

How Investment in Becoming Nation's First CAP 15189 Accredited Integrated System of Labs Produces Lower Costs, Improved Quality, and Happier Patients

Richard J Zarbo, MD

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2013 Henry Ford Health System, Pathology and Laboratory Medicine

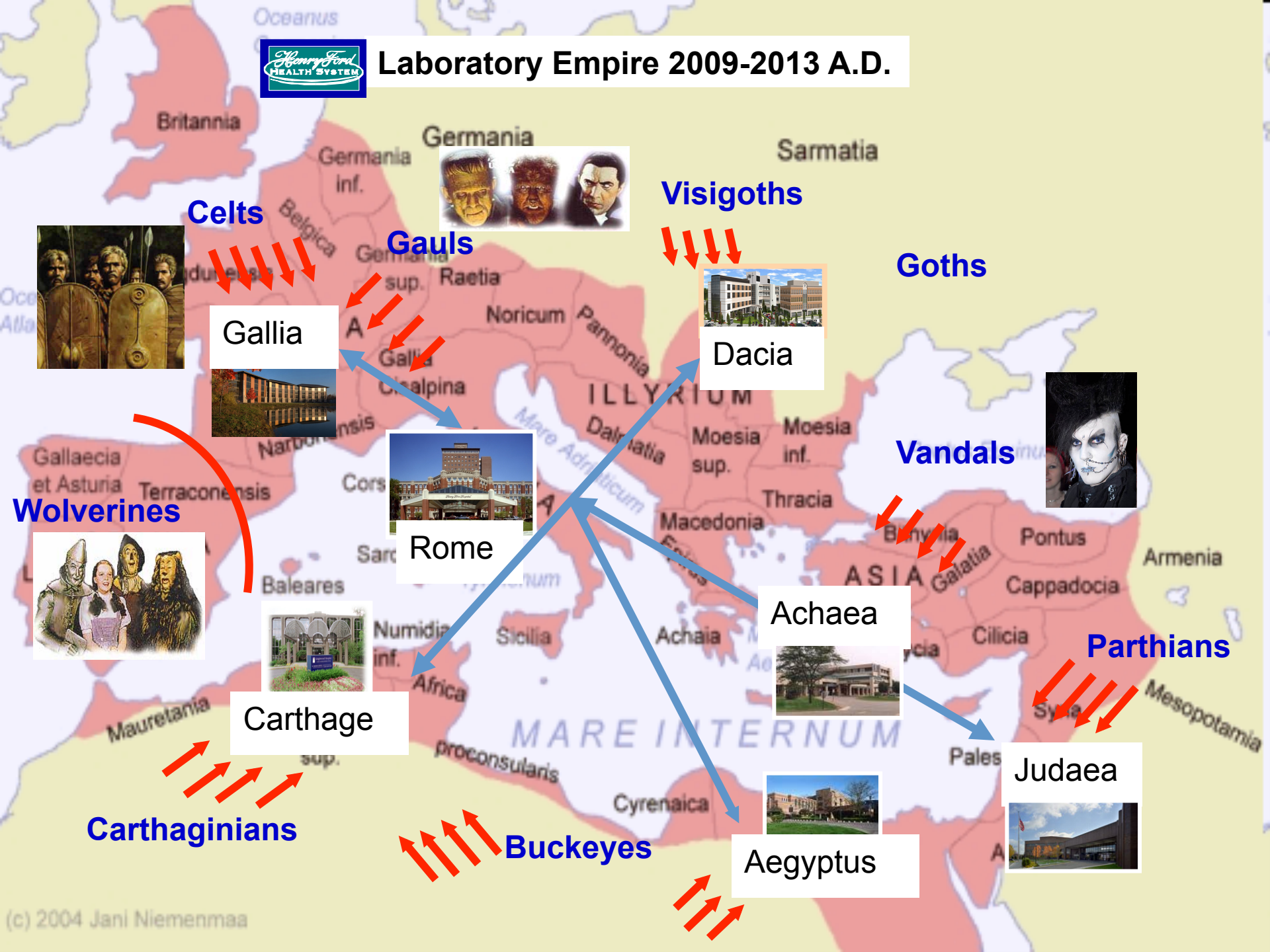
In Pursuit of Survival

It's a Circus Out There





Laboratory Empire 2009-2013 A.D.



Celts



Gauls

Gallia



Visigoths



Dacia

Goths



Vandals



Parthians



Judaea



Achaia



Aegyptus



Rome



Carthage



Carthaginians



Buckeyes



Wolverines



Melding Lean Integration ISO 15189

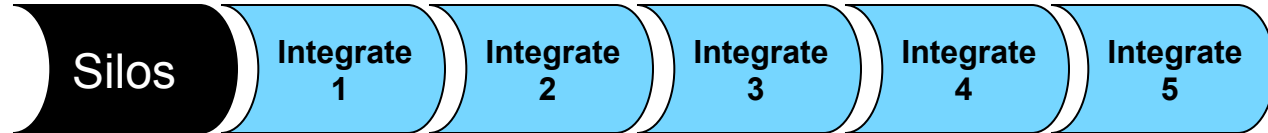


“Well done is quickly done”

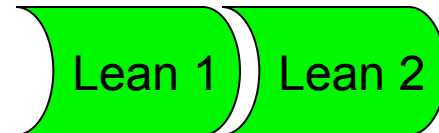
Julius Caesar
Author, General, Politician

Quality Progression

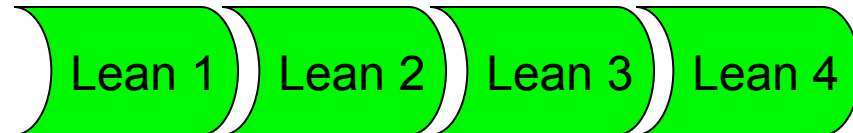
Lean, Integration, ISO



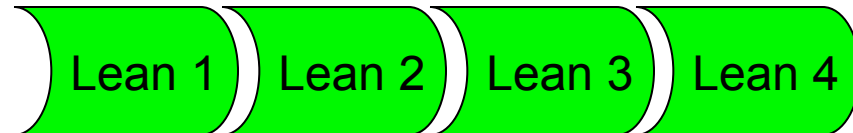
Community hosp #3



Community hosp #2



Community hosp #1



LESSON

“It’s not that I’m so smart, it’s just that I stay with problems longer.”

Albert Einstein

Why ISO?

LESSON

“The competitor to be feared is one who never bothers about you at all, but goes on making his own business better all the time.”

