Validation of Interfaces: Our Home Grown Approach to Effectively Feed Lab Data into the Myriad of HIS, LIS, EHRs and Mobile Devices in Today's Connected Healthcare System

Presented by

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North Shore LIJ Laboratories

CONFIDENTIAL EDUCATION LAW 6527 - PUBLIC HEALTH LAW 2805, J., K., L., M.

Goals and Objectives

- To identify common strategies to effectively validate lab interfaces
- To describe the most effective approach and tools to accomplish validations
- To eliminate unnecessary steps in the validation process
- To create a workable plan to validate various electronic laboratory interfaces

North Shore LIJ At-A-Glance

NSLIJHS Vital Statistics

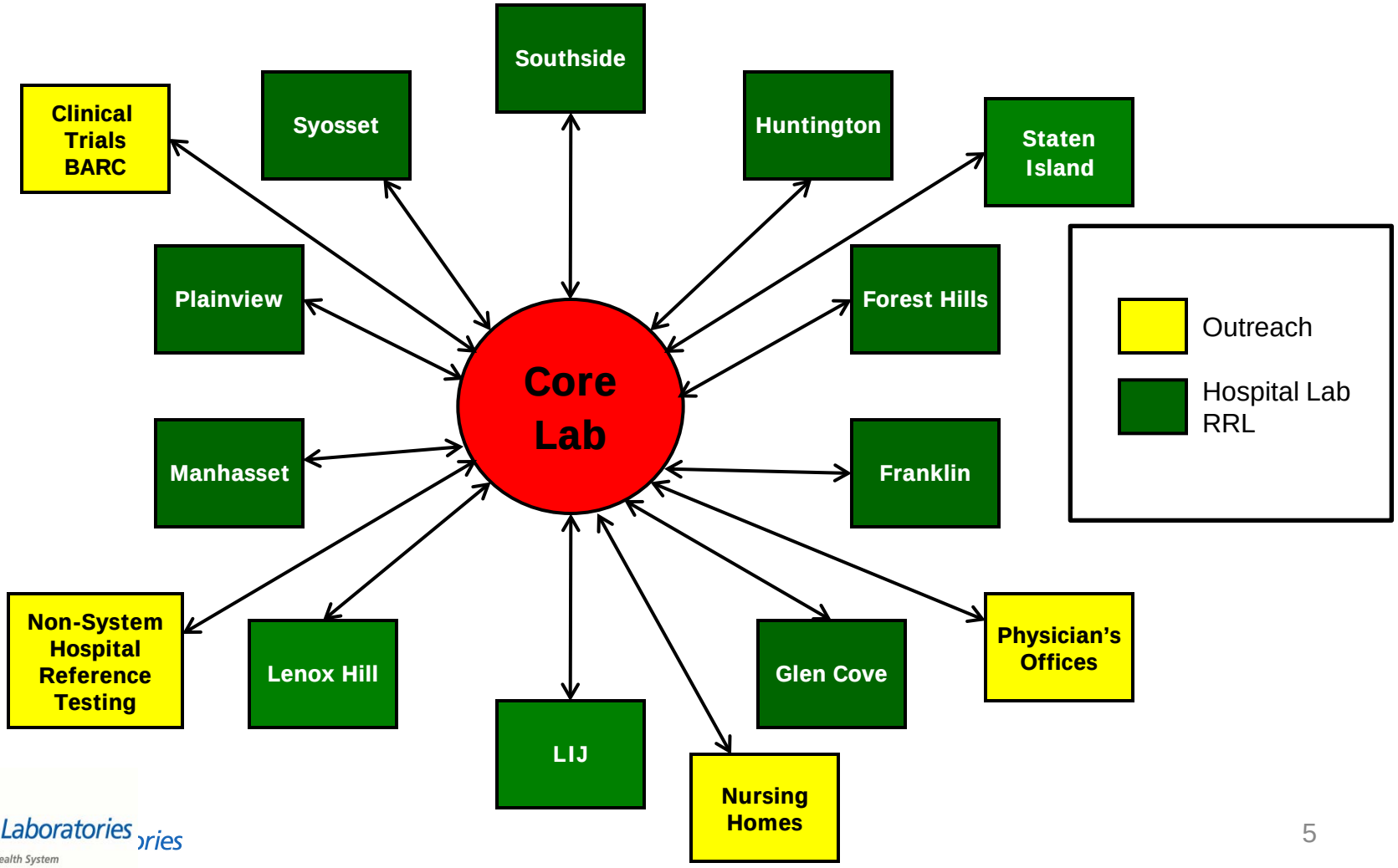
2013 Key Facts

- 12 Hospitals (6000 hospital and Long term care beds).
- Owner/operator of North Shore LIJ CareConnect Insurance Company, Inc.
- 3 Skilled Nursing Facilities.
- Nearly 400 ambulatory and physician practices.
- Service area of 7 million people in Long Island, Queens, Manhattan and Staten Island.
- Home of the largest “Corporate University” in the healthcare industry – Center for Learning and Innovation

2013 Economic Impact

- $7 billion operating budget
- More than 48,000 employees – Largest private employer in NYS
- More than 9,400 physicians
- More than 10,000 nurses
- More than 4,725 volunteers

Laboratory Network
NorthShore LIJ



North Shore LIJ Laboratories
North Shore-Long Island Jewish Health System

Our Model - Consolidated Laboratory Network

- Central “Core” Laboratory
- 12 Hospital Based Labs
- $300 Million Annual Operating Budget
- 1400 FTEs/ 80+ Pathologists
- 16+ Million Billable Tests
- 180,000 Surgical Specimens
- 30 + Patient Service Centers
- Multiple Ambulatory Sites

North Shore LIJ Laboratories
North Shore-Long Island Jewish Health System

Our Model - Consolidated Laboratory Network

- Strategically Located Core Laboratory – 60,000 sq. ft.
- Anatomic Path Subspecialty – 25,000 sq. ft.
- LIS & Billing – 15,000 sq. ft.
- Rapid Response Laboratories (RRL)
- Standardized Test Menu
- Standardized LIS (Cerner)
- Standardized Laboratory Instrumentation
- Standardized Policy and Procedures

Core Laboratory

- Strategically Located – Highly Automated
- 40 - 50 Percent Hospital Lab Tests
- Routine Testing
- Microbiology/Virology
- Esoteric – Molecular, Virology, Special Testing
- Reference Testing – All Send Outs
- Subspecialty / Pathology
- Active Sales Department

Core Laboratory Business Lines 2013

Business Line	Volume	Revenue
Physician	5,813,566	$ 111,058,701
Nursing Home	511,102	$ 4,632,674
Clinical Trial	150,910	$ 3,660,636
Reference	40,062	$ 890,394
Total Outreach	6,515,640	$ 120,242,406
Hospital	1,737,305	$ 31,589,143
TOTAL	8,252,545	$ 151,831,549

North Shore LIJ Laboratories
North Shore-Long Island Jewish Health System

Find the Right Partner-Alignment

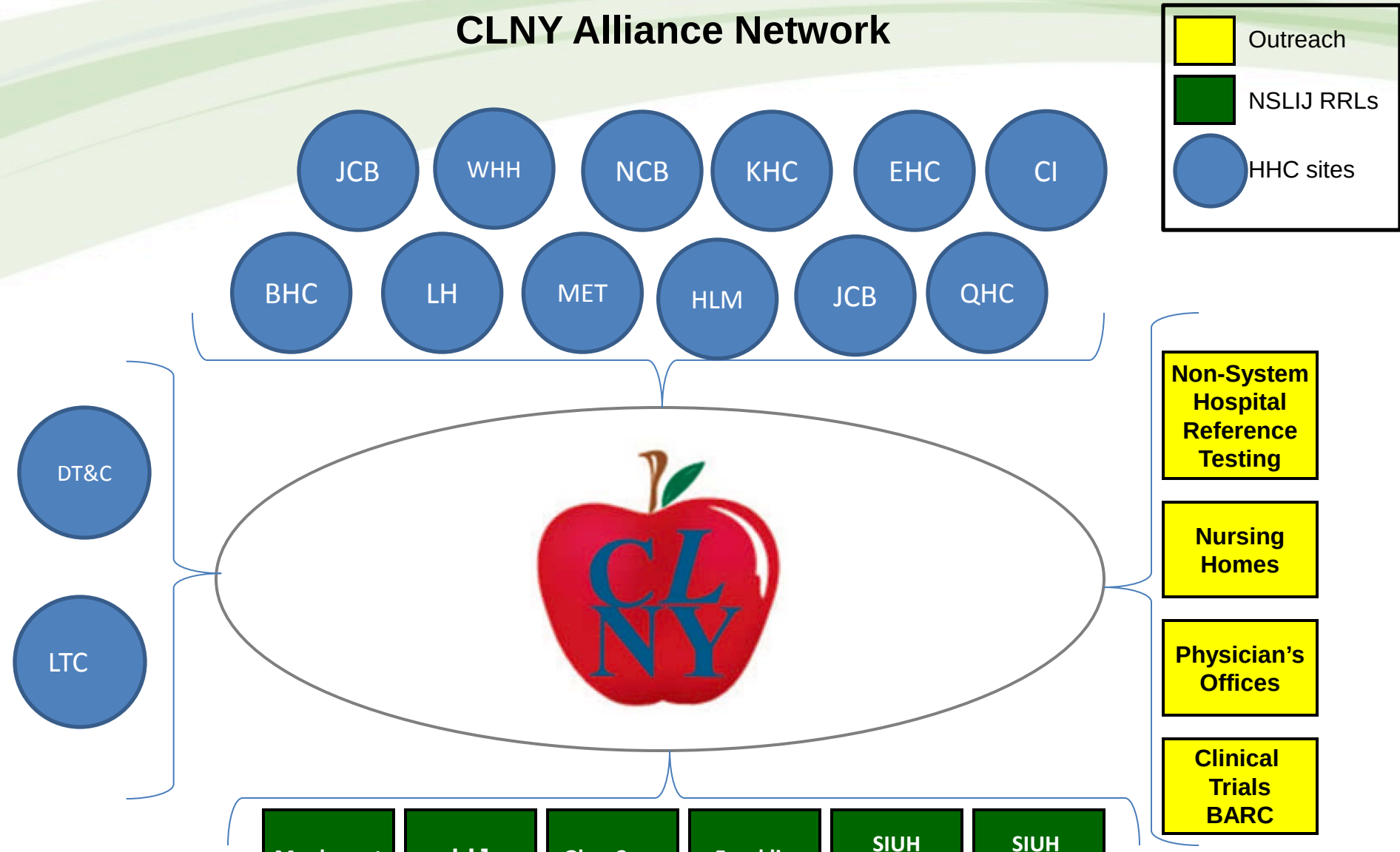
NSLIJ

- Central "Core" Laboratory
- 12 Hospital Based Labs
- $260 Million Annual Operating Budget
- Approx. 1400 FTE's
- 16 Million Billable Tests/year
- Not-for-Profit Health System
- Focus on Patients, Community and Education

HHC

- 4 "Core" Laboratories
- 11 Hospital Based Labs
- $260 Million Annual Operating Budget
- Approx. 1400 FTE's
- 16 Million Billable Tests/year
- Public-Benefit Corporation
- Focus on Patients, Community and Education

CLNY Alliance Network



Why Validate?

- Regulatory Requirement
- Patient Safety
- Ensure all elements of a computer system perform as expected
  - Accurately and Reproducibly
- Good business practice
  - Find and Resolve Problems
- Prevent Possible Litigation

HOW MUCH VALIDATION IS NEEDED?

