Anticipating IQCP:
What We've Learned about QC and More by Using QMS, Lean and Continuous Improvement

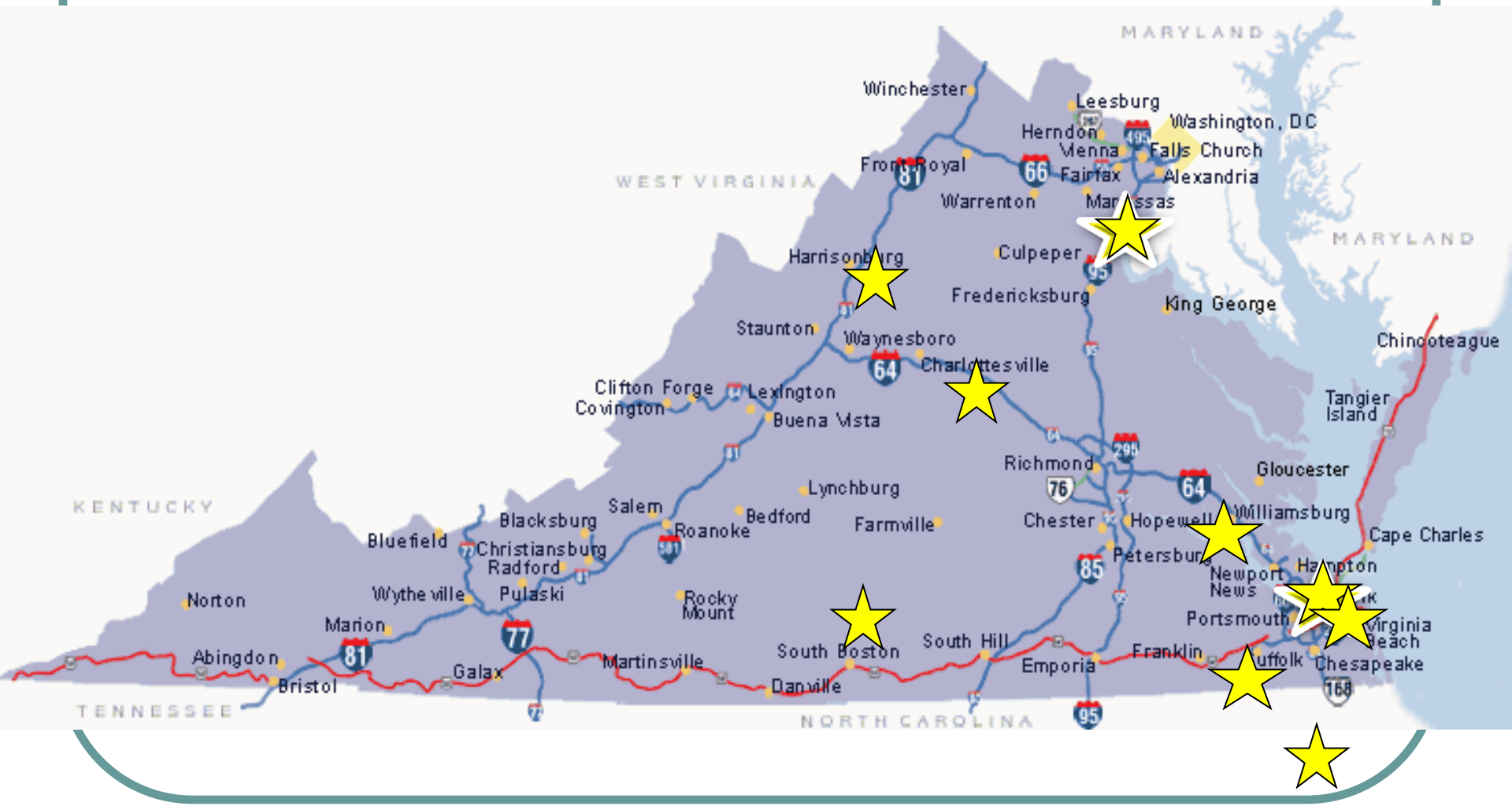
Lab Quality Confab
October 21, 2014

Lou Ann Wyer, MS, MT(ASCP), CQA (ASQ)
Sentara Healthcare

Objectives

- Explore key points of quality journey to current state
- Describe risk assessment principles and list components to evaluate within a POCT process
- Identify strategies to prepare for the development of a risk-based quality control plan for a POCT system
- Define quality assessment plans for post-implementation monitoring for effectiveness

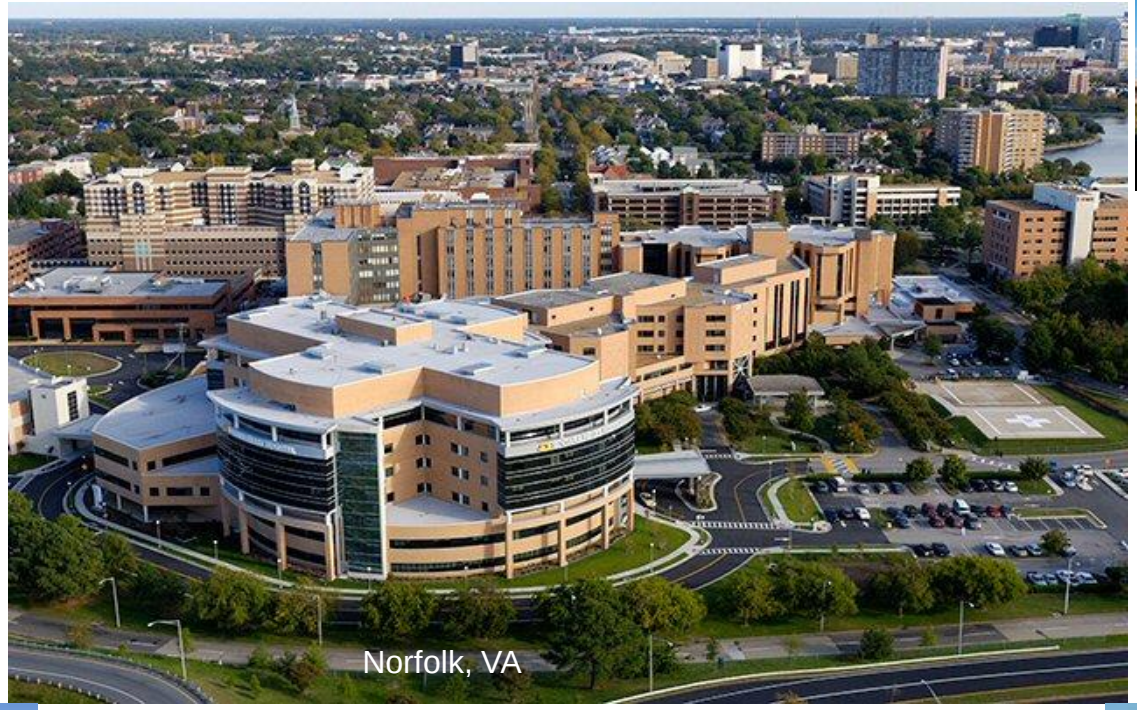
Virginia strong and growing



Sentara Healthcare


Williamsburg, VA


Hampton, VA


Norfolk, VA

Norfolk, VA


Virginia Beach, VA


Suffolk, VA


Woodbridge, VA


Virginia Beach, VA

Quality Journey

- Lab Quality Department
  - CLSI Key to Quality
  - 6 CQA(ASQ)
  - QMS
    - Document Control
    - Safety Culture
    - Internal audits
  - System Assessments
    - CAP
    - AABB
    - DNV

