

# **Using Ongoing Risk Assessments in All Labs to Yield Big Dividends: Why Northwell Health Now Provides Risk Assessments to Hospital Labs in Other Systems**

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# Goals and Objectives

## **Presentation Purpose:**

- To share our experiences of creating and utilizing ongoing risk assessment tools to ensure high quality laboratory services, customer satisfaction and compliance with regulatory requirements. Over the past few years Northwell Health Laboratories have had the opportunity to successfully utilize this knowledge and these risk assessment tools in other hospital laboratories some of which were under the request of the New York State Department of Health (NYSDOH). The NYSDOH as well as other healthcare facilities have reached out to Northwell Health Laboratories because of our proven track record regarding our ability to meet the intent of the regulatory standards at the time of the surveys, to appropriately respond to NYSDOH deficiencies, and to successfully implement and sustain improvements across the spectrum of our laboratory services.

## **Learning Objectives:**

- To perform a gap analysis to determine where the laboratory is at risk with respect to meeting regulatory compliance, providing quality laboratory services and meeting the needs and expectations of customers.
- To develop a risk assessment toolbox which will assist in meeting the quality system essentials and technical standards of regulatory agencies.
- To share the benefits of successfully incorporating risk assessment processes into the culture of laboratory operations.

## **Take Home Message :**

- Attendees will be able to effectively adapt and develop their own risk assessment tools in order to yield “BIG” dividends in their own laboratory settings.

## Key Facts

...The first and largest integrated health system in NY State



- 21 hospitals
- Children's Hospital
- 2 Psychiatric Hospitals
- 4 Nursing/Sub-acute facilities
- 450 ambulatory locations
- 13,600 affiliated physicians
- 3,000 member physician medical group
- Broad geographic coverage
- 7 Counties - 10.8 million population
- Provides care to 4 million persons
- 27% inpatient share
- \$9.5 billion revenue
- Insurance Company – Over 90,000 members
- 61,000 employees
- Largest private employer in NYS
- Major academic and research center
- Comprehensive and full continuum of care

# Northwell Health Laboratory Network

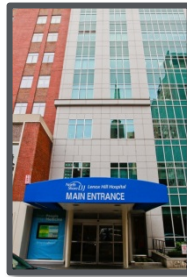
- Central “Core” Laboratory
- 19 Hospital Based Labs
- \$335 Million Annual Operating Budget
- 2000+ FTEs/ 80+ Pathologists
- Approx 24+ Million Billable Tests
- 200,000 Surgical Specimens
- 30+ Patient Service Centers
- Multiple Ambulatory Sites
- Urgent Care Centers
- Point of Care Testing at Physician Offices

# Northwell Health Laboratory Network

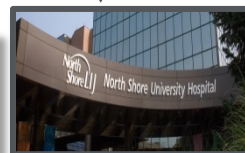
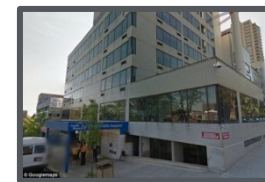
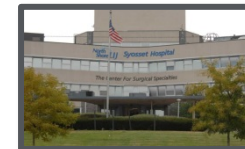
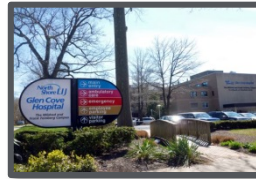
Outreach Doctors