Regulatory and Accrediting Agencies

- FDA - CFR title 21, part 11
- CLIA – 493.1291(a) – Standard: Test Report
- CAP -Gen 48500 – Interface Result Integrity
- ISO 15189 – 5.10.3- Information System Mgmt
- NYS DOH – LIMS S4 – Validation
- CLSI -AUTOo8-A Managing and Validating Laboratory Information Systems

Regulatory and Accrediting Agencies

- FDA/CLIA – 493.1 291(a) – Standard: Test Report
  - The Lab must ensure test results and other patient specific data are accurately and reliably sent from the point of data entry to final report destination.
- CAP -Gen 48500 – Interface Result Integrity
  - There is a procedure to verify that patients results are accurately transmitted from the point of data entry to patient report prior to implementation, every two years thereafter.
- NYS DOH – LIMS S4 – Validation
  - Laboratory shall validate any system changes including new and revised software/hardware changes prior to their use for specimen testing, reporting and report keeping functions. Medical Director and Lab Management must approve any installation validation of new systems.

Pre Lean Validation Team Structure

- Team Lead by LIS Dept Only
  - System Hospital HIS Interfaces
  - EMR Interfaces
- Each LIS Division Developed Own
    - Validation and Post Validation Plans
    - Testing and Approval
    - Documentation
      - Final Documentation and Approvals
      - Maintained by own team
- Minimal Interaction with Lab

NSLIJ Lab Validation Challenges

- Formed alliance with NYC Health and Hospitals
  - Required interfaces between their HIS/LIS and our LIS
  - Involved interfacing 21 HHC sites via middleware to Core Lab LIS in 8 months
- Rapid growth in the number of outreach clients resulted in the need for rapid validation of various new EMRs
- Demand for availability of Laboratory results via high tech electronic handheld devices

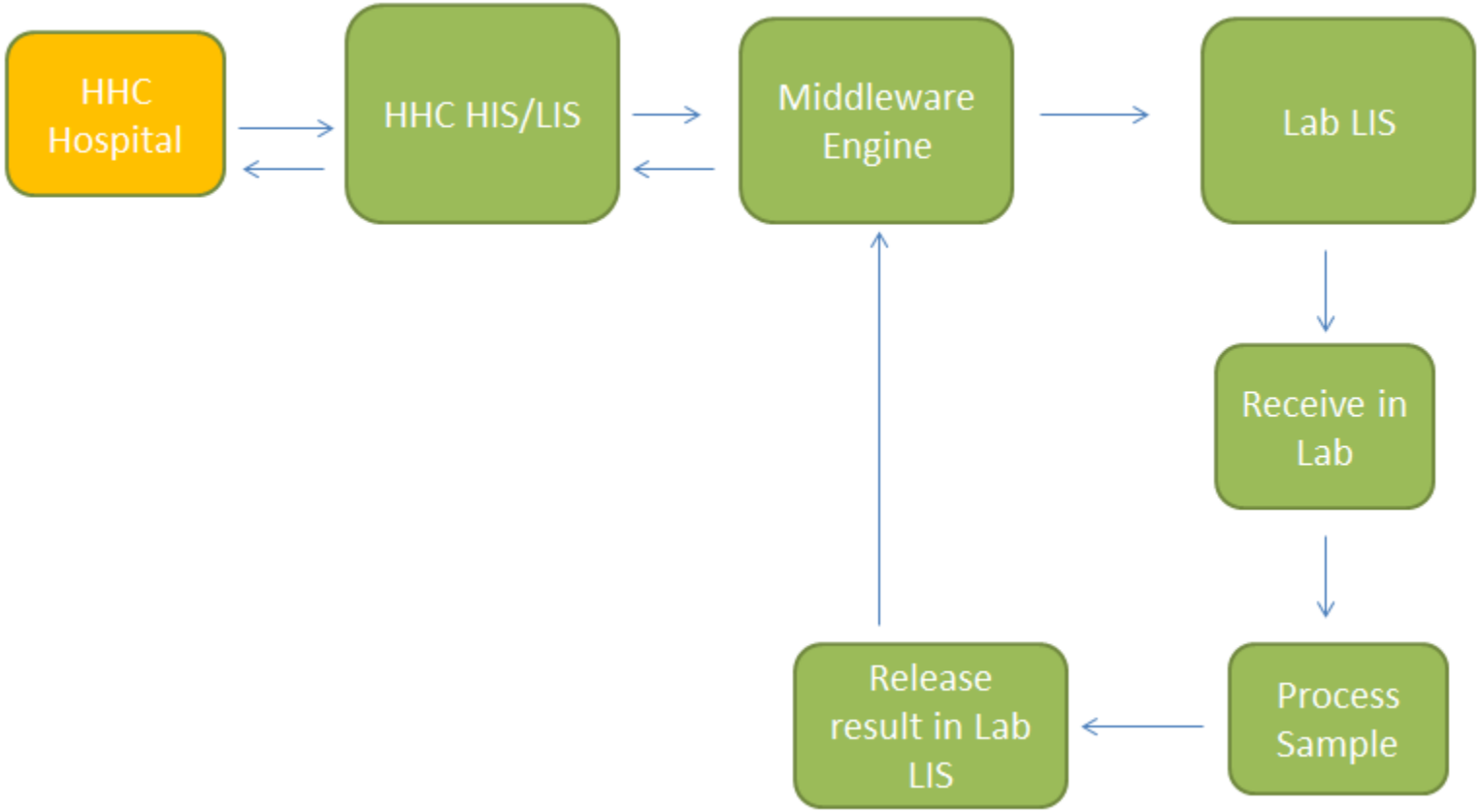
Hospital Validation-NYC HHC

North Shore LIJ Lab

Hospital Validation-NYC HHC

- NYC Health and Hospitals Corporation Initiative
- 21 Sites
- 8 Hubs
  - Each Hub Differs from the Others
- Scope of Project required working with IT Consultants

HHC HIS/LIS Data Flow



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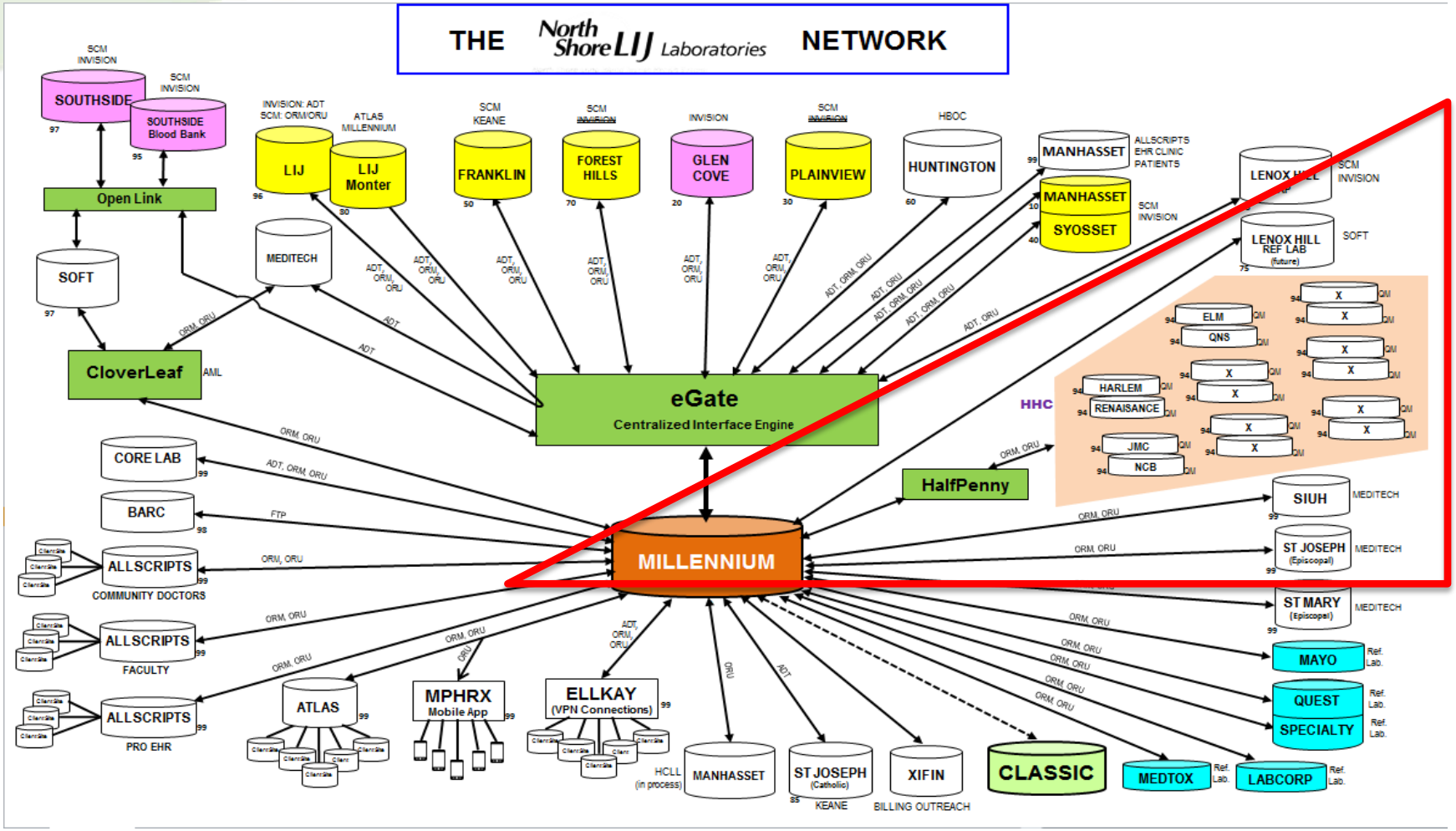
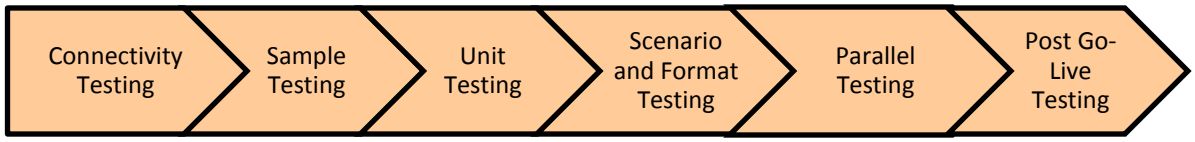
HHC/NSLIJ Lab Data Flow



Pre-Lean Initial Validation Plan

- Original HHC HIS/LIS Validation



- Initial Validation Plan Included 6 Phases:
  - Connectivity Testing
  - Sample Testing
  - Unit Testing
  - Scenario and Format Testing
  - Parallel Testing
  - Post Validation Testing