Stages of Maturity in Quality Culture, QMS and Conformity to ISO 9001

Quality Culture refers to the degree of awareness, commitment, collective attitude and behavior of the organization in regards to quality.
Conformity to ISO 9001 relates to the maturity of the organization's QMS, and the extent to which it meets the requirements of ISO 9001 (It is recognized that specific minor nonconformities might be detected even in organizations that show an overall high degree of maturity and conformity to ISO 9001).
Stage 4 Goal Sentara more preventive than corrective actions

Stage 1

Low Maturity Quality Culture
Immature QMS
Nonconforming to ISO

Potential Issues:
Understanding what the standard requires; why NC is being raised, and/or what needs to be done in order to meet the requirements of ISO 9001.
Action:
Advice on "***how to***" implement the QMS and/or resolve any non-conformities raised.

Stage 2

Mature Quality Culture
Immature QMS
Nonconforming to ISO

Potential Issues:
While a mature quality culture, NC are still seen & CA are not sustained or are ineffective
Actions:
Explore how effective current methodologies used to meeting the requirements of ISO 9001
Explore Gaps in the way the tools are being deployed.
Identify any systematic problems and address appropriate non-conformities

Stage 3

Low Maturity Quality Culture
Mature QMS
Conforming to ISO

Potential Issues:
May not have a "quality culture" throughout organization.
The QMS might have been implemented under pressure from customers or external parties, and built around the requirements of the standard rather than on the organization's own needs and expectations.
The QMS may be operating in a parallel way with the way the organization carries out its routine operations, generating redundancy and inefficiency.
Action:
Focus on "Opportunities for Improvement"

Stage 4

Mature Quality Culture
Mature QMS
Conforming to ISO

Potential Issue:
The organization may feel that routine surveillance visits are superfluous and not value added
Action:
Obtain a better understanding of leaderships expectations and how the surveillance visits can add value

Sentara Lean

- Standardized work
  - Processes, P&Ps
- User friendly
  - 5S
  - Kanban
- Unobstructed throughput

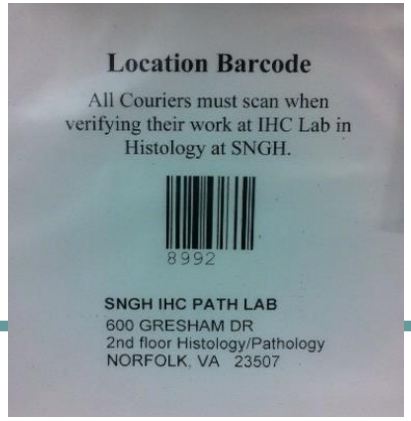
Lab Safety Initiatives

- Specimen Management
- Safety Stand Down
- Specimen Logs
- Courier Services
  - Lab location scanning
  - Standardized courier orientation

  & training; unannounced audits (eliminate transport bags, drop all)
- Man Overboard
- It's all about trash….
- Leadership rounding with intent

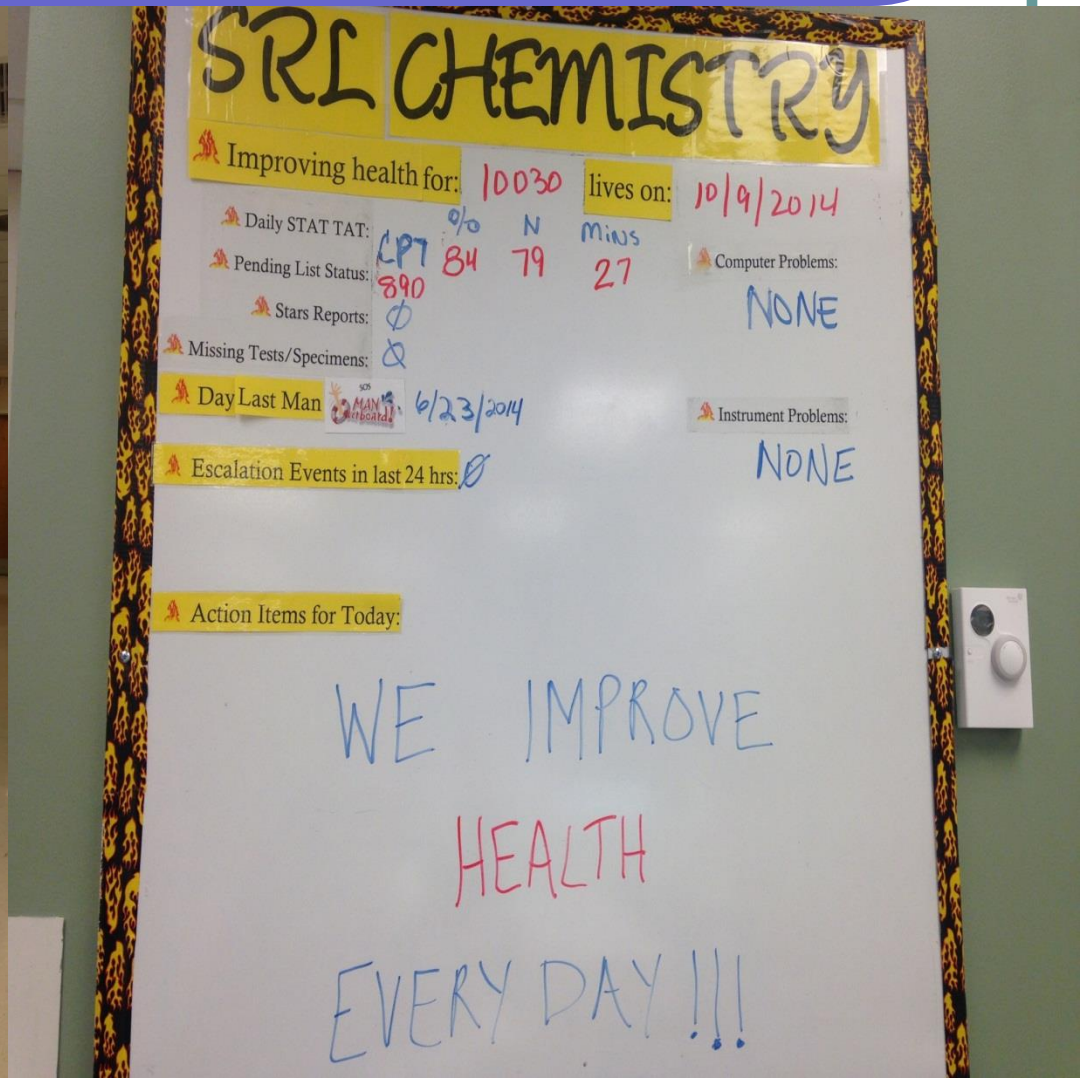
Safety First!

