Using Six Sigma and Lean Principles to Improve Laboratory Operations

Big Bang Makeover of the Clinical Laboratory: Key Lessons for Work Flow, Analyzers, and Service Improvements

Atlanta, GA

Purpose/Objectives

• **Purpose:**
  – To provide an overview of using Six Sigma and Lean Principles in chartering, designing and implementing a full scale Lean project in a large laboratory setting.

• **Objectives:**
  – Understand how each phase of DMAIC was used to execute a full scale Lean design effort
  – Understand which key Lean tools were used in measure/design/implementation
  – Understand how interactions of physical, process, technological, and organizational changes contribute to a large scale Lean effort.
Outline

- Who we are
- Why Improving Lab Operations is Important to Quest Diagnostics
- The Journey
- Key Learnings

Who we are

- **Focus:**
  - Patients
  - Growth
  - People
- **Vision:**
  - Dedicated People Improving the Health of Patients Through Unsurpassed Diagnostic Insights
- **Company Background**
  - 40,000+ Employees
  - 900+ Clinical Scientist PhDs/MDs
  - Patient Service Centers
  - Rapid Response to Esoteric Laboratories
  - 145 million patient encounters annually
- **Values:**
  - Quality, Integrity, Innovation, Accountability, Collaboration, Leadership
- **Six Sigma/Lean Journey**
  - 2000 - 2008
Why Improving Lab Operations is Important to Quest Diagnostics

**PATIENTS**
1. Reduce Patient Anxiety Time
2. Reduce tests not performed

**PEOPLE**
1. Shortage of technical workforce
2. Staffing of night shift
3. Improve technical skills
4. Reduce potential blood exposure
5. Reduce ergonomic Injuries
6. Improve staff involvement

**GROWTH**
1. Improve equipment utilization
2. Improve productivity
3. Improve supply utilization

The Journey
The Journey – Integrating Six Sigma

Three Major Six Sigma Process Methodologies

Complex project required adequate training/development

Using DMAIC & Lean to Define Project

**DEFINE (Project Charter)**
- Business Case
- Problem Statement
- Project Scope/SIPOC
- Project Goals
- VOC/CTQs
- Resources
Using DMAIC & Lean to **Define** Project

**DEFINE (Project Charter)**

- Project Scope

Atlanta Lab

**SIPOC & Project Scope**

Scope expanded and spanned from specimen collection to result release

**Using DMAIC & Lean to **Define** Project**

**DEFINE (Project Charter)**

- Project Resources

Atlanta Lab

- Regional VP
- Six Sigma VP
- Lean MBB

**Steering Committee**

- Managing Director
- Process Owners
- IT/Facilities/Safety/HR/Finance/Purchasing

**Other Resources**

- Six Sigma BBs & GBs
- Facilities Manager
- Safety Officer
- Medical Director
- IT Manager/Director
- HR Director
- Medical Director
- Materials Management
- Customer Service Director
- Architect
- Construction Manager
- Contractor

- Field Operations
  - Patient Service Centers
  - Logistics

- Lab Operations
  - Processing
  - Clinical
  - AP
  - Microbiology
  - Medical

Cross functional team included local & national resources
Using DMAIC & Lean in **Measure**

**MEASURE**
- Origin of Work Streams
- Logistics Mode & Arrival Profile
- Pre-Analytical, Analytical & Post Analytical Process Steps
- Current Floor Plan (CAD)
- Inventory Turns
- Productivity
- Safety Records
- Quality Metrics
- Service Metrics

- Product Family Matrix
- Current State VSMs
  - Daily Testing Volumes
  - Lead Time
  - Cycle Time
  - Batch Sizes
  - Staffing by Dept/Shift
  - WIP
  - Uptime
  - Rework %
  - Information Flow

Extensive Data Collection Plan/Baseline Measurements

Using DMAIC & Lean in **Measure**

**MEASURE**
- Logistics Arrival Profile

Uneven & late inflow limits capacity utilization
Using DMAIC & Lean in **Measure**

