

**Sharing a New Ideal:
How Tomorrow's Understaffed, Multi-Site Lab
Organization Will Combine Automation, Technology,
and Performance Improvement To Meet Its Mission**



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Purpose & Objectives



PURPOSE

Provide an overview of the dynamics of today's IVD industry with emphasis on how tomorrow's key organizations will be using automation, technology, quality management and performance indicators to raise the bar in meeting customer satisfaction.

OBJECTIVE

Gain insights into the dynamics of today's multi-site clinical laboratory organization, the challenges it faces, and approaches used to enhance performance in support of its mission.

For Starters...

Similarities of High Performing Labs to Auto Racing

Formula One Grand Prix Race



Daytona Race



Drag Race



Market Segmentation: Similarity

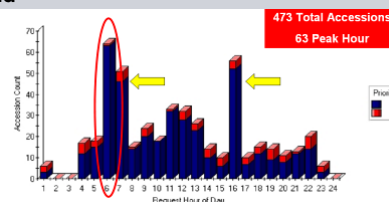
Hospital Labs



Grand Prix



- Average Speed → MEDIUM ~ 30 to 50% of Top End
- Peak Duration → Short to Medium Intervals
- Backup Capacity → Good
- Productivity → Medium
- KPI → STAT Turn Around Time



Market Segmentation: Similarity

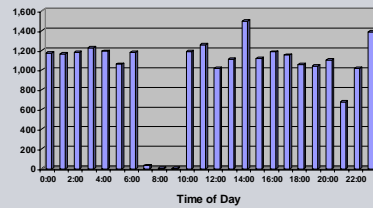
Reference Labs



Daytona



Number of Total Samples
Checked Into ADVIA LabCell By Hour (May 6/7)



- Average Speed → HIGH ~ 85% of Top End
- Peak Duration → Long
- Backup Capacity → Low < 25%
- Productivity → Very High
- KPI → Finish Line

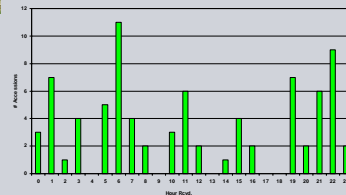
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Market Segmentation: Similarity

Emergency Labs



Drag Strips



- Average Speed → Short Burst
- Peak Duration → Short
- Backup Capacity → Central Lab
- Productivity → Low
- Price Sensitivity → Low
- KPI → Turn Around "Time is Tissue"

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Presentation Agenda



Mission

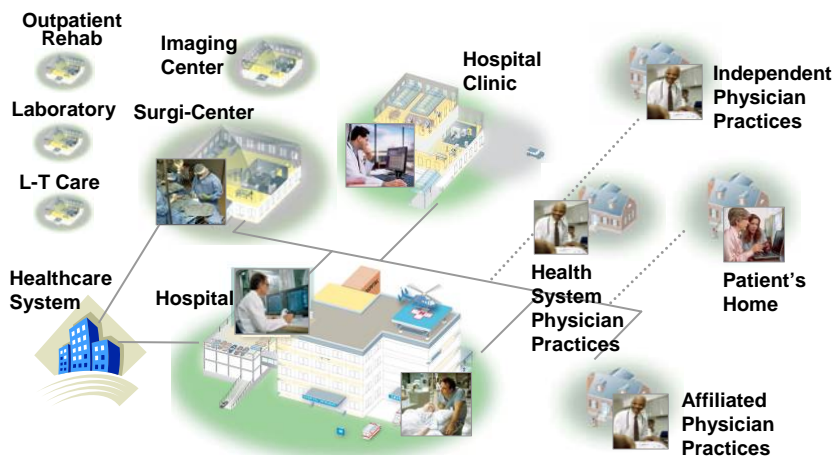
Today's IVD Industry

Trends and Challenges in Multi-Site Lab

Workflows Discussion / Needs

Combining Automation, Technology, and Performance Improvement

The Lab is a Vital Contributor to the Healthcare Network



Today's IVD Market

- Approximately 70 percent of the medical decisions are based upon the data obtained from laboratory testing performed by medical technologist/clinical laboratory scientists. ¹
- Tests today are performed today in many locations:
 - Clinical laboratory
 - Physician Office
 - Satellite locations
 - Patient Home / Residence
- Increasing Pressure to
 - Decrease Costs
 - Improve Productivity / Quality / TAT
 - Reduce Errors



