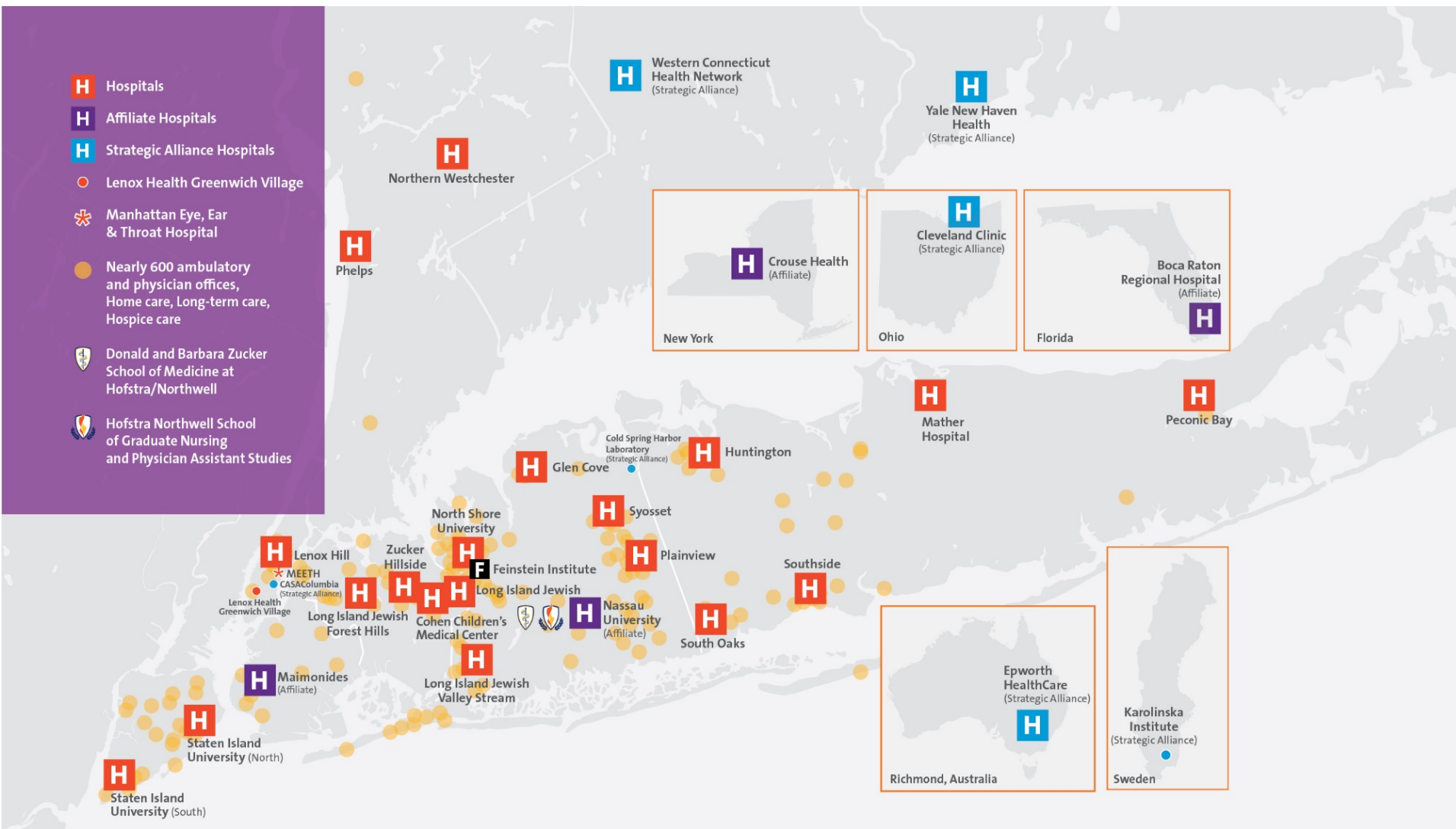


Challenging the Status Quo for Quality Control in an Integrated Health System Lab: How we improved our QC performance, converted 15 lab sites and saved \$250,000

Hannah Poczter, Cari Gusman, Dimple Patel, Robert Aniceto
LabConfab, October 9th , 2018

-  Hospitals
-  Affiliate Hospitals
-  Strategic Alliance Hospitals
-  Lenox Health Greenwich Village
-  Manhattan Eye, Ear & Throat Hospital
-  Nearly 600 ambulatory and physician offices, Home care, Long-term care, Hospice care
-  Donald and Barbara Zucker School of Medicine at Hofstra/Northwell
-  Hofstra Northwell School of Graduate Nursing and Physician Assistant Studies





- 
- Nearly 15,000 affiliated physicians, including about 4,000 employed doctors and more than 3,100+ members of Northwell Health Physician Partners
 - More than 15,000 nurses
 - More than 4,725 volunteers
-
- \$11 billion annual operating budget
 - More than 66,000 employees — the largest private employer in New York State
 - Service area of nearly 11 million people



Northwell Health contributes more than \$1 billion in community benefit (12.65 percent of operating expenses) by participating in more



than 3,800 unique programs, serving 5 million community members and training 20,000 health professionals.

Operating statistics

- 2 million+ patients treated annually
- Over 4.3 million patient encounters
- Nearly 39,000 births
- 286,690 hospital discharges
- 635,293 emergency visits
- 732,171 home health visits
- 184,323 ambulatory surgeries
- 106,422 ambulance transports

*2016 det

...more than a health system.