Clinical Trials



System Hospitals



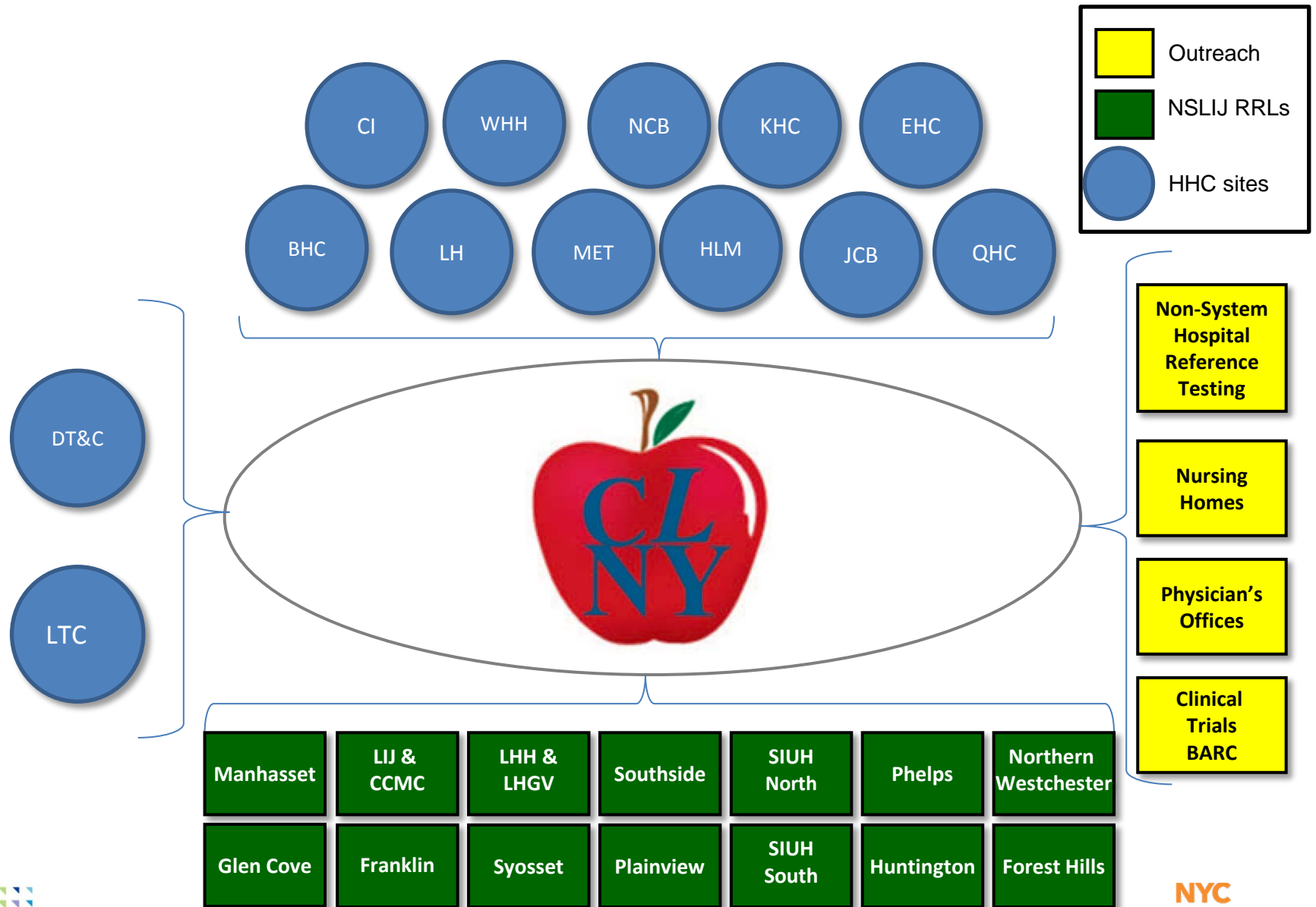
Non-Affiliated Hospitals



Nursing Homes



# CLNY Alliance Network





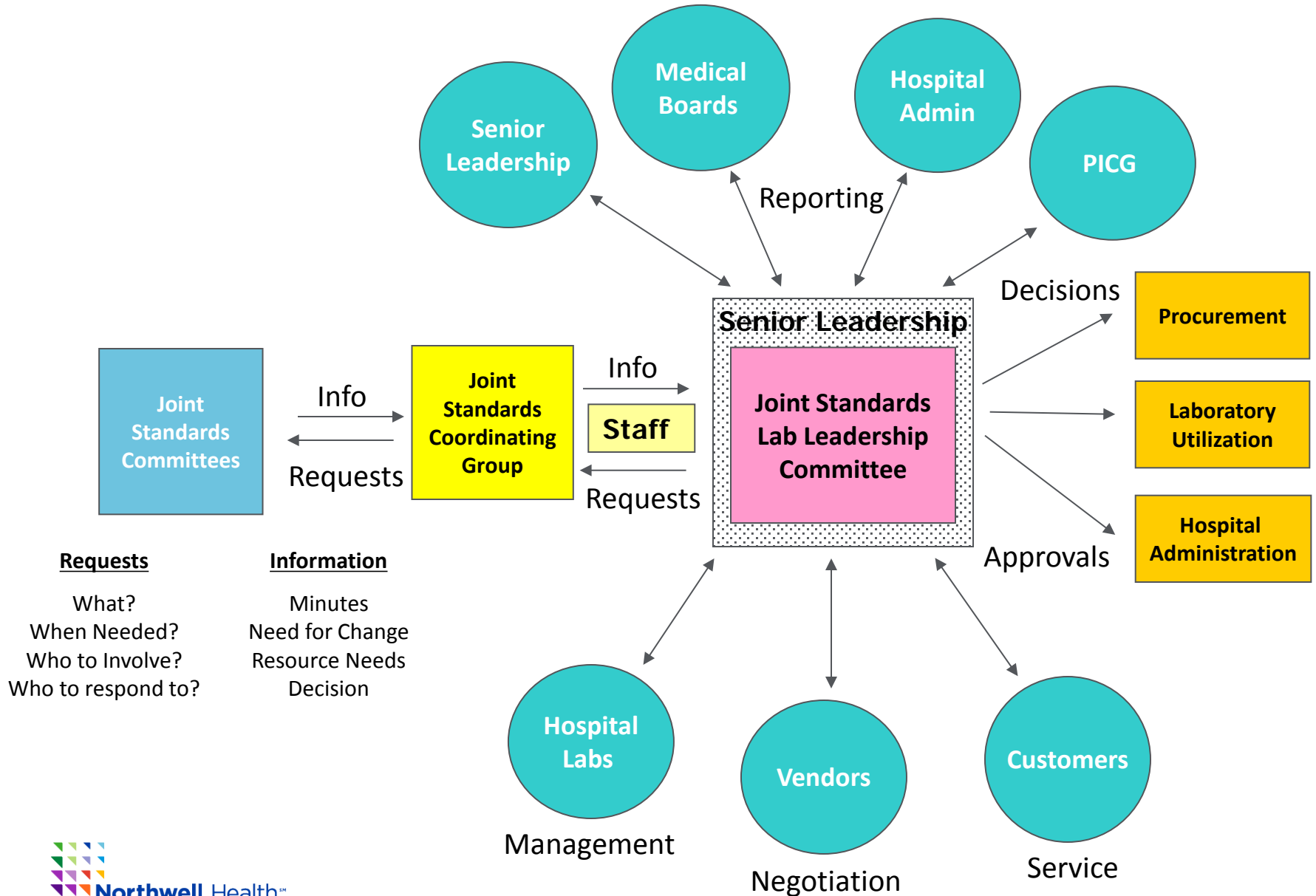
# System Network Model

## Shared Consolidated Core Laboratory

- Centralized Clinical and Administrative Leadership
- Standardized Equipment across all Laboratories
- Standardized SOPs
- Single Integrated Lab Information System - Cerner
- Centralized Microbiology, Esoteric, Reference
- Centralized Quality and Competency Program
- Centralized POCT Division
- Consolidated Data Warehouse



