



Using Automation to Manage High Volume Growth While Keeping Service Levels High

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UT SOUTHWESTERN
MEDICAL CENTER

Outline

- Campus laboratories structure and needs
- Laboratory automation process
- Outcomes and lessons learnt



Campus

- Campus laboratories:
 - Spread-out.
 - Different State/County reporting and financial structures
 - Desire to maintain standardization while addressing the individualistic different needs

PMH Clinical Chemistry

- Central Laboratory
- Outpatient Clinics Laboratory
- 120 Staff (Chemistry, Hematology, UA, LSS)
- >4500 daily specimens
- 7,500,000 annual reportable result

UTSW Hospitals Clinical Chemistry

- St Paul's Site
 - 27 Staff
 - 900 Specimens received per day
 - 2,012,964 Tests per year
- Zales Lipshy Hospital's Site
 - 300 Specimens received per day
 - 1,204,450 annual test volume
- Seay Lab site
 - 8 staff includes phlebotomy
 - 100 Specimens per day

Needs & Concerns

- Lengthy unacceptable turn around time
- Old standalone scattered analyzers (> 7 years old)
 - Frequent failures,
 - High running costs
- Decreasing number of staff (11 vacant positions unable to fill)
- Increasing workload (5%) average annual increase
- Several touch points (7) per specimen and lengthy wait times
- Service improvements / consolidation and standardization
- Need to improve throughput and efficiency
- Need to decrease errors and meet JC national safety goals

Obvious Challenges

- Limited space
- Old 1952 building
- Need to replace air-conditioning system
- Compete with other hospital projects
- Maintain laboratory support for busy trauma center
- Staffing issues / challenges

Clinical Chemistry Automation Timeline

Time / Task	2007	2008	2009	1 2010	5 2010	6 2010	7 2010	2 2011	2011- 2012
CC Automation Committee membership	Jan								
Lean & workflow analysis	Jan								
RFI	April								
Site Visits	Nov-Dec	April							
RFP	Sept								
Selection		Jun							
Renovation		Dec	Jan						
Urine DOA (replace AxSym)		Dec							
Chemistry and Immunoassays			April						
Serum Indices							X		
MPA Go live						X			
Auto-verification / IT enhancement									X
Eliminated Batch Processing				X					
Streamlined standardized QC processes					X				
Eliminated CV repeats			Aug			X			
9 minutes Troponin								X	

Clinical Chemistry Automation Committee

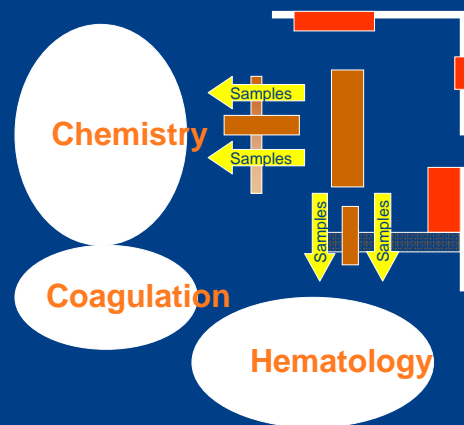
- Wide membership:
 - Clinical Chemistry Laboratory:
 - Lab Supervisors, Assistant Managers, Manager, Medical director
 - Information Technology:
 - IT officers
 - Biomedical Engineering:
 - Biomed Tech
 - Buildings and Facilities:
 - Engineer
 - Members at large:
 - Pathology Administrative Director
 - VP for Clinical Support
 - PCAC

Workflow Analysis

Pre-



Post-



Literature review and data research

- Request for Information (RFI)
 - Presentations by all possible vendors on available systems
 - Answers questionnaire
- Literature review:
 - Publications (few)
 - CAP participation summaries
 - CAP list of instrumentation, CAP Today instruments reviews, Middleware reviews

Questionnaire to vendors

- Methodologies requirements:
 - Accommodate current test menu with additional open channels
 - Acceptable test performance
 - All assays will be FDA-approved for clinical use and supplied without interruption
 - Maintenance time will be acceptable
- Turnaround time
 - 90th percentile for routine and stat assays should be 30 min for chemistries and 40 min for immunoassays
 - The system should have the ability to prioritize super STAT specimens

Sites Visits

- Developed a questionnaire Checklist
- Identified visit team members (One team 2-3 visits per final 2 vendors)
- Selected sites