**MEASURE**

- Product Family Matrix


- Testing performed manually or automated
- Specimens placed in instrument Rack
- Load Specimens and QC on to Instrument
- Run and monitor Instrument
- Check QC, Accuracy, Outliers for repeats and Sample integrity (L-H)
- Extra specimen workup (i.e. ultra centrifugation, dilution etc)
- % Repeat Runs
- Result Entry Mode (into LIS)
- Result Release Mode: Manual release results (by batch or accession)
- Print/Pending list
- Find additional specimen if ONS
- Manual or auto bank specimens
- Instrument shut down
- Organize and re-supply work area

Developing the Product Family Matrix was the Foundation

Using DMAIC & Lean in **Measure**

**MEASURE**

- Product Family Matrix

Bubble Diagrams used to develop Product Family Matrix
Using DMAIC & Lean in **Measure**

**MEASURE**
- Current State Value Stream Maps

Current State Value Stream Maps identified opportunities to use Lean strategies.

Using DMAIC & Lean in **Measure**

**MEASURE**
- Current State Floor Plan

Current State Layout Design was used to evaluate flow at a high level.
Using DMAIC & Lean in **Measure**

**MEASURE**
- Spaghetti Mapping

Current State Spaghetti Diagrams were used to evaluate movement of specimens, people and materials

Integration of Lean Objectives

1. **Identify and Eliminate/Reduce Time-Traps/Smooth Distribution**
2. **Identify and Eliminate/Reduce Non-Value Added Steps**
3. **Co-Locate Value Added Steps**
4. **Reduce Work in Process (WIP)**
5. **Reduce/Optimize Batch Size**
6. **Decrease set-up time** (Cross Training is often implemented)
7. **Reduce Complexity/Increase Flexibility**
8. Create a physical working environment that complements/supports the flow of work, is **safe, clean and encourages the efficient and timely flow of specimens**, supplies, ideas and information.
9. Create a working **environment** that forces all process steps to be **open and visible**.
Future state focused on reduction of NVA

Using DMAIC & Lean in Analyze

ANALYZE/DESIGN

• Ideas for Future State

Over 300 projects were identified as “blue sky opportunities” & then prioritized:

<table>
<thead>
<tr>
<th>Improvement Opportunity</th>
<th>Weighting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Family</td>
<td></td>
</tr>
<tr>
<td>Business $ Impact - H (9) M (3) L (1)</td>
<td>10</td>
</tr>
<tr>
<td>Ease of Implementation - H (5) M (3) L (1)</td>
<td>6</td>
</tr>
<tr>
<td>$ Cost - H (1) M (3) L (5)</td>
<td>3</td>
</tr>
<tr>
<td>IT Resource Needed H (1) M (3) L (5)</td>
<td>2</td>
</tr>
<tr>
<td>Processor to other Activity (Yes/No)</td>
<td></td>
</tr>
<tr>
<td>Score</td>
<td></td>
</tr>
<tr>
<td>Is this a BB, GB or Nike Project?</td>
<td></td>
</tr>
<tr>
<td>What is Predecessor?</td>
<td></td>
</tr>
</tbody>
</table>

63 Green Belt & Black Belt Projects were prioritized with anticipated cost/benefit

Not every good idea could be implemented within the timeframe
Using DMAIC & Lean in Analyze

**ANALYZE/DESIGN**
- **Major design elements selected**
  - Improve logistics Inflow
  - Implementation of alternate front end specimen processing system
  - Conveyance
  - Automated Sort Aliquot
  - Cell Design by Product Family including 5S & Lean Supply Chain (PFEP)
  - High priority IT enhanced systems projects
  - Organizational changes to support automation