Henry Ford

Implementing Successful Change

“The effort is usually a time consuming and highly complex 8-step process, never a 1-2-3, hit-and-run affair”

1. Create a sense of urgency
2. Put together a strong enough team to direct the process
3. Create an appropriate vision
4. Communicate that new vision broadly
5. Empower employees to act on the vision
6. Produce sufficient short-term results to give efforts credibility and dis-empower the cynics
7. Build momentum and use that to tackle the tougher change problems
8. Anchor the behavior in organizational culture

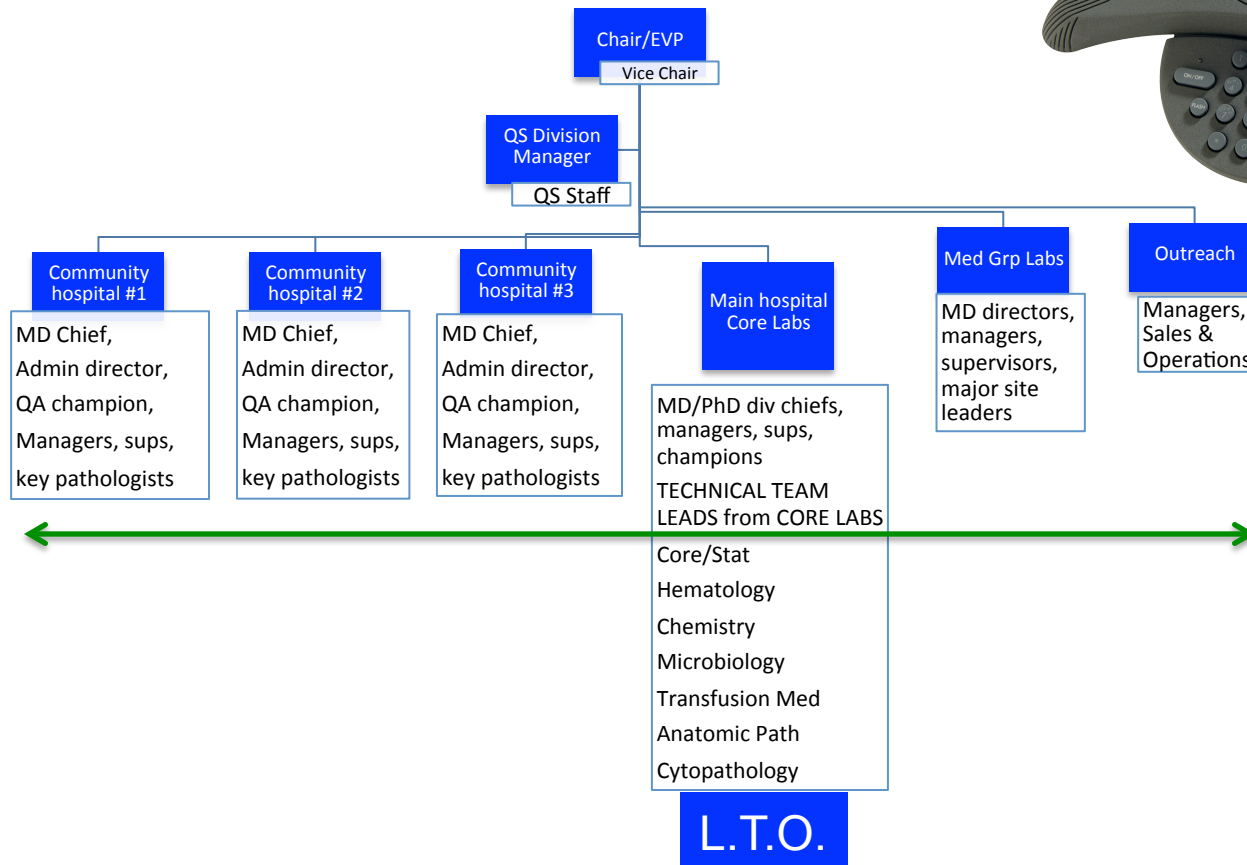
“Managers who opportunistically skip steps or proceed in the wrong order rarely achieve their aspirations”

On What Leaders Really Do -John Kotter

LESSON

Systems don't produce quality, people do!

Horizontal & Vertical Management System-wide Pursuit of Quality



Start with Very Good Leadership and Assemble Good Teams

The Stars of Quality



ISO grafted onto pre-existing

Worker Empowered Problem Solving Culture

Henry Ford Production System

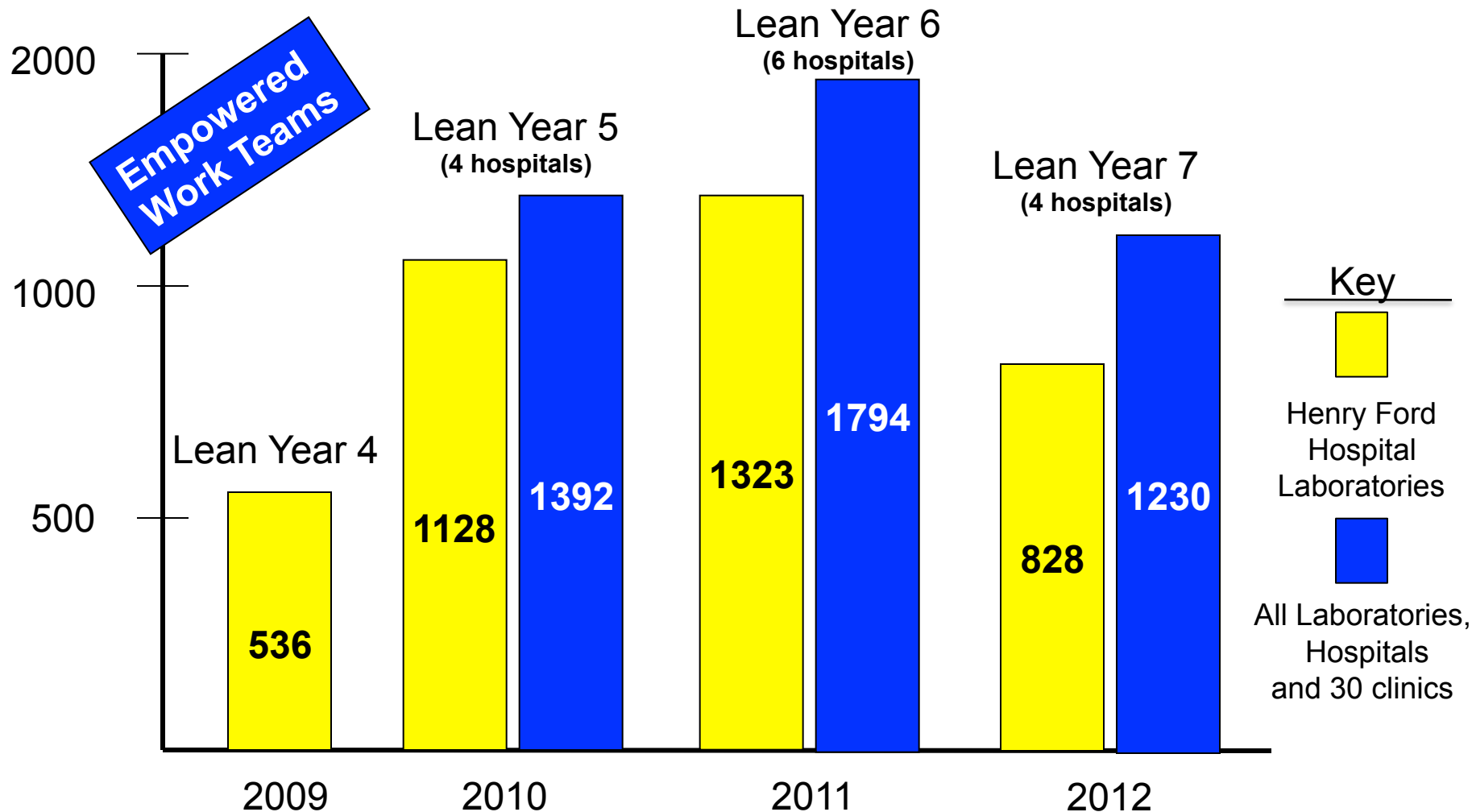
“Quality is doing it right when no one is looking”