Pre-Lean Initial Validation

- Initial Validation Plan

Phases	Step 1	Step 2	Step 3	Step 4	Step 5	Step 6	Step 7	Step 8
Category	**Orders in Quadramed (@HHC IT location)**	**Review or Orders in Cerner (@NSHS)**	**Resulting Orders – Performed in house (@NSHS)**	**Result Orders – Sendout tests (@NSHS)**	**Quadramed (@HHC IT Location)**	**Quality Management (@NSHS)**	**Xifin – Billing System**	**HHC Signoff**
Tasks	Place orders for the requested tests in Qmed LIS system. Build and trasmit manifest	Receive the specimen in lab (scans label) Captures screenshot of the order in Cerner Check Quadramede Manifest Check Quadramed label Print Cerner label	Enters results Print screen of results from Cerner in Order Result Viewer (ORV). Print patient chart with the results from Cerner	Build transfer list Log in transfer list/transmit orders Contact ref lab Review results in Cerner when provided by ref lab Print patient chart with the results from Cerner	Print screen of results from Quadramed Print patient chart with the results from Quadramed Match screenshots to packets	Review Packets Identify Issues Work with LIS on resolution/retest Validation of reports and Utilization, TAT, Pending Reports Final Sign off	Validate Charging for all tests Pull billing reports and validate format and accuracy	Review Packets, Validate result format in Qmed, Validation of reports and Utilization, TAT, Pending Reports Final Sign off
Scope	38 Orders 4 Patients 10 Orders max per patient 10 Patients max per Manifest	38 Orders 10 Orders max per patient 10 Patients max per Manifest	10 Orders 1 Patient	20-30 Orders 3 Patients	38 Orders 4 Patients 10 Orders max per patient 10 patients max per Manifest	38 Orders 4 Patients 10 Orders max per patient 10 Patients max per Manifest	38 Orders 4 Patients 10 Orders max per patient 10 Patients max per Manifest	38 Orders 4 Patients 10 Orders max per patient 10 Patients max per manifest
Resources	1 HHC LIS	1 NS LIS Analyst	1 NS LIS Analyst	1 NS LIS Analyst	1 HHC LIS, 1 NS LIS Analyst	1 NS QA	1 NS Analyst	1 HHC LIS Analyst, 1 HHC Project Sponsor
Skills	Accessioning Skills, Ordering Experience	Accessioning Skills, Ordering Experience	LIS Analyst	LIS Analyst	1 Accessioning	1 Q.A	1 Xifin Specialists	Clinical Representative
Duration	4 Hours	4 hours	2 hours	4 hours	4 hours	4 hours	4 hours	4 hours
In Timeline	Day 1	Day 2	Day 3	Day 3	Day 4	Day 5	Days 6-10	Days 6-10
Comments	Days 4-5 troubleshooting issues	Test Script will include name of test in Quadramed and name of test in Cerner (translation of test names between two systems		Core lab will work with each independent reference lab to coordinate resulting of orders	Same FTE that has been trained on placing orders	Need a result example of every test from Quadramed (provided by HHC). This process needs to start at beginning of a testing cycle.	Only performed for the first site	Performed for each Qmed hub

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Pre-Lean Initial Validation

- Test Script Checklist

	A	G	H	I	J	K
3						
4	Patient Name	TestHLM, UnitNine	TestHLM, UnitNine	TestHLM, UnitNine	TestHLM, UnitNine	TestHLM, UnitNine
5	Quadramed MRN	73	73	73	73	73
6	QUADRAMED 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)
7	Quadramed Accession Number	2000152-1	2000152-1	2000152-1	2000152-1	2000152-1
8	Quadramed Ordered Date/Time	12/18/2013	12/18/2013	12/18/2013	12/18/2013	12/18/2013
9	Quadramed Manifest Number	36	35	35	35	35
11	NSLIJ Core Lab Received By	sriley2	sriley2	sriley2	sriley2	sriley2
12	Cerner Accession Number	99-13-352-70015	99-13-352-70006	99-13-352-70006	99-13-352-70006	99-13-352-70006
13	Cerner Financial Number					
14	CERNER ORDER DESCRIPTION	C1 Esterase Inhibitor	Amylase Isoenzyme	Hepatitis Delta Antibodies	Polio Virus Antibodies	Haloperidol
15	Cerner Packing List (if send out test)(In front of Manual)					
16	Results from Cerner Posted (Pass/Fail)	Pass	Pass	Pass	Fail	Pass
17	Comments				Cancelled. To be retested	
18						
19	VALIDATION DOCUMENTATION RECEIVED					
20	HHC Order	X	X	X	X	X
21	HHC Manifest	X	X	X	X	X
22	Cerner Order	X	X	X	X	X
23	Cerner Results	X	X	X		X
24	Cerner Chart	X	X	X		X
25	Screenshots of results in Qmed EMR/HIS	N/A	N/A	N/A	N/A	N/A
26	HHC Chart	X	X	X		X
27	Reference Lab Chart	X	X	X		X
28	Xifin Charge:	N/A	N/A	N/A	N/A	N/A
29	Verified By:	N/A	N/A	N/A	N/A	N/A
30	Completed Testing Script Spreadsheet					
31						
32						
33	Reviewed / Approved By:					
34						
35	Date:					
36						

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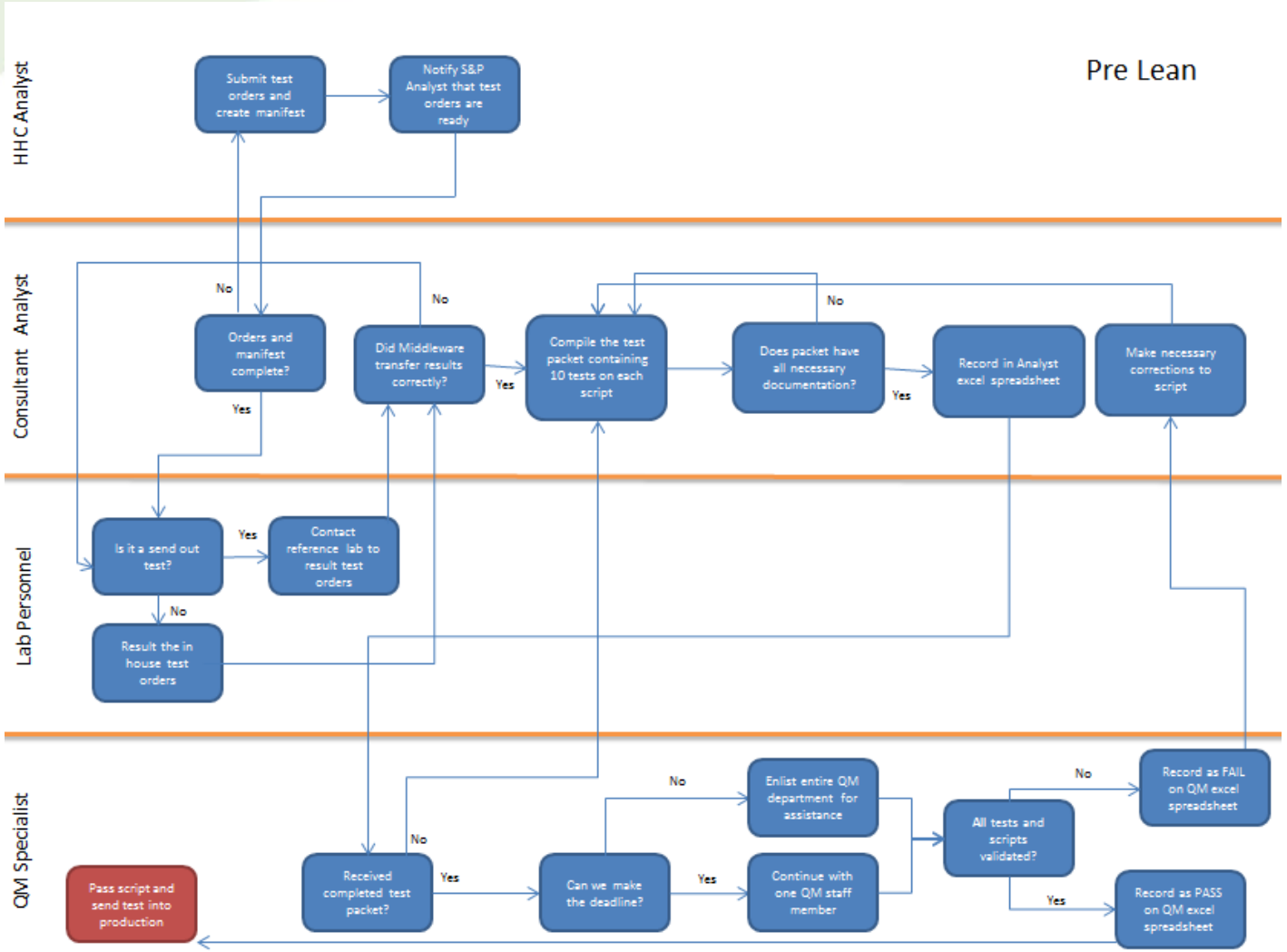
Pre-Lean Validation Plan/Checklist Issues

- Too many tests validated per patient causing high rate of script failure
- Documentation was difficult to obtain from all parties involved (HHC/NSLIJ/Reference Labs)
- Validation test plan/test script checklist were difficult to follow
- Lack of communication
  - Many different people involved at many different locations (HHC LIS/Consultants/NSLIJ LIS/Middleware LIS/ Lab Operations/Quality Management
  - Misunderstanding of roles and responsibilities of each person

Pre-Lean Validation Plan/Checklist Issues

- Tracking of Issues
  - Many versions of issue logs
  - Poor documentation on logs
  - Lack of consolidation of issues
- Documentation of validation performed by LIS and not communicated to QM
  - Unable to tell which tests failed and which passed
  - If failed, where was documentation of retest?
- Writing of new scripts while running of retests
  - Became disorganized and confusing

Pre-Lean Validation Process Flow



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Lean Process

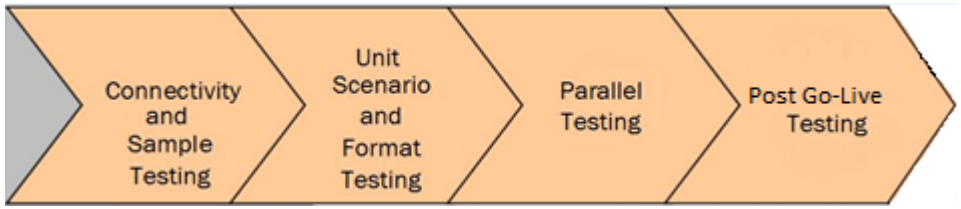
- Took 3 months of weekly meetings
- Engaged Laboratory Operations, LIS and Quality Management
- Identified Non-Value Added Steps and removed from the validation plan
- Identified Process Improvements and implemented them

Post Lean Validation Team Structure

- NSLIJ Laboratories Validation Structure
  - LIS Department - Hospital Group
  - Lab Operations
  - Lab Technical Personnel
  - Quality Management

Post Lean Validation Plan

- Streamlined Validation Plan
  - Combined connectivity and sample testing
  - Combined unit testing and scenario /format testing

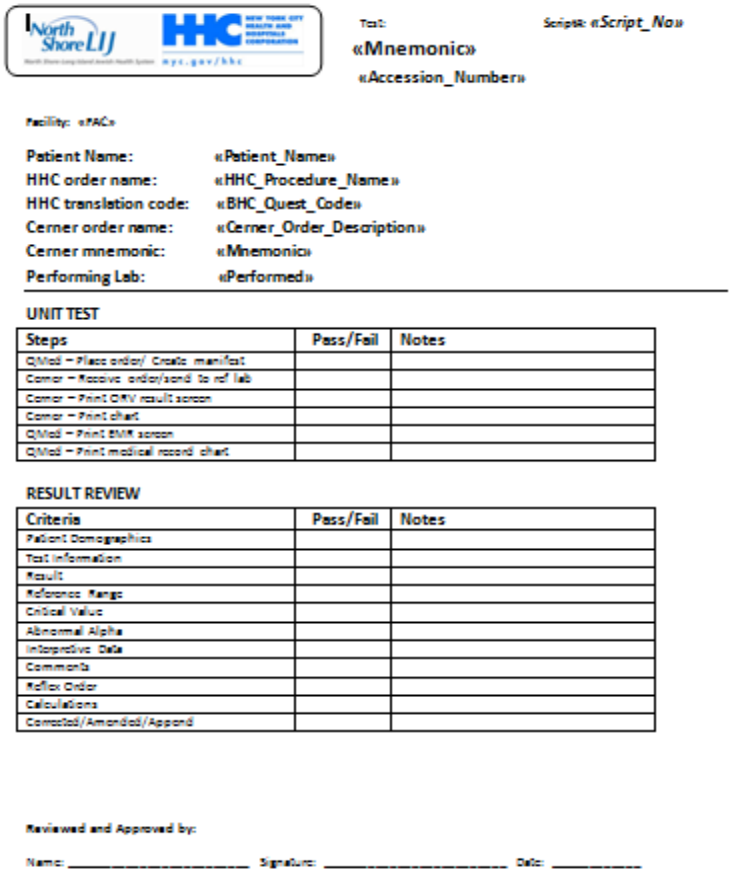


Post Lean Validation Plan

- Changes included:
  - Reduction in the number of documents required by the test script.
  - Streamlined script to include only one test / test patient to allow for completion of the script from beginning to end and facilitate tracking of failures/issues.
  - Use of a shared test script tracking spreadsheet by LIS and QM called the “SMART SHEET”
  - Obtain and review test compendium for each site and prioritize test scripts
  - Improved communication through the implementation of “touch point” meetings
  - Assignment of outstanding test scripts to a designated person