Framework for detailed design

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**ANALYZE/DESIGN**
- **Process Model**
  - Logistics inflow/hr by work stream
  - Processing req/hr/FTE by work stream
  - # & type of specimens
  - Aliquots per specimen
  - Aliquoter & sorter specimens/hr

Utilized internal and external resource expertise to validate the automated sorter/aliquoter equipment requirements
Using DMAIC & Lean in **Analyze**

**ANALYZE/DESIGN**
- Equipment Criteria Sheet

**900 Items Inventoried**

“Equipment Criteria Sheet” was utilized to document requirements in a “future state” design

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Using DMAIC & Lean in **Analyze**

**ANALYZE/DESIGN**
- Systematic Layout Planning

SLP was used to design at a product family level, cell level & bench level
ANALYZE/DESIGN

- Ergonomic/Safety Evaluation

Company wide 2002-2005 OSHA recordables were evaluated.

Data evaluated current state workstation designs and the benefits of future state processing work cell design, including future state integration of conveyance and automated sort/aliquot equipment.

External resource conducted analysis including posture, motion, force, duration & frequency of hands, wrists, elbows, shoulders, neck, back & legs.

Final design recommendations integrated both the recommended workflow design changes and ergonomic design elements. Modifications for workstation height, reach, and process functions were made and included in the final design.

Final workstation design incorporated ergonomic recommendations

<table>
<thead>
<tr>
<th>KEY</th>
<th>Component</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Acid Cabinet</td>
</tr>
<tr>
<td>B</td>
<td>Aspirator</td>
</tr>
<tr>
<td>F</td>
<td>Balance</td>
</tr>
<tr>
<td>BPS</td>
<td>Beckman Power Supply</td>
</tr>
<tr>
<td>C</td>
<td>Centrifuge (Floor Model)</td>
</tr>
<tr>
<td>CA</td>
<td>Cabinet (Under Counter)</td>
</tr>
<tr>
<td>CW</td>
<td>Cell Washer</td>
</tr>
<tr>
<td>CY</td>
<td>Cytofuge</td>
</tr>
<tr>
<td>CO</td>
<td>Conveyor</td>
</tr>
<tr>
<td>CT</td>
<td>Cart</td>
</tr>
</tbody>
</table>

IMPLEMENT/IMPROVE

- Detailed Equipment Inventory was used to develop move plan

1700 Items were catalogued to be moved

<table>
<thead>
<tr>
<th>Dept.</th>
<th>Number</th>
<th>Key</th>
<th>Architectural #</th>
<th>Elevation #</th>
<th>Equipment ID</th>
<th>Department</th>
<th>Cell Name/Section</th>
<th>Components</th>
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<tr>
<td>25000</td>
<td>E11</td>
<td>2179B</td>
<td>E14</td>
<td>105</td>
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<td>2179B</td>
<td>E14</td>
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<td>2179B</td>
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<td>E14</td>
<td>109</td>
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<tr>
<td>25000</td>
<td>E19</td>
<td>2179B</td>
<td>E14</td>
<td>110</td>
<td>Cin-Chem Immulite Section 6</td>
<td>5) Immulite</td>
<td></td>
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<td>25000</td>
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<td>2179B</td>
<td>E14</td>
<td>111</td>
<td>Cin-Chem Immulite Section 7</td>
<td>6) Immulite</td>
<td></td>
<td></td>
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<tr>
<td>25000</td>
<td>E19</td>
<td>2179B</td>
<td>E14</td>
<td>112</td>
<td>Cin-Chem Immulite Section 8</td>
<td>7) Immulite</td>
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<td>2179B</td>
<td>E14</td>
<td>113</td>
<td>Cin-Chem Immulite Section 9</td>
<td>8) Immulite</td>
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<td></td>
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<tr>
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<td>E19</td>
<td>2179B</td>
<td>E14</td>
<td>114</td>
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<td>Q</td>
<td>2179B</td>
<td>E13</td>
<td>115</td>
<td>Cin-Chem Immulite Section 10</td>
<td>CRT</td>
<td></td>
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</tbody>
</table>
### Using DMAIC & Lean in **Improve**
### IMPLEMENT/IMPROVE
- Equipment Inventory Sheet

