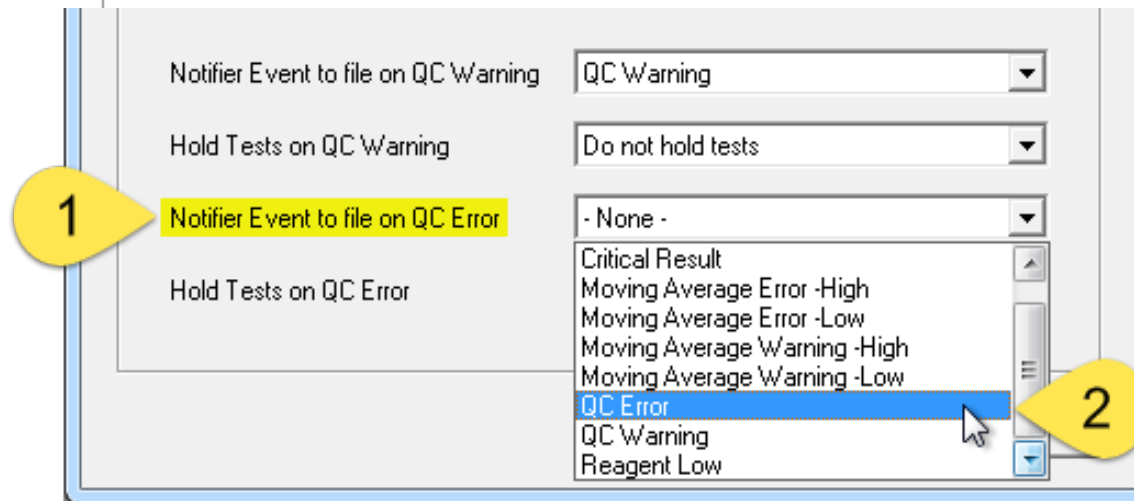
Close

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:



The screenshot shows a configuration window for QC Warning. It has four rows of settings:

Notifier Event to file on QC Warning	QC Warning
Hold Tests on QC Warning	Do not hold tests
Notifier Event to file on QC Error	- None -
Hold Tests on QC Error	Critical Result Moving Average Error -High Moving Average Error -Low Moving Average Warning -High Moving Average Warning -Low QC Error QC Warning Reagent Low

Callout 1 points to the 'Notifier Event to file on QC Error' row. Callout 2 points to the 'QC Error' option in the dropdown menu for 'Hold Tests on QC Error'.

Light Pole:



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:

Notifier Event to file on QC Warning: QC Warning

Hold Tests on QC Warning: Do not hold tests

Notifier Event to file on QC Error: - None -

3 Hold Tests on QC Error

Do not hold tests

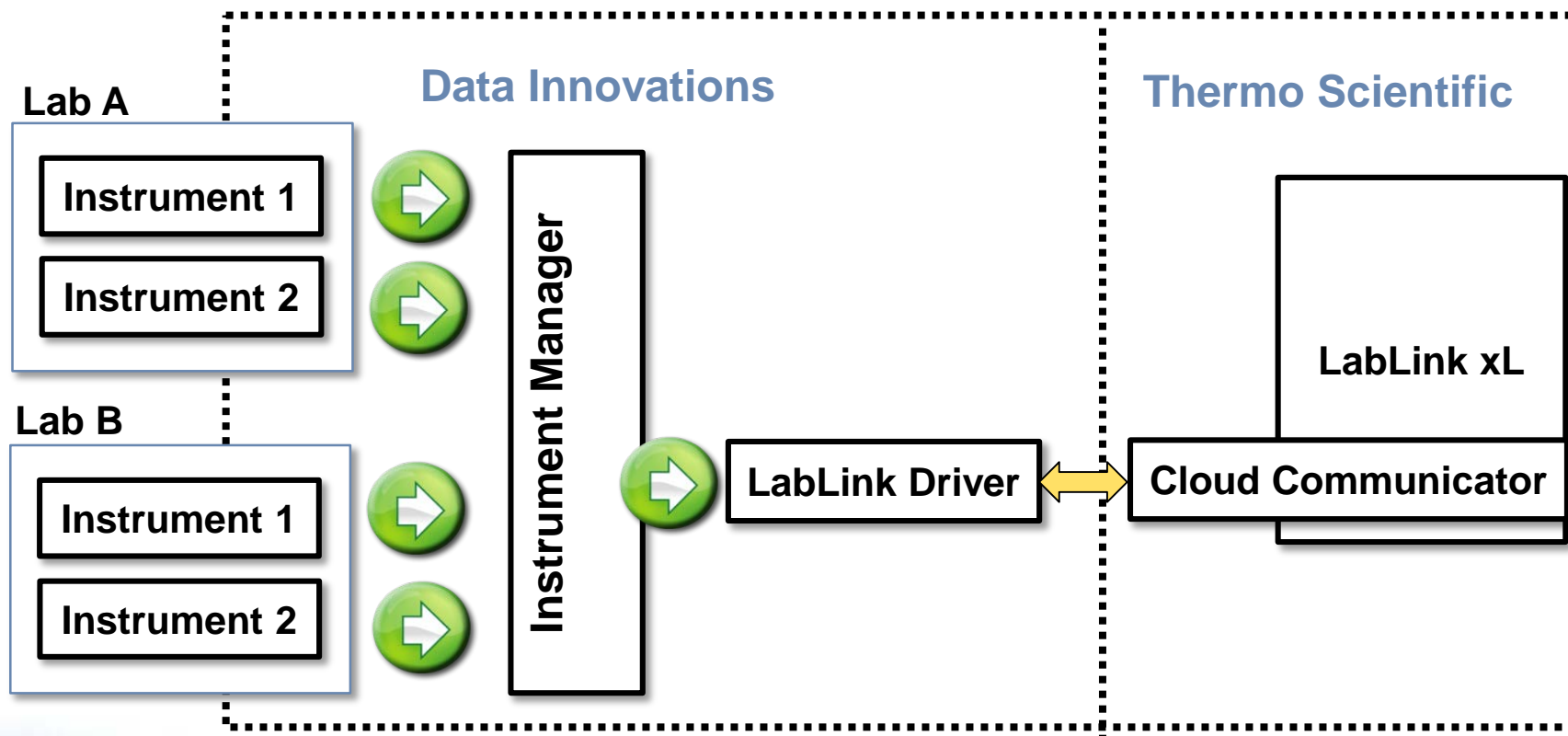