Source:
The University of Southern
Mississippi Medical Technology

IVD Market Developments

Demand Drivers

1. Improve early detection and diagnosis of diseases
2. Increase accuracy
3. Better predict outcomes (prognosis).
4. Improve productivity by automating methods



Source:
American Association for Clinical Chemistry
LabTest Online® October 2010

IVD Market Developments

Fueling Growth

- Rapid advancements in new tests driven by research, personalized medicine, and tailored treatment
- New technology / methods
- Growing emphasis in Molecular and Genetic testing
- Expanding Point of Care
- Self testing for chronic sufferers

Source:
Boston Biomedical Consultants, Inc.
October 2010

Presentation Agenda



Mission

Today's IVD Industry

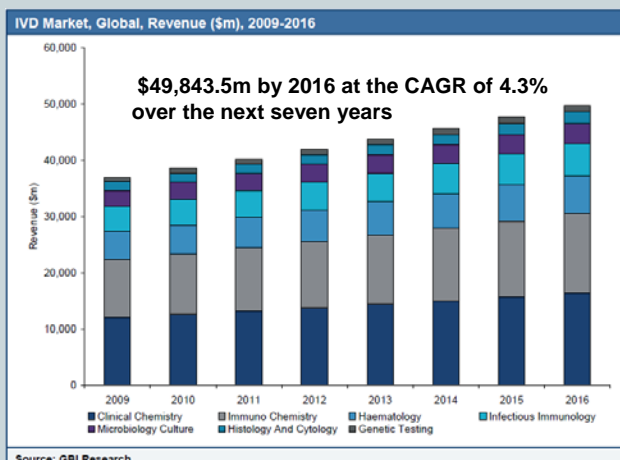
Trends and Challenges in Multi-Site Lab

Workflows Discussion / Needs

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Performance Improvement

Growth Trends & Projections for IVD Testing

IVD Anticipated Growth over Next 6 Years



DRIVERS:

- 1) New technological advancements
- 2) A shift towards more complex immunochemistry tests to Point of Care (POC)
- 3) The adoption of cost cutting measures such as increased automation and self testing.

Source:
GBI Research
January 2010

CAGR (Compounded Annual Growth Rate)

Complexities in Laboratory Management

CHALLENGES

N. America

- **Skilled Labor Shortages**
 - Attracting and retaining skilled labor
 - Aging workforce
- **Tight money supply**
 - Lack of Capital to Invest
 - Little or no money to remodel
- **Effective data management**
 - Need for integrated diagnosis
 - Real-time management dashboard tracking metrics
- **Partnering with Medical Staff to enhance patient care**