Hospitals

Five tertiary hospitals

- Lenox Hill Hospital, Manhattan
 - Manhattan Eye, Ear & Throat Hospital
- Long Island Jewish Medical Center
- North Shore University Hospital
 - Sandra Atlas Bass Heart Hospital
- Southside Hospital
- Staten Island University Hospital, North

Three specialty care hospitals

- Cohen Children's Medical Center
- South Oaks Hospital
- Zucker Hillside Hospital

11 community hospitals

- Glen Cove Hospital
- Huntington Hospital
- Long Island Jewish Forest Hills
- Long Island Jewish Valley Stream
- Northern Westchester Hospital
- Mather Hospital
- Peconic Bay Medical Center
- Phelps Hospital
- Plainview Hospital
- Staten Island University Hospital, South
- Syosset Hospital

Four affiliate hospitals

- Boca Raton Regional Hospital
- Crouse Hospital
- Maimonides Medical Center
- Nassau University Medical Center

Education

- Donald and Barbara Zucker School of Medicine at Hofstra/Northwell
- Hofstra Northwell School of Graduate Nursing and Physician Assistant Studies
- More than 1,600 medical residents and fellows
- 126 resident and fellow programs
- More than 1,200 medical student rotations
- Elmezzi Graduate School of Molecular Medicine
- Center for Learning and InnovationSM
- Patient Safety InstituteSM
- Bioskills Education Center
- Nursing school affiliations with 37 colleges and universities

Research

Feinstein Institute for Medical Research

- 50 research laboratories
- 4,000 researchers and staff studying molecular medicine, genetics, oncology, brain research, mental health, autoimmunity and bioelectronic medicine
- 2,100 research studies and 15,000 participants

Post-acute services

- Home Care Network
- Hospice Care Network
- Peconic Bay Home Health Services
- RegionCare Inc.

Acute inpatient rehabilitation

- Glen Cove Hospital
- Phelps Hospital
- Staten Island University Hospital, North
- Southside Hospital

Sub-acute rehabilitation

- Orzac Center for Rehabilitation
- Peconic Bay Skilled Nursing and Rehabilitation Center
- Stern Family Center for Rehabilitation

Outpatient rehabilitation

- Glen Cove Hospital
- Nicholas Institute of Sports Medicine and Athletic Trauma
- Northern Westchester Hospital
- Peconic Bay Outpatient Therapy and Rehabilitation Center
- Phelps Hospital
- Southside Hospital
- Sports Therapy and Rehabilitation Services (STARS): East Meadow, Franklin Square, Great Neck, Huntington, Manhasset, Massapequa, Rego Park, Roslyn Heights, Woodbury
- Staten Island University Hospital, North and South
- Transitions of Long Island®

Population health management

- Northwell Health Solutions

Emergency medical services

- Center for Emergency Medical Services
- SkyHealth (helicopter emergency medical service)