Selection of laboratories to be visited:

- The following was considered:
 - Similar hospital demographics to Parkland:
 - Bed size
 - Patient population
 - Services
 - Similar laboratory demographics to Clinical Chemistry at PMH:
 - Annual test volume
 - In-patient samples volume
 - Out-patient samples volume (including out-reach clinics)

Items to be considered (queried) during site visit (Checklist):

- General:
 - Reasons for automation
 - Automation systems considered & reasons for selecting current system
 - Staffing before and after automation
 - Length of time to implement system
 - Length of training
 - Sequence of implementation
 - Problems encountered
 - Frequency of automation downtime
 - Space requirements / environmental changes needed
 - Have you moved laboratory since implementation? Are you planning to do so and if yes have you discussed this with the vendor?

Visits Checklist:

- Analytical:
 - Tests menu
 - Specimen type
 - Percentage of serum to plasma
 - Throughput
 - Percentage of orders placed as STAT / Super STAT
 - What is your acceptable TAT (? 30 minutes)
 - Percentage of add-ons
 - Duration of post-analytical sample storage
 - Percentage of non-standard specimens / short volume (i.e. pediatric, urine, body fluid)
 - Robustness of barcode reader and sample identification
 - Who places the barcode on the tubes?

Visits Checklist:

- Centrifugation:
 - Centrifuge spin time
 - Number of centrifuges. Is it sufficient?
 - What back up system do you have? (Action taken during specimen breakage in centrifuge)
 - If not temperature controlled. How sensitive samples including referrals are handled?
 - Handling of previously spun samples

Visits Checklist:

- Open-channel assays
 - Are you using any?
 - Are there any limitations or difficulties encountered?
- Calibration stability
- Reagent preparation
 - Loading reagents
 - Ready made or require additions
 - On board and bench stability
- Clot detection and indices
 - Are you using them and if not please explain?

Visits Checklist:

- I.T.:
 - Laboratory information system (including middleware)
 - Problems with interfacing
 - Method of order-entry accessioning, especially for outpatient/ outreach samples
 - Autoverification
 - Quality control reviews (ability to interface with BioRad Unity)
 - Notification of expired quality control or calibration
 - Error notification—sensitivity, specificity, and depth of detail
 - Ease of use
 - Ability to find any sample, at any time, and retrieve it

Visits Checklist:

- Staff and Clients satisfaction:
 - How many employees are needed to run the system on each shift
 - Does it alter during peak volume. What are their different duties
 - What feedback did you get from Staff / Clients
- Maintenance requirements
 - Who does the maintenance (level of experience required)
 - When is maintenance performed? And why?

Visits Checklist:

- Vendor-related issues:
 - Frequency of service calls
 - Ability to troubleshoot and repair without service call
 - Location of service office / center
 - Level of service training (how many super user trained)
 - On-site engineer during initial set up and operation
 - Do you have a partnership arrangement with the vendor?
 - Is the vendor attending to the future needs such as changing workload, test menu (addition / deletion of tests), addition / removal of instrumentations, restructuring and rearrangement of line.

Significant findings and important issues for US:

- Tests menu / open channels
 - Third party vender support
- I.T. interface
- Indices (High % rejections)
- Sample volumes/pediatric handling
- Reagent preparation
- Maintenance requirements
- Turnaround time
 - 90th percentile for routine and STAT assays should be 30 min for chemistries and 40 min for immunoassays
 - The system should have the ability to prioritize super STAT specimens
- Sample type acceptability (plasma improve TAT)
- Centrifuge spin time
- Robustness of bar code reader and sample identification
- Problematic tests
 - Poor qc /assay performance
 - Frequent dilution to allow for AMR
 - Frequent repeats
- Loading reagents
 - On the “fly”
- Different tube sizes
- Analyzers can be manually operated in the event of a track failure

RFPs / Selection

- Studied RFPs (2 reviewed)
- Two vendors identified
- Invited vendors for in-depth presentations
- Several vendor interactions and explanations of the RFPs) clarifications.
 - Tubes types, test availability (in-development)
- Financial committee:
 - Administrative Director, Managers, Purchasing, etc..