Challenges in today's laboratories worldwide

CHALLENGES

Error Reduction impacting Quality and Performance

- Labeling at the Source of Collection



Presentation Agenda



Mission

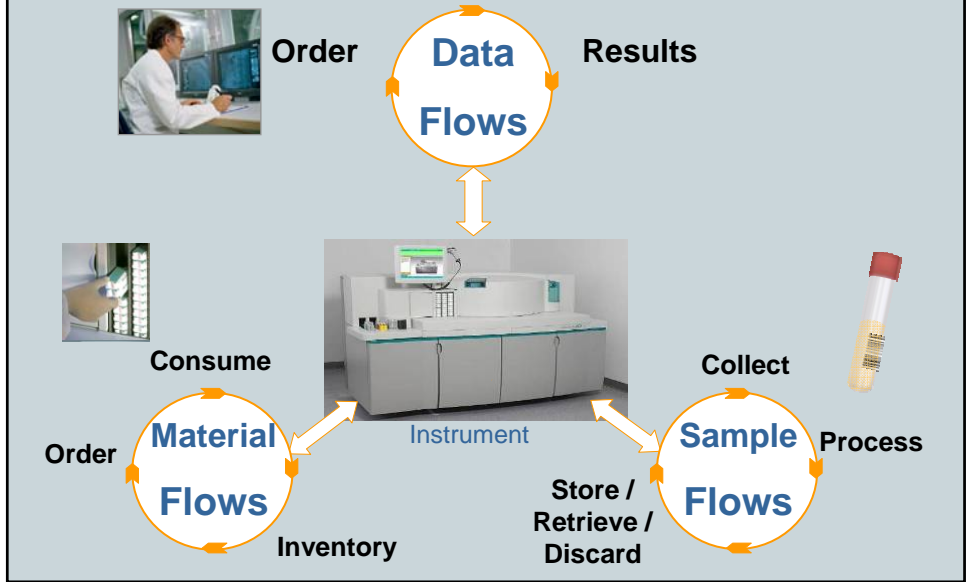
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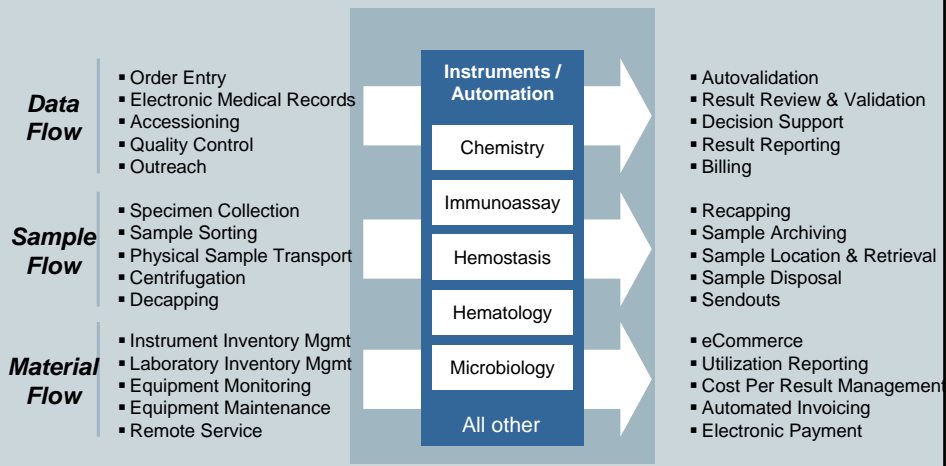
Combining Automation, Technology, and Performance Improvement

Three Independent WORKFLOWS within the Clinical Laboratory are Defined by Instrument



Details on the FLOWS within Multi-Site Labs are even more challenging

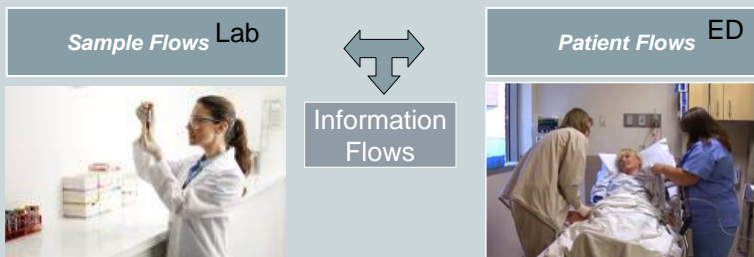
The Lab is a highly regulated and complex 24/7 departmental business!!!



In order to manage the complexity, Labs are relying upon Quality Management Systems and Tools

Focus: Eliminate Waste
Key Tool: Value Stream Map
Look for: Consolidation of Processes
Promote: Continuous Flow vs. Batch
Resources: Cross functional team

Ex: Lean RIE to Optimize processes & improve ED TAT



Today's Agenda



Today's IVD Industry

Trends and Challenges in Multi-Site Lab

Workflows Discussion / Needs

Combining Automation, Technology, and Performance Improvement

Today's Best Practice Laboratory is Driving ...

... Process Improvement across the Healthcare Network



Example #1 – Focus on Performance Improvements



“Denver Health’s Response to Rising Cost”

Healthcare Innovation:

“Getting It Right: Perfecting the Patient Experience,” has been a key factor in reducing waste in our system and improving the bottom line, while at the same time it has enhanced efficiency and ensured continued high quality of care.”