Laboratory services

- Northwell Health Labs
- 40 Blood-testing service centers

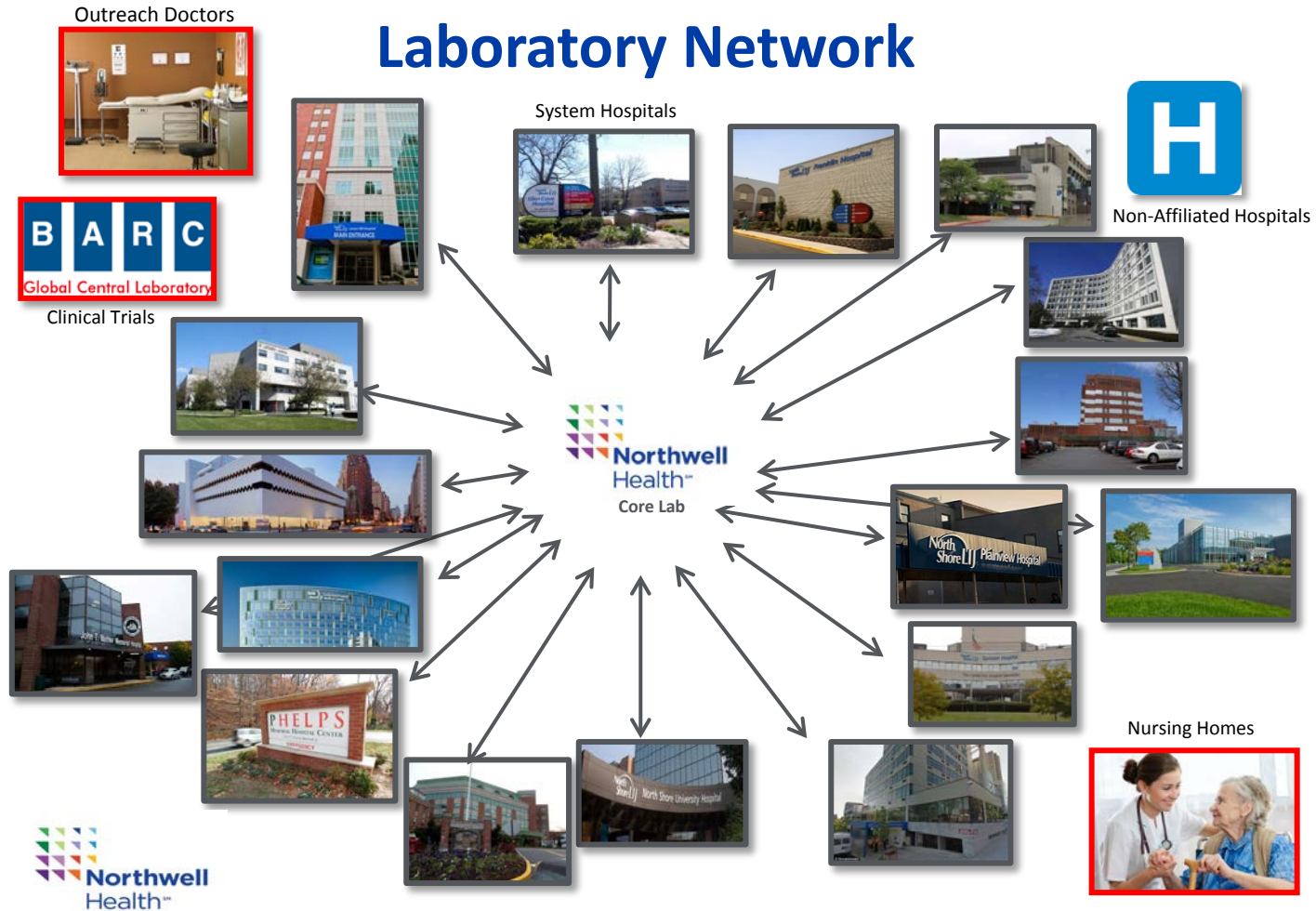
Ambulatory specialty centers

- Ambulatory specialty centers
- Bay Shore Women & Children's Specialty Center
- Center for Advanced Medicine, Lake Success
- FalconStor Center at Queens Crossing, Flushing
- Imbert Cancer Center
- Lenox Health Greenwich Village, New York, NY
- Manhattan Eye, Ear & Throat Hospital, New York, NY
- Manorville Medical Park
- Multi-Specialty Center, Glen Cove
- Multi-Specialty Center, Rego Park
- Primary Specialty Center, Bay Shore and Woodbury
- Surgical Specialty Centers, Bay Shore, Greenlawn and Smithtown