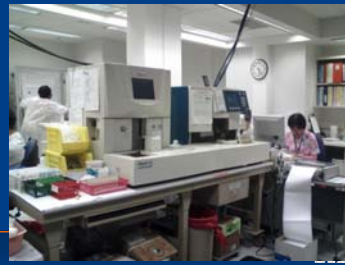
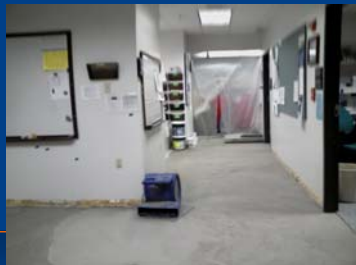
Instruments selection criteria

- Cost
- Efficiency:–
 - Capacity
 - Test menu
 - Consolidation
- I.T.
- Reagents stability / Volume
- Maintenance
- Use of primary tubes
 - Reduce number of aliquots
 - Ability to prepare aliquots for other sections of the laboratory and for send-outs

Construction and Remodeling

- Plan carefully:
 - Reallocate work areas
 - Remove bench space
 - Remove carpet
- Physical space
 - Electrical outlets
 - I.T. connectivity
 - Water supply
 - Drainage

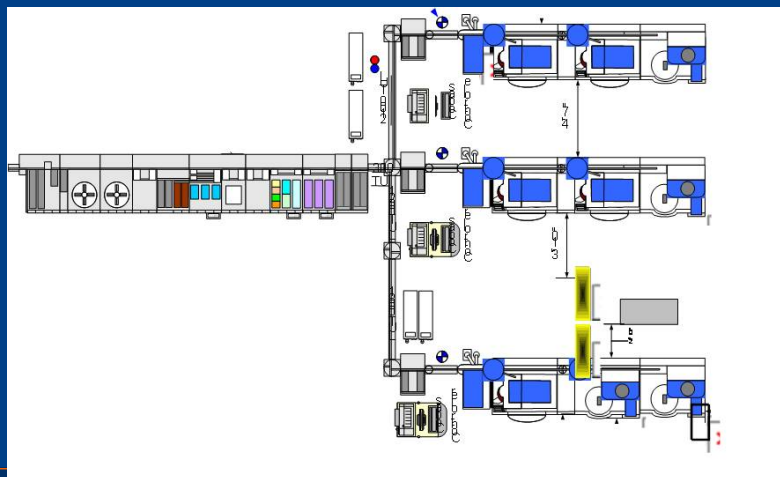
Construction Phase 1



Construction Phase 2



Automation Line with Analyzers



Automation Line with Analyzers Today



Implementation

- Slot checker
- Tests distribution
- Staff training
 - On-site
 - At Roche facilities
- Validation studies
 - Correlations
 - Reference ranges

Impact / Outcomes

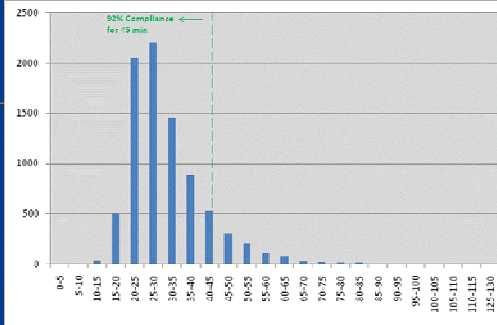
- **General**
 - Instruments consolidation
 - Improved assay quality
 - Consolidated testing (e.g. Pre-albumin)
- Bar-Coded Aliquots for:
 - Other lab areas
 - Referral Labs (send-outs)
 - Research, etc..
- IHL Interference (Indices)
 - Removed subjectivity
 - Allowed discrete analysis

Impact / Outcomes:

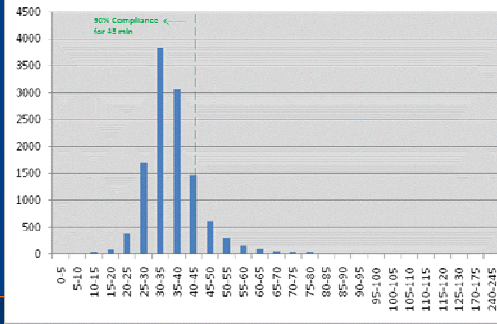
- Changes in turnaround time and throughput
 - Improved consistency
- Consolidation of instrumentation:
 - 9 standalone analyzers removed
 - 4 different manufacturers (AxSym, Olympus, Centaur, BNII)
- IHL removed subjectivity and allowed discrete analysis
- Automated sample tracking and retrieval /Bar-coded aliquots
- Reduced referral testing. Brought tests in-house
- Improved assay performance
 - 9 minutes (TnT, i-o-PTH)
 - Transaminases (P-5-P)
 - Improved precision Folate/ hCG, etc..
 - Improved AMR