Patricia A. Gabous, M.D., CEO

Uncompensated care increased from \$318 million in 2008 to \$362 million in 2009

Source:
Denver Health
2008/09 Annual Reports

Example #1 “Denver Health’s Response to Rising Cost”



Example Healthcare Innovation:

“A good deal of credit for our success in remaining financially viable this year goes to our **LEAN initiative**, which, through process improvement efforts, has **reduced waste** in every corner of our health care delivery system. Using the principles of LEAN, employees throughout the enterprise joined together in three to five cross-departmental groups twice each month, and focused attention on specific areas in which waste can be removed. In 2009, the initiative gained significant momentum, and \$24 million of the **\$42 million total financial benefit** occurred in this year alone.



Patricia A. Gabow, M.D., CEO

One significant source of pride emanating from our transformation project is our unique development of an **internal corps of LEAN Black Belt experts** – the only **one of its kind in the nation**. We have **trained 200 employees**, from surgeons to mid-level managers, in the principles of LEAN. They then look to reduce waste every day in their departments. Black Belt projects accounted for \$8.8 million of the total \$42 million in financial benefit.

Source:
Denver Health
2008/09 Annual Reports

Best Practices → Overall Operation

Note worthy: Denver Health operates a Highly Complex Clinical Diagnostics Lab with ~100s customized order capability and multiple priorities...

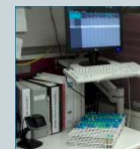
- **Lean Quality Management Driven**
 - **Visual Cues; Measurements; Priority Management**
- **Effective Use of Non Technical Labor**
- **Electronic Archival Tracking for Central Lab**
- **Auto Verification and Auto Release**



Smiling Faces

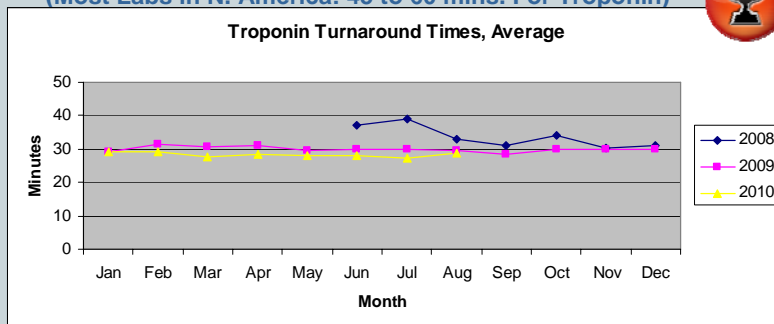


SpecTRACK

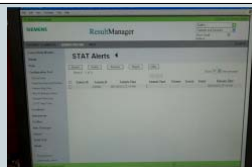


Best Practices → KPI: In Lab Turn Around Time

- In Lab Commitment: 30 minute TAT at 90th percentile
(Most Labs in N. America: 45 to 60 mins. For Troponin)



- In Lab Monitoring for Chemistry:
STAT Alert > 20 minute TAT



Focus on Continuous Performance Improvement

Example: Lean Project Plan and Summary

| # | Name/Description | Lead | Start Date | End Date | JDI | R/E | Project |
|----|--|------------|------------|----------|-----|-----|---------|
| 5 | Outpatient Charge Capture – Facility Billing | Billing | | | | X | |
| 2 | Outpatient Lab Ordering | Ord | | | | X | |
| 5a | Physician Billing Charge Capture | | | | | X | |
| 1 | CHS Outpatient Flow | | | | | X | |
| 1a | Pre-analytical Stand | | | | | X | |
| 9 | Specimen C | | 8/1/10 | 8/1/11 | | | X |
| 12 | Re | | 2/7/11 | | | X | |
| 18 | Spec | Lab | 8/1/10 | 12/31/10 | | | X |
| 16 | Anatom | AP | 3/7/11 | | | X | |
| 13 | IT/Lab O | IT / Lab | 4/4/11 | | | X | |
| 14 | Hazardous materials – RCRA | Operations | 8/2/10 | 8/2/10 | X | | |

5 Lean Black Belts in the Lab

Example #2 – Solving Tough Problems in Operations



“Driving Operational Excellence Daily”