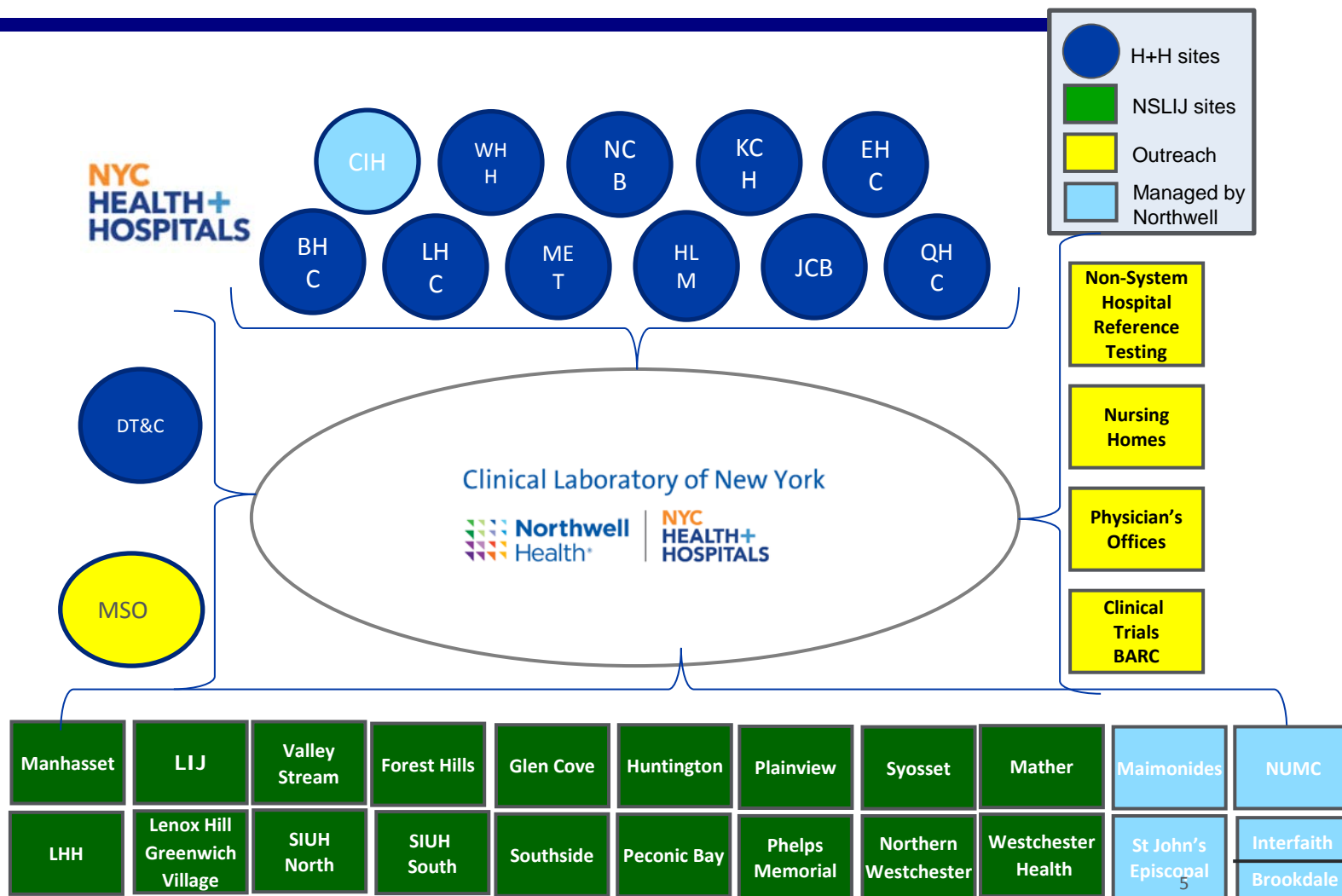
Diagnostic imaging

- **Diagnostic Imaging**
 - Bohlen Women's Imaging Center, Islip
 - Grossman Imaging Center (Peconic Bay Medical Services PC)
 - Northern Westchester Hospital Radiology at Yorktown Heights
 - Northwell Health Imaging at
 - Bay Shore
 - Center for Advanced Medicine
 - Garden City
 - Glen Cove
 - Great Neck (two locations)
 - Great South Bay (Islip)
 - Greenwich Village
 - Smithtown
 - Syosset
 - Northwell Health Reichert Family Imaging at Huntington
 - Phelps Hospital Radiology at Croton-on-Hudson
 - Phelps Hospital Radiology at Dobbs Ferry
 - Schlanger, Gottlieb, Partners Council Breast Imaging Center
 - The Breast Imaging Center at Staten Island University Hospital
 - Verrazano Imaging at Staten Island University Hospital

Northwell Health Laboratory Network



CLNY Alliance Network



Northwell Health Laboratories

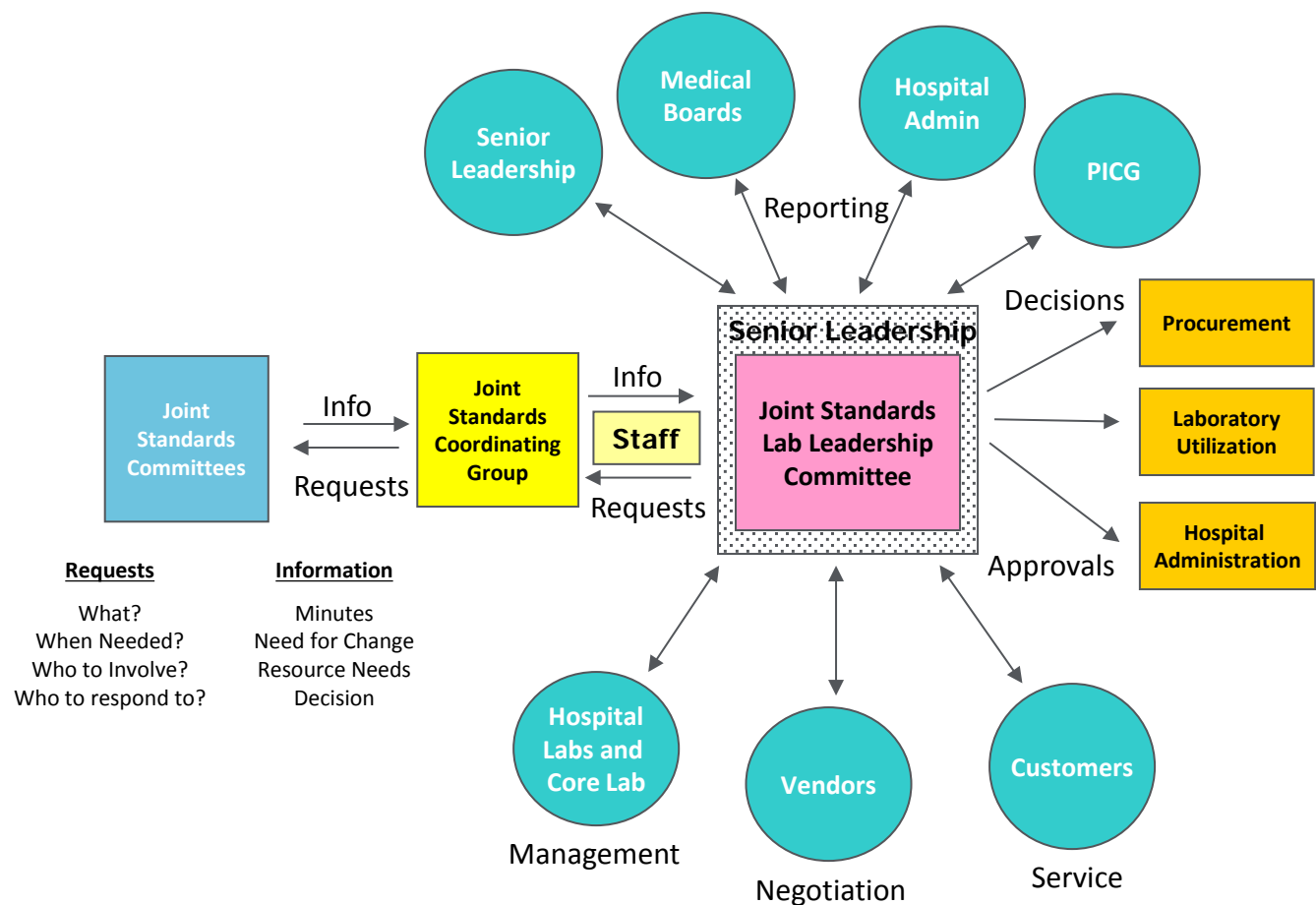
- Central “Core” Laboratory
- 18 Hospital Based Labs
- \$550 Million Annual Operating Budget
- 2000+ FTE’s/ 110+ Pathologists
- 30+ Million Billable Tests
- 200,000+ Surgical Specimens
- 40+ Patient Service Centers –
 - 430,000 Ambulatory Blood Draws
 - 220,000 Nursing Home Draws
 - 84,000 Home Phlebotomy Draws
 - 500,000 Logistics pick ups
 - Over 1 million Customer Service Calls
 - 99% Physician Satisfaction – Likelihood to recommend
 - 96% Patient Satisfaction Survey Scores
 - 1000+ Client Result/Order Interfaces