Potassium TAT

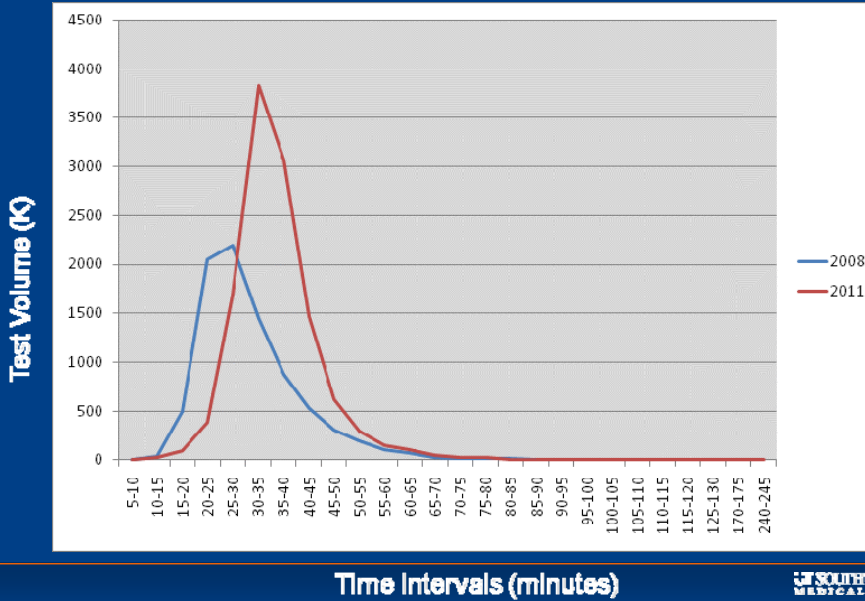
Pre Automation
Oct 2008



Post Automation
Oct 2011

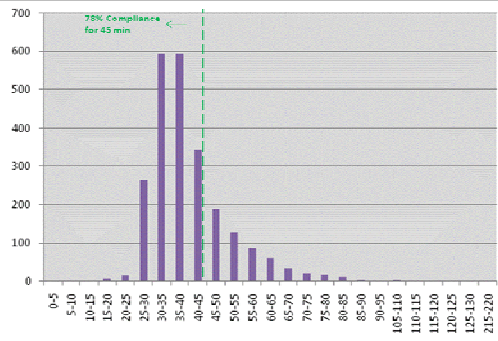


Potassium TAT

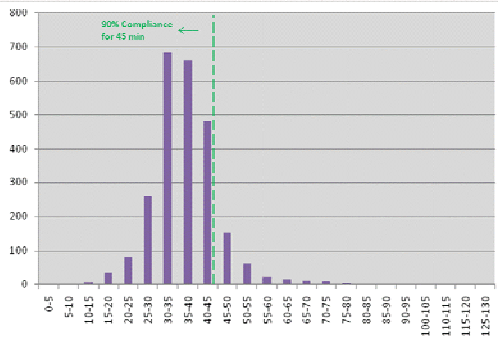


Troponin TAT

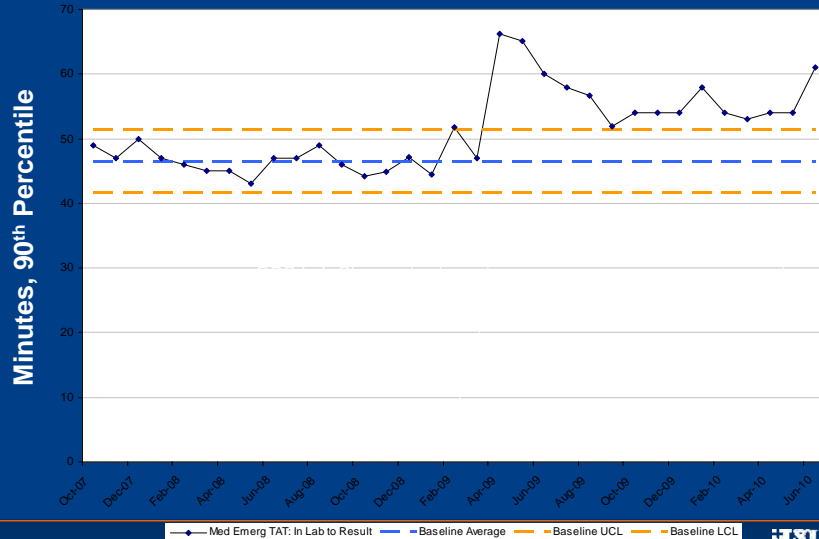
Pre Automation
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Post Automation
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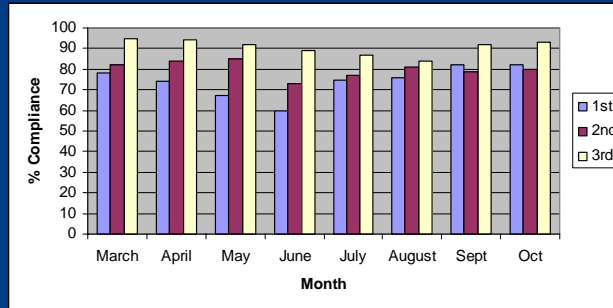


STATs In Lab to Result TAT (90th Percentile, Goal: 45 min)