-Henry Ford

Total Process Improvements

Pathology & Laboratory Medicine Service Line

Henry Ford Production System



ISO Accreditation Re- Focus

1. Quality Management Systems, Technical Processes, Error & Risk, Document Control, Occurrence Management, CAPA, Effectiveness, Internal Audits
2. Management Standards
3. Technical Standards & Employee Engagement

4 Yr. Pathway to ISO as a System

- Leadership sets clear goal
- Provide resources and infrastructure (horizontal management authority, electronic document control system, document taxonomy, education)
- Designate strong leader for overall operational oversight
- Hybridize CLIA and ISO standards (crosswalk)
- Identify system wide gaps from internal analysis
- Establish programs and processes where none exist
- Initial Internal Gap 2009-2010: Number each major gap, identify leader responsible for specific gap closure
- Form and assign horizontal technical teams to standardize gap closure and write standardized documents under electronic document control
- Engage staff in owning gap closure through Lean culture
- Push weekly ISO quality agenda and follow-up through new System-wide Quality Technical Team
- 2nd Round Internal Gap 2011-2012: identify further gaps in:
 - Policies, procedures, forms
 - Posted documents under control
 - Staff education in basics and expectations of ISO
 - Volunteer internal auditors education and practice in audit process
 - Competency documentation
 - Performance of internal audits to assure we are doing what we say we do