Suffolk, Nassau, Queens, Manhattan, Westchester

Lab Service Line Support Functions

- Logistics
- Client Service
- Marketing
- Phlebotomy
- Quality and Regulatory/Compliance
- Laboratory Information Services
- Informatics
- Billing
- Business Development / Project Management
- Management Service Organization

Joint Standards Committee Process



System Network Model

Shared Consolidated Core Laboratory

- Centralized Clinical and Administrative Leadership
- Standardized Equipment across all Laboratories
- Standardized SOP's
- Single Integrated Lab Information System - Cerner
- Centralized Microbiology, Esoteric, Reference
- Centralized POCT Division
- Centralized Quality and Competency Program
- Centralized Quality System Manual (QSM)
- **Centralized Quality Control Program**



Northwell Health Labs (Core) Space

Current Space

10 Nevada

- Lab Space: 21,600 SQF
- Support: 11,800 SQF
- Office: 7,700 SQF
- Clinical Trials/ DNA Lab: 16,900

5 Dakota

- LIS and Administration: 10,000 SQF

175 Community

- Billing: 5,700 SQF

6 Ohio

- Anatomic Pathology : 18,500 SQF
 - Pathologist and Cytologist Offices

Total: 92,200 SQF

Future Space

CFAM , 450 Lakeville Road1Q 2019

- 110K SQF
 - Core Laboratory
 - Anatomic Pathology
 - Administration

Little Neck Parkway– Infectious Disease: 3Q 2018

- 39K SQF

5 Dakota

- LIS – 6K SQF

175 Community

- Billing: 5,700 SQF

6 Ohio

- Anatomic Pathology : 18,500 SQF
 - Pathologist and Cytologist Offices

Total: 170,200 SQF

Core Lab at the Center for Advanced Medicine (CFAM)



Core Lab Little Neck Parkway



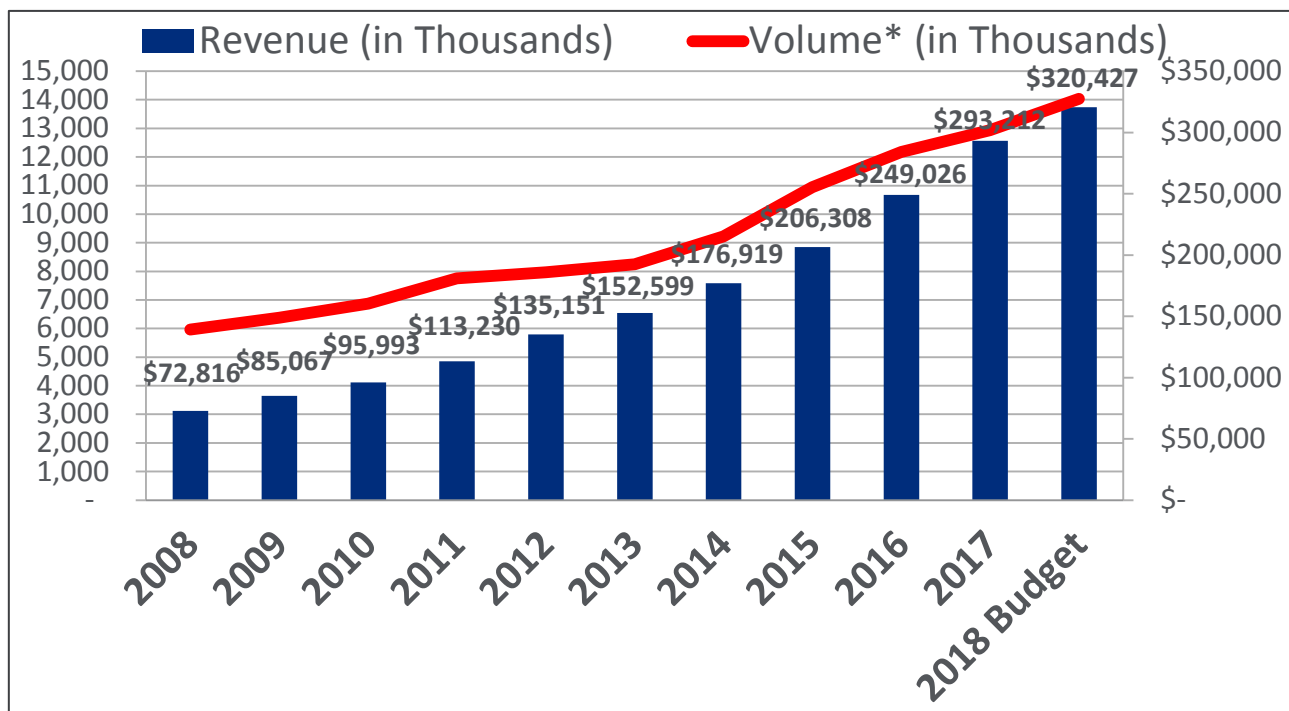
Strategic Rationale for Expansion

- Both the CFAM and Little Neck expansions are driven by the expanding market demands and geographic territories of Northwell Health.
- These automated, cutting edge facilities will be one of the most advanced laboratories in the world.