5S Specimen Boxes



Locked Transport Boxes

Kanban, Leadership Rounding

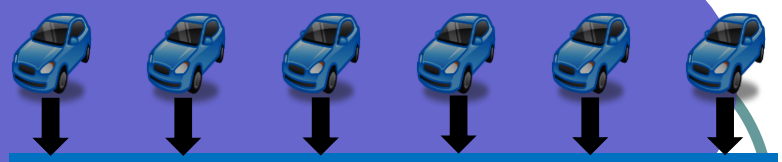


Hospitals

Specimen Receipt Logs / Accession Logs

Problem Resolution Logs

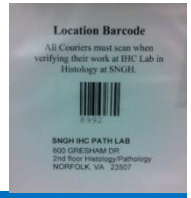
Couriers



Transport Logs

Barcode Tracking

Laboratories

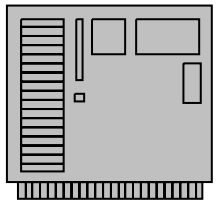


Wingman Verification Transport Logs

Destination Barcodes

Pathology

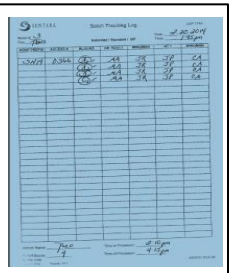
Processing



Batch Tracking Logs

Vantage Tracking

Embedding
Microtomy
Slide Distribution



Wingman Verification Batch Tracking Logs

Quality Assurance Forms

IQCP

- Individualized Quality Control Plan
- Alternative CLIA quality control (QC) option that will meet the CLIA regulations for **nonwaived** tests (42CFR493.1250)
- Includes:
  - Risk assessment
  - Quality control plan
  - Quality Assurance plan

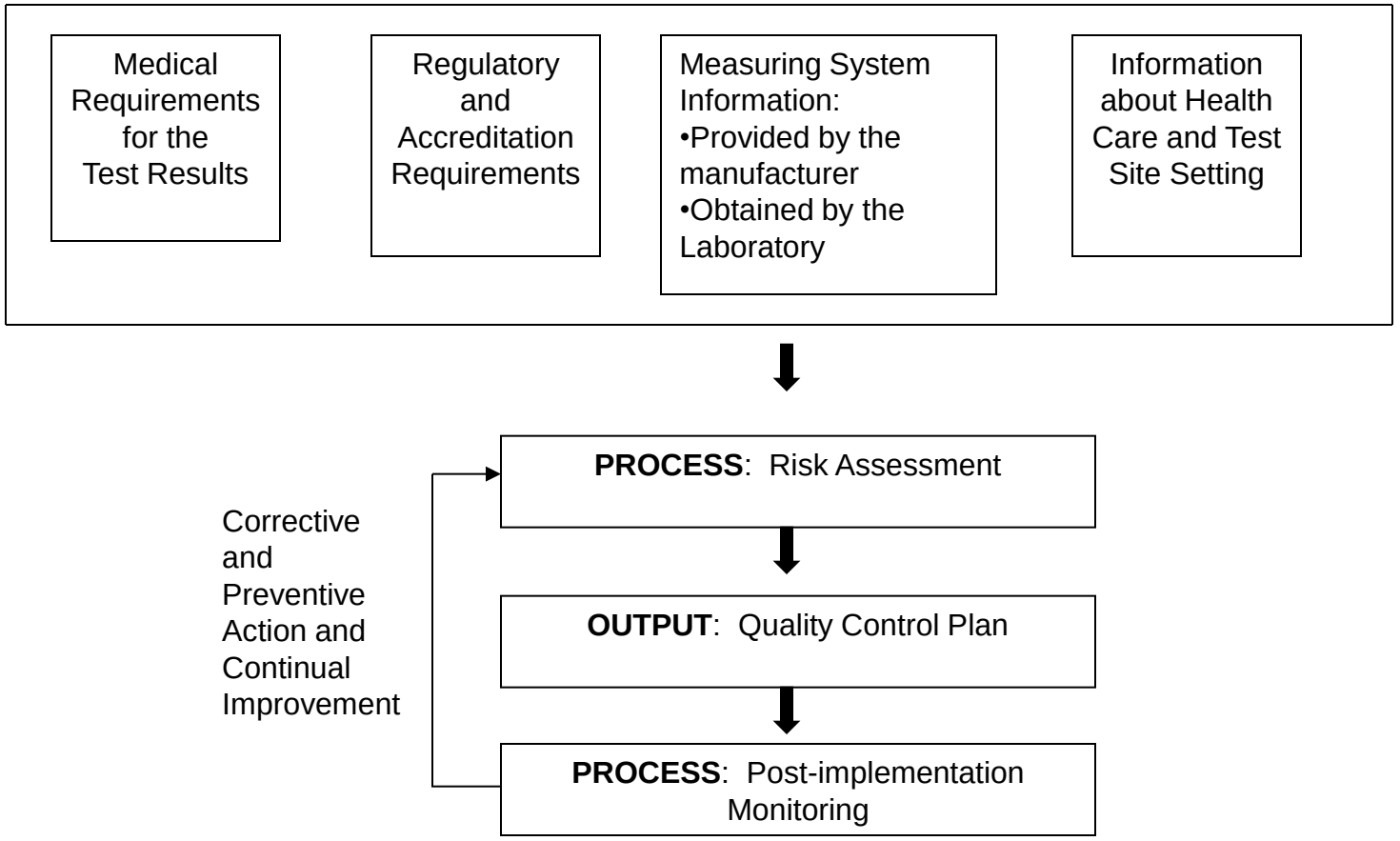
Why IQCP?

- Changes in healthcare environment & delivery of services
- Advances in technology
- QC no longer fits all
- EQC too limited
- IQCP provides a flexible program/plan for the future that includes the entire testing process

Case Study for Risk Assessed QC Plan

- Sentara POC Program
  - 350 i-STATs
  - 12 facilities
- Lactate, POC method
- Lactic acidosis - forerunner of major medical illnesses
  - High mortality rate
    - values > 4mmol/L

Measuring System Information



CLSI. *Laboratory Quality Control Based on Risk Management; Approved Guideline*. CLSI document EP23-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2011.

Types of QC in our QC Toolbox

Quality Program Element	Strengths	Weaknesses	Does My System Have This?
LQC **Liquid based quality control materials**	•Readily available •Sequestered lot number •Long out-date •Ranges already established •Know if performance is acceptable	•Cost	•Yes, LQC materials provided by the manufacturer •Establish in-house ranges •Perform 1H/1L each analyzer monthly
Function Checks	•Internal and automatic •Monitors electronics of test system •Quality checks prevent reporting of results	•May not monitor the entire process (i.e., sample) •Does not detect hemolysis or interferences	•Yes, except for hemolysis index and interferences
Calibration Verification	•Identifies that calibrators, reagents, instrument, and calibration algorithm are working	•Labor intensive	•Yes, material provided by manufacturer •Perform with each new/replacement device •Perform on each cartridge type twice per year
Proficiency Testing	•Confirms proper technique by testing personnel •Confirms proper operations of test system	•Does not carry over to individual patient samples	•Yes, provided by CAP •40 measurements (2011)

