



## **ACHIEVING TRUE LEAN IN HEMATOLOGY WITH FULL AUTOMATION, INTEGRATION, & PAPERLESS SOLUTIONS**

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### *Who we are: Mercy Medical Center*

- 476 bed hospital serving a 5 county area and parts of Southeastern Ohio.
- First in:
  - Angioplasty in an emergency dept (World)
  - Accredited Chest Pain Center (Nation)
  - Cardiac Catheterization in a Community Hospital (Nation)
  - ER use of cardiopulmonary bypass (Nation)
  - Drug-eluting stent Angioplasty (Ohio)

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## *Who we are: Department of Pathology and Laboratory Medicine*

- Clinical and Anatomic Pathology
  - Main Laboratory
  - 6 offsite StatLabs with drawsites
  - 3 offsite patient service centers
  - Outreach program covering 5 counties
- Early adopter (2004) of Lean practices
  - Chemistry, Hematology, and Phlebotomy
- 2005 Six Sigma introduced
- CAP, AABB, FDA, JCAHO accredited

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## *Who we are: Department of Pathology and Laboratory Medicine*

- 2008 billable tests: 1.47 million
- 2009 projected: over 1.53 million
- Goals:
  - All results to ED within 30 minutes of receipt
  - All stats completed within 1 hour of receipt
  - Improve our LEAN processes

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## *Our journey into innovation.....*

- 2006 Issues
  - Increased volumes
  - Aging workforce—diminished pool of experienced workers
  - Turn around Time (TAT) a priority
  - Productivity and Budget constraints
  - Increasing volumes of Hgb A<sub>1</sub>C
  - Too many differentials
  - Goal to autoverify
  - Need to cross train personnel
  - Process was not fully “Leaned”

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## *Our search began.....*

- Vendors
  - Who sells Hematology?
  - Reliability, instrument flexibility
- WOULD IT MEET OUR LEAN CRITERIA?
  - Less Hands-on time
  - Personnel could be cross-trained
  - Autoverification
  - Paperless (“GO GREEN”)
  - Minimal downtime
  - What about the A<sub>1</sub>c testing?
  - Footprint

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## Vendor presentations (Dec 06)

- Vendor presentation to
  - COO and Director of Purchasing
  - Lab Administration and Medical Director
- Important points
  - What solution was available for our lab?
    - Volume of CBCs/day:
    - Throughput of instrument
    - If automated line: Time splits at each junction
    - How would this contribute to improvements in TAT?
    - Could we autoverify and go paperless?
    - How big was the configuration


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## Workflow Assessment

The diagram illustrates the laboratory workflow assessment. It shows a layout of the lab with various departments and equipment. Red arrows trace the path of samples from a 'Before' box, indicating the flow through Hematology, Coagulation, and Microscopy. The departments shown include Chemistry, Hematology, Coagulation, Microscopy, and Urinalysis. Specific equipment labeled includes Unical Dxl 800, Chem Setup, Fuge, Processing, Tube Station, Desk, Sandbox Flig, Primary Hemat. Analyzer, Blood Smear, Body Fluid, Special Coag, and Dacie Stratos.


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 **Our choice:**

- Combine Hematology with HbA1c testing
  - HbA1c run more frequently
  - Random access
  - Free up tech time
  - Auto-verify
- Middleware
  - Fewer differentials
  - Paperless hematology
- Patient and Physician
  - Faster turn-around-time
  - Earlier Decisions




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 **Preparing for the "blessed event"**

- Paperwork
- Homework
- Paperwork
- Paperwork
- Paperwork

– Oh My, how much is there?



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## *We need a team*

- MMC
  - Core Lab Manager
  - Quality Coordinator
  - LIS Coordinator
  - Primary operator
- Vendor
  - Facilitator

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## *Installation*

- It took time and resources
  - Laboratory
  - Sysmex
  - BioRad
  - LIS vendor
  - IS department
  - Plant and Engineering



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## *When do we "go live"?*


- Testing
  - Emulator
  - Wet testing
- Training
  - Middleware
  - Instrument
  - Line

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## *Instrument & Rules Validation Process*


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## Implementation Process

- Instrument validation- studies performed by Vendor
- Vendor Rules development and testing:
  - Heme and A1c rules template
  - Instrument data emulator for rules testing
  - Guided testing via test plans

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## Example Hematology Decision Rules

<u>Type of Rule</u>	<u>Rule Definition: Criteria for rule</u>	Automated action taken by Automation Line	Operator message to be displayed
<b>Multi-level and multi-action</b>	If <u>WBC</u> <2 or >35 and <5 <u>days</u> old then <u>hold</u> CBC/Diff <u>order</u> rerun and smear	Rerun CBC & Diff & make smear	WBC Critical: Call criticals
<b>Data comparison, multi-parameter</b>	If PLT <u>delta</u> +/- 50% and <u>PLT</u> 0-99	Run for Optical Plt & make smear	PLT Delta failure, Confirm by smear estimate. Check for clumps. Call Criticals