Post-Lean Validation

- Test Script Checklist
  - Patient Demographics
  - Test Name
  - Result Value or Text
  - Result Review
    - UOM
    - Reference Range
    - Critical Flagging
    - Abnormal Alphas
    - Calculations
    - Interpretive Data
    - Reflex Orders
    - Comments
  - Corrected Results



Test: «Mnemonic»
«Accession_Number»

Script#: «Script_No»

Facility: «FAC»

Patient Name: «Patient_Name»
HHC order name: «HHC_Procedure_Name»
HHC translation code: «BHC_Quest_Code»
Cerner order name: «Cerner_Order_Description»
Cerner mnemonic: «Mnemonic»
Performing Lab: «Performed»

UNIT TEST

Steps	Pass/Fail	Notes
CMed – Place order/ Create manifest		
Cerner – Receive order/send to ref lab		
Cerner – Print ORV result screen		
Cerner – Print chart		
CMed – Print BMP screen		
CMed – Print medical record chart		

RESULT REVIEW

Criteria	Pass/Fail	Notes
Patient Demographics		
Test Information		
Result		
Reference Range		
Critical Value		
Abnormal Alpha		
Interpretive Data		
Comments		
Reflex Order		
Calculations		
Corrected/Amended/Append		

Reviewed and Approved by:

Name: _____ Signature: _____ Date: _____

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Post-Lean Validation

- Test Script Tracking Status

Account ? Help Search... Upgrade

Home | Bellevue Unit Testing Status Detail | Gouverneur Unit Testing Status Detail | Coler Unit Testing Status Detail | Lincoln Unit Testing Status Detail

	QM Result	Script #	Patient Name	Quest Order Code	HHC Order Procedure Name	Cerner Mnemonic	Cerner Order Decription	Volume
1	Pass	1	NSLIJ,LHCA	36637T	10-Hydroxycarbazepine, Serum (Qu	OXCARB	Oxcarbazepine	1
2	Pass	2	NSLIJ,LHCB	8352X	17-Hydroxy Pregnenolone Level,Ser	Pregnenolone (ESO)	Pregnenolone (ESO)	17
3	Pass	3	NSLIJ,LHCC	17180X	17-Hydroxy Progesterone Level,Ser	HYPROG ESO	17-Hydroxyprogesteror	136
4	Pass							
5								
6								
7	Pass							
8	Pass							
9	Pass							

Upgrade smartsheet

Gouverneur Unit Testing Status Detail | Coler Unit Testing Status Detail | Lincoln Unit Testing Status Detail

Performed (Inhouse/SO)	LIS Pass	LIS Status	Date Reported	Date Resolved	Status	Assigned To	LIS Issue Notes/Comments	QM Issue	QM Issue Notes/Comments	Qm Issue Identified
SO	Yes	Sent to QM	07/23/14	07/23/14			Missing Ref Range, UC	No patient care issue ic		
SO	Yes	Sent to QM	07/28/14				Per QM Abnormal flag	No patient care issue ic	8/22 Issue resolved by Jeanne. (1) Result is high but no flag on both CERNER and Qmed. (2) Accession numbers are different in CERNER and Qmed.	
SO	Yes	Sent to QM						No patient care issue ic	7/30 - Reprinted and sent new documentation to QM Accession numbers differ in Qmed and CERNER.	
SO	Yes	Sent to QM						No patient care issue ic	7/30 - Reprinted and sent new documentation to QM Accession numbers differ in Qmed and CERNER.	
SO		In Cerner								
SO	Remov						Per JBK, Test cancelle			
SO	Yes	Sent to QM						No patient care issue ic		
SO	No	Sent to QM					8/6 - ETimms: Critical fl	Critical flagging missing	8/22 Issue resolved by Jeanne.No flags for critical Acetone level in CERNER or Qmed.	
SO	Yes	Sent to QM						No patient care issue ic		

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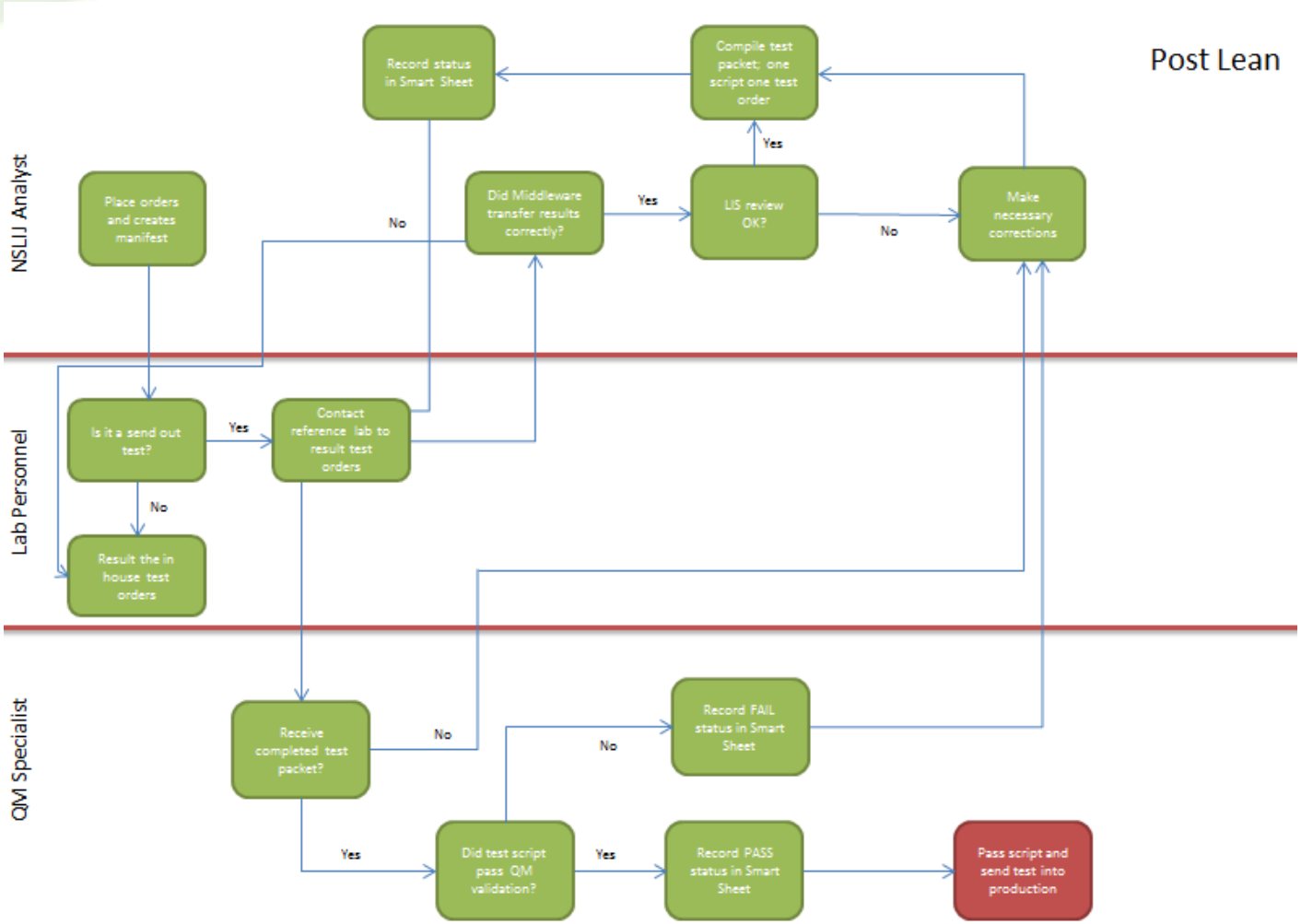
Post-Lean Validation Process Flow



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HHC Common Validation Errors

- Truncation of Textual Test Results/Comments
- Report Formatting Issues
- Logical Display of Results
- Flagging of Abnormal Result
- Accurate Reference Ranges/Units of Measure
- Validation of User Display of Results
- Handling of Complex Reports Containing an Abundance of Text and Tables which can Become Scrambled

Validation Documentation

- Hard or Electronic Copy Acceptable
  - Interface Implementation Test Plan Overview Approval Page
  - Interface Test Script Validation Approval Page
    - IT Director and AVP Labs – NSLIJ Labs
    - Medical Directors - NSLIJ Labs and HHC Site
  - Table of Contents
  - Test Plan Overview Process Document
  - Manifests with Test Orders
  - Test Scripts
  - Scenario

Validation Statistics/Metrics

- To Date there were
  - Thirteen sites validated
  - Approximately 3000 test results validated
  - Approximately 400 UNIQUE tests validated
- Lean Metrics
  - Pre-Lean Resources Metrics– Approx 15 FTE
  - Post-Lean Resources Metrics-Approx 5 FTE
    - Approximately 67% Reduction in Resources!
    - Or Savings of $430,125 per hub

Validation Statistics/Metrics

- Lean Metrics-Cont
  - Average Turn Around Time (TAT) per HHC hub
    - Pre-Lean = Approximately 3 months
    - Post-Lean = Approximately 1 month
  - Average Volume of Failed Scripts
    - Pre-Lean = 69 out of 196 test scripts (35%)
    - Post-Lean = 6 out of 229 test scripts (3%)

Hospital Validation Summary

- Test Compendiums, Test Definitions and Test Nomenclature Should Be Compared and Standardized prior to performing validations
- Make the test validation plan flexible enough to handle situations that come up
- Perform trial run of the process from start to finish to get out all of the kinks and the process of passing data around
- Organization of binders for presentation to the client makes all the difference!

Hospital Validation Outcome

From:

- Chaos
- Stress
- Long Hours
- Excessive Rework
- Poor Communication

To:

- Cohesive Teamwork
- Calm
- Efficient Validation Team
- Correct the First Time
- Daily Touch Point Meetings

Looking Forward to the Next Challenge of Implementing a New HIS System for HHC and Other Hospitals Joining the NSLIJ Team!