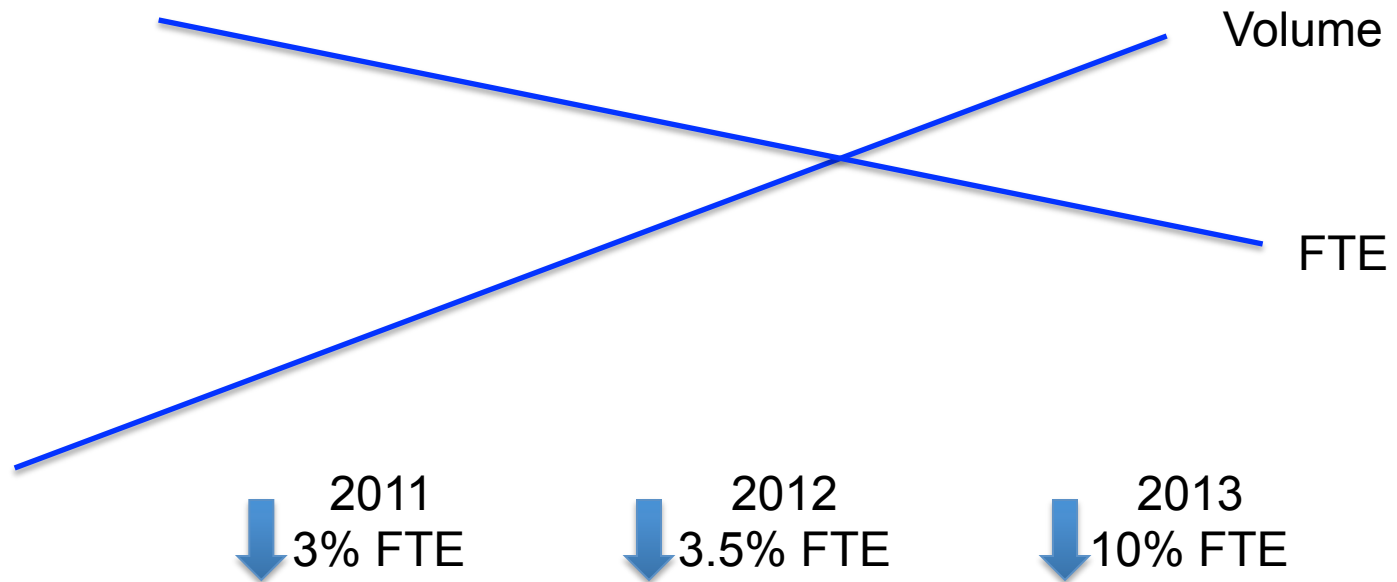
Winners from ISO Pursuit

Deeper Dives in Quality

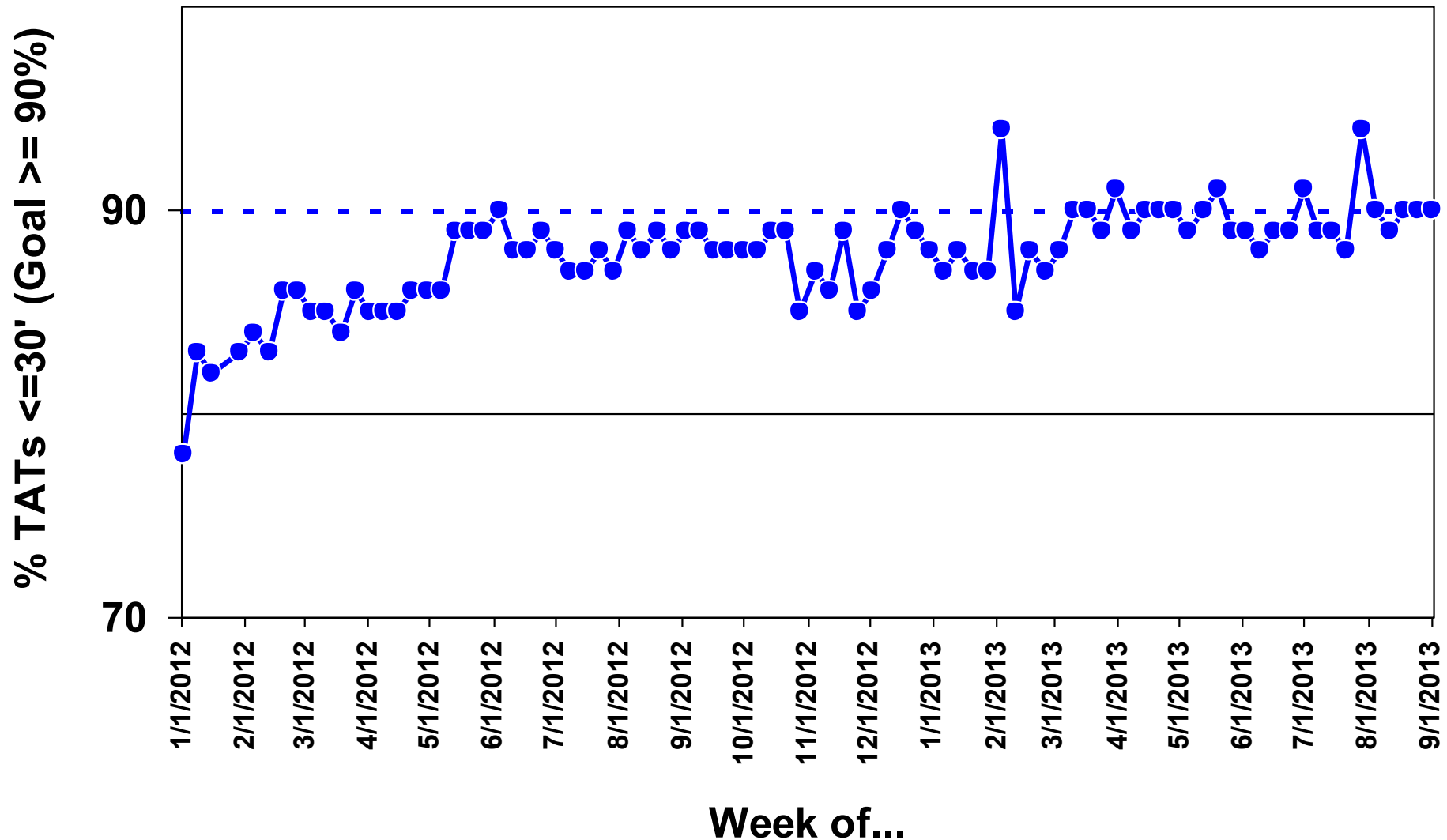
- Deviation management
- Control of non-conformities
 - Corrective & Preventive Action documentation
 - Monitoring for effectiveness
- Document control
 - Change management
 - Posted documents + job aides under control
- Management Review
- Internal ISO training & audit teams
- Deeper focus on metrics
- Deeper adherence to Lean disciplines