Do not hold tests

Hold this test

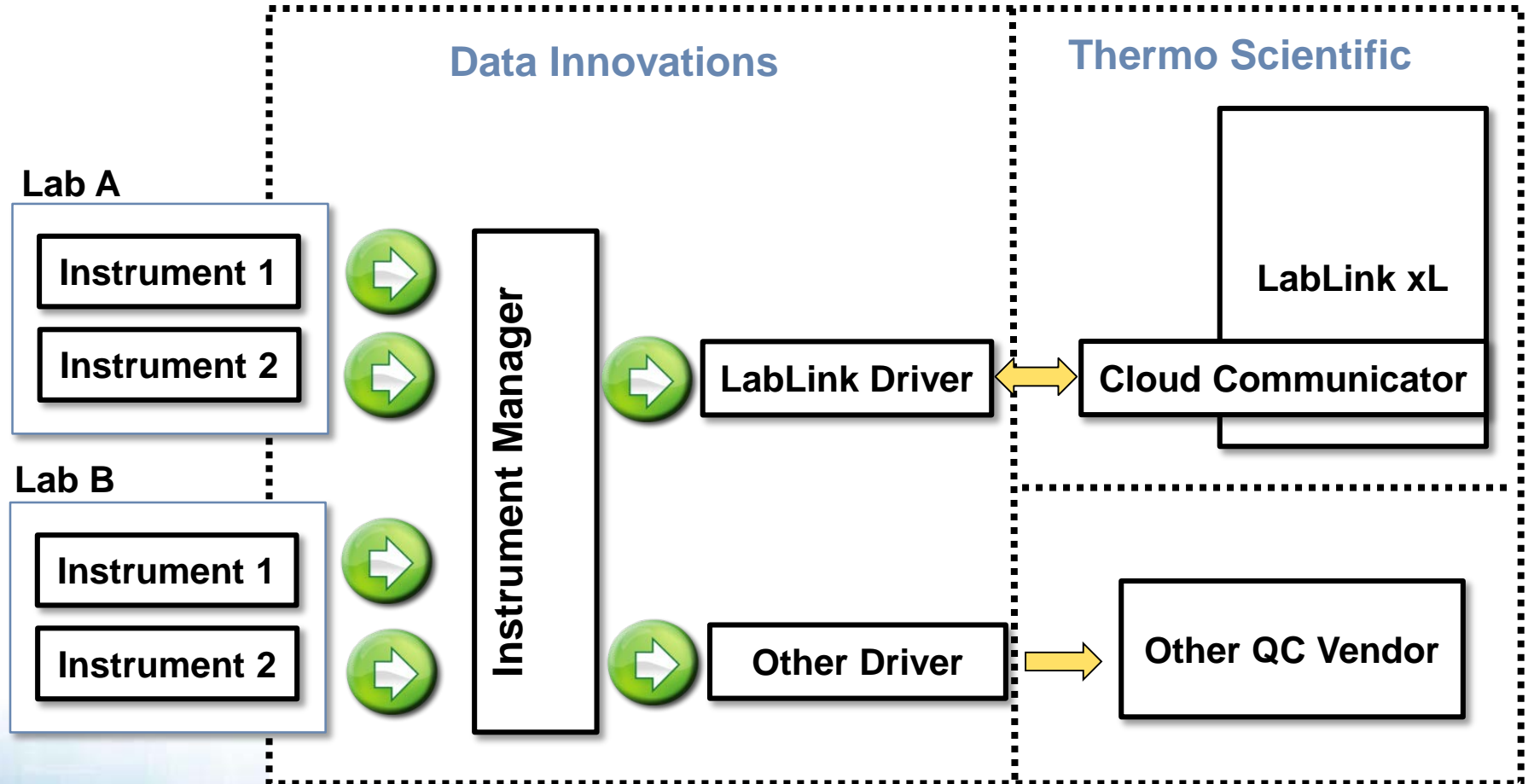
4 Hold all tests

Close

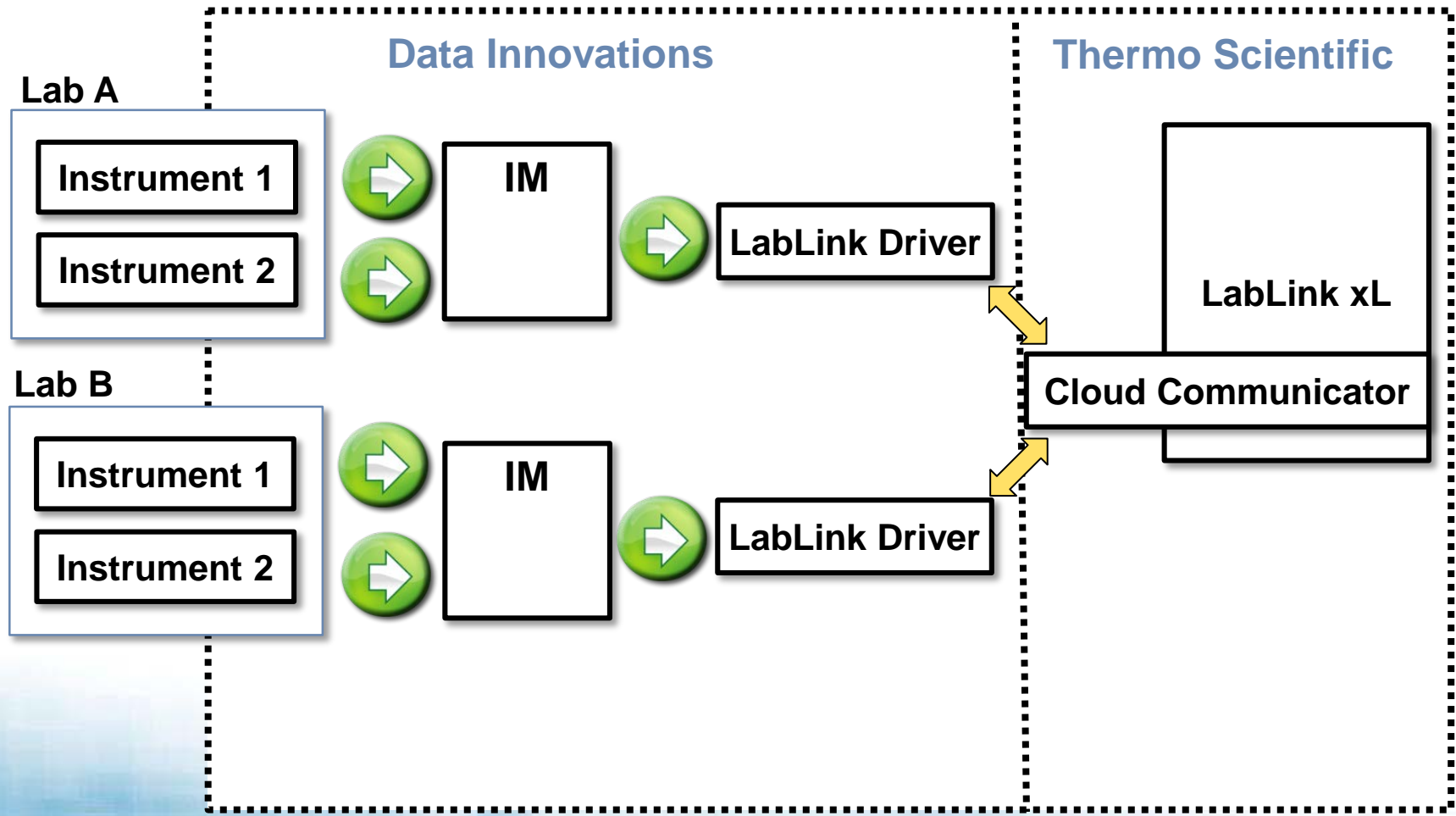
Multiple Labs, One QC Program



One Instrument Manager, Multiple QC Vendors