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## Testing the A1c rules

- Rules Document
  - Emulator
  - Wet testing
- Our current practices
- Rule Example :
  - If Total Area is too high, then dilute sample and rerun

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## Example A1c Decision Rules

Type of Rule	Rule Definition: <u>Criteria for rule</u>	Automated action taken by Automation Line	Operator message to be displayed
Single parameter	If TAREA <1.1	Repeat A1c	HbA1c, Low Total Area: Check sample volume and integrity of aspiration needle. Rerun per lab protocol. Make a 1:100 dilution and repeat test.
Multi-parameter, multi-level	If LA1c >4.6 and < 6.5 and HbA1c% <8.2	Repeat A1c	HbA1c, Labile too high: Incubate blood for 24 hours at room temperature and rerun. If rule still triggers, sendout.

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## *Weekly conference calls*

- Critical to project
- Vendor and Lab team
- As many team members as possible
- Problems brought to surface
- Solutions discussed

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## *When do we "go live"*

- Ambitious versus realistic goal
  - Outside forces
    - IS connectivity
    - Staffing
    - Electrical
    - Interface

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## Implementation Process

- Training
  - Instrument – How does it work?
  - Maintenance – Is it different?
  - Results – Are the printouts the same?
  - Integration with the Line – How many alarms?
  - Sysmex WAM – what?

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## GO Live?

- Date was postponed
  - Ambitious
  - IS issues not instrument
- May be needed
  - Don't pressure to move forward
  - Credibility and acceptance at stake
    - Remember your users

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## *It's not a BED OF ROSES*

- New technology
  - Line versus instrument issues
  - Middleware versus Meditech
  - Where is the specimen?
  - Sorter issues
  - Where is the specimen?

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## *Change is always hard*

- Tenured Staff
- This is how we have always done it
- Why do we need to change?
- I am out of my comfort level
- New way of thinking/doing/outcomes

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*In retrospect.....*

What could we have done better?

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## *Personnel issues*

- Personnel encouragement
- Positive reinforcement
- Numbers
  - TAT for Emergency dept
  - Fewer differentials

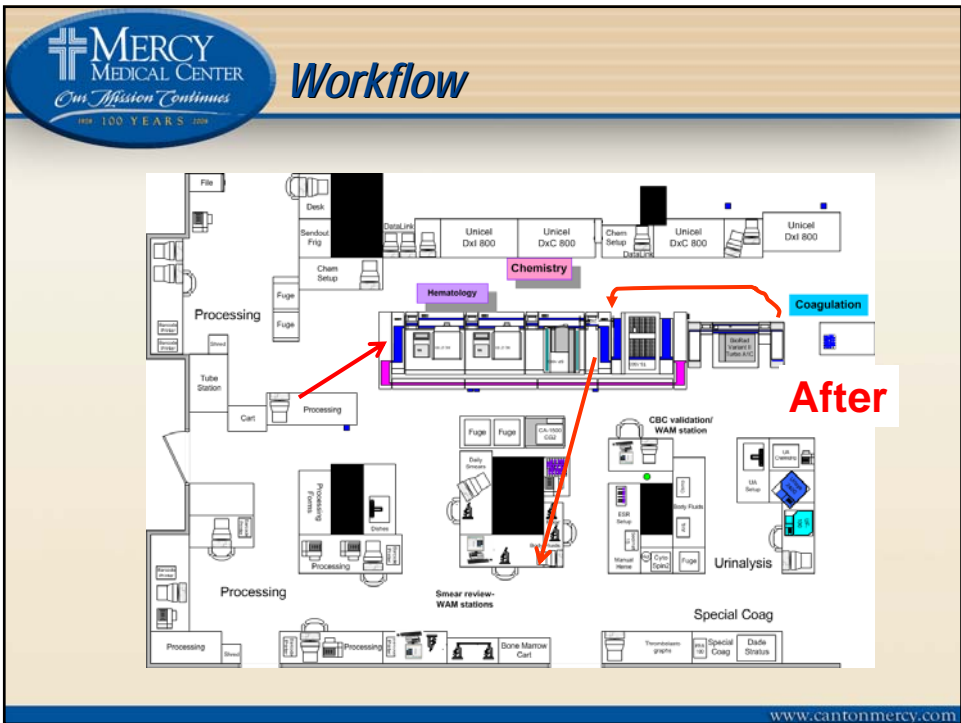
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# Outcomes



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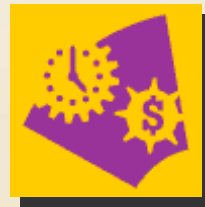