Operational Quality

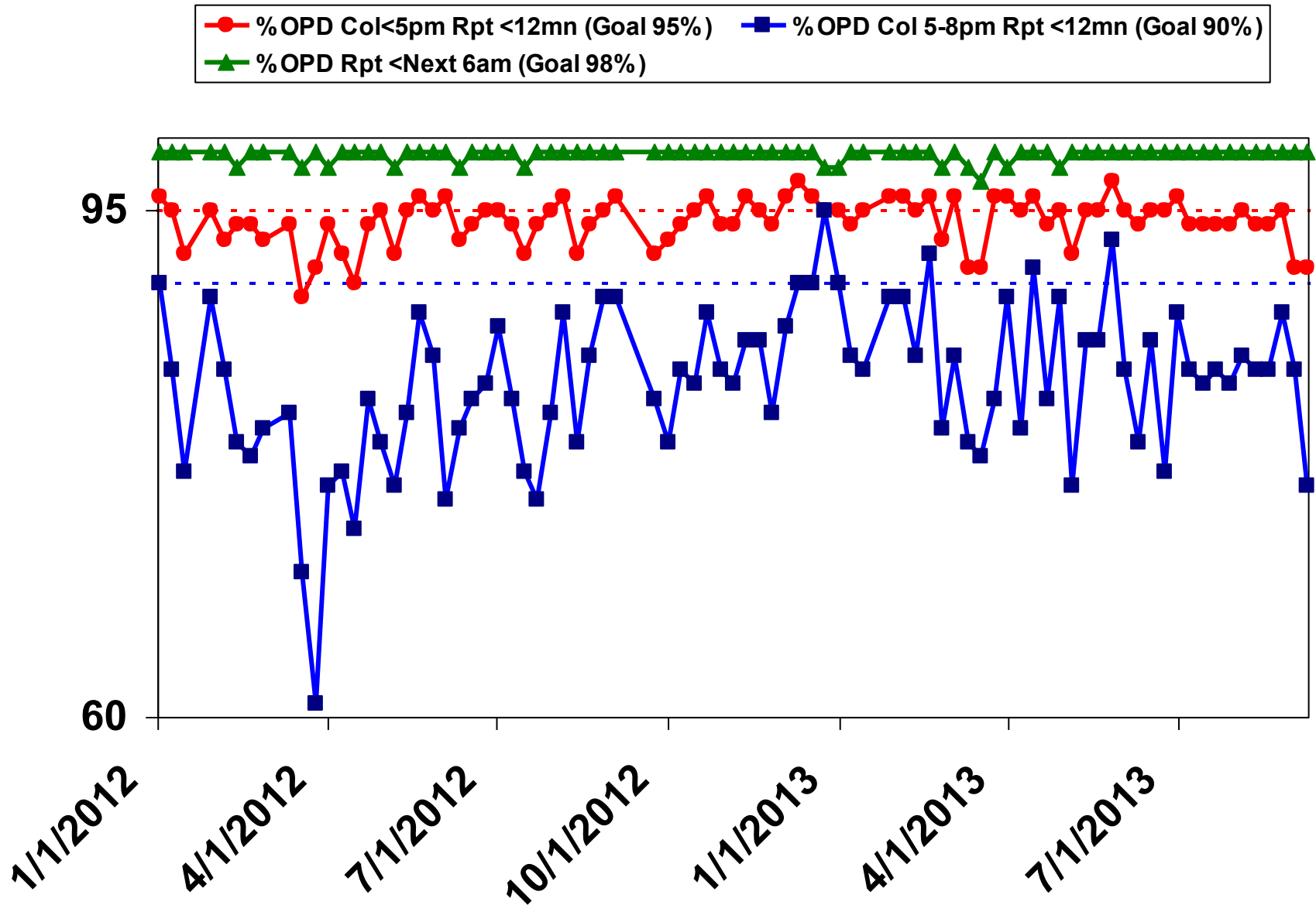
Challenge



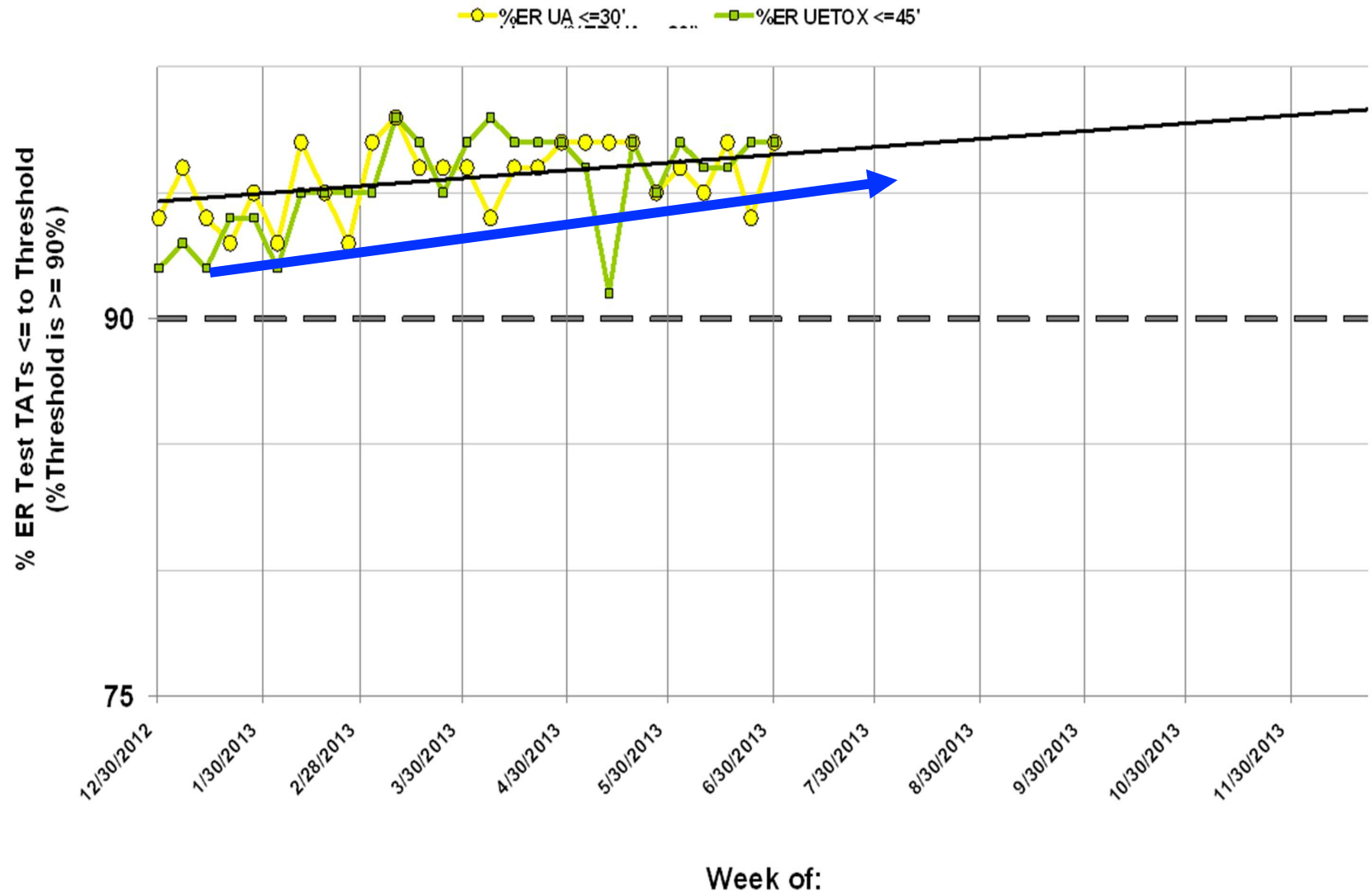
ER Core Lab Test TAT < 30 min



Routine OPD Test TAT –Core Lab

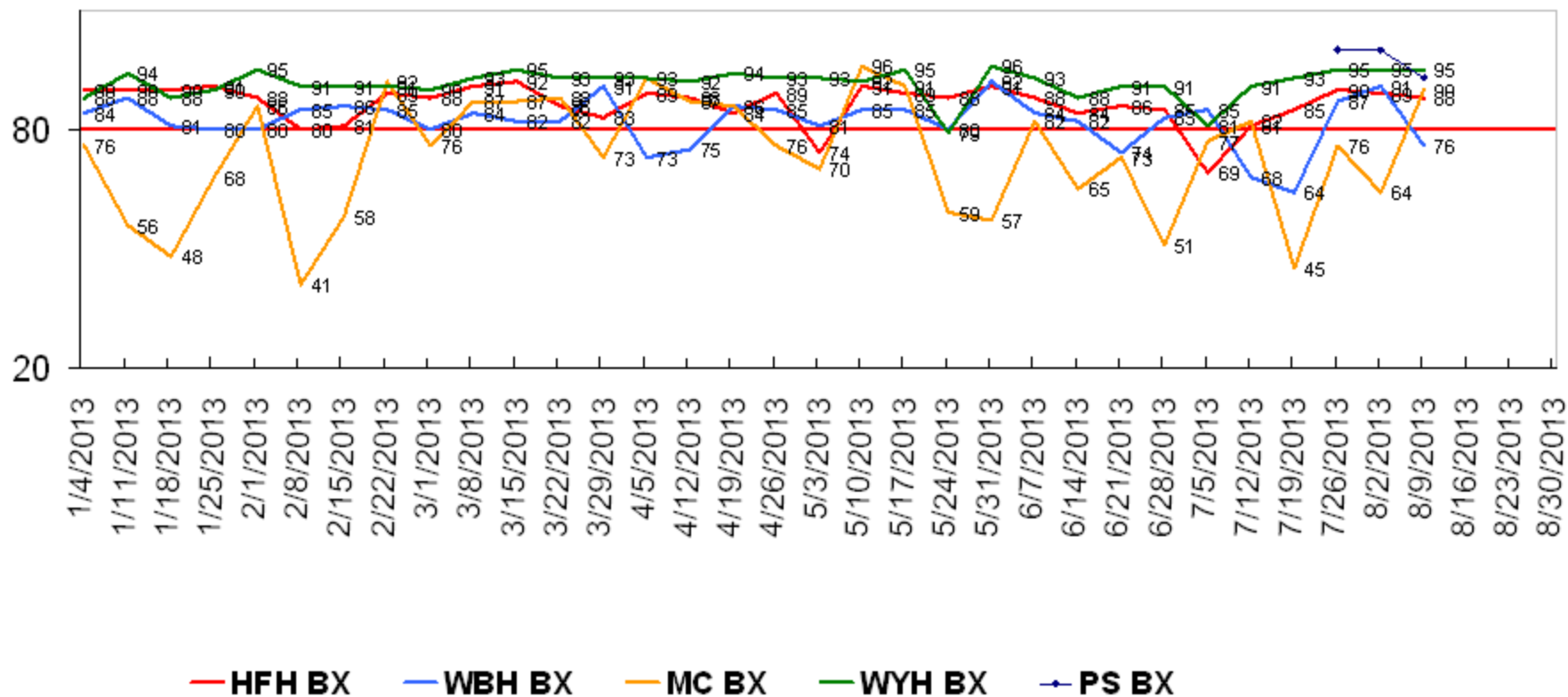


ER Stat Urine Test TATs