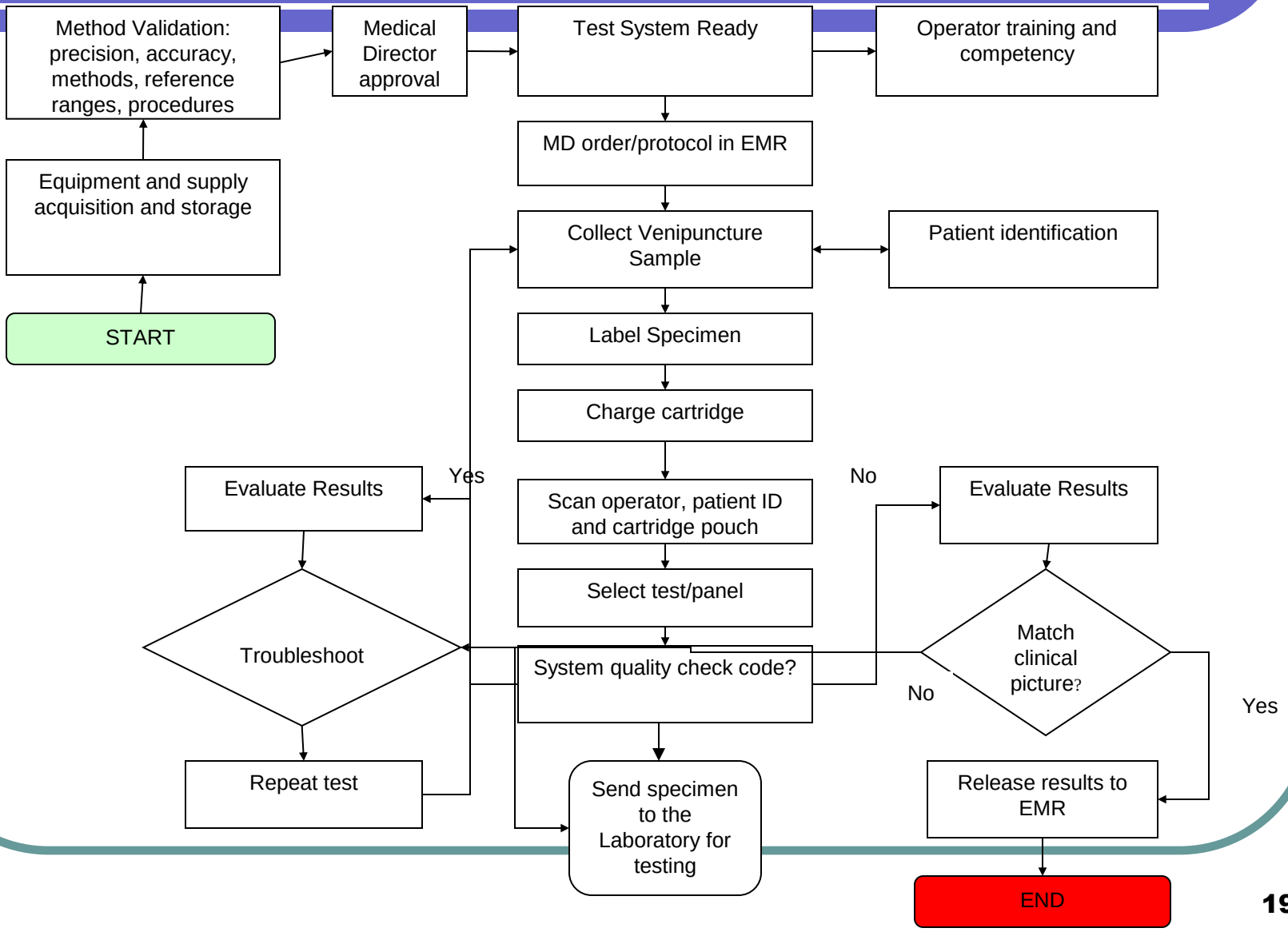
Types of QC in our QC Toolbox

Internal Proficiency-Method Comparisons	• Confirms comparison of methods for random selected tests • Ensures POC method is aligned with lab method or another analyzer	• Does not carry over to each patient test (unit-use)	• Yes, conducted by POCC • Perform patient sample for each sensor type monthly • Perform LQC for each analyzer monthly
Identification of Implausible Values	• Informs operator/POCC of results outside established ranges • Software rules stop values from automatically posting to the chart	• Does not determine reason for value (operator, specimen, etc) • May delay results from getting to chart	• POCC monitors daily
New employee orientation	• All new employees who will be using test system • Direct observations • Conducted by POCC for consistency • Identify learners who need more 1:1 • First impressions of POCT	• Resource heavy	• Yes, conducted by POCC

