



Carolinan HealthCare System

Utilization of MALDI-ToF Mass Spectrometry in the Clinical Microbiology Laboratory

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SWACM Annual Meeting
September 6, 2017
St. Louis, MO

LEAN Philosophy in the Clinical Microbiology Laboratory

Background

The success of CHS overall and the Laboratory Outreach program resulted in significant volume growth, creating numerous operational challenges.

- CMC laboratory served as an acute care lab and as the core lab for CHS Metro hospitals.
- The department experienced 50% growth over five years
- The volume of routine tests from physician offices reached a level where the acute care needs of the CMC campus were being adversely affected.
- Growth resulted in testing being spread across five locations, presenting challenges to quality and efficiency.
- Lab functions at CMC and CMC-Mercy are rapidly outgrowing their facilities.

Options Considered

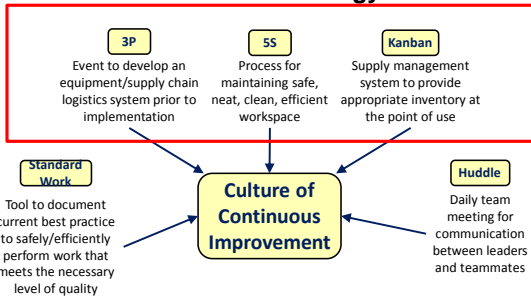
- Locate consolidated core lab at CMC.
- Transition CMC into an acute care lab; develop a new facility to consolidate specialized testing and routine outreach testing.
- Outsource all specialized testing and routine outreach testing
- Maintain specialized testing; outsource routine outreach testing
- Do nothing

Carolinan HealthCare System: *Microbiology*

- Full Service Lab
 - Bacteriology
 - Mycobacteriology
 - Mycology
 - Virology
 - Molecular microbiology: *C. difficile*, positive blood cultures
 - Minimal parasitology: EIA, WORM, INSECT
- Core Lab
 - Levine Cancer Institute
 - Levine Children's Hospital
 - Reference Lab for non-system hospitals in the region
- Teaching of medical technology students, Pediatric ID residents/MSIV
- Frequent site for method comparison and workflow studies
- High sample volume allows utilization of continuous flow

Pre-2013

LEAN Terminology



3P Process was Utilized for Design

- People, Preparation, Process

3P is an event to develop and define a Lean equipment and supply chain logistics system before the start of implementation



The 3P Event Week

- Training
- Brainstorming
- Idea creation
- Narrow to one
- Build
- Simulate
- Adjust
- Simulate
- Repeat
- Finalize



35 Concepts to 1 Micro and AFB/Mycology area



Team at Work!



3P – Participants Are Challenged



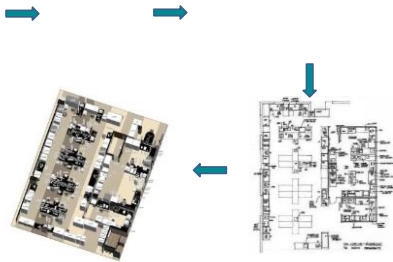


Ideas in Motion: Master 3P Event

Making Sure the Space is Right! Full Scale Design Buildout



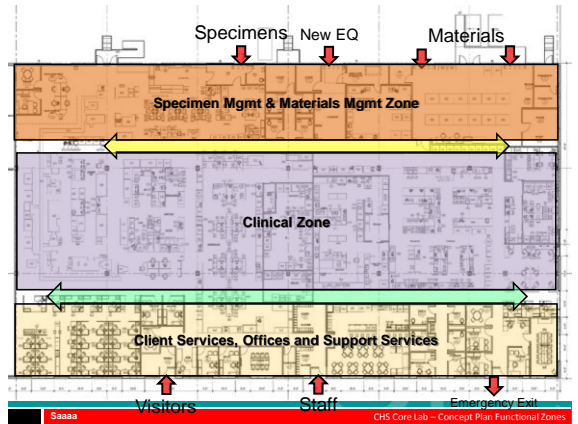
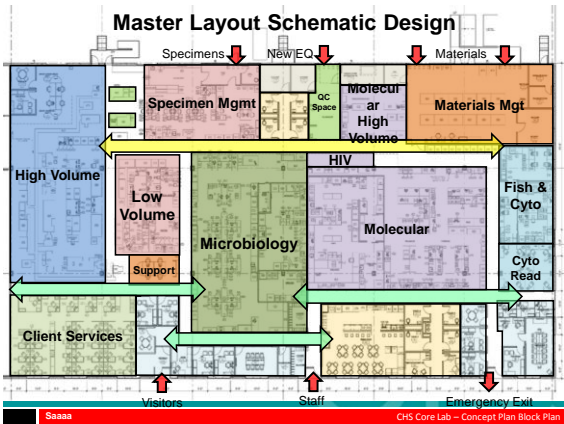
The Evolution of a Design



- Bactecs
- Setup Hoods
- Blood Hood
- WASP
- Sample Drop Off



Master Layout Schematic Design



Recap of All 3P Events

- 9 Events
- 176 Days
- 39 Departments
- 103 Lab Teammates**
- 138 CHS Teammates
- 1,976 Years of Experience
- 5,692 Hours of Design Time



Great Design!