Multiple Instrument Managers, One QC Program



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

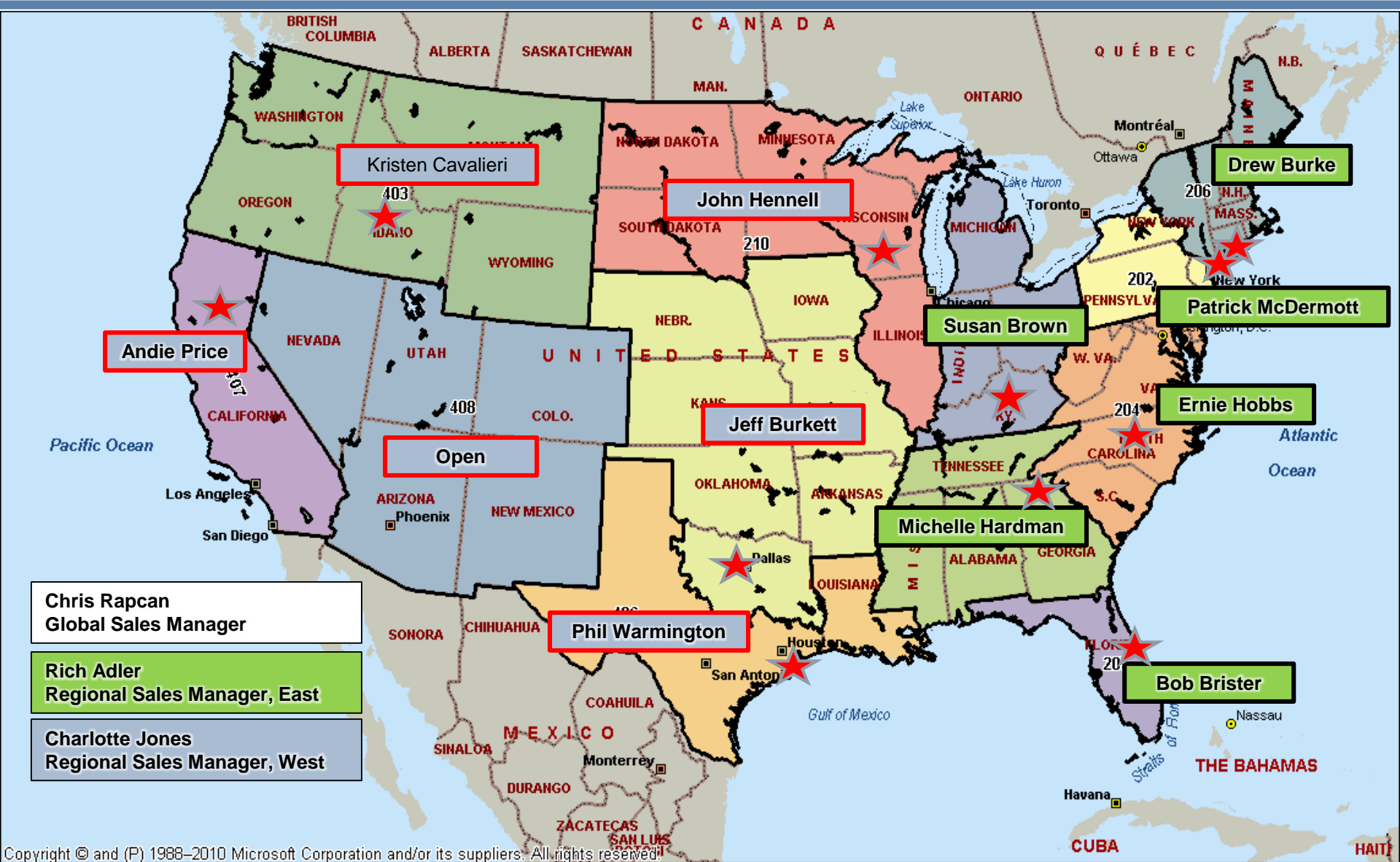
You will receive an installation checklist :