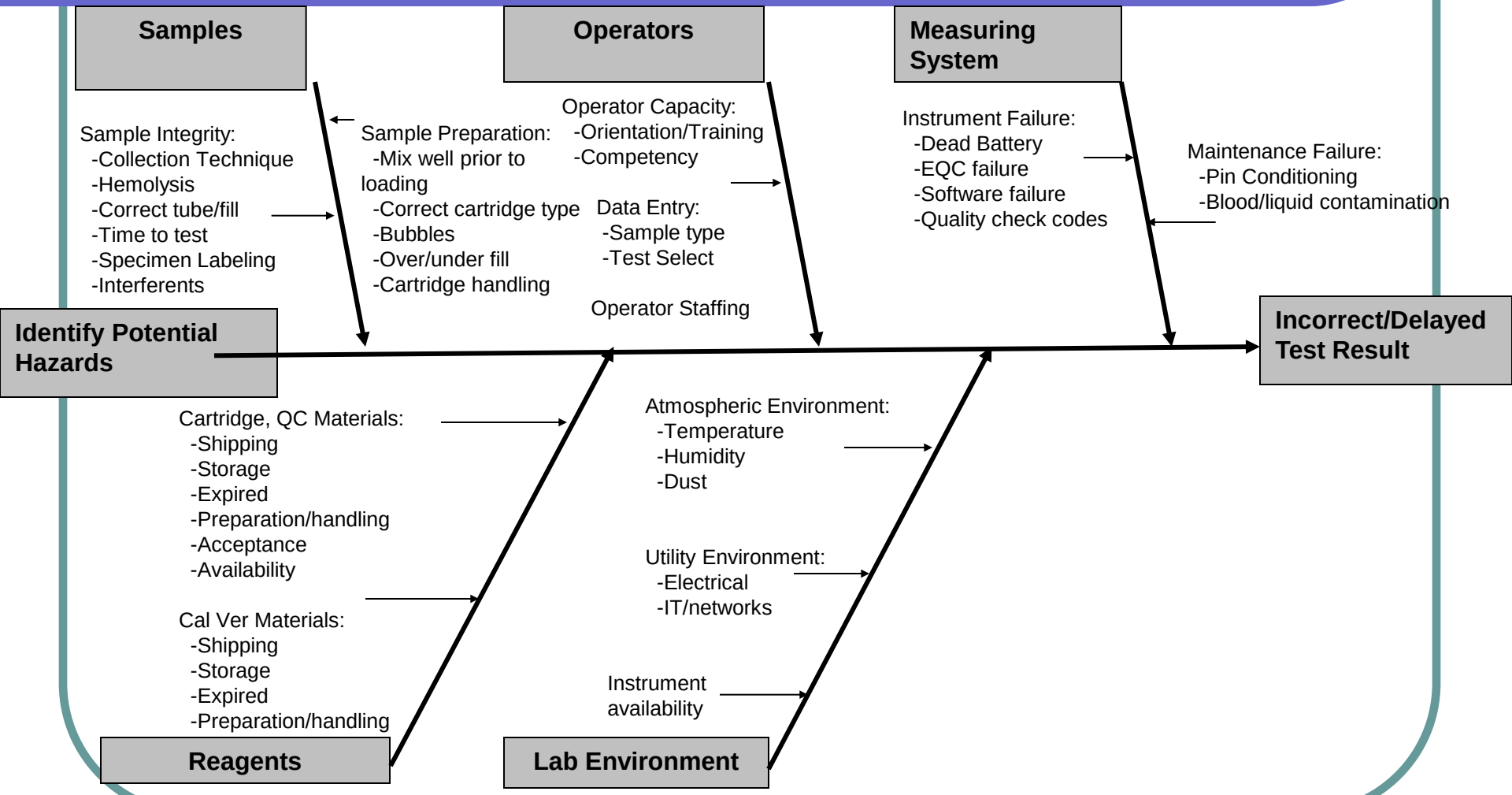
Information for Risk Assessment

- Regulatory and Accreditation Standards
- Measuring system
- Literature Search
- Lab and testing unit information
- Medical requirements for test results
- Known interferences

Process Map


Method Validation: precision, accuracy, methods, reference ranges, procedures
Medical Director approval
Test System Ready
Operator training and competency
MD order/protocol in EMR
Equipment and supply acquisition and storage
Collect Venipuncture Sample
Patient identification
START
Label Specimen
Charge cartridge
Evaluate Results
Yes
Scan operator, patient ID and cartridge pouch
No
Evaluate Results
Select test/panel
Troubleshoot
System quality check code?
Match clinical picture?
No
Yes
Repeat test
Send specimen to the Laboratory for testing
Release results to EMR
END

Fishbone Diagram – POC Lactate



TEST SYSTEM: Point-of-Care Whole Blood Lactate

			Means of Failure Detection				
Steps	**Failure Mode**	**Causes**	***Internal Controls***	***External Controls***	***Engineering Controls***	***Operator Training***	***General Comments or Other Laboratory-Implemented Monitor***
List the stage or aspect of the test system's process under investigation.	*List all manners in which failure could occur in this step.*	*List all causes of the failure mode that have the potential to produce incorrect test results.*	*Are there internal biological or procedural controls to detect failure?*	*Can external controls increase the probability to detect failure?*	*Are there manufacturer checks to reduce the probability of failure?*	*Can operators reduce or detect failures through training?*	*What other processes can the laboratory implement to detect failure?*
Measuring System Error Message or Malfunction	Instrument Failure	Electronic instability	Internal QC performed every 8 hrs. FAIL message displays on screen	External electronic simulator performed as needed	Lock-out for failures	Train operators to perform external simulator when needed. Contact POCC for assistance.	POCC's review EQC results daily
		Dead Battery	Battery status displayed on analyzer screen	NA	Battery status displayed on analyzer screen	Train operators to routinely observe battery status.	Two 9-volt lithium batteries, or rechargeable battery available in the laboratory
		Quality Check Codes	Each code is indicative of a type of error	No	Guardian reports	Contact POCC for assistance. Review troubleshooting tips with operators.	Train POCC's on software applications and identification/follow-up to quality check codes. Review quality check codes monthly for trending.