<table>
<thead>
<tr>
<th>Equipment Name</th>
<th>Room Name / Number</th>
<th>Equipment Generic Name</th>
<th>Quantity</th>
<th>Manufacturer</th>
<th>Model No.</th>
<th>Weight (lbs)</th>
<th>Depth (in)</th>
</tr>
</thead>
<tbody>
<tr>
<td>673 Immunology</td>
<td>Immunology / 2179T</td>
<td>Centrifuge</td>
<td>1</td>
<td>IEC</td>
<td>Centra MP4</td>
<td>100</td>
<td>21</td>
</tr>
<tr>
<td>674 Immunology</td>
<td>Immunology / 2179T</td>
<td>Centrifuge</td>
<td>1</td>
<td>Beckman</td>
<td>Allegra 6</td>
<td>120</td>
<td>27</td>
</tr>
<tr>
<td>675 Immunology</td>
<td>Immunology / 2179T</td>
<td>Centrifuge</td>
<td>1</td>
<td>IEC</td>
<td>Centra MP4</td>
<td>100</td>
<td>21</td>
</tr>
<tr>
<td>676 Immunology</td>
<td>Immunology / 2179T</td>
<td>Centrifuge</td>
<td>1</td>
<td>Vanguard</td>
<td>V6500</td>
<td>&lt;25</td>
<td>12</td>
</tr>
</tbody>
</table>

“Equipment Criteria Sheet” was tied to Numbers on Architectural Plans

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### Using DMAIC & Lean in **Improve**
### IMPLEMENT/IMPROVE
- Hourly Move Schedule

<table>
<thead>
<tr>
<th>Phase 1 Move</th>
<th>Scale</th>
<th>Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase 1 Move</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Begin Move</td>
<td>Techs</td>
<td>Techs</td>
</tr>
<tr>
<td>2. Hex 1 (4 Process Tables with workstations)</td>
<td>Techs</td>
<td>Techs</td>
</tr>
<tr>
<td>2. Hex 8 (4 Process Tables with workstations)</td>
<td>Techs</td>
<td>Techs</td>
</tr>
<tr>
<td>3. Hex 9</td>
<td>Techs</td>
<td>Techs</td>
</tr>
<tr>
<td>3. Hex 2</td>
<td>Techs</td>
<td>Techs</td>
</tr>
<tr>
<td>1. Induction</td>
<td>Techs</td>
<td>Techs</td>
</tr>
<tr>
<td>2. 1st Floor/Building</td>
<td>Techs</td>
<td>Techs</td>
</tr>
<tr>
<td>1. Floor 9</td>
<td>Techs</td>
<td>Techs</td>
</tr>
</tbody>
</table>

Coordination was essential—everyone had responsibilities.
Using DMAIC & Lean in **Improve**

**IMPLEMENT/IMPROVE**
- IT Project Management

**System Updates**
- New front end processing system Implementation
- Interface enhancements
- Label modifications
- Measurement tools (Lean Six Sigma Utility Report)

**Infrastructure Changes/Upgrades**
- Data-line/Cabling strategies
- Hardware changes
- Phone System Coordination

<table>
<thead>
<tr>
<th>IT Devices Relocated</th>
<th>600</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interfaced Instruments</td>
<td>296</td>
</tr>
<tr>
<td>Qty of Cables Demo'd</td>
<td>415</td>
</tr>
<tr>
<td>Qty of Cables Installed</td>
<td>726</td>
</tr>
</tbody>
</table>

52 miles of CAT5E Cable installed enabling faster data transfer and increased capacity

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Using DMAIC & Lean in **Improve**

**IMPLEMENT/IMPROVE**
- GB/BB Project Plan

![Project Table]

Projects tracked monthly to ensure coordination & on time completion
5S ownership is at a sub-department level—this concept was launched in 2005 and refined during & following construction.