# Joint Standards Committee Process



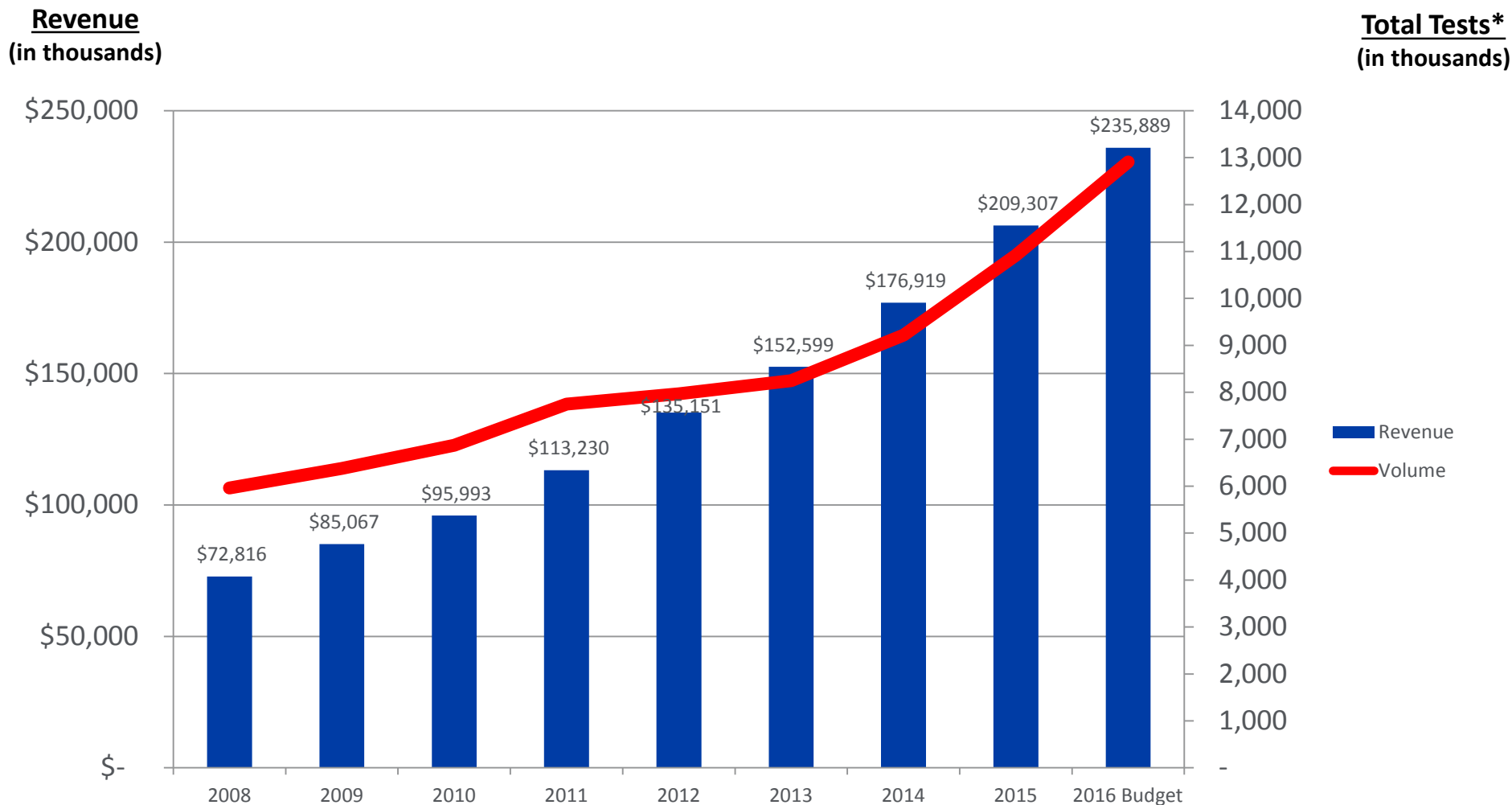


# Core Laboratory Business Lines

2015

Business Line	Volume	Revenue (\$)
Physician Office	7,775,138	\$ 145,933,589
Nursing Home	498,688	\$ 5,184,051
Clinical Trials	77,729	\$ 1,770,053
Reference Testing	647,182	\$ 19,467,196
<b>Total Outreach</b>	<b>8,998,737</b>	<b>\$ 172,414,888</b>
Hospital	1,948,042	\$ 33,892,843
<b>Total</b>	<b>10,946,779</b>	<b>\$ 209,307,732</b>

# Core Lab Growth



***Since 2008, revenue has increased by 224% and total tests have increased by 117%***

# Challenges

- Increased competition and aggressive tactics from commercial laboratories
- Consolidation in all aspects of health care including laboratory services
- Transparency – price, outcomes, ratings
- Financial cutbacks over time
- Lack of resources to maintain regulatory compliance and delivery of high quality services



# Opportunities



- Continued investment in quality, workforce and level of laboratory services.
- We became a recognized leader in our region.
  - At the request of regulatory agencies, we have been asked to assist other Laboratories at risk.
  - We continue to receive requests by other laboratories to provide risk assessments and gap analysis.

**These requests prompted us to perform additional self assessment of our laboratories in terms of risk.**

# Top National Deficiencies



DEFICIENCY	CAP	CMS	CLSI
Competency Assessment	X	X	X
Procedure Manual	X	X	
Proficiency Testing Evaluation	X	X	X
Comparability of Instruments/Methods	X	X	X
Instrument /Equipment / Maintenance	X	X	
Method Validation and Verification	X	X	X
Safety	X	X	
Lab Director Responsibilities	X	X	X
Waived and Quantitative QC	X	X	X
Patient and Specimen ID	X	X	X
Adverse and Nonconforming Events	X	X	X
Document Control	X	X	