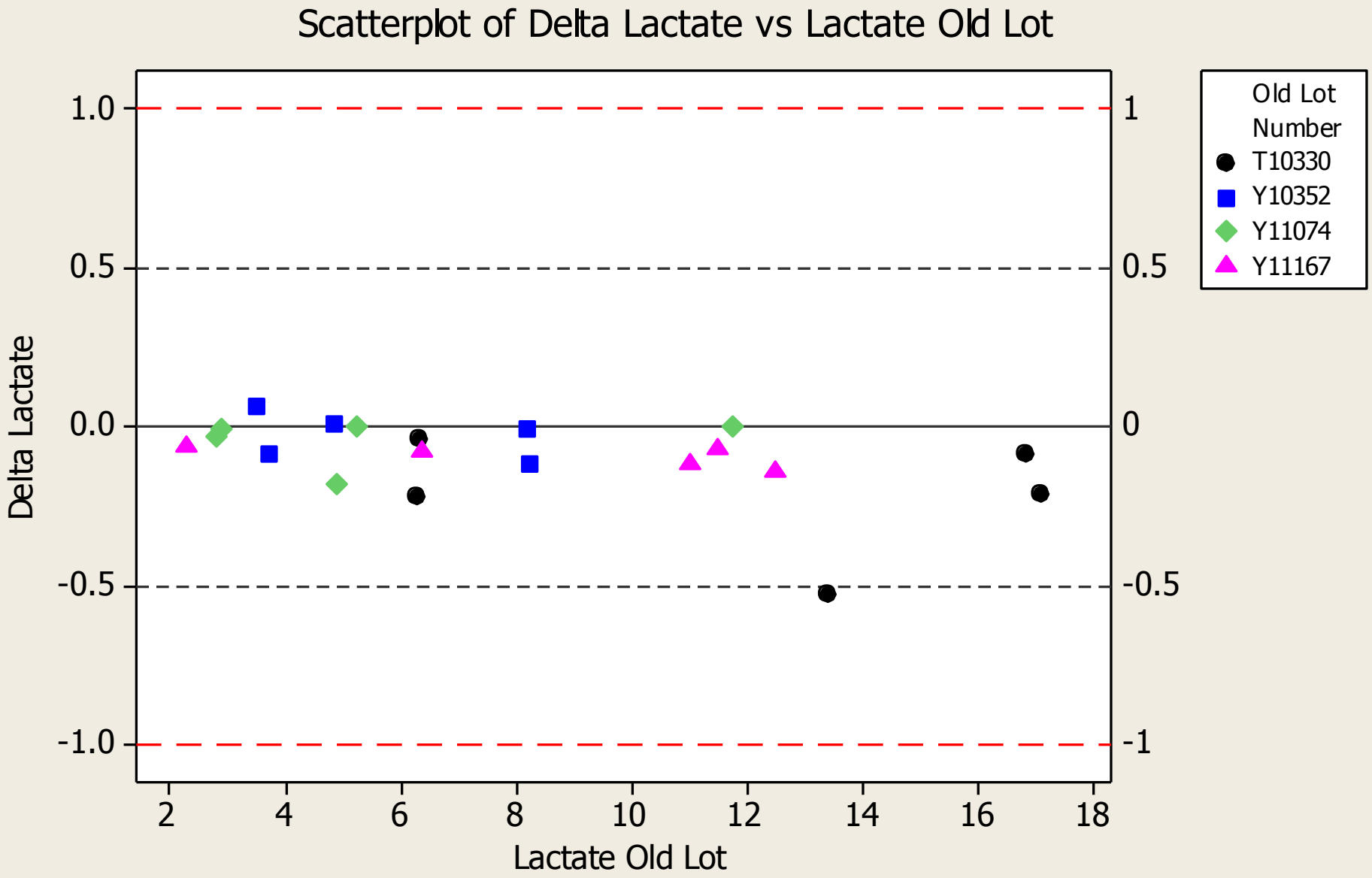
Residual Risk Assessment

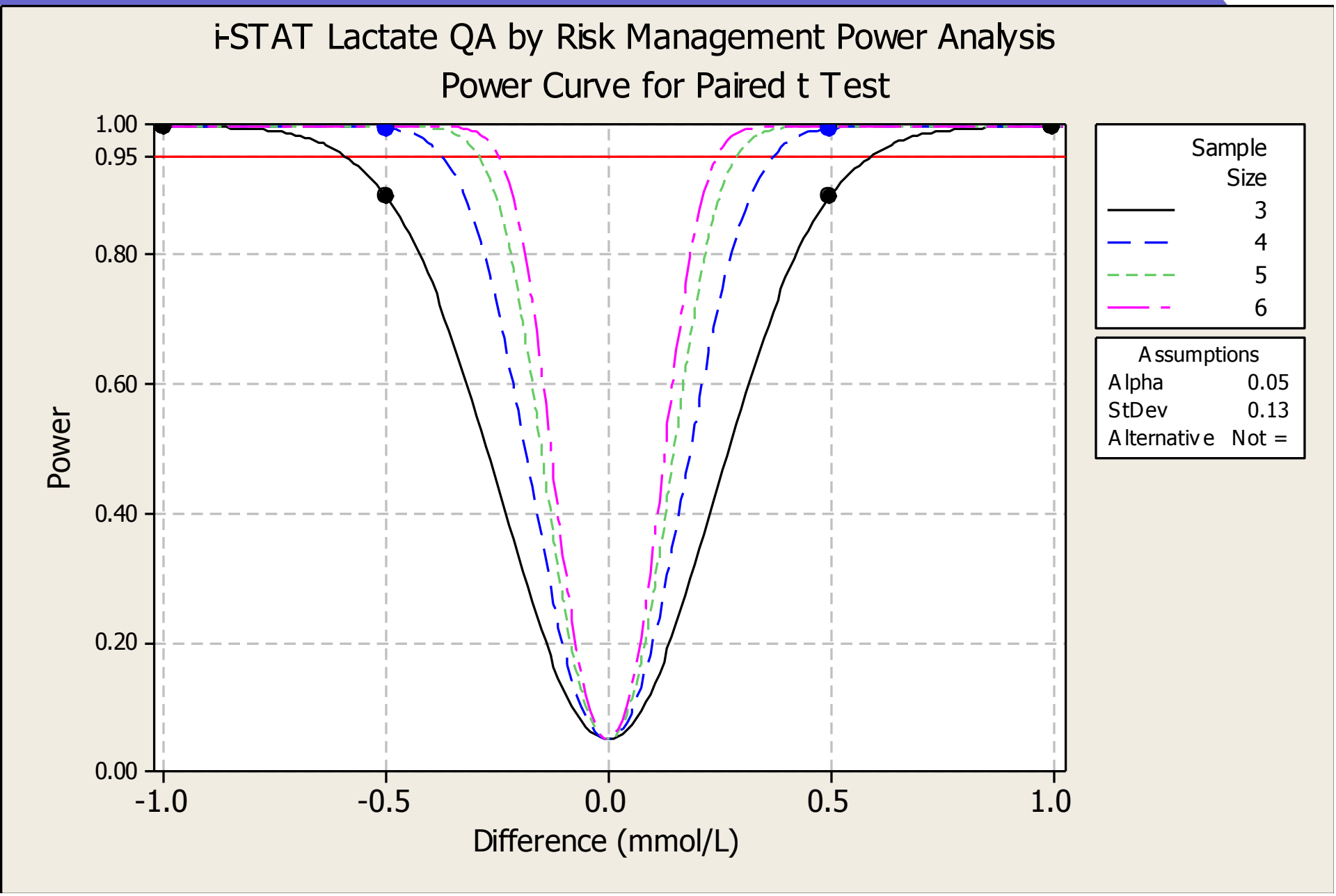
TEST SYSTEM: Point-of-Care Whole Blood Lactate

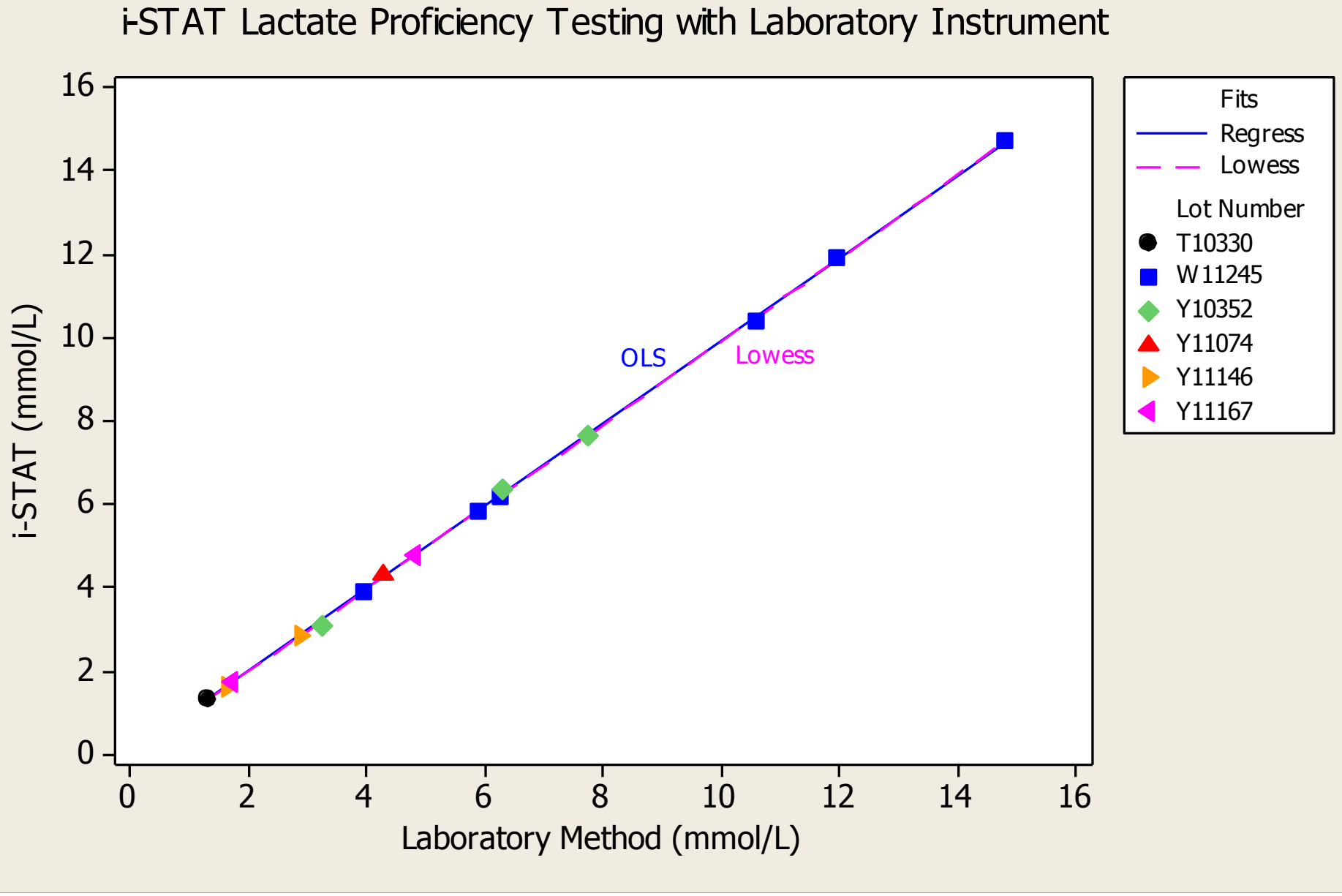
Targeted Failure Mode (Hazard)	Measuring System Feature or Recommended Action	Known Limitation of Feature or Recommended Action	Control Process Effective?	The IQCP Actions Required to Address Known Limitations	Residual Risk Acceptable? (Yes/No)
Operator Competency	Operator Lock-out (mandatory Operator ID required for trained staff)	Provide multiple forms of competency to address testing & QC procedures, maintenance, troubleshooting, proficiency samples	Y	Operator Lock-out QC Lock-out Transmission Lock-out Skills Fairs E-learning interactive modules Direct Observations Proficiency testing Results review	Y
Shipping (Cartridges)	Temp control card with a four-window indicator to monitor temp during transit.	Perform LQC with each shipment	Y	Perform LQC # and patient samples with each shipment	Y