- Provides > 50 millions lab tests to over 10 million patients and nearly 20,000 physicians in Canada
- Toronto Lab Processes more than 18K Samples per day in Chemistry with installation of a Single Line Automation in 2008
- Continuous Operations 24/7
- Faces Labor Shortages
- Highly Regulated
- Quality Focused



Source:
April Gamache
Sr. Vice President Operations
October 2010

Example #2 – Solving Tough Problems in Operations



Underlying Strategies to “Driving Operational Excellence”

- Establish an Environment of Continuous Improvement
- Establish a Common Language & Tool Kit
- Implement Rigorous Measurement Processes – Start with the Facts
- Learn from Mistakes
- Adopt Best Practice (UPS for tracking samples)
- Improve Capabilities to Solve Problems as they are identified
- Create an Organization of Mentors
- Expand Knowledge within the organization

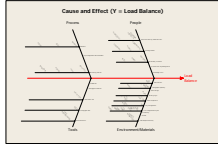


Source:
April Gamache
Sr. Vice President Operations
October 2010

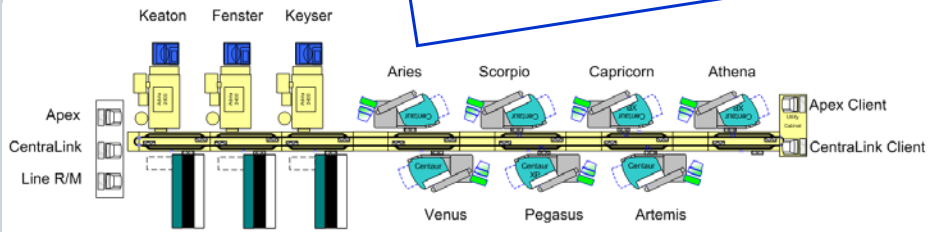
Combining Automation, Technology, and Performance Improvement



Value Stream Map – Optimize Processes -- Automate – Measure
– Workload Balance – Seek Further Improvement



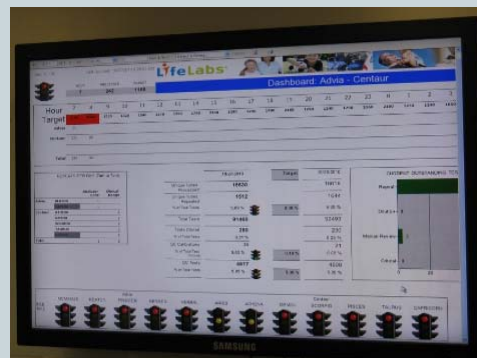
3 Six Sigma Black Belts



Lab Operations Dashboard

Visual management of the automation line

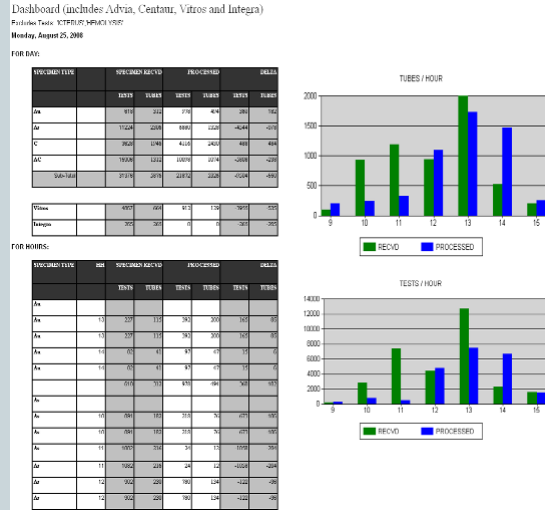
- Expected levels of tube processing allows technologists & technicians the ability to identify problems before they impact expected specimen turn-around times
- The red/yellow/green indicators also indicate severity of the issues and prompt the right response for lab personnel to take with the system



Specimen Management Dashboard

- “Web portals were established to provide real-time receipt of specimens by the various types required to be resulted”
- “This enabled operations group to identify potential backlogs that could occur and take appropriate action to resolve”