- ✓ *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



Copyright © and (P) 1988–2010 Microsoft Corporation and/or its suppliers. All rights reserved.

Thermo Scientific QC Sales Representatives

Sales Representative	Territory	Cell Phone	Email
Drew Burke	NYC, E. NY, CT, MA, RI, VT, NH, ME	TBD	Andrew.Burke@ThermoFisher.com
Patrick McDermott	PA, NJ, W. Upstate NY	(917) 993-1948	patrick.mcdermott@thermofisher.com
Ernie Hobbs	VA, WV, MD, DE, NC, SC	(336) 705-7742	ernie.hobbs@thermofisher.com
Michelle Hardman	GA, AL, MS, TN	(678) 571 3204	michelle.hardman@thermofisher.com
Bob Brister	FL	(386) 506-9267	bob.brister@thermofisher.com
Susan Brown	KY, OH, IN, Lower MI	(502) 514-5039	susan.d.brown@thermofisher.com
John Hennell	IL, WI, MN, ND, SD, Upper MI	(608) 957-4587	john.hennell@thermofisher.com
Jeff Burkett	N. TX, OK, AR, MO, KS, NE, IA	(972) 322-5291	jeffrey.burkett@thermofisher.com
Phil Warmington	S. TX, LA	(713) 320-8379	philip.warmington@thermofisher.com
Open	CO, UT, NV, NM, AZ	Open	Open
Andie Price	CA, HI	(916) 292-2921	Andrea.price@thermofisher.com
Kristen Cavalieri	WA, OR, ID, MT, WY, AK	(208) 488-5503	kristen.cavalieri@thermofisher.com
Steve Boone	Inside Sales Representative	(510) 979-5000 e.165-3265	steve.boone@thermofisher.com
Lovetta Barkus	Inside Sales Representative/Bids	(510) 979-5000	lovetta.barkus@thermofisher.com
Field Implementation Specialist			
Kristen Harter	US	(440) 715-3428	kris.harter@thermofisher.com
Regional Sales Managers			
Charlotte Jones	West	(916) 704-1935	charlotte.jones@thermofisher.com
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

Phone: 1-800-232-3342

Option 2, then 1

lablink.QAP@thermofisher.com