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EMR Validation-Outreach Clients

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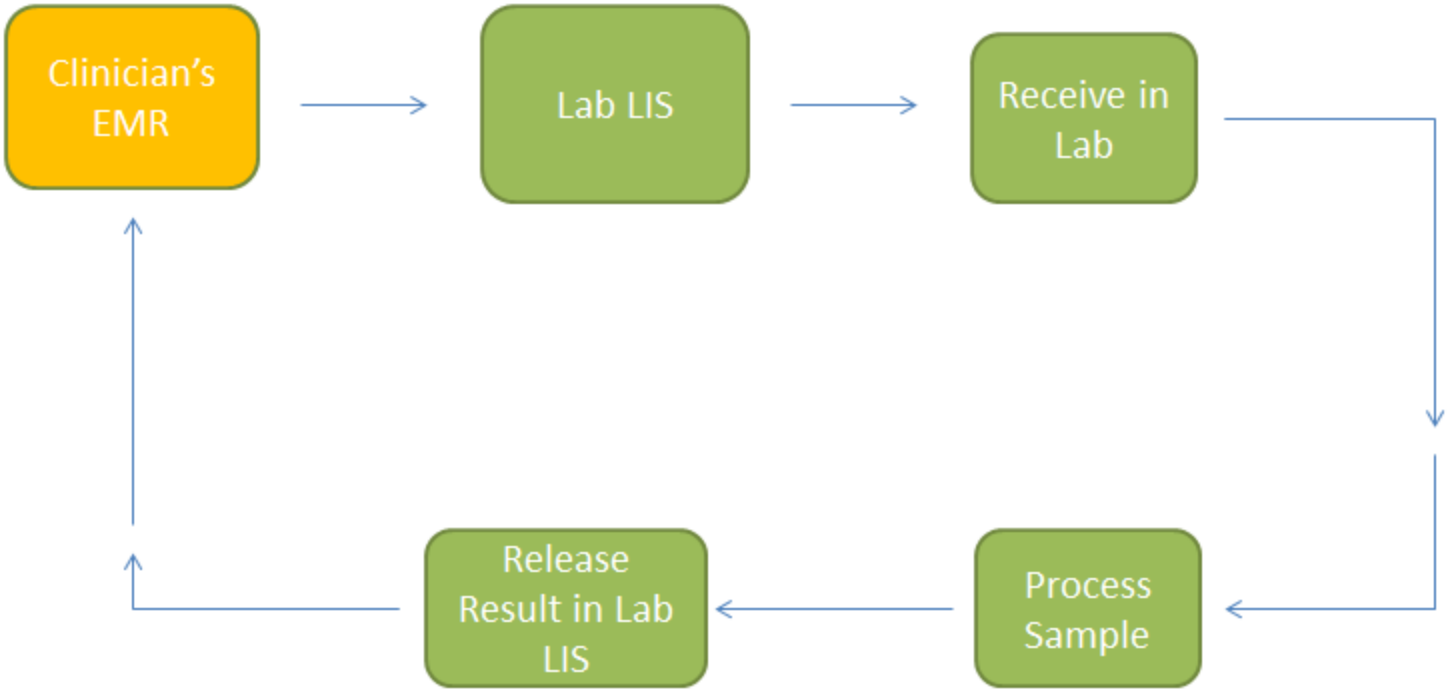
EMR Validation-Outreach Clients

- Faced with an Ever Growing Number of Outreach clients with a myriad of EMRs requiring interface validations to our LIS simultaneously
  - 100s of sites
  - Number of different EMRs – A LOT!
    - Allscripts, Atlas, Comtron, i-Patient, Epic, etc
- To Perform Validation Must Engage EMR Vendors, LIS Outreach Team and Clients

EMR Data Flow



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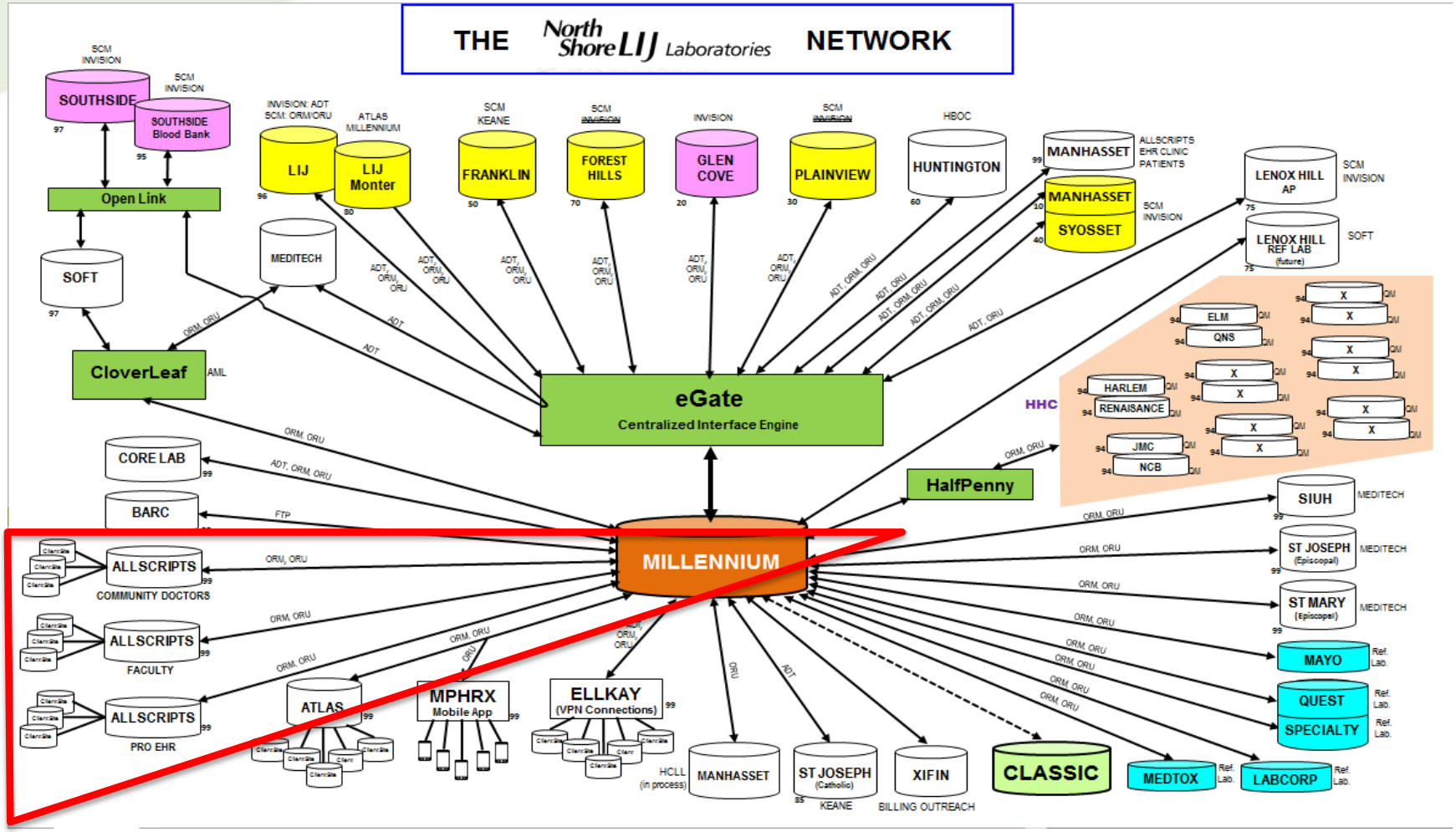
EMR/NSLIJ Lab Data Flow

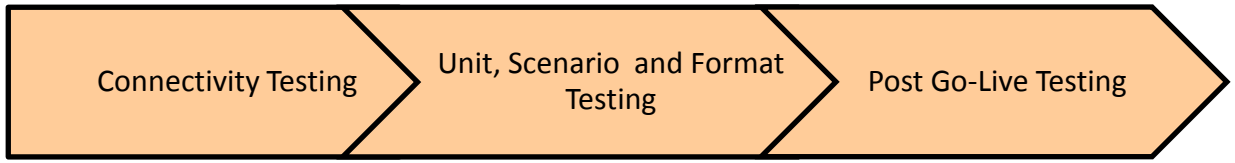


EMR Lean Validation Structure

- We Learned Many Lessons from HHC HIS/LIS Validation Lean Process. These were adapted for use in Outreach EMR Validations
- Streamlined Validation Plan and Test Script Checklist based on HHC Lean Process
- Streamlined Team Approach Incorporating LIS, QM, Lab Operations, Sales, Client and/or Vendor.

EMR Lean Validation Plan

- Streamlined Outreach Client Validation Plan



- Validation Plan Includes 3 Phases:
  - Connectivity Testing (Combined with Sample Testing)
  - Unit, Scenario and Format Testing (Combined)
  - Post Validation Testing
    - Parallel Testing Eliminated – "Dry Run"

Lean Validation Plan

- Streamlined Outreach Client Test Script Checklist

Step #	System	Step	Expected Outcome	Documentation	Pass / Fail	Issue	Resolution	Date/ Initials
1	Client	Register: **AllscriptPro, Test2** NAME: **AllscriptPro, Test2** GENDER: **Female** MRN: **Please provide** Insurance Primary: **MEDICARE** Insurance Secondary: **MEDICAID** Relationship Type: **Self for Primary/Self for Secondary** Requisition #: **1533-00955**	Patient is registered	Req	PASS			4/24/2014
2	Client	Place **ROUTINE** orders for 5302000 - METABOLIC 5300145 - LDH 5300437 - TSHX 5302212 - GLYC 5600010 - UA 5300102 - LIPID 5500290 - CBC/DIFF 5300710 - URIC24 (AOE:Refer to AOE sheet) 5300520 - CRCLEAR	Orders are placed	Req	PASS			4/24/2014
3	Client	Verify Requistion and labels printed.	Requisition and labels	Sample	PASS	Labels will print once		4/24/2014
4	LIS	Verify Patient registration	Patient registration is correct in HNAM	Screen Print	PASS			4/24/2014
5	LIS	Verify orders display	Orders display in HNAM with correct priority and route to appropriate collection list	Screen Print	PASS			4/24/2014
6	LIS	Receive orders into HNAM	Status updates in HNAM to "In Lab"	Screen Print	PASS			4/24/2014
7	Client	Verify status update of orders/In Lab/In Process	Status is updated to complete/in process for micro's	Screen Print	PASS			4/24/2014
8	LIS	Lab to result orders with a combination of Low, Normal, High and Critical. Micro's can be resulted as prelim's. **RESULT TSH AS ABNORMAL >20.. RESULT UA AS ABNORMAL FOR**			PASS			4/24/2014
9	Client	Verify status update of orders	Status is updated	Screen Print	PASS			4/24/2014
10	LIS	Verify status update of orders	Status is updated	Screen Print	PASS			4/24/2014
11	Client	Verify status update of orders/In Lab/In Process	Status is updated	Screen Print	PASS			4/24/2014
12	Client	Lab to result orders with a combination of Low, Normal, High and Critical. Lab to finalize any pending	Expect finals across the boa	Screen Print	PASS			4/24/2014
13	LIS	Verify all orders are complete		Screen Print	PASS			4/24/2014
14	Client	Send final documentation of script to LIS	Final Report	Report	PASS			4/24/2014