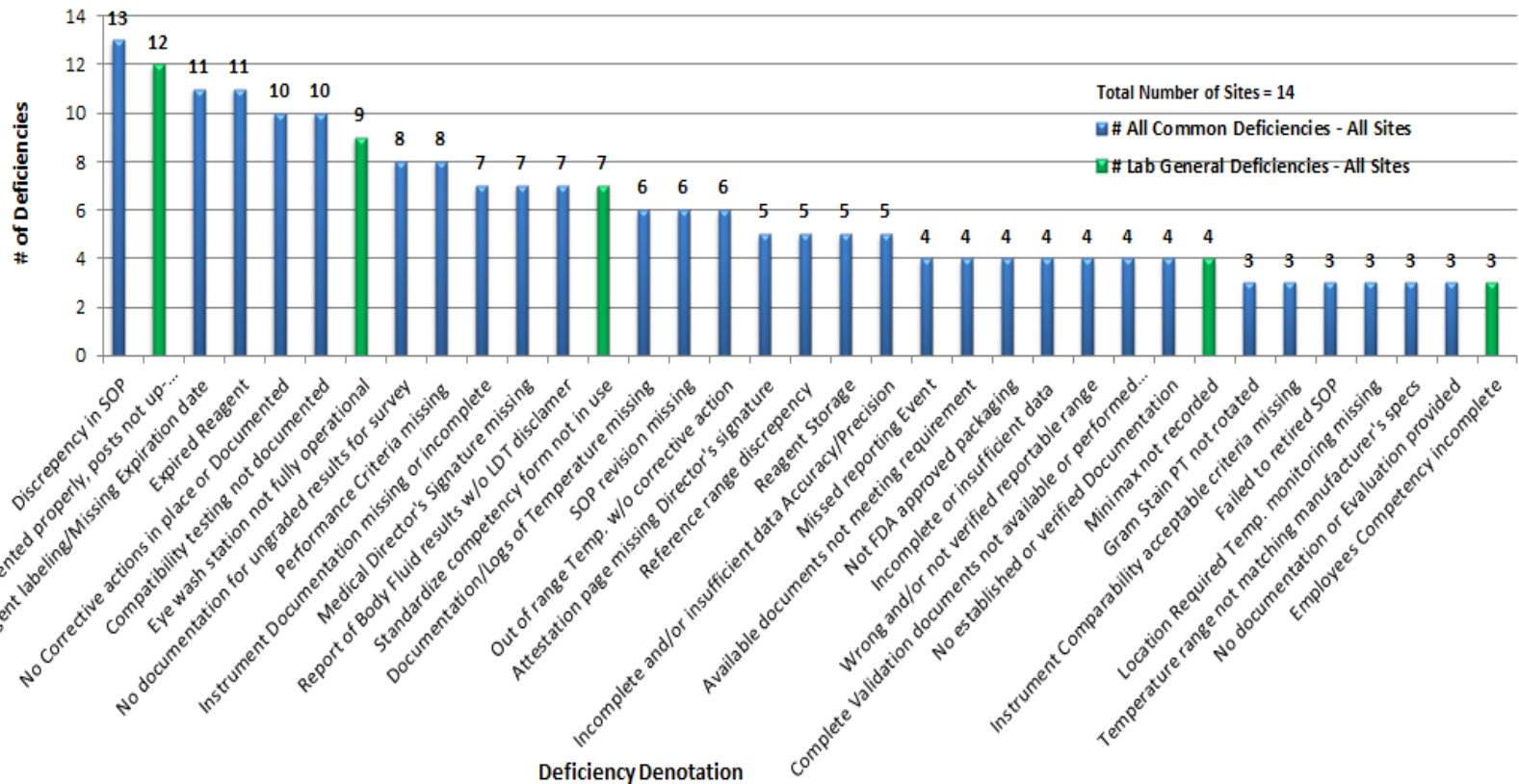
# Top Northwell Health Labs Repeat Survey Deficiencies



DEFICIENCY	NYSDOH	CAP
Supervision of Test Performance	X	
Function Checks and Preventive Maintenance	X	X
Reagent Lot Verification	X	X
Inventory Control	X	
Reagent Labeling	X	X
Reagent Expiration	X	X
Instrument Correlations	X	X
Method Validation	X	X
Reference Intervals/Report Content	X	X
Safety – Medical Waste/Eye Wash Document	X	X
Accurate SOPMs	X	X
Calibration Verification Procedure	X	X

# Northwell Health Risk Assessment – CAP Survey Deficiencies

CAP All Common Checklist and Lab General Checklist Deficiencies





# Northwell Health Risk Assessment – Survey Deficiencies

Legend: N = No Deficiency/No repeat   D = Primary Deficiency   R = Repeat Deficiency   NA = Not Applicable							
<b>Supervisor Responsibilities</b> <i>A qualified individual, under the general direction of the laboratory director, shall supervise technical personnel and the reporting of findings, perform tests requiring special scientific skills, and, in the absence of the director, be responsible for the proper performance of all laboratory procedures.</i> <i>Responsibilities of a laboratory supervisor include:</i>							
	NYS						
	2010	2012	2014	2016	Deficiency	Corrective Action	Sustained
a) day-to-day supervision of test performance by testing personnel.	N	D	R	R	<p>&lt;2016&gt; Documentation of review of results is not being performed in Diagnostic Immunology for RRA with IPA testing. This is a repeat deficiency previously cited during the March 16, 2016, and April 16, 2016, routine surveys.</p> <p>&lt;2014&gt; There is no evidence of supervisory review of the quality control for specific gravity using Phastchromes, Urinalysis, and Clinitek quality control from January to February 2016. This is a repeat deficiency from the April 16, 2016 routine survey.</p> <p>&lt;2012&gt; In Phastchromes, review of Clinitek main quality control records indicated that the recorded pH value of prepared neutral buffered water is 7.0 while the pH meter used to verify the pH do not contain indicators for pH 7.0/20. The Bio-Rad Canna-ur unaccept quality control range used in Immunology RRA testing was listed as 1.0/20 to 11/20. The laboratory received 11/40 to 11/20 without reassignment of an acceptable range. Acceptable ranges were changed on the quality control sheets during the audits.</p>		

Deficiency Summary: by Repeats	
Standard	# of Deficiencies
Reagents Sustaining Standard of Practice 4 (REAG S4): Inventory Control	4
Reporting Sustaining Standard of Practice 1 (Reporting S1): Report Content	4
Human Resources Sustaining Standard of Practice 8 (HR S8): Competency Assessment - Technical Staff	3
Operating Procedures Sustaining Standard of Practice 2 (SOPM S2): Content	3
Reagents Sustaining Standard of Practice 5 (REAG S5): Labeling	3