Northwell Health Core Lab

Financial Growth



*Total tests includes hospital reference testing, HHC testing and outreach/other testing

Since 2008, revenue has increased by 340% and total tests have increased by 135%

“Mini-LEAN”

**ARE U
WASTING TIME?**



- Multiple Sensing Sessions – before “ Mini-Lean” event
 - 1 day Event
 - Initial report out after 1 day Event
 - Baseline metrics established
 - Monthly Progress – establishing quality and process related metrics
 - Sustainability achieved by reporting metrics monthly
-
- **Not Enough Time!**
 - **Not Enough Money!**
 - **Not Enough Staff!**
 - **Not Enough Buy-In!**

Current Assessment of Work Flow

1. Pre-analytic

- From Specimen Pick Up (Logistics) to drop off
- Specimen accessioning/sorting/distribution to departments

2. Analytic

- Instrument readiness
 - Maintenance
 - Calibration
 - **Quality Control**
- Specimen loaded on analyzers
- Test Result Review and Release

3. Post analytic

- Specimen retrieval
- Specimen archiving

4. Other process workflows

- Reference Testing
- Supplies Inventory and Delivery to Departments

New QC Product Expectations

- Long shelf life
- Sequestration
- Open vial stability
- Commutability
- Medically relevant levels
- Control consolidation
- Vendor relationship
- **Price**



Reasons for Transition: ???

- **Service and support level of the current vendor**
 - Lots depleted before lot sequestered longevity
 - Vendor Inventory Issues
 - Product not meeting measuring/clinical decision points
 - Limited opportunities of client feedback on product needs and performance
 - Software Challenges
- **Competitive pricing**

Mini Lean Baseline Metrics

QC Materials Component for Chemistry Controls

	<u>Required Control Runs</u>	<u>Total Control Runs/day</u>
CORE LAB	(16 vials x 3 shifts) + 1 Chem vial/hour	72
RRL LABS (14)	(11 vials x 3 shifts) x 14 sites	462
Total QC runs per Day NW Health System Labs		534

Mini Lean Baseline Metrics

QC Labor Component for Chemistry Controls

	<u>CORE LAB</u>	<u>RRL's</u>
QC Handling Time	30 min	15 min
Programming the analyzer	45 min *5 instrument lines	15 min
Total Time	75 min	30 min

Timing in life is everything.....

Northwell Health System Standardized Quality Control Program

- Centralized oversight of Quality Control Management Program by the Method Development Group (QC cops!!)
- Regulatory Requirements
- Harmonization of rules (Westgard)
- Central Repository of QC data (LIS)
- Sequestering/Validation of new QC lots
- QC Evaluation – Monthly (Intra- and Inter- [System Wide])
- System level feedback to Methods Committee
- Validation Toolbox



QC Validation Tool Box

Initial Validation Plan

- Developed with Medical Leadership - Core Laboratory
- Validation Procedure – Core Laboratory
- Statistical Summary – Core Laboratory

Subsequent System Wide Validation Plan

- Developed with Medical Leadership – RRL's
- Validation Procedure – RRL's
- Statistical Summary – RRL's



Initial Product Validation Timeline - Core Laboratory

1. ***Crosswalk current QC Materials to proposed QC Materials: 3/27 – 3/31/17***
 - Instruments/ test menu/QC and ranges
2. ***Validation Plan Approved – 4/7/2017***
3. ***Validation Procedure: 2 lots***
 - A. Sequestered lot – 4/17 to 5/3/2017
 - a) Routine Chemistry Assays
 - b) Immunoassay Assays
 - B. End of shelf life lot – 4/17 to 4/28/2017
4. ***Statistics and data analysis performed***
 - 5/8/2017 data analysis
 - 6/30/2017 summary report

Validation Plan

Elements of the Validation Plan

- Stability
- Precision
- Accuracy

Additional Elements to evaluate

Workflow:

Efficiency

Ease of use

Validation Procedure – Core Laboratory

Materials and Methods:

- New QC product Routine Chemistry and IA were tested against previous QC products
- 26 Routine chemistry tests and 26 Immunoassay tests ran over 13 days
- CVs were compared against previous QC products and CV ratio was calculated for every test

NEW VENDOR QC MATERIAL CORE LABORATORY EVALUATION

APRIL – MAY 2017

LEVEL:	1	2	3
ALB	0.8		0.9
ALKP	0.4		0.7
AMY	0.8		0.7
BUN	0.0		1.0
CA	0.9		0.8
CHOL	0.7		1.0
CL	0.9		1.0
CO2	0.9		1.2
CPK	1.1		0.3
CREA	0.3		0.8
CRP	2.6	0.8	0.6
DBILI	0.6		1.7
GGT	3.3	0.6	
GLU	1.2		1.3
HAPTO	0.5	0.4	0.2
HDL	0.8		0.5
IRON	1.3		0.4
K	0.8		1.4
LDH	0.8		1.2
LDLD	0.8		0.4
LIPASE	0.7		0.5
MG	0.6		0.8
NA	1.1		1.5
PHOS	0.3		1.3
SGOT	1.1		1.0
SGPT	0.7		1.5

CV ratio vs Previous product

≥ 1.2 larger imprecision:



≤ 1.1 Lower imprecision:



Not tested (QC level not used):