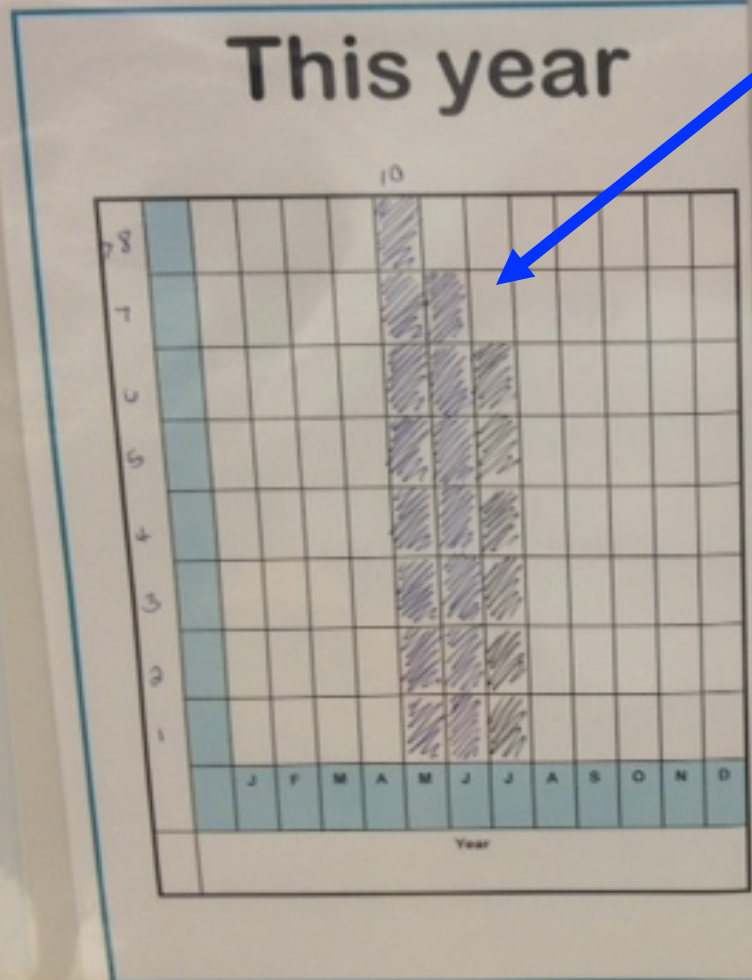
BIOPSY Report Timeliness

2013 Biopsy YTD TAT: Goal 80% in 2 Days



Safety

Patient Safety



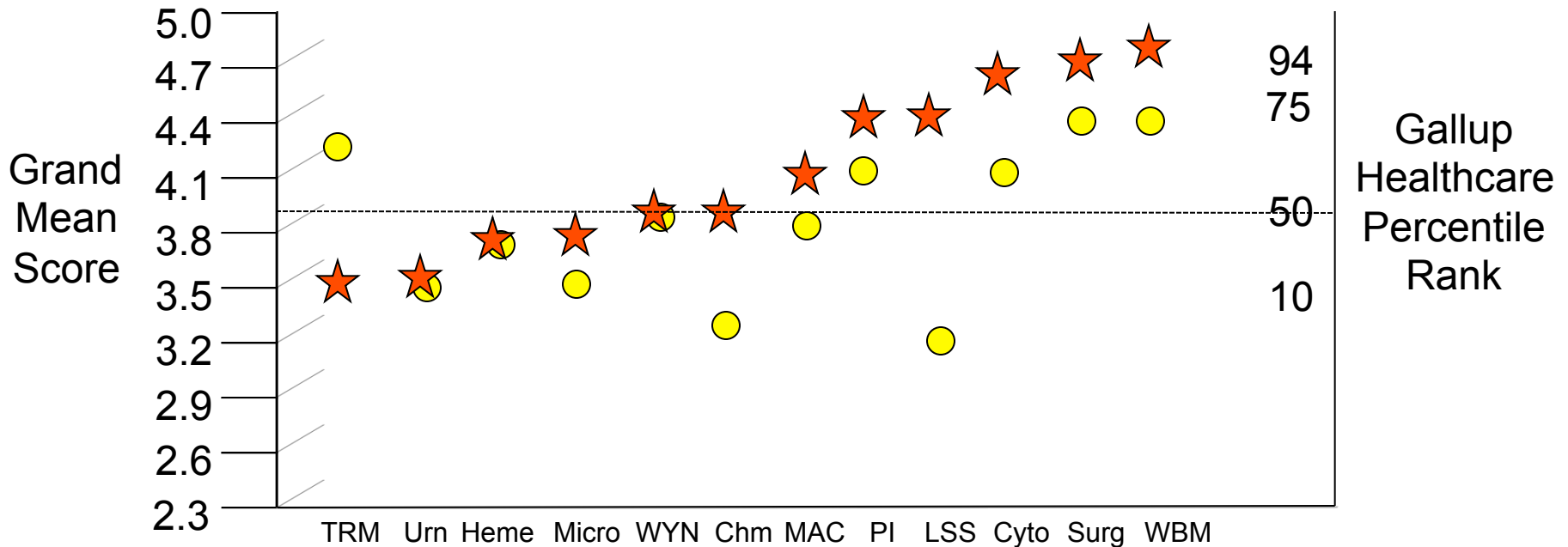
Steady
Drop in
Critical
Value
Callback
Failures