Data to Support QC Plan

- LQC
- Old lot vs. new lot
- Acceptance studies
- Internal proficiency with patient samples
- CAP acceptable limits

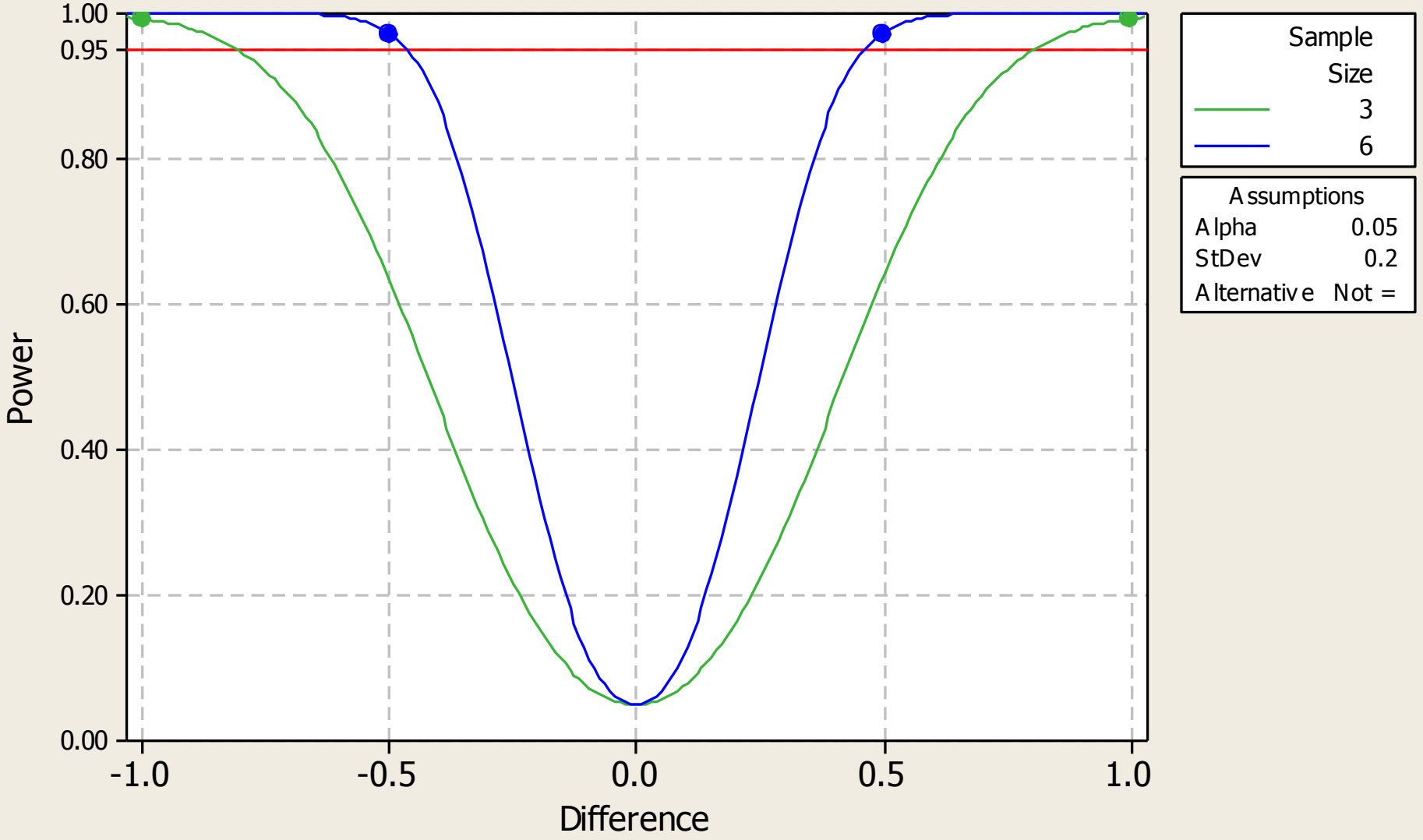

Scatterplot of Delta Lactate vs Lactate Old Lot
Delta Lactate
Lactate Old Lot
1.0
0.5
0.0
-0.5
-1.0
1
0.5
0
-0.5
-1
2
4
6
8
10
12
14
16
18
Old Lot Number
T10330
Y10352
Y11074
Y11167