N: 30-45, 13 days

LEVEL:	L1	L2	L3
AFP	1.3	0.5	
B12	0.7		0.7
CEA	1.2	0.8	1.0
CORT	0.9	1.0	0.7
E2	0.6	1.2	1.1
FERR	1.1		1.0
FOL		0.9	0.9
FPSA	0.6	0.6	0.7
FSH	0.9	0.9	1.0
FT3	1.0	1.1	
FT4	1.4	1.3	
IGE	0.8	1.2	1.0
HCG-BETA	2.3	0.9	0.8
LH	1.4	1.1	1.0
INSULIN	0.7	0.8	0.8
PRL	0.9	0.9	1.0
PRO-BNP	1.4	0.9	0.8
PROG	0.7	1.3	1.2
PSA		1.0	0.8
PTH	0.8	1.2	1.2
T UP	0.9	0.8	
T3	1.0	1.1	
T4	1.4		0.8
TESTO	1.6	0.9	0.1
TN-T	0.0	1.4	0.1
TSH	2.7		0.9

Ratio of new product CV over previous product CV | “CV ratio” = CV_{TP}/CV_{PP}
 Tables above in heat map format

Consolidation of QC Material

Previous Control Products



New Control Products



Efficiency through Workflow Process

Fewer number of vials to pour:

- Reduces set up time – less vials to process and program on the instrument
- Routine Chemistry → 45 test and IA → 27 test (ROCHE only)
- Less waste – fewer sample cups
- Reduces handling error due to less product handling

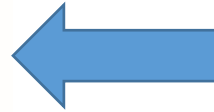


Efficiency through Ordering and Storage

- Fewer products to order as products has been consolidated
- Small packaging – more space in refrigerator/freezer for other products

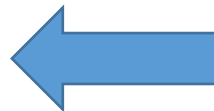


Total Efficiency of consolidated QC Materials



Up to 75% fewer vials
to cover test menu

Up to 80% storage space reclaimed



Up to 75% reduction in dead volume
waste

Vendor Audit – July 2017



New QC Product Manufacturing Facility

- Fresh frozen product
- Commutability
- Proprietary manufacturing processes



Saint Vincent University Hospital lab, Dublin



Audit Guidelines and Outcome

1. Safety & Facilities Procedures
2. Human Resource Procedures
3. Document Control Procedures
4. Manufacturing Procedures
 - Raw material
 - Product preparation
5. Materials Management Procedures
 - Labeling
 - Storage
 - Distribution
6. Technical Procedures
7. Complaint Management
8. General Quality Systems
9. Quality Control Program
10. Quality Evaluation Procedures

Audit Outcome:

- **Very successful with no deficiencies**

Systemwide Validation (May – Aug 2017) Timeline

1. Crosswalk created: 5/1 – 5/5/2017
 - Instruments/ test menu/QC and ranges
2. Webinar with laboratory leaders – 5/9/2017
3. Validation Plan – System wide - 5/22/2017
4. Testing:
 - Routine Chemistry- 6/19 to 6/30/2017
 - IA– 7/17 to 7/28/2017
5. Statistics and data analysis – 8/2/2017
6. Summary Report and Medical leadership approval
 - 8/4/2017



Northwell Health System Wide

Go-Live!!

September 19, 2017

One year later.....



- **Converted sites**
 - Core Laboratory
 - 14 Rapid Response Laboratories
 - 3 Additional sites to convert – pending instrument conversion
- **Product usage** – significant decrease 419 boxes → 208 boxes per month
- **Product Stability** – remarkable
- **Overall Satisfaction with QC material** - High
- **QC performance** - No issues/glitches
- **QC evaluation** - Daily, weekly and Monthly.. business as usual
- **Vendor Support** - continuous on-site and remote support is incredible
- **Over 25% cost savings on QC materials and labor**
- **Future plans:**
 - Working with vendor on R&D with product development
 - Connectivity solutions – Corelab and NW sites

No QC deficiencies for 2017 CAP and 2018 NYS inspection outcome for all the Northwell Sites

Efficiency Through Product Consolidation

Previous QC vials	<u>Required Control Runs</u>	<u>Total Control Runs/day</u>
CORE LAB	(16 vials x 3 shifts) + 1 Chem vial/hour	72
RRL LABS (14)	(11 vials x 3 shifts) x 14 sites	462
Total Vials Per Day		534

New Vendor QC Vials	<u>Required Control Runs</u>	<u>Total Control Runs/day</u>
CORE LAB	(6 vials x 3 shifts) + 1 Chem vial/hour	42
RRL LABS (14)	(6 vials x 3 shifts) x 14 sites	252
Grand Total Runs Per Day		294

240 less QC runs per day System wide which translates to a 45% decrease in product utilization