Michael Hartman
Lean Sigma Master
Black Belt



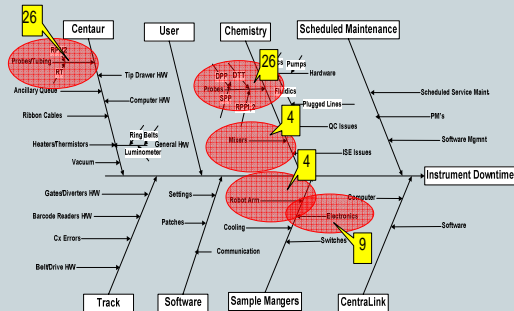
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Focus on Process Improvement

- “With the automation taking care of processing, operations could focus on identifying issues with capacity”
- “Lean Sigma played a critical role in unlocking the true capacity of the platform and providing a framework for ongoing improvement”

Michael Hartman
Lean Sigma Master
Black Belt

Root Cause Analysis



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Chartering the Future

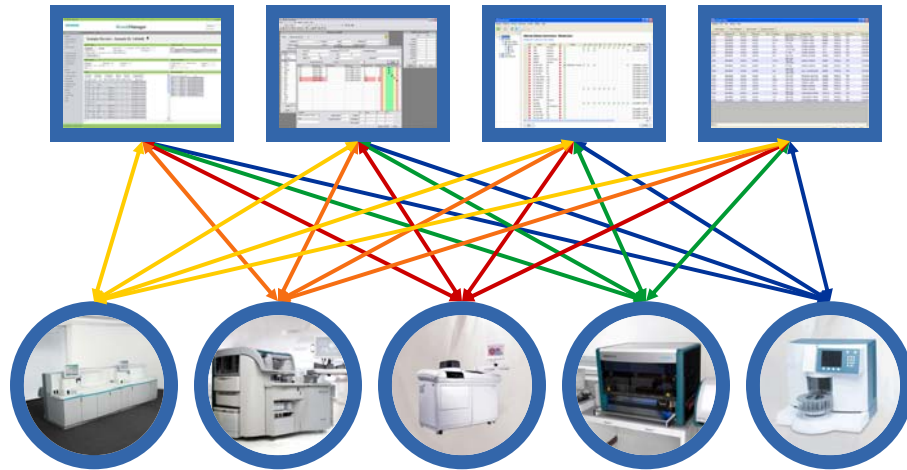


These are two great examples of where Multi-Site Lab Organization are Combining Automation, Technology, and Performance Improvement To Meet Its Mission

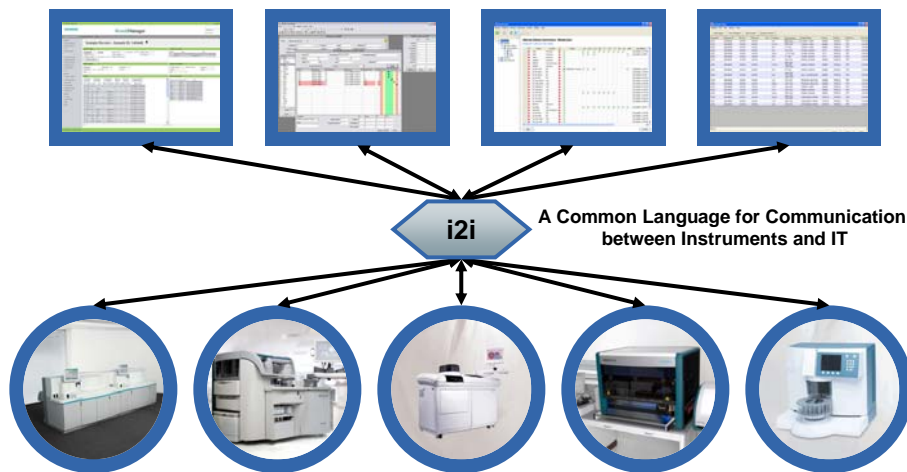
Looking ahead ... where's the next major opportunity



As an Industry, we must solve Today's Complex Connectivity and....



Meet the Laboratory's Needs with a Common Language for Communications that contributes to Efficient Process Control



Thank You



The Lab's Formula for Success

**Driving Hard while
Combining Automation,
Technology, and
Performance Improvement**