Starting from the Ground Up!



5S

- Sort, Set in order, Shine, Standardize, Sustain

A process and method for creating/maintaining a safe, clean, neat arrangement of the workplace, which provides a specific location for everything and eliminates anything not required



LEAN



Kanban

Supply management system to provide appropriate inventory at the point of use

- 5 – 10 days worth, based on usage and product lead time

Supermarket

2 bin Kanban

POU Storage



Continuous Improvement

Repeat event process when adding new equipment or changing processes (e.g., RMD and MALDI)



Key Improvements

- Specimen Flow Improvement:
- Distance specimen traveled from receipt in technical area to result
 - High Volume Chem / Heme: 82% Improvement
 - Low Volume Chem / Heme: 75% Improvement
 - Microbiology: 82% Improvement
 - Molecular: 88% Improvement
 - Immunology: 87% Improvement
 - Cytogenetics / Bone Marrow: 88% Improvement



Key Improvements

- Turnaround Time Improvement:

Improvements in TAT (end of July) Collect to Result	
Negative Urine Cultures	12%
Urine Cultures	13%
CBC	14%
Chem 7	30%
Chem 12	29%

Key Improvements

- Inventory Improvement (Kanban):
- Reduction in on-hand inventory
- Minimize "Push" systems (ie: standing orders)
- Lab techs more available to perform value-added work (ie: patient testing)
- **Eliminated all counting and manual ordering (1500 items)**
- **Techs are not involved in the ordering process**



Key Improvements

Flow	Before (feet)	After (feet)	% Improved
High Vol Chem / Heme	1189	210	82%
Low Vol Chem / Heme	1081	265	75%
Micro - Urine	1619	260	84%
Micro - Gram Stain	1008	205	80%
Molecular - CF	2652	327	88%
Immunology – PRA	2338	293	87%
Cytogenetics – Bone Marrow	2800	339	88%

Published Data

A Lean Laboratory
Operational Simplicity and Cost Effectiveness of the Luminex xTAG™ Respiratory Viral Panel

Michelle E. Sheridan, Mandeep D. Joshi, Paul A. Reed,† Eusebio Diaz,† Majeed Majeed,† N. Krishna Laksh,† and Beverly B. Ringold*

†First author contributed and reviewed the results of this study. Michelle E. Sheridan, Mandeep D. Joshi, Paul A. Reed, Eusebio Diaz, Majeed Majeed, N. Krishna Laksh, and Beverly B. Ringold* contributed equally and substantially to the experimental design of this study and the analysis of the experimental data. Michelle E. Sheridan, Mandeep D. Joshi, Paul A. Reed, Eusebio Diaz, Majeed Majeed, N. Krishna Laksh, and Beverly B. Ringold* contributed equally and substantially to the experimental design of this study and the analysis of the experimental data. Michelle E. Sheridan, Mandeep D. Joshi, Paul A. Reed, Eusebio Diaz, Majeed Majeed, N. Krishna Laksh, and Beverly B. Ringold* contributed equally and substantially to the experimental design of this study and the analysis of the experimental data.

- Switch from culture to a molecular assay for respiratory pathogens decreased hands-on time from 503 h to 80 h

- Significant improvement in 1st time run success for 4 molecular assays
- Improvement in TAT for 8 molecular tests (34% - 68%; 12 h – 5 d)



Adoption of Lean Principles in a High-Volume Molecular Diagnostic Microbiology Laboratory

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July 2014 Volume 32 Number 7

Journal of Clinical Microbiology

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MALDI-ToF – LEAN Decisions

1. Where will the instrument be placed?
2. Where will reagents be stored?
3. What organisms will you run on MALDI?
4. How will those organisms get to the instrument?
5. Who will be trained?
6. Who will run the instrument?
7. What shifts will use MALDI?
8. How will patient information be entered into the MALDI?
9. How will results be entered into the LIS?
10. What about QC? Calibration?