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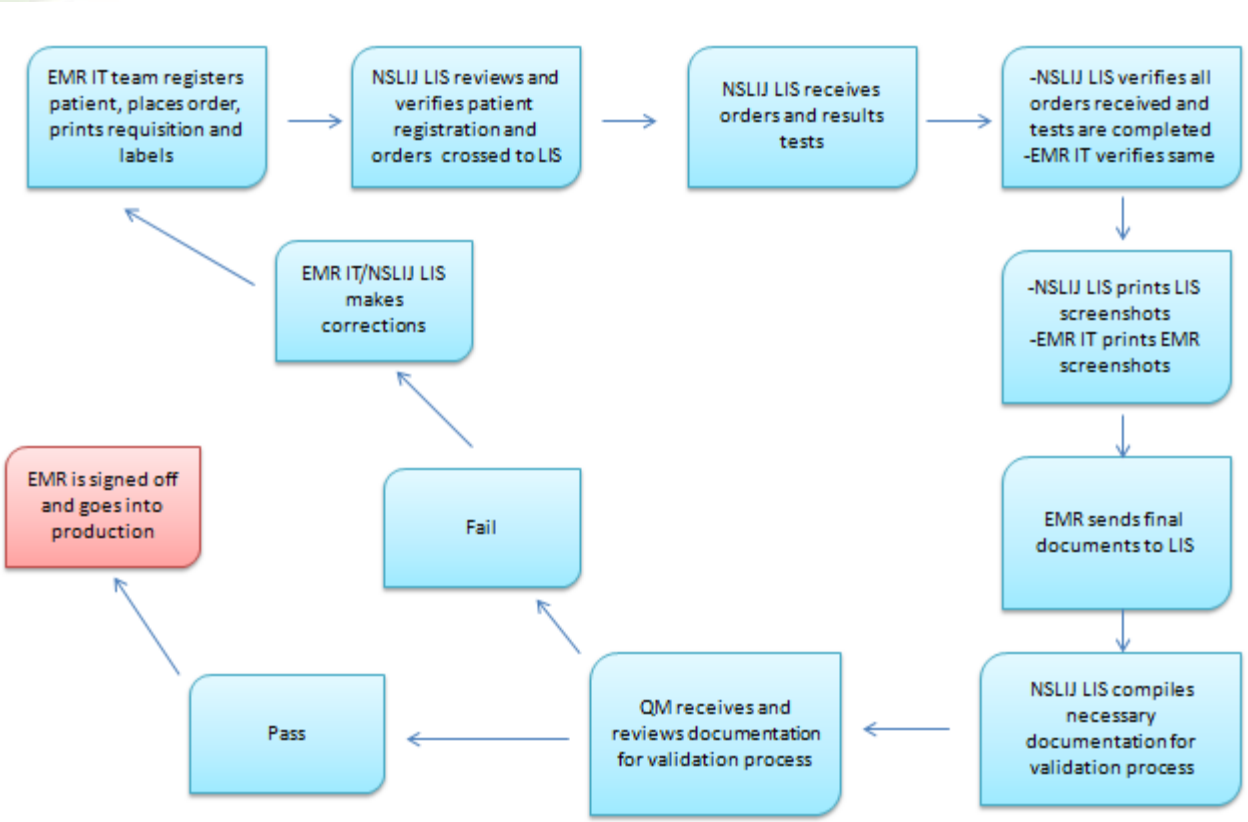
Lean EMR Validation Process Flow



New Streamlined EMR Validation Plan

- Patients and Tests to Validate Included:
  - Performed in Test Environment
  - Approx 10 Test Patients
  - Primarily High Volume and Esoteric Tests
  - Approx 1 – 15 Tests/ Test Patient
    - Various Areas of Lab
      - Chem, Special Chem, Serology, Hematology, Coagulation, UA
      - Blood Bank, Microbiology, Anatomic Pathology
      - Cytogenetics, Molecular Genetics
      - Reference Testing
  - Post Validation Testing
    - Occurs After Go-Live Using Same Validation Plan Criteria

New Streamlined EMR Validation Plan

- Fields to Validate Included:
  - Patient Demographics
  - Billing and Insurance Information
  - Test Name
  - Result Review
  - Comments
  - Reflex Order
  - Corrected/Amended/Appended Results

EMR Validation Errors

- Performing Facility Issues
  - Duplicate Listings
- Incomplete Order Comments
  - Gestation Age Missing Units
  - Weeks vs Days
- Missing Reference Ranges and Units
  - Vitamin D and K
- Calculation Issue
  - Creatinine Clearance and Uric Acid Blended as One Test
- Collection and Report Time Discrepancies

EMR Validation -What Worked Well

- Issues Faced Previously During the HHC Validation are No Longer Problematic
  - Electronic communication of validation documents from one person to another worked well
  - Documentation of validation steps performed by LIS and communicated to QM via spreadsheet worked well
  - Running of retests and subsequent documentation was more organized
  - Good documentation on the issue log was noted

EMR Validation -What Didn't

- Unanticipated Billing Issue Arose
  - 1° and 2° Insurance data transposed in Billing System
- Obstacles Faced During the Validation Process
  - EMR Vendors
    - Can be Very Uncooperative
  - Clients
    - Oftentimes Lack IT Support, Knowledge and Resources
    - Do Not Truly Understand the Importance of Lab Data Integrity
    - Not enough lead time to perform validation
    - Tend to be Reactive Rather Than Proactive
- However, the overall the EMR Validation Process Worked Very Well!

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EMR Validation Outcome

From:	To:
– Unilateral LIS Approach	– Multidisciplinary Approach
– Limited Expertise	– Benefits of Technical, QM, Operations, Sales Expertise
– Missed Errors	– Quality Validation
– Working in Silos	– Benefits of Collaboration
– Complex Broken Process	– Streamlined Process that WORKS!

Armed and Ready for the Multitudes of EMR Validations to Come!

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Mobile Device Validation

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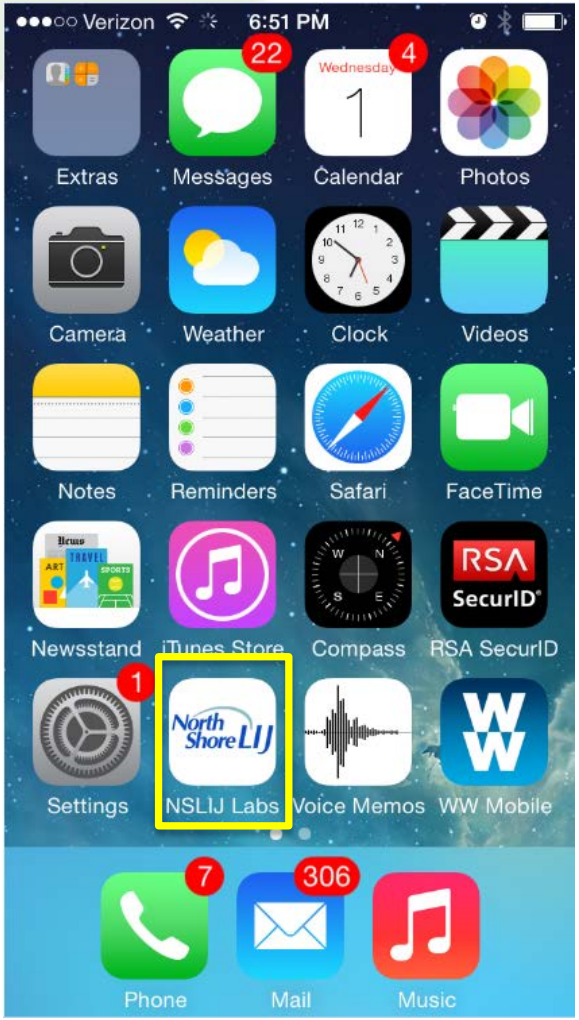
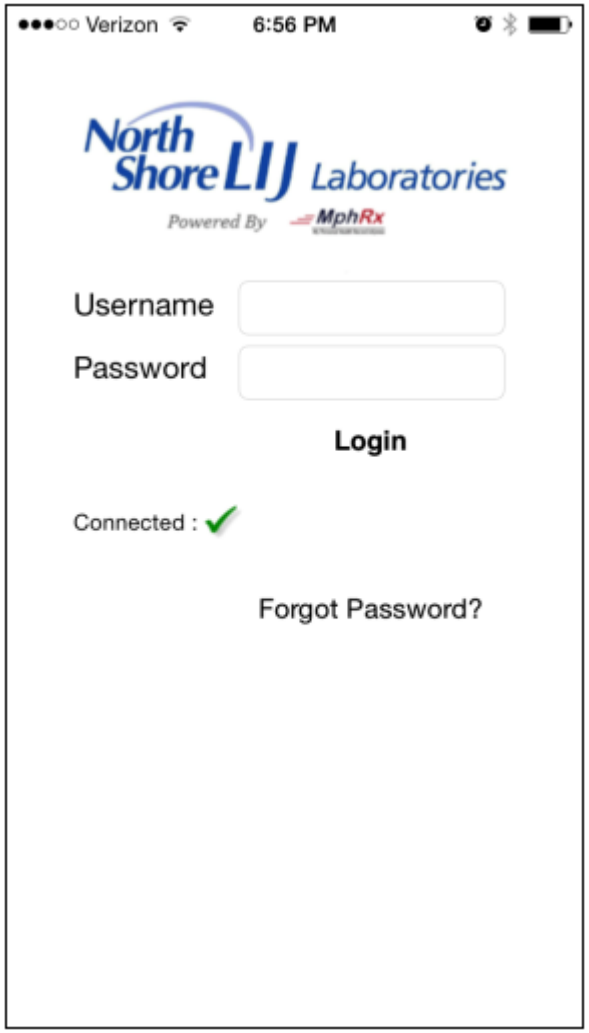
Mobile Device Validation

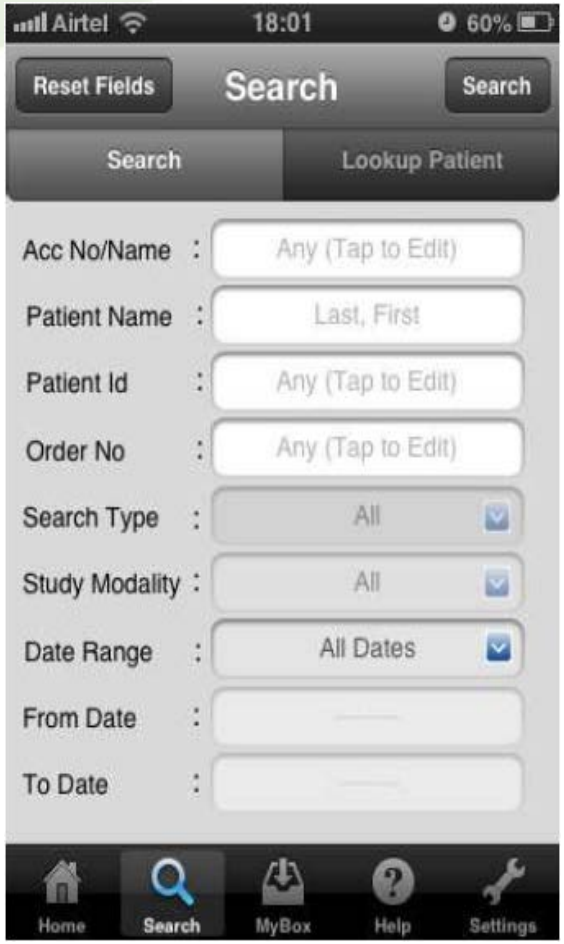
- Demand for rapid laboratory result data availability was fueled by advent of various high tech electronic handheld solutions
- Number of different Devices
  - iPhone
  - Androids
- Yes… the NSLIJ Laboratories now have an “App” for that!