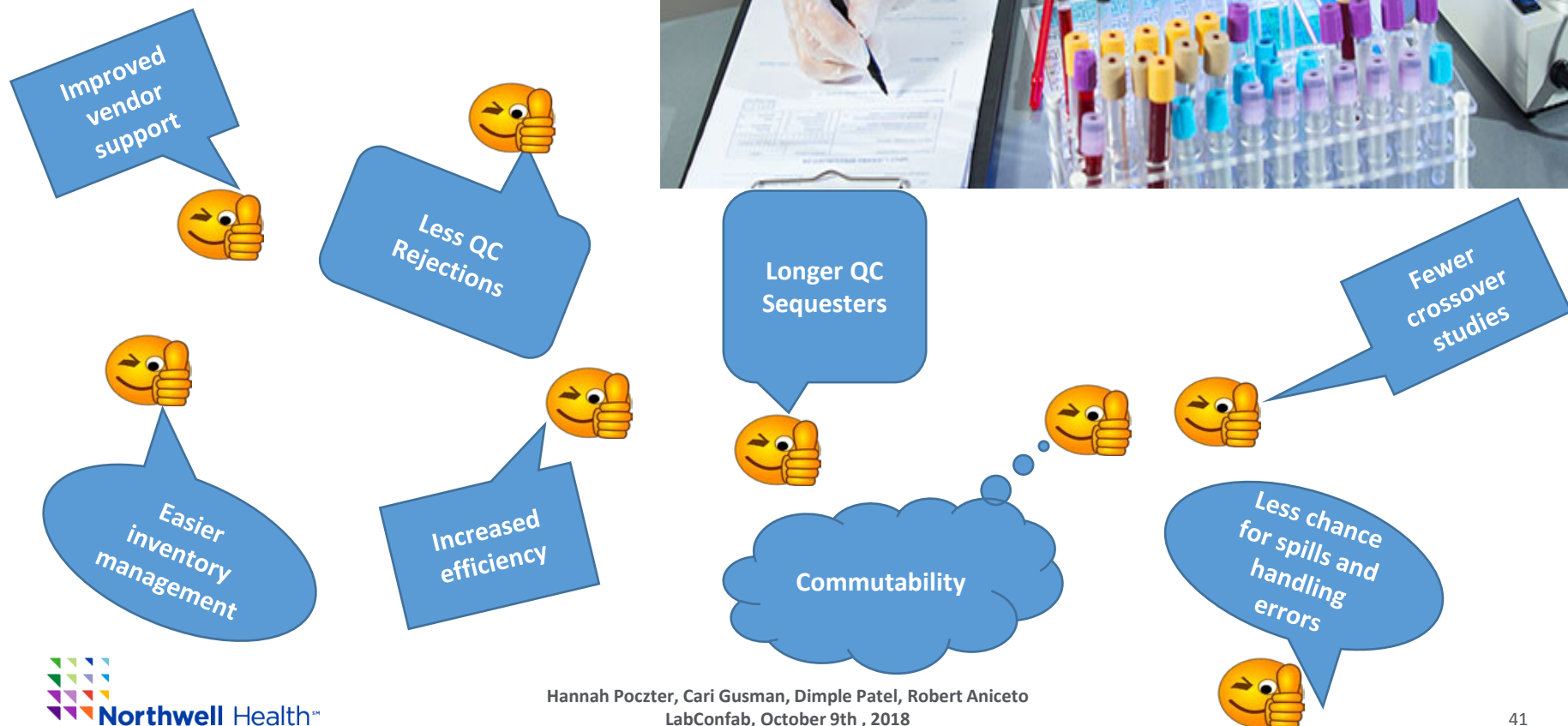
Efficiency Through Labor Reduction

Daily QC Runs

	<u>Previous QC Run</u>		<u>New Vendor</u>	
	CORE LAB	RRL's	CORE LAB	RRL's
QC Handling Time	30 min	15 min	20 min	10 min
Programming analyzer	45 min	15 min	25 min	5 min
Total Time	75 min	30 min	45 min	15 min
			40% Less	50% Less

- **Additional labor savings**
 - Decreased frequency of sequestered lot validations
 - Less materials to validate

Where are opportunities for QC related enhancements?



Testimonials

- | | |
|-------------------|--|
| Min C. (Tech) | “Less QC products for all the tests in the instruments” |
| Carmen B.(Tech) | “One product to pour, less chance to misspour and repeat. Big bottles for S plus to share with multiple analyzers” |
| Ray D. (Tech) | “All in one! Convenient and easy to remember what QC to use” |
| Hoda E. (Tech) | “I liked that controls are consolidated into one. Easier to handle less products and remember what to use” |
| Andrew S. (Tech) | “Easy to use, less materials to pour and less waste” |
| Matthew K. (Mgr.) | “I would like to use this QC materials in my other job” |

Lessons Learned

What Went Well.....

1. Early engagement of management and staff ensured the buy in and successful implementation across the entire health system laboratories
2. Structured validation plan
3. Project managed by the Core Laboratory Method Development team
4. On site vendor audit– manufacturing plant and end product users at local hospital laboratories reaffirmed the quality and confidence of the QC material

Lessons Learned

What Could Have Gone Better.....

1. Under estimated efforts required to maintain project timeline
2. Most of efforts were placed in QC validations(i.e. – data evaluation) and not on shipment of product and distribution

Words of Wisdom

We have to disrupt ourselves so we can continue to improve.

Unless we want to use the product
We don't invest in it !!



Who is Technopath?

Technopath Clinical Diagnostics – Founded in 2004 in Ireland, specializes in **consolidated** quality control solutions, informatics systems for the In-Vitro Diagnostic market

- Global contracts with **Abbott and Beckman**
- Managing Data for **>10,000 laboratories**
- Products used by **>13,000** customers in over **120** countries
- FDA approved and ISO certified



Technopath Clinical Diagnostics USA

- **Joint Venture** of Technopath Clinical Diagnostics and Northwell Health



TECHNOPATH
CLINICAL DIAGNOSTICS
USA

References

1. Reichberg, S.B and Aniceto, R.T (2018) "*Quality Control Materials With Extended Availability.*" American Association of Clinical Chemistry Annual Scientific Meeting Abstract A-259, page S87.

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Questions?