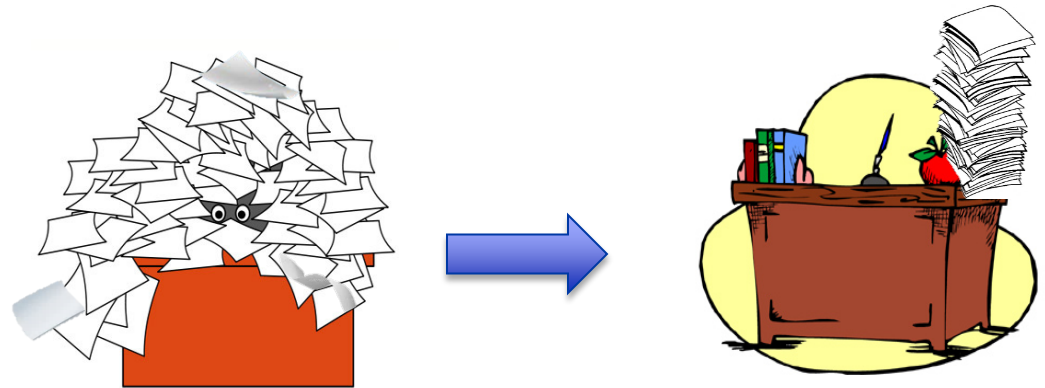
Deficiency Summary: by Standard	
Standard	# of Deficiencies
Operating Procedures Sustaining Standard of Practice 2 (SOPM S2): Content	5
Reporting Sustaining Standard of Practice 1 (Reporting S1): Report Content	5
Director Sustaining Standard of Practice 3 (DIR S3): Director Responsibilities	4
Laboratory Equipment Sustaining Standard of Practice 2 (LE S2): Function Checks and Preventive Maintenance	4

# Risk Assessment – Repeated Deficiency



## Benefits

- ✓ Organized display of previous inspection deficiencies from both individual labs and across the System Labs
- ✓ Helped to see the “BIG” picture
- ✓ Focused our risks
  - Regulatory
  - Patient Safety
  - Quality



# Evolution of Risk Assessment Tools



## WHY DEVELOPED...

- Provide an organizational framework for Management
- Assist Management with tracking “real time” regulated functions/documentation
- Help Management of ancillary services
- Create standardization across the system

		Likelihood		
		Low	Medium	High
Impact	High			
	Medium			
	Low			

# Risk Assessment Toolkit

- Deficiency Crosswalk
- Management Task Checklist
- Supervisor Checklist
- Validation Toolbox
- Interface Validations
- PSC Checklist
- POCT Checklist
- Reference Range Validations
- Competency and Training Tools
- Logistics Checklist



# Risk Assessment - Management Task Checklist

## History

Track Required Tasks at Infrequent Timed Intervals

- Instrument Correlations / Linearity
- Non-Proficiency Testing Analytes
- Calculations verification
- Pipette Calibration / Timers / Thermometers
- Auto-verification
- Water Cultures



# Risk Assessment – Management Checklists



## Management Task Checklist 2016 Core Laboratory

### Process:

1. First week of each new month check for due dates on tasks due following month (example: September review will be for tasks due in October)
2. Send email reminder to appropriate technical staff to include task and due date
3. Review previous months assigned tasks
4. Review that task was completed. Completed date/initial is when data is analyzed, evaluated, and filed in the appropriate log book.
4. Finalize task on checklist.
5. Assign task new due date as required by regulation

TASK DUE WITHIN 30 DAYS

Reminder sent

COMPLETED FOR 2016

TASK DUE WITHIN 60 DAYS

Instrument Correlations						
<b>Required: Semi-Annual</b>			*Completed Date/Initial is when data is analyzed, evaluated and filed in the Instrument Correlation Log Book			
<b>Hematology</b>	Due Date	Reminder Date	Completed Date	Due Date	Reminder Date	Completed Date
Sysmex XE5000						
Beckman Iris						
Integra 800 CTS						
<b>Coagulation</b>	Due Date	Reminder Date	Completed Date	Due Date	Reminder Date	Completed Date
ACL TOPS						

# Risk Assessment - Management Task Checklist

## Benefits

- ✓ Reduction in Deficiencies
- ✓ Ensure Quality of Testing
- ✓ Living Document – addition of new instrumentation
- ✓ Further Standardization/System Laboratories





# Risk Assessment – Supervisory Daily Task Checklist

## History


### ➤ Enormous Amount of Documents and Daily Checks

- ☐ Instrument Maintenance Forms
- ☐ Temperature checks – reagent proper storage
- ☐ Reagent open/expired date
- ☐ QC run
- ☐ Review of pending tests/ensure TAT is met
- ☐ Management Reports

Examples: Error Correction, Exception,  
Critical Values, Cancellations



# Risk Assessment – Supervisory Checklists

			
Daily Maintenance Documentation			
Date: _____			
	Day Shift	Evening Shift	Night Shift
Maintenance Documentation	Maintenance Documented	Maintenance Documented	Maintenance Documented
	✓	✓	✓
<b>Hematology</b>			
Abbott Sapphire 1			
Abbott Sapphire 2			
Excyte Mini			
<b>Coagulation</b>			
Beckman Coulter ACL Advance 1			
Beckman Coulter ACL Advance 2			
<b>Urinalysis</b>			
Siemens Clinitek Atlas			
<b>Chemistry</b>			
Vitros 5600 1068			
Vitros 5600 1078			
Radiometer ABL 800 Flex 1			
Radiometer ABL 800 Flex 2			
<b>Serology</b>			
Vidas			
<b>Supervisory/Lead Signature</b>			