Employee Engagement

Employee Engagement Surveys

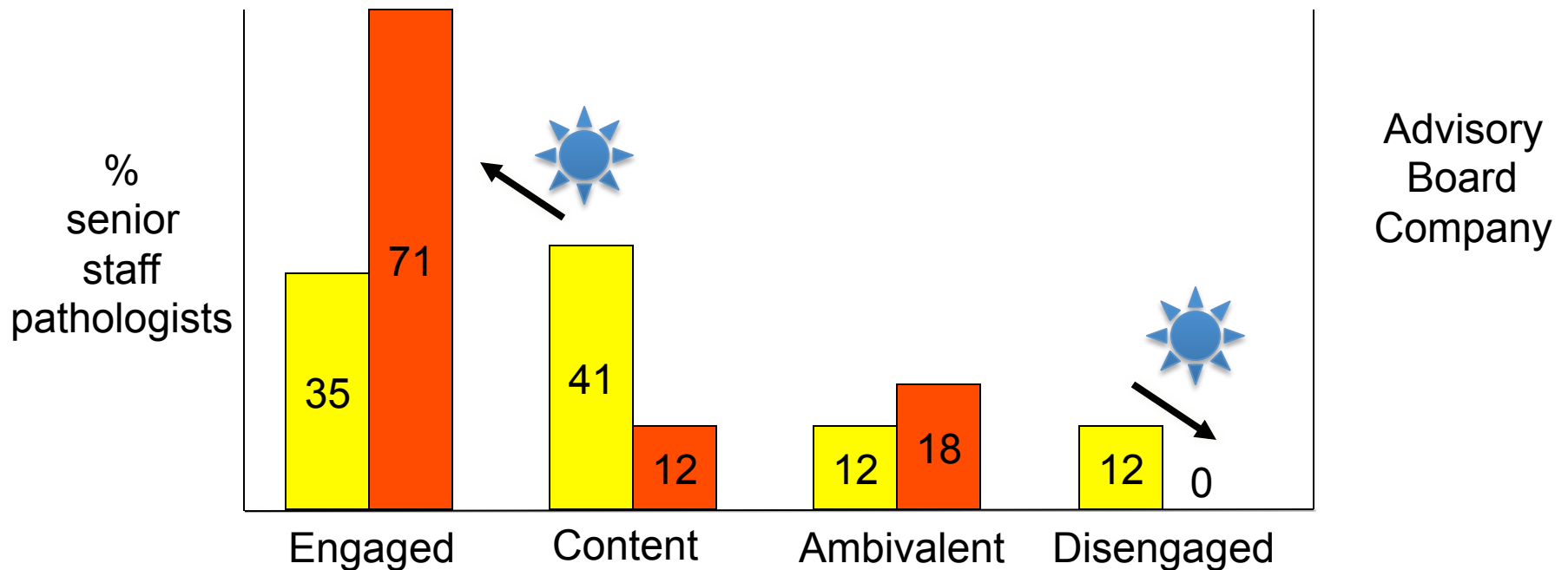
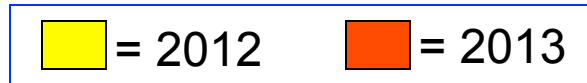
Pathology and Lab Medicine Service Line