Potassium TAT by Shift

Goal: 90% Compliance for 45 minutes

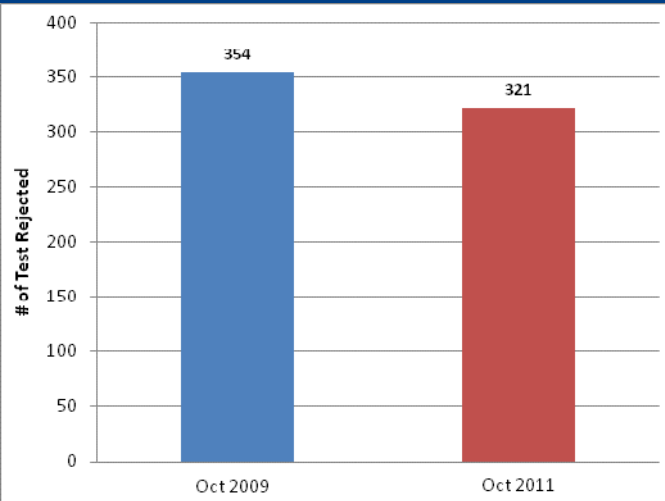


Shift 1: 7a-3:30p
Shift 2: 3p - 11:30p
Shift 3: 11p - 7:30a

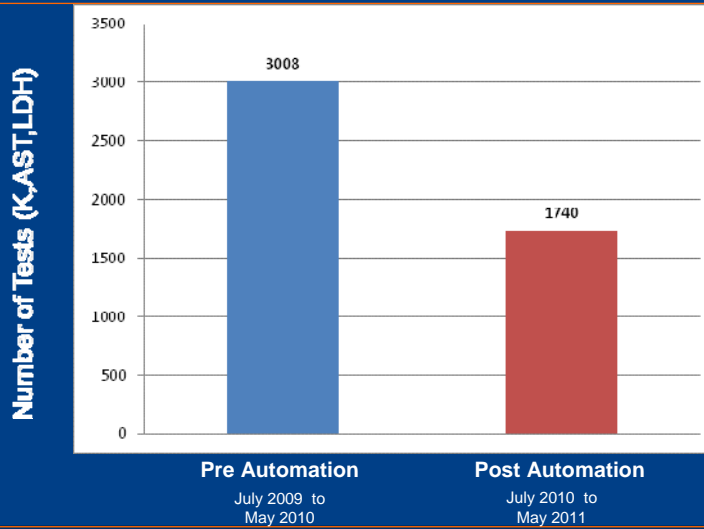
Indices

- % rejection
- Limits set by manufacturer
- Lab selected and verified limits

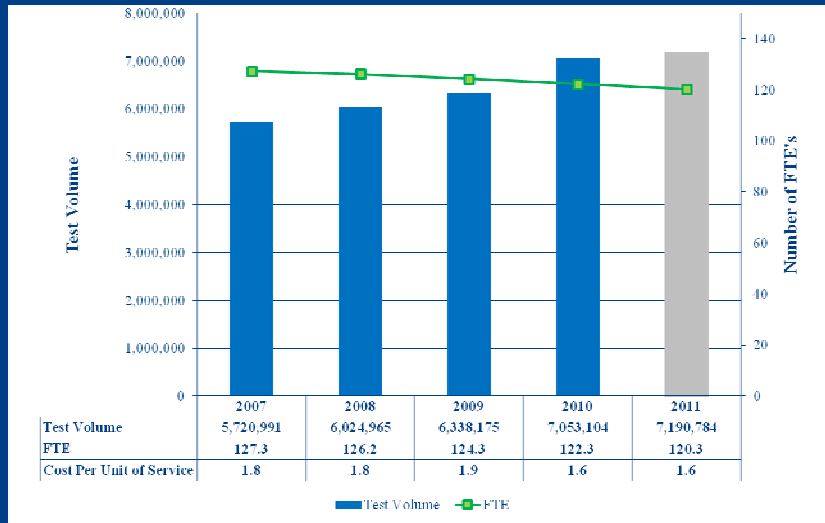
Impact of indices use on number of K tests rejected due to hemolysis



Impact of indices use on number of tests not performed due to hemolysis



ROI and Reduced Cost Per Unit of Service



5.5% reduction in FTE's and a 10% reduction in cost per unit of service while absorbing 5% annual increases in test Volumes

Other Financial Impact

- \$200,000 savings (closure of outpatient lab) absorbed the workload and staff

Staff Impact (The hidden benefit)

- Staff satisfaction (comments):
- “ Automation has reduced touch points and allowed the techs to better focus on analyzing the data”
“additional testing without extra staffing”
- ”standardization and simplified workflow” “created monitoring tools to meet the STAT needs”

Done correctly

- RFI
- Checklist for site visits
- Stepwise replacement of analyzers and transfer of testing
- Delayed MPA attachment
- Involved hospital leadership and clinical staff

Stepwise Replacement of Analyzers

Date	Action	Consequence	Advantages
December 2008	Urine Drugs of Abuse (Screen)	Removed one Equipment (AxSym Abbott Diagnostics)	Consolidation
April 2009	General Chemistry	Removed four Equipments (Olympus Diagnostics)	Consolidation Improved assay quality
April 2009	Hormones (Immunoassays)	Removed three equipments	Improved assay quality Consolidated testing (e.g. Pre-albumin)
June 2010	Automation of Samples Preparation & Processing	New	Standardization Bar-Coded Aliquots for: - Other lab areas - Referral Labs (send-outs) - Research, etc..