# Risk Assessment – Supervisory Daily Task Checklist

## Benefits

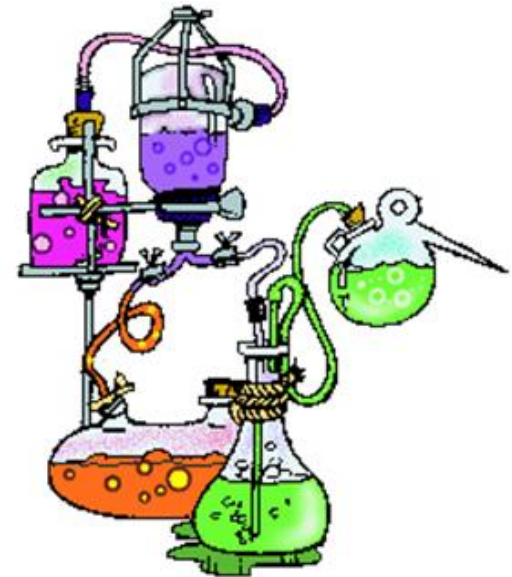
- ✓ Organized review of daily tasks
- ✓ Time Savings - Monthly Supervisory Review completed
- ✓ Staff engaged
- ✓ Ensures regulatory requirements were met
- ✓ Decrease in deficiencies in future inspections
- ✓ Ensures patient safety



# Risk Assessment - Instrument Validation Tool Kit

## History

- Multiple deficiency across system
- Validations missing key components requirements
- Complexity of instrument validations
- Validation Committee Developed
- Validation plan developed



# Risk Assessment – Instrument Validation Tool Kit

## Validation Toolkit Contents

- Linearity
- AMR
- Correlation
- Precision
- Carry Over
- Concordance
- Reference Interval

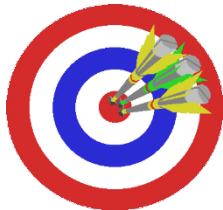
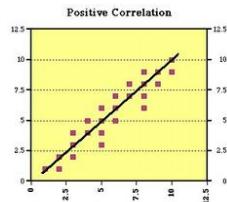
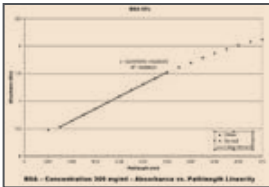
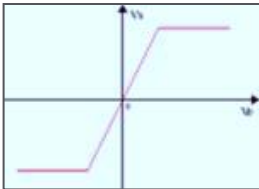


## Benefits

- ✓ Standardization of “kit” components/Central Repository
- ✓ Eliminate Guesswork
- ✓ No Deficiencies

# Risk Assessment - Validation Tool Kit

## Validation Plan



**Procedure:** Complete the chart below prior to the performance of a method validation.

Step 1: Print the Validation Check List

Step 2: Print the Validation Tool Box Procedures

Step 3: Set up WWW (What, Who, When)

Validation Plan for: \_\_\_\_\_

ACTIVITY	WHAT	WHO	WHEN	CRITERIA FOR ACCEPTANCE
AMR 99.1.6.4.10				
LIMIT OF QUANTIFICATION 99.1.6.4.15				
CARRYOVER 99.1.6.4.11				
CONCORDANCE 99.1.6.4.12				
CORRELATION 99.1.6.4.13				
DILUTION 99.1.6.4.14				
PRECISION WITHIN RUN 99.1.6.4.16 99.1.6.4.17				
PRECISION BETWEEN RUN 99.1.6.4.16 99.1.6.4.17				
REFERENCE INTERVAL 99.1.6.4.18				

**Legend:**

What: Directions as per procedures from validation tool box

Who: Responsible party, indicate vendor or laboratory

When: Deadline for expected completion of task

# Risk Assessment – Interface Result Integrity Validation

## History

- Instrument Interface
- Accurate Display of Lab Data Transmission
- LIS task
- Complexity of Validations



## Benefits

- ✓ Developed customized plan, SOP, templates and “scripts” to ensure pre- thru post-analytic data was captured during validation
- ✓ Dedicated Interface Validation Team - \$\$\$



# Risk Assessment – Interface Checklist

Patient Name	TestHLM, UnitNine	TestHLM, UnitNine	TestHLM, UnitNine	TestHLM, UnitNine	TestHLM, UnitNine
Qualifirmed MRN	73	73	73	73	73
Qualifirmed ORDER DESCRIPTION	C1 Inhibitor Functional (Send Out)	Amylase Isoenzymes, Serum (Send Out)	Hepatitis D Ab Total (Send Out)	Polio (Type 1,2,3) Ab, CF, Serum (for recent infection) (Send Out)	Haloperidol, Serum (Send Out)
Qualifirmed Accession Number	2000152-1	2000152-1	2000152-1	2000152-1	2000152-1
Qualifirmed Ordered Date/Time	12/18/2013	12/18/2013	12/18/2013	12/18/2013	12/18/2013
Qualifirmed Manifest Number	36	35	35	35	35
NSLJ Core Lab Received By	sriley2	sriley2	sriley2	sriley2	sriley2
Accession Number	99-13-352-70015	99-13-352-70006	99-13-352-70006	99-13-352-70006	99-13-352-70006
Financial Number					
Qualifirmed ORDER DESCRIPTION	C1 Esterase Inhibitor	Amylase Isoenzyme	Hepatitis Delta Antibodies	Polio Virus Antibodies	Haloperidol
Packing List (if send out test)(In front of Manual)					
Results from Qualifirmed Posted (Pass/Fail)	Pass	Pass	Pass	Fail	Pass
Comments				Cancelled. To be retested	
VALIDATION DOCUMENTATION RECEIVED					
Order	X	X	X	X	X
Manifest	X	X	X	X	X
Order	X	X	X	X	X
Results	X	X	X		X
Chart	X	X	X		X
Screenshots of results in Qmed EMR/HIS	N/A	N/A	N/A	N/A	N/A
Chart	X	X	X		X
Reference Lab Chart	X	X	X		X
Charge:	N/A	N/A	N/A	N/A	N/A
Verified By:	N/A	N/A	N/A	N/A	N/A
Completed Testing Script Spreadsheet					
Reviewed / Approved By:					
Date:					

# Risk Assessment – Patient Service Centers

## History

- 30+ Locations in NYC Metropolitan Area
- Staffed by Phlebotomists
- Waived testing (PT/INR)
- Face of the Laboratory
- Heavily Regulated



## Benefits

- ✓ Patient Satisfaction and Safety
- ✓ Decreased number of deficiencies
- ✓ Ensure Quality Oversight