Mobile Device Validation





Mobile Device Validation



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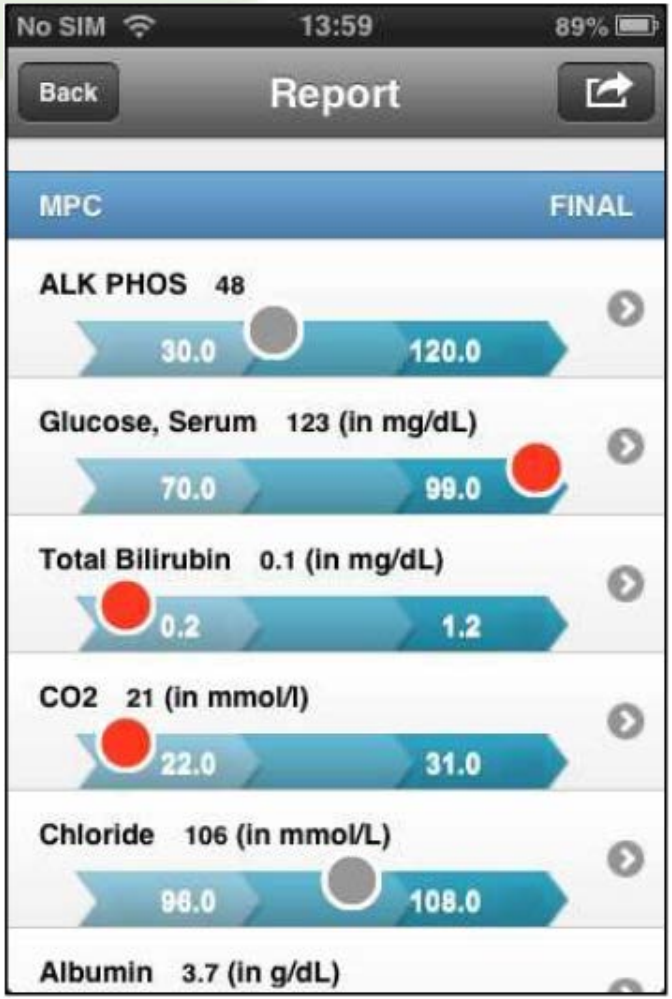
Mobile Device Validation



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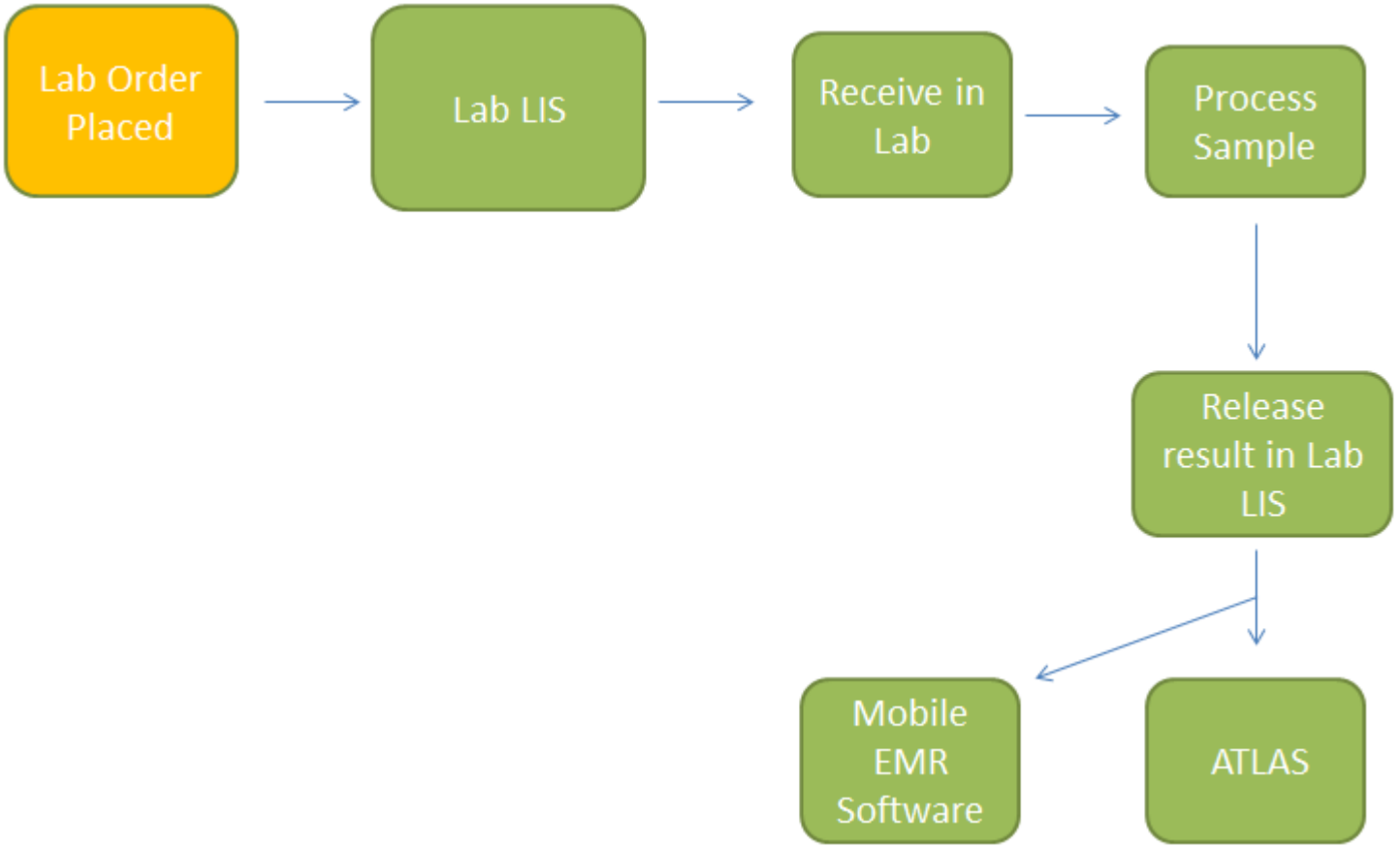
Mobile Device Data Flow



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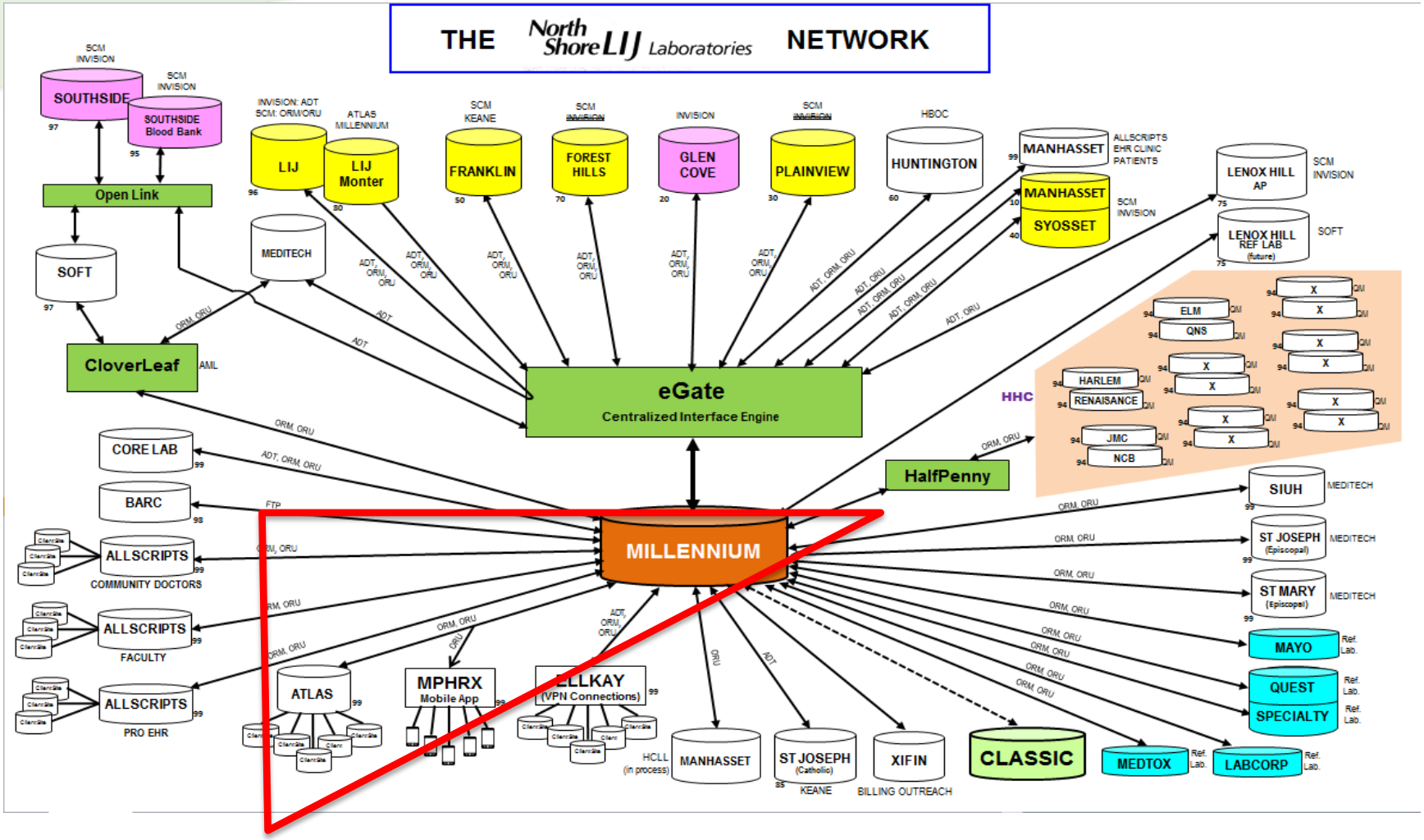
Mobile App/NSLIJ Lab Data Flow



Mobile Device Validation

- Scope of the project required working with the Application vendor, LIS and QM Departments and Sales
- Three Lab Result formats requiring validation:
  - Application Website – “Hard Copy”
  - iPhone App Display
  - Android App Display
- In the case of Smart Phone apps, security validations were also required

Mobile Device Validation

- Validation plan was formatted from prior LIS interface validation plans.
- The Validation Team included QM working together with LIS, the App vendors as well as Sales and a “Beta-Test” Physician Client.

Mobile Device Validation Plan

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10 Nevada Drive, Lake Success, NY 11042

VERIFICATION OF TRANSMITTED RESULTS FORM FOR I-PHONE AND ANDROID APP

Choose Department: Chem ___ Special Chem___ Hem___ Coag___ Serology___ Allergy___

Drug Screen___ Blood Bank___ Reference Testing___ Micro___ Virol___ Molec___ AP___

Cytopath ___ Mol Genetics (MAN)___ Cytogenetics (MAN)___ Flow Cyto(MAN)___ UA____

Specimen Identification: _____

	Review	Date	Initial	Comments
1. Patient Chart (request a chart in Millennium) with patient demographics vs. MpkRx patient demographics in Cell Phone Screen (Hard Copy to Cell Phone Screen - Attestation)				
2. Patient Chart (request a chart in Millennium) with **NORMAL** results vs. MpkRx result in Cell Phone Screen including Reference Range and units (Hard Copy to Cell Phone Screen - Attestation)				
3. Patient Chart (request a chart in Millennium) with **ABNORMAL** results vs. MpkRx result in Cell Phone Screen (Hard Copy to Cell Phone Screen - Attestation)				
4. Patient Chart (request a chart in Millennium) with **CRITICAL** results vs. MpkRx result in Cell Phone Screen (Hard Copy to Cell Phone Screen - Attestation)				
5. Patient Chart (request a chart in Millennium) with a **CHANGED** result vs. MpkRx result in Cell Phone Screen				
6. Patient Chart (request a chart in Millennium) with **INTERPRETATION** vs. MpkRx result in Cell Phone Screen				
7. Patient Chart (request a chart in Millennium) with **CHARTABLE COMMENTS** vs. MpkRx result in Cell Phone Screen				

Verification of Transmitted Results Form for i-Phone and Android App 99.1.7.1.5 Effective Date: 6/3/13

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10 Nevada Drive, Lake Success, NY 11042