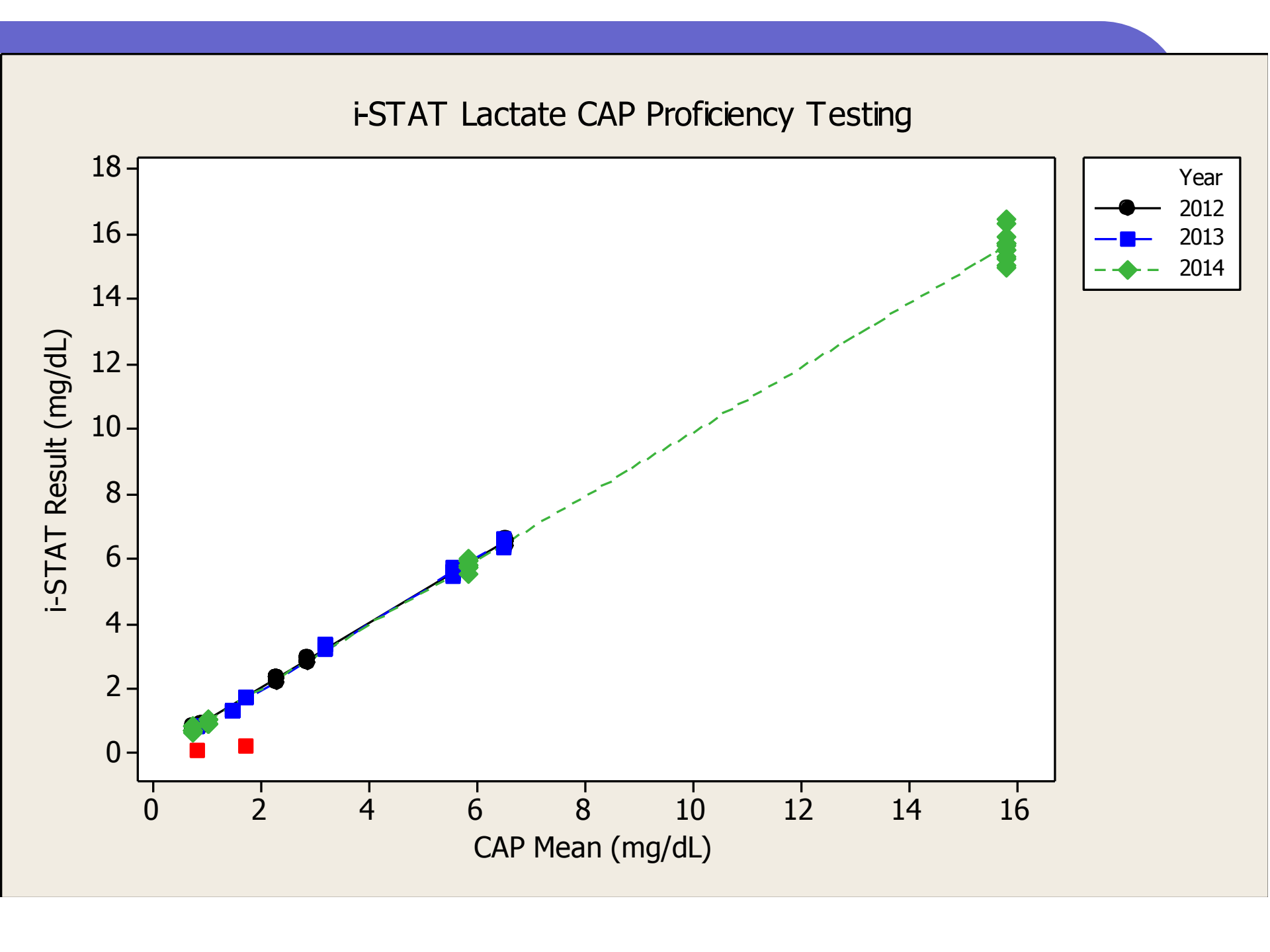

i-STAT Lactate QA by Risk Management Power Analysis
Power Curve for Paired t Test
Power
1.00
0.95
0.80
0.60
0.40
0.20
0.00
-1.0
-0.5
0.0
0.5
1.0
Difference (mmol/L)
Sample Size
3
4
5
6
Assumptions
Alpha 0.05
StDev 0.13
Alternative Not =


i-STAT Lactate Proficiency Testing with Laboratory Instrument
i-STAT (mmol/L)
Laboratory Method (mmol/L)
0
2
4
6
8
10
12
14
16
OLS
Lowess
Fits
Regress
Lowess
Lot Number
T10330
W11245
Y10352
Y11074
Y11146
Y11167

i-STAT Lactate QA by Risk Management Power Analysis Control Level 1

Power Curve for 2-Sample t Test




i-STAT Lactate CAP Proficiency Testing
i-STAT Result (mg/dL)
CAP Mean (mg/dL)
0
2
4
6
8
10
12
14
16
18
Year
2012
2013
2014

Lactate Testing – QCP

QC Toolbox	QC Plan
Electronic QC	• Every 8 hours • QC, Operator, Transmission Lock-outs
Acceptance studies	• 2H/2L LQC, 5 patients with each shipment old vs new lot
Monthly LQC	• 4H/4L (min), each cartridge type
Calibration Verification	• 3 levels in triplicate, every 6 months

Lactate Testing – QCP

QC Toolbox	QCP
Internal proficiency for comparative methods	• 1 patient monthly for each sensor type vs Lab analyzer
External Proficiency program	• CAP survey sets
New/replacement devices	• LQC (2 H/2 L x10) • Patient sample (1) • Calibration verification (3 levels in triplicate)

Lactate Testing – QCP

QC Toolbox	QCP
Orientation/Training Competency	• Provided by POCCs • Interactive e-learning • Direct Observations • Proficiency surveys • Skills Fairs • Results review

Alternative IQCP Solution

i-STAT 1 Activated Clotting Time (ACT) (Pre-analytic)

Abbott i-STAT ACT EZ-QCP Introduction | Fishbone Diagram

PRE-ANALYTIC: SECTIONS (1-4) ..... Patient ID | Sample Collection | Sample ID | Sample Presentation

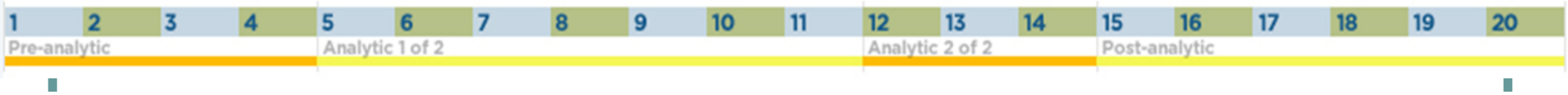
RISK MITIGATION REPORTS ..... Patient ID | Sample Collection | Sample ID | Sample Presentation

RESIDUAL RISK SCORES ..... Patient ID | Sample Collection | Sample ID | Sample Presentation | Residual Risk Scores by Category

PRE-ANALYTIC SUGGESTION REPORT ..... Pre-analytic Suggestion Report

PRE-ANALYTIC ACTION PLANS ..... SOP | Training Checklist | Direct Observation | Competency Quiz | Problem Solving

IQCP ..... Individualized Quality Control Plan



i-STAT 1 Activated Clotting Time (ACT) (Analytic #1 of 2)

Abbott i-STAT ACT EZ-QCP Fishbone Diagram

ANALYTIC, 1 of 2: SECTIONS (5-11) ..... Access | Operation | Cleaning | Configuration | Cartridges | Quality Control | Linearity

RISK MITIGATION REPORTS ..... Access | Operation | Cleaning | Configuration | Cartridges | Quality Control | Linearity

RESIDUAL RISK SCORES ..... Access | Operation | Cleaning | Configuration | Cartridges | Residual Risk Scores by Category

ANALYTIC SUGGESTION REPORT .....Analytic Suggestion Report

ANALYTIC ACTION PLANS ..... SOP | Training Checklist | Direct Observation | Competency Quiz | Problem Solving

IQCP ..... Individualized Quality Control Plan

Generates Action Plans

	Responsible party	Target completion date	Actual completion date	Signed off by
... ensure that testing personnel perform ACT proficiency testing in i-STAT 1 analyzer Proficiency Testing mode. *The prewarmed or non-prewarmed calibration is not applied to ACT tests performed in the Proficiency Testing mode.*				
... alternate instruments when testing PT, if applicable.				
... alternate testing personnel when testing PT.				

Generates IQCP Report

Proficiency Testing:

We perform educational Proficiency Testing with 2 challenges three times per year.

Training:

- Standard Operating Procedure (SOP) covers:

Test result review

Limitations and interferences

Post-Implementation Monitoring - QA

- Evaluate the effectiveness
- Unacceptable findings?
  - Troubleshoot
  - Determine cause
  - Assess the risk to the patient
  - Corrective action
    - Modify QC Plan to prevent recurrence
- Document, document, document

Lessons Learned

- Start early
- Consider all current processes
- Review current data
- Monitor for effectiveness
- It’s a journey

Q&A

Questions?