# Risk Assessment – PSC Checklists

## Phlebotomy Patient Service Center – Facility and Management Checklist



### PSC – Facility & Management Checklist

Facility: \_\_\_\_\_ Reviewer: \_\_\_\_\_ Date: \_\_\_\_\_

#### Part 1 - Facility Checklist – Onsite

Criteria Observation	Met	Did not Meet	Comments
Patients are signing in on the appropriate sign in Sheets (PSC ONLY)			
Refrigerator, Freezer & Room Temp Units checked (PSC ONLY)			
Hours of operation posted correctly (If applicable) (PSC ONLY)			
Evacuation plan posted (PSC ONLY)			
"Services at this Site" & "Pts Rights" Posted (PSC Only)			
Permit posted conspicuously (PSC Only)			
Refrigerator signs posted (PSC ONLY)			
First Aid kit up to date (PSC ONLY)			
Exit/Entrance sign posted (PSC Only)			
MSDS/SOPM on site and updated (PSC Only)			
Location stickers or Generator's label placed on biohazard & red bags (PSC Only)			
Eyewash installed (PSC Only)			
Fire Extinguisher is tagged			
Biohazard stickers affixed on: (check each item)			
Refrigerator (specimen)			
Bio Containers			
Sharp Containers			
Draw Rooms			
Processing Rooms			
Centrifuge			



### PSC – Facility & Management Checklist

Facility: \_\_\_\_\_ Reviewer: \_\_\_\_\_ Date: \_\_\_\_\_

#### Part 2 - Phlebotomy Management Review Checklist - Onsite

Criteria Observation	Met	Did not Meet	Comments
Phlebotomist disinfects Hands before and after Each patient			
Phlebotomist don gloves			
Phlebotomist greets pts and identifies themselves in a professional manner.			
Phlebotomist uses double identifiers- full name & DOB			
Phlebotomist verbalizes Procedure to patient			
Phlebotomist applies tourniquet appropriately			
Phlebotomist draws tube In correct order			
Phlebotomist removes tourniquet			
Phlebotomist labels all tubes (first & last name) in front of the patient			
Phlebotomist correctly dresses site			
Phlebotomist maintains confidentiality of Patient (HIPPA)			
Phlebotomist fills out requisition according to protocol (Number and Type of tubes; draw site; collection time/date)			
Observe centrifugation			

# Risk Assessment – Patient Service Center

## Patient Identification Checklist



### PSC – Patient Identification

Facility: \_\_\_\_\_ Reviewer: \_\_\_\_\_ Date: \_\_\_\_\_

#### Part 3-Patient Identification During Collection in the PSC

	Met	Not Met	Comments
1. Source document/label used to verify ordered tests.			
2. Staff brings source document with them in draw room with the patient/patient's bedside.			
3. <u>If patient is able to participate:</u> Staff asks patient for full name and DOB. (if not, go to 4).			
4. <u>If patient is unable to participate:</u> Staff asks family to state patient's full name and DOB. (if not, go to 5).			
5. <u>If patient is unable &amp; family not present:</u> Staff compares source document (requisition or label) to ID band.			
6. Staff compares patient's/family's statement to ID band or source documents (requisition or script/label).			
7. Staff labels specimen in the presence of patient immediately after collection of specimens.			

#### On-Site Review Follow Up/ Corrective Action and Preventive Action

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Supervisor: \_\_\_\_\_ Date \_\_\_\_\_

Management: \_\_\_\_\_ Date \_\_\_\_\_



# Risk Assessment – POCT

## History


- Physician offices, Hospital/Ambulatory Sites, PSC, Health Fairs (>200 sites)
- Many Waived Tests  
Examples: PT/INR, UA, limited CHEM and H&H, etc.
- Testing performed by Non-laboratory personnel

## Benefits

- ✓ Physician/Patient Satisfaction
- ✓ Decreased number of deficiencies
- ✓ Ensure Quality Oversight



# Risk Assessment – POCT Checklist

		
NS-LIJ CORE LABORATORY MONTHLY QA AUDIT		
Location: _____ Date: _____ For Month: _____		
<b>QUALITY CONTROL</b>	<b>MET</b>	<b>NOT MET</b>
Internal Controls documented		
Coaguchek		
COAGUCHEK $\geq 3.5$ (#)		
COAGUCHEK $\geq 3.5$ CORRECT DOCUMENTATION # NOT MET		
External Quality Controls documented		
Coaguchek		
<b>TEMPERATURE CHARTS</b>		
Refrigerator Temperature documented daily		
Refrigerator Temperature documented within allowable tolerance limits		
Refrigerator Temperature corrective action documented		
<b>MAINTENANCE LOG FORM</b>		
Maintenance Log Form documented on day of use/slash on days not in use		
Maintenance Log Form Operator initials documented		
<b>PRODUCT LABELING</b>		
Room Temperature Products Labeled with open date		
Room Temperature Products all are within expiration date		
Room Temperature Products Labeled with opened expiration date		
<b>CENTRIFUGE</b>		
Maintenance		
RPM check		
GE Ground check		
<b>MEDITAPE/PATIENT LOG/EMR REVIEW</b>		
Patient name documented		
Patient date of birth documented		
Operator name documented		
MD name documented		
Onboard Internal QC documented		
Reagent information documented		
Patient Result documented		
Number of Meditapes/Patient /EMR Reviewed		
<b>SAFETY</b>		
Eyewash operation documented		
Counter top decontamination documented		
Centrifuge maintenance documented		
Universal Precautions assessed on day of site visit ie: closed lab coat/closed toe shoes/gloves		
<b>NUMBER OF TESTS PER INSTRUMENT/METHOD</b>	<b>Month</b>	<b>Criticals</b>
BNP		
Cholestech		
Coaguchek		

# Accomplishments

- Central Repository of Risk Assessment Tools
- Improved Quality of Laboratory Testing as Evidenced by Decreased Number of Repeat Deficiencies
- Ongoing Application of Risk Assessment in Laboratory Operations.
- Integration of Risk Awareness into Lab Culture
  - Management
  - Staff Engagement