July 2010	Automated Sample Suitability Checks (hemolysis, Lipemia, bilirubin)	New	Removed subjectivity Allowed discrete analysis

Stepwise construction to maintain workflow and regular operation.



PCAC Significant Contributions to the Automation Project:

- Assisted the laboratory with:
 - Substitution of:
 - NT-Pro BNP for BNP
 - Troponin T for Tn I.
 - Magnesium unit change from mEq/L to mg/dL
 - Dissemination of information and support for possible use of limited testing during implementation phase
 - Reference Range changes
 - Introduction of new tests:
 - FT3
 - UIBC, etc..

Would've done differently !

- I.T. training and realization
- Education on DI –Instrument manager software capabilities
- Determine prerequisite processes necessary for stepwise implementation
- Identify problematic assays on the new platforms;
 - Ammonia
 - Therapeutic drugs (antibiotics / transplant), DOAU
 - 3rd party reagents

Benefits:

- Instruments removed from lab (n=9) (4 separate contracts)
- Eliminated 7 FTEs
- Redeployment of staff (IT, UA, Special Chemistry)
- Stopped repeating Critical Values (improved TAT)
- Handling poor quality samples;
 - Removed subjectivity
 - Allowed discrete testing
- Increased capacity (out-patient lab closure)
- Eliminated “batching” of samples (e.g. TSH)
- Reduce percentage of outliers
- No discrimination between “STAT” and “routine”
- Improve and expand test menu
 - Tn-T (rapid 9 minutes)
 - Intra-operative PTH

Future:

- Use of middleware software to improve test utilization
- Auto-verification
- Expand Reflex and Reflexive testing
- Develop Diagnostic Pathways
- Expand test menu
- Modification of criteria for sample indices based on in-house studies
- Incorporate the knowledge and lessons gained in the new hospital and design (Experience transfer)