Original 5S Plan—improvements were made to ensure consistency and integrate the new product family organization.

Sort resulted in disposing of 18 cubic yards of unneeded items.
The majority of sorting, aliquoting & decapping is now automated

**Using DMAIC & Lean in Improve**

**IMPLEMENT/IMPROVE**

- Processing Workstations/Conveyors

**Using DMAIC & Lean in Improve**

**IMPLEMENT/IMPROVE**

- Organizational Changes/Job Reporting Structure

*New Department: Automated Tech Ops*

*Job Responsibilities:*

- Running automated sorter aliquoters
- Troubleshooting routine problems
- Documenting maintenance/downtime/problems/tubes not processed by the aliquoter or sorter (bad labels, slant gels, etc.)

Key learning – operators need to have aptitude for technology
**IMPLEMENT/IMPROVE**

- Automated Sort Aliquot

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**‘Lab Ready’**
- Specimens in instrument racks
- Specimens in direct bins

**‘Default Rack’**
Default rack specimens represent defects that require staff to intervene. Defects can arise from:
- Clots in specimens
- Slanted gel in the barrier tube
- Barcode failure

Two Streams of Output – ‘Lab Ready’ and ‘Default Rack’

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**IMPLEMENT/IMPROVE**

- Automation requirements

- Consistent & accurate label placement
- Consistent bar code print quality
- Adequate volume/no large clots
- Round bottom primary tubes
- Flat gel spin for serum separator tubes
- Consistent feedback process if specifications not met
- Technical aptitude of sorter/aliquoter operators
- Quality/Operational/Service Metrics

Automation no longer “hides” sub optimized processes
Departments know exactly when specimens will be picked up and when and where they will be delivered.

Using DMAIC & Lean in Improve

**IMPLEMENT/IMPROVE**
- Standard Work Instructions

**Standard Worksheet**
Provides specific instructions including:
- Step by step details
- Delivery route
- Delivery times

Using DMAIC & Lean in Improve

**IMPLEMENT/IMPROVE**
- Technical Areas

Work can be seen across the building; Aisles open.
Using DMAIC & Lean in Improve

IMPLEMENT/IMPROVE

• Technical Areas

Supplies in work cells

Work cells organized – 5S

Using DMAIC & Lean in Improve

IMPLEMENT/IMPROVE

• Lean Supply Chain

Pass Thru Refrigerator

Supermarket

Delivery Aisles
**Using DMAIC & Lean in Control/Verify**

<table>
<thead>
<tr>
<th>Metric</th>
<th>Improvement</th>
<th>Chart Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lab Accidents</td>
<td>42%</td>
<td>Automated Aliquoter volumes more consistent</td>
</tr>
<tr>
<td>Turn Around Time</td>
<td>33%</td>
<td>Kaizen Process flow changes important</td>
</tr>
<tr>
<td>Manual Req Processing</td>
<td>35%</td>
<td>Productivity gains offset by adds for automation</td>
</tr>
<tr>
<td>Improper Specimens</td>
<td>33%</td>
<td>Auto sort beneficial; June 08 IT enhancement</td>
</tr>
</tbody>
</table>

**Lessons Learned**

- This project was successful due to the **people** in Atlanta that remained **committed and focused**.
- The **Six Sigma culture** (with trained Green Belt resources) supported the completion of 63 projects. **Leadership** from the top was essential.
- **Team structure** and project management oversight is critical in a project of this magnitude.
- **Organizational structures/policies** may need to be changed to support the new work content and processes.
- **Technology** changes alone are **not enough** to create a lean environment.
- Employees need **coaching/training/mentoring** during the change event.
- Succession plan necessary – team members changed – the **project** must be **structured & supported** in a way to continue progress.
Questions?