	Review	Date	Initial	Comments
8. Patient Chart (request a chart in Millennium) with patient demographics vs. MpkRx patient demographics in Patient Chart (Hard copy vs Hard Copy)				
9. Patient Chart (request a chart in Millennium) with **NORMAL** results vs. MpkRx Patient Chart including Reference Range and units (Hard copy vs Hard Copy)				
10. Patient Chart (request a chart in Millennium) with **ABNORMAL** results vs. MpkRx Patient Chart (Hard copy vs Hard Copy)				
11. Patient Chart (request a chart in Millennium) with **CRITICAL** results vs. MpkRx Patient Chart (Hard copy vs Hard Copy)				
12. Patient Chart (request a chart in Millennium) with **CHANGED** results vs. MpkRx Patient Chart (Hard copy vs Hard Copy)				
13. Patient Chart (request a chart in Millennium) with **INTERPRETATION** results vs. MpkRx Patient Chart (Hard copy vs Hard Copy)				
14. Patient Chart (request a chart in Millennium) with **CHARTABLE COMMENTS** results vs. MpkRx Patient Chart (Hard copy vs Hard Copy)				

Reviewer (Hard Copy): _____ Date:_____

Reviewer: (Cell Phone): _____ Phone Type: _____ Date:_____

Reviewed by QA: _____ Date:_____

Summary of Review:

- ☐ Acceptable; no errors found
- ☐ Not acceptable, requires follow up
- ☐ Comment: _____

Approved by: _____ Date:_____

R:\NSLIJ Laboratories\QUALITY SYSTEM MANUAL\99.1.7 Information Management\99.1.7.1 INFORMATION MANAGEMENT\99.1.7.1.5 VERIFICATION OF TRANSMITTED RESULTS FORM FOR I-PHONE AND ANDROID APP.doc

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Mobile Device Validation Plan

- Scope limited to primarily outreach patients
- Included approximately 50 different patients
- Approximately 85 different tests validated
- These tests were from all areas of the Lab
  - Main Automated Lab
  - Specialty Lab Sections
  - Reference Section
- Focused on High Volume Tests

Mobile Device Validation Plan

- Fields to Validate Included:
  - Patient Demographics
  - Test Name
  - Result Review
  - Comments
  - Reflex Order
  - Corrected/Amended/Appended Results

Mobile Device Validation Findings

- General Issues
  - Initially, App was running too slow
  - Physicians needed patient phone link
- Specific Lab Result Issues
  - Pediatric Ages <1 year rounded to 1 year
  - “+” signs did not cross as alpha-numeric characters and hence did not appear in Molecular Genetic karyotype results
  - Text alignment issues making results difficult to read
  - Patient Demographic Issue – Phone numbers missing
  - Report Subsection Order was Different than Chart Copy
  - Corrected Report did not show prior result
  - Reference Lab report had green dot on phone display indicating a normal result when it was actually abnormal

Mobile Device Validation Findings

- A number of issues were identified pertaining to the data feed which related to patient care. These required an LIS fix of the Cerner output feed.
    - Extraneous comments and page numbers present
    - Missing Disclaimers /Performing Lab/ Pt Phone Number
- Website “hard copy” and phone displays reflected similar information and was dependent on the integrity of the data feed
- Most issues were addressed and revalidated
- Some compromises made regarding:
    - Report subsection order
    - Placement of footnotes

Mobile Device Security Validation Plan

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10 Nevada Drive, Lake Success, NY 11042

VERIFICATION OF SECURITY FORM FOR I-PHONE AND ANDROID APP

Choose Phone: i-Phone_____ Manufacturer:_____ Model: _____

Android_____ Manufacturer:_____ Model: _____

	Reviewer	Date	Criteria Met?	Comments
1. New Account Creation • Create a new account • Take screen shot of home page with account name				
2. Password Validation • At least 6 alphanumeric characters long • Must include at least one numeric character • Demonstrate one in compliance: o Write Compliant Password Here: _____ • Demonstrate one out of compliance o Write Noncompliant Password Here: _____ • Print Successful Password Login Screen • Print Unsuccessful Password Login Screen				
3. Validation of Automatic Log-out • At 3 minutes o Record Actual Log-out Time: _____				
4. Ability to Revoke User Access • Revoke Access Prior to Log-on • Attempt to log-on • Print Screen of result • Revoke Access After Log-on • Time to revoke privileges o Record action time to revoke here: _____ • Print Screen of result				
5. Password Reset Process				

Verification of Transmitted Results Form for i-Phone and Android App Effective Date: 10/4/13
99.1.7.1.7 V1

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• Reset Password for account • Take screen shot of password reset window • Enter new compliant password o Write compliant Password Here: _____ • Take screen shot of successful password reset • Take screen shot of unsuccessful password reset				
6. Access Control Restriction Validation (Core Lab Users) • Create Account for **Limited Patient** Access - Limited Features and Limited Database Access • Print Screen • Access **limited features and limited patient** result • Print screen • Access other than **limited features and limited patient** result • Print screen				
7. Access Control Restriction Validation (Core Lab Users) • Create Account for **Operational Administrator** Access - **Most Features and All Database Access** • Print Screen • Access any patient result (Any L, J, or M, etc., patient) • Print screen • Access feature other than Operational Administrator • Print screen				
8. Access Control Restriction Validation (Core Lab Users) • Create Account for **Superuser** Access - All Features and All Database Access • Print Screen • Access **All Features and All Database** patient results • Print screen				
9. Access to Specific Patient Population Validation (Physician Users) • Create Account for **Internal Physician Access** • Print Screen • Access **Full Patient Database** patient result • Print screen				
10. Create Account for **Referring Physician Organization** (Physician Users)				

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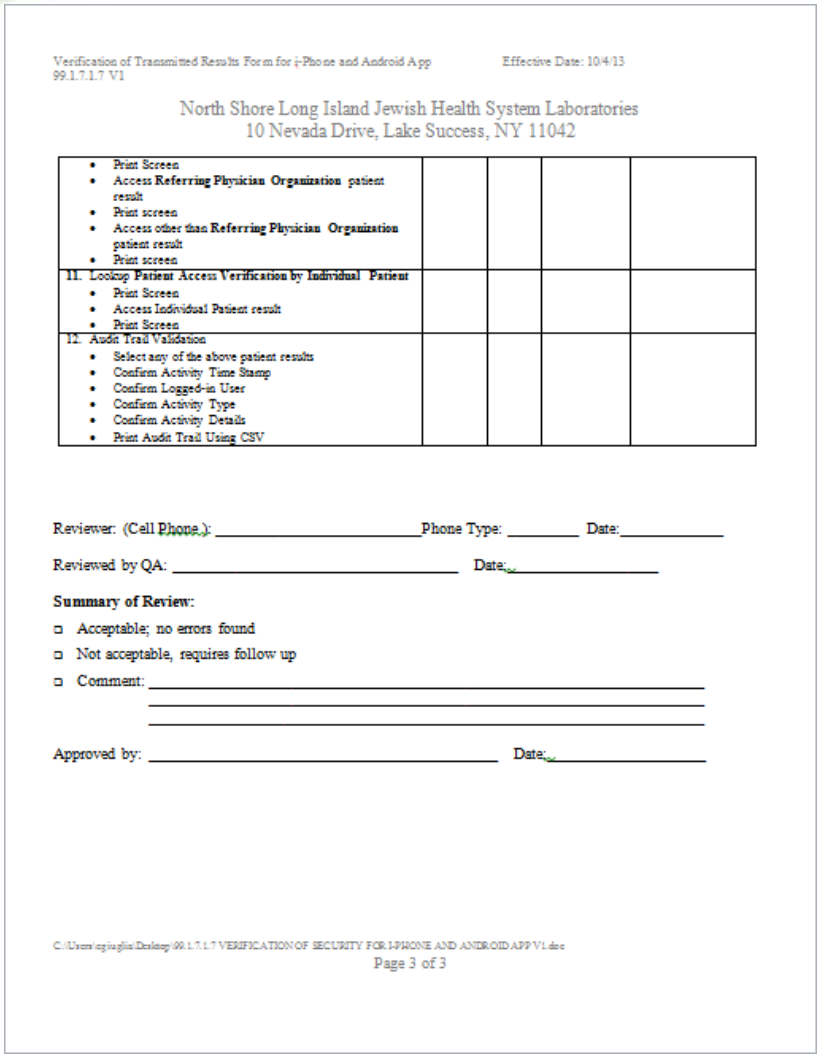
Mobile Device Security Validation Plan



Verification of Transmitted Results Form for i-Phone and Android App 99.1.7.1.7 V1 Effective Date: 10/4/13

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• Print Screen • Access **Referring Physician Organization** patient result • Print screen • Access other than **Referring Physician Organization** patient result • Print screen				
11. Lookup **Patient Access Verification by Individual Patient** • Print Screen • Access Individual Patient result • Print Screen				
12. Audit Trail Validation • Select any of the above patient results • Confirm Activity Time Stamp • Confirm Logged-in User • Confirm Activity Type • Confirm Activity Details • Print Audit Trail Using CSV				

Reviewer: (Cell Phone): _____ Phone Type: _____ Date:_____

Reviewed by QA: _____ Date:_____

Summary of Review:

- ▫ Acceptable; no errors found
- ▫ Not acceptable, requires follow up
- ▫ Comment: _____

Approved by: _____ Date:_____

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Page 3 of 3

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Mobile Device Security Validation Plan

- For Both iPhone and Android
- Creation of Account
- Password Validation
  - 6 alphanumeric and one numeric
  - Demonstrate compliance and Non-Compliance
- Automatic Logout Validation
  - At 3 minutes

Mobile Device Security Validation Plan

- Ability to Revoke User Access
  - Validate Privilege Revocation and Time
- Password Reset Validation
- Access Control
  - Limited Patient access – NSLIJ Lab
    - Limited Features/Limited Patients
  - Patient Result Access by Individual Patient
    - Access only individual patient results
- Audit Trail Validation

Mobile Device Security Validation Plan Findings

- There were NO Major Security Issues
- There were minor security enhancements
  - Password security level raised from Low to Moderate
  - HIPAA Attestation Required
    - to obtain a user ID and Password
    - with a strong recommendation to lock Smart Phones
  - Confidential Fax Coversheet Developed

Mobile Device Validation Plan Review

- Levels of Review for Both Testing and Security Validations
  - Sales
  - LIS Liaison
  - Quality Management
  - Medical Director

Mobile Device Validation Summary

- Unexpected issues occur and may be found in downstream data flow processes and interfaces
- Differences existed between the iPhone and Android display of results
  - Validated each platform individually
- Visual displays of data on handheld devices can be misleading
  - Green to Gray Dot Issue
- Special characters in result fields require special consideration during validations
- Age calculations as well as result calculations are important
- Smart phone device app displayed a high level of security

Mobile Device Validation Outcome

From:

- Out of the Box Solution
- Misleading Display of Results
- Slower Product
- Relatively Secure App

To:

- Customized App
- Accurate Depiction of Laboratory Data
- Rapid App
- Enhanced Security

Approximately 576 NSLIJ App Users and Counting….

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Elements for Successful Interface Validations

- Creation of a New Section within the QM Department to Lead Validation Efforts
- Selection of the Right Validation Team including the Right Stakeholders
- Creation of a Comprehensive Validation Plan
- Developing Effective Communication Tools for Team Members
- Ensuring Ample Time for the Validation to be Properly Performed

Elements for Successful Interface Validations

- Careful initial planning may still requires lean engineering to streamline processes especially when processes are complex
- Validation processes can reveal issues with your own host LIS environment
- A Well Thought Out and Piloted Validation Plan will Streamline Current and Subsequent Validations

Concluding Remarks

- With the advent of the CMS EHR Incentive Programs the Laboratory Will be Required to Establish and Maintain Even More Interface Connections in the future.
- Having Knowledge of Issues that We Encountered will May help You with your Own Validation Processes
- The Ultimate Goal Being the Provision of Accurate, Readable, Understandable Laboratory Reports for Clinicians to Properly and Safely Treat Their Patients.

THANK YOU!

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- egiuglia@nshs.edu