**INSPECTION READY ANY DAY AND ANY TIME!**





# Opportunities for External Risk Assessment




- **What Does It Take?**
  - ✓ Right Expertise to perform risk assessments in all aspects of Lab Medicine
  - ✓ Right Tools to assist in the provision of ongoing quality
  - ✓ Right Resources to assist others

# External Risk Assessment

- **What Do We Do?**
  - ✓ Perform a comprehensive audit
  - ✓ Based on findings, a risk assessment is developed
  - ✓ Prioritize risks ranging from high to low risk
  - ✓ Report presented to management of facility
  - ✓ Implement risk assessment tools
  - ✓ Perform audits for sustainability

# Risk Assessment Report for LQC University Hospital Lab

 <b>LABORATORY AUDIT OUTCOMES AND RISK ASSESSMENT</b>					
Laboratory Name: LQC University Hospital				Date: 10/5/16	
<b><u>RISK ASSESSMENT</u></b>					
<b>Findings</b>	<b>Method*</b>	<b>Risk Category/Score** &lt;ex. QC-3&gt;</b>	<b>Observation</b>	<b>Action Plan</b>	<b>Responsibility and Completion Date</b>
<b>Quality System Manual</b>	DO	Patient Safety -3	STAT body fluid pending on a tracker board since a day before		
<b>Proficiency Testing</b>	RR	Proficiency Testing-2	PT failure Urine chemistry — no corrective action		
<b>Quality System Manual</b>	DO	NYS -1 Noncompliance/Low Regulatory Impact - Equipment	Instruments not in use without a sign (freezer, in the corridor)		

## **RISK SCORE LEGEND**


1= Other/NYS Noncompliance/Low Regulatory Impact

2= Quality Issue

3 = Patient Safety/High Risk/Regulatory Noncompliance with NYS DOH POC

NA = Not Applicable

# Risk Assessment Report for LQC University Hospital Lab

		<b>LABORATORY AUDIT OUTCOMES AND RISK ASSESSMENT</b>	
<b>Laboratory Name: LQC University Hospital</b>		<b>Date: 10/5/16</b>	
<b><u>RISK ASSESSMENT</u></b>			
<b>Risk Category</b>	<b>Risk Score 1,2 or 3</b>	<b>Immediate Remediation (within 2 weeks)</b>	<b>Long Term Remediation</b>
Quality System Manual (QSM)	2- SOP for Audits does not indicate frequency. (QSM)	Lab Leadership needs to review those SOPs in QSM which are important to patient care.	Lab Leadership needs to review remaining SOPs in QSM.
Document Control (QSM)	1- No version history, inconsistent numbering, Medical Director sign-off as "Recommended" instead of "Approved" (QSM)		All SOPs and associated documents require document control.
Proficiency Testing (QSM)	3- SOP needs to be amended to reflect regulatory requirements, follow-up and NYS DOH POC response of the deficiencies. Example: SOP states that both lab staff and Medical Director will evaluate proficiency testing. There is only evidence of Medical Director signature. The POC states that the Medical Director will evaluate Proficiency Testing results within 2 weeks. SOP not amended to reflect this.	Amend SOP within 2 weeks.	Evaluate Proficiency Testing results for trending.

## **RISK SCORE LEGEND**

1= Other/NYS Noncompliance/Low Regulatory Impact

2= Quality Issue

3 = Patient Safety/High Risk/Regulatory Noncompliance with NYS DOH POC

NA = Not Applicable

# Risk Assessment Report for LQC University Hospital Lab



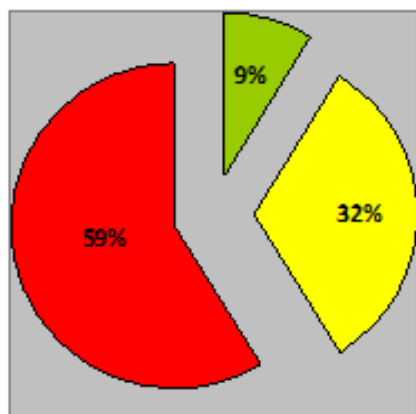
## LABORATORY AUDIT OUTCOMES AND RISK ASSESSMENT

Laboratory Name: LQC University Hospital

Date: 10/5/16

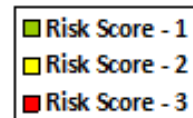
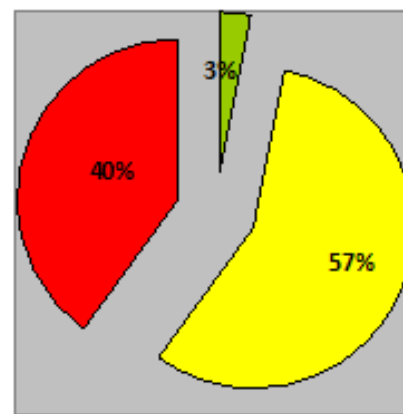
### RISK ASSESSMENT SUMMARY FOR LQC UNIVERSITY LABORATORY

#### Risk Assessment by Risk Category



Total Number Risk Categories	22
Number Score 1 Categories	2
Number Score 2 Categories	7
Number Score 3 Categories	13

#### Risk Assessment by Cited Deficiency



Total Number Deficiencies	88
Number Score 1 Deficiencies	3
Number Score 2 Deficiencies	50
Number Score 3 Deficiencies	35

# Benefits

- **What is the Northwell Health Benefit?**
  - A recognized regional laboratory brand
  - Create new long term partnerships
  - New Consulting Service Line!
- **What is the Client Benefit?**
  - Lab Management and Staff competent
  - Increased lab quality and patient safety
  - Change of lab culture and lab perception
  - Create new long term partnership with Northwell!



## In Conclusion... Take Away!

- 1- Use of RISK assessment tools ensures that Laboratories are NOT at RISK for losing permits, clients, jobs and monies.
- 2- Risk Assessment processes can be implemented at any size laboratory.
- 3- We did it.... YOU CAN DO IT TOO!



# Thank You

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