## Turn-Around-Time & Review Rate

- Average TAT for CBC: 6.2 minutes
- Differential review rate decreased

from 20% to <13%



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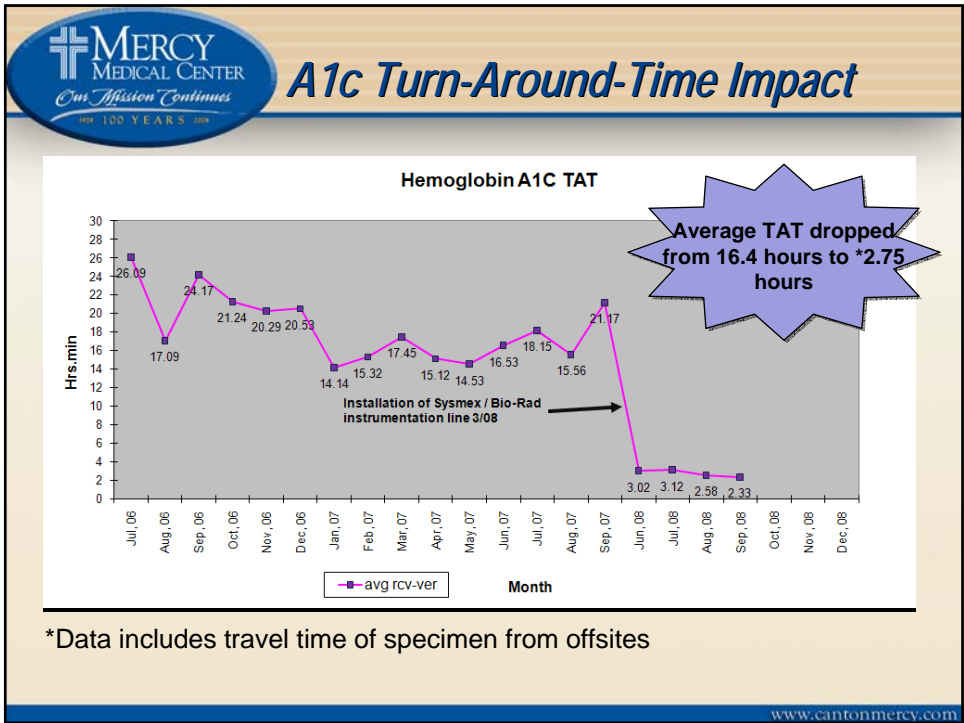


## A1C

### LEAN Objectives Achieved

- Labor Savings
  - One tube draw for CBC and HBA1c
- TAT average improved 82%
  - from 16.4 hrs to 2.75 hrs (receive to verify)
- Data Review
  - Over 95% of samples are autoverified
- Resource Reallocation
  - 0.5 FTE available for other testing

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### Hematology Automation plus Sysmex WAM - What we gained!

- Auto-verification
- Paperless environment
- Additional capacity to add new testing without new staff
- Reduce opportunities for error
- Standardized sample and data workflow
- Staff cross-training
- HBA<sub>1</sub> C “on demand”

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## Our Automated LEAN Work Cell

Processing

Automated Lavender Top Management®

Automated Chemistry

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## Our Lavender Top Management® Configuration

Bio-Rad VARIANT™ II TURBO Link-A1c

TS-500- Automated sorting, re-routing and archiving

SP-1000i- Smear prep

XE-2100 XE-2100


Hematology testing


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 **Hands-Free Repeat/Reflex Testing**



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 **"All-in-One" Data Station**



Multi-application Sysmex WAM workstation:

- CBC Validation
- Smear review /diff station
- LIS access

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Visual STAT sample differentiation.

"Operator Alert" -displays rule and user-defined instructions for tech.

Single view of CBC and A1c exception results.

CBC, Diff results

A1c results

Flexible validation options: partial (CBC) and full (CBC+A1c results) validation

No more instrument printouts

Same review process- all techs, all shifts

Review by exception- Techs focus on "abnormal" samples

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## Auto-verification Outcomes

**A1c Milestones Achieved:**


1. Auto-verification of A1c's
2. 2179 data study- 95% auto-verified
  - 77 (3.5%) flagged by the rules
  - 49 (2.2%) reported after review

Systemx WAM

**Hematology Milestones Achieved:**

1. Auto-verification from Day 1 of live
2. Over 85 % of samples auto-verify
3. Paperless


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## *OUTCOMES—LEAN ACHIEVED*

- ✓ Standardized workflow
  - One tube for CBC and A1c
- ✓ Data Review—auto-verification
  - Over 85% of CBCs
  - Over 95% of A1c
- ✓ TAT improvement
- ✓ Labor Savings/Resource Reallocation
  - 0.5 FTE (Heme) retired not replaced
  - 0.5 FTE (Chem) available for other testing

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## *Points to remember*

It is a team effort

- Laboratory
- Vendor
- LIS vendor
- IS department
- Plant and Engineering
- It will disrupt the lab
- Change is never easy

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 **Take home message**

- Time
- Energy
- Teamwork



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