● = 2010 ★ = 2012



Pathologist Engagement Surveys

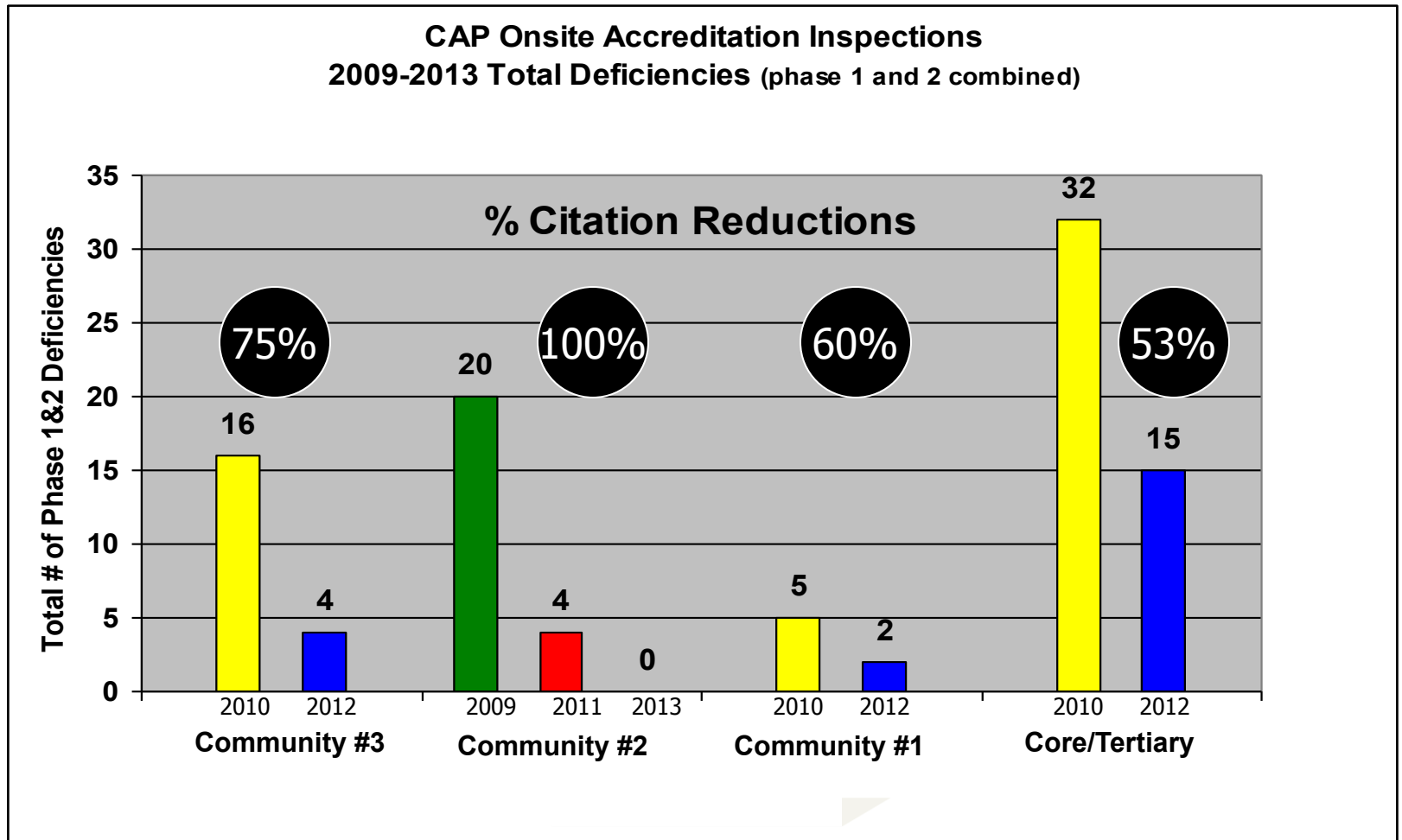
Pathology and Lab Medicine Service Line



Regulatory Quality

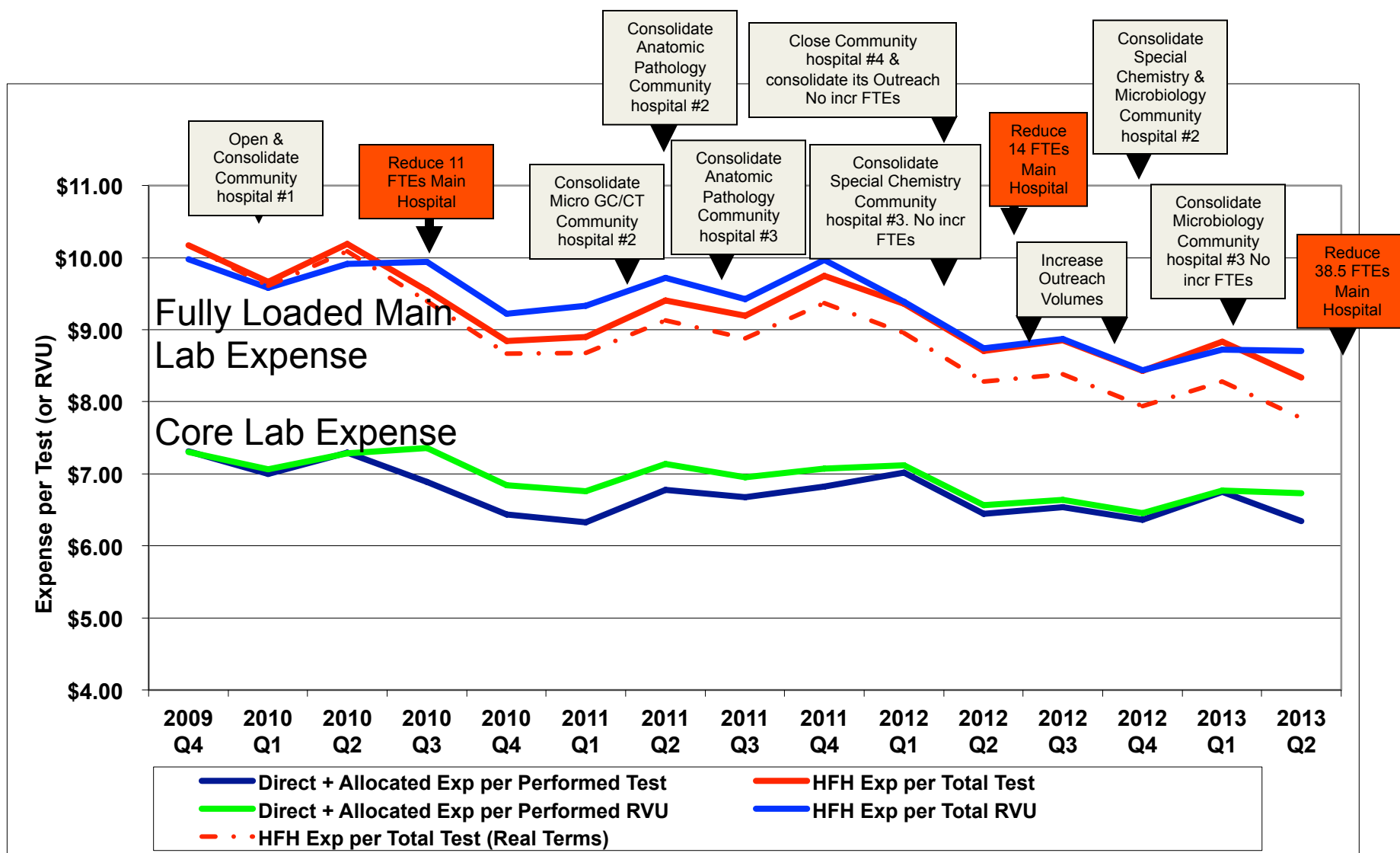
CAP Inspection Deficiencies

Henry Ford Acute Care Hospitals



Cost

Main Hosp & Core Lab Unit Cost Trends



Success Management Discipline ISO

Managing for Quality

Deming Culture

Deming's Redefinition of Management

“In companies that have embraced Deming's vision, **management's job is to 'work on the system'** to achieve continual product and process improvement.

The Deming-style manager must-
ensure a system's consistency and reliability, by bringing
level of **variation in its operations within predictable limits**, then by
identifying opportunities for improvement, by
enlisting the **participation of every employee**, and by
giving subordinates the practical benefit of his experience
and the **help they need to chart improvement strategies.**”

(A. Gabor)



Middle Management

CAMBRIDGE, Mass. (2007)–

Middle management resistance to change is now the number one obstacle to implementing the innovative business system known as lean production, according to a new survey completed by nearly 2,500 business people and conducted by the Lean Enterprise Institute, a nonprofit management research center.

Middle management resistance was cited by 36.1 percent of respondents in LEI's annual survey about lean business system implementation in the U.S. The top 3 obstacles to implementation were **middle management resistance (36.1%), lack of implementation know-how (31%) and employee resistance (27.7%).**

The latest findings were based on responses to a survey distributed electronically to 77,200 subscribers to LEI's monthly e-letter.

Managers Checklist

Managers Weekly Checklist

"You get what you inspect not what you expect"

- 1. Deviations/Non-conformances outliers and trends**
- 2. Temp humidity checks -completeness of documentation, root cause and corrective actions**
- 3. 5S activity documentation**
- 4. Posted job aides and all visuals reviewed and updated**
- 5. New or revised procedures reviewed with staff and staff competencies verified**
- 6. New problems of risk (mis-ID, safety) and resolutions discussed**
- 7. DM Board metrics review leading to interventions and process improvements**
- 8. Ongoing and planned process improvements reviewed**
- 9. Inventory and kanban check**

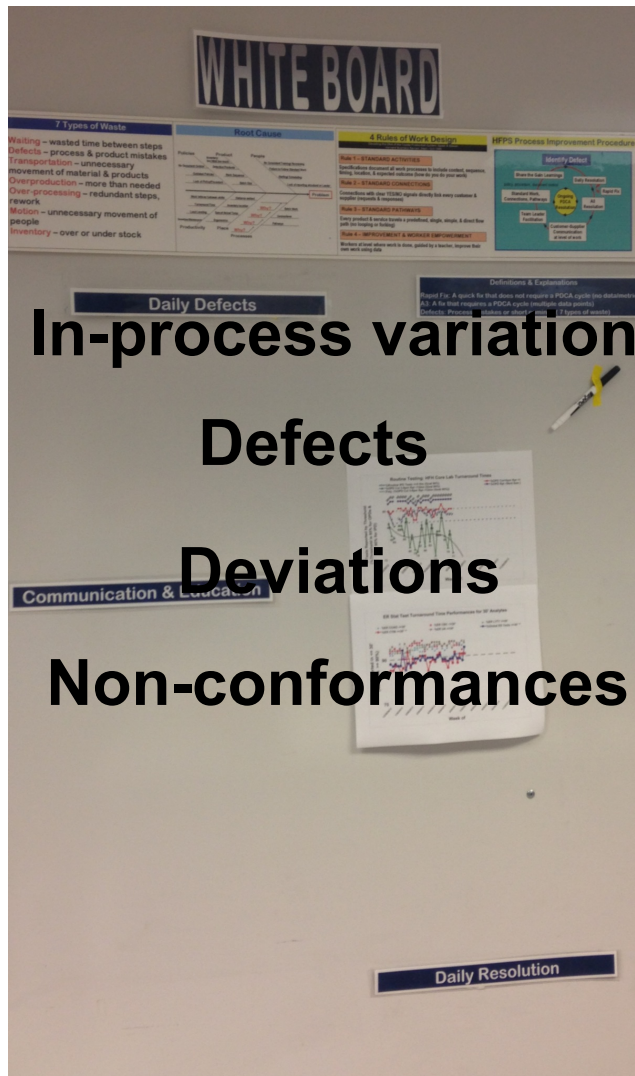
Daily Management

Saluti: Gaurav Sharma MD, Brian Barnett, John Sekowski, Sandy Phelps

“What’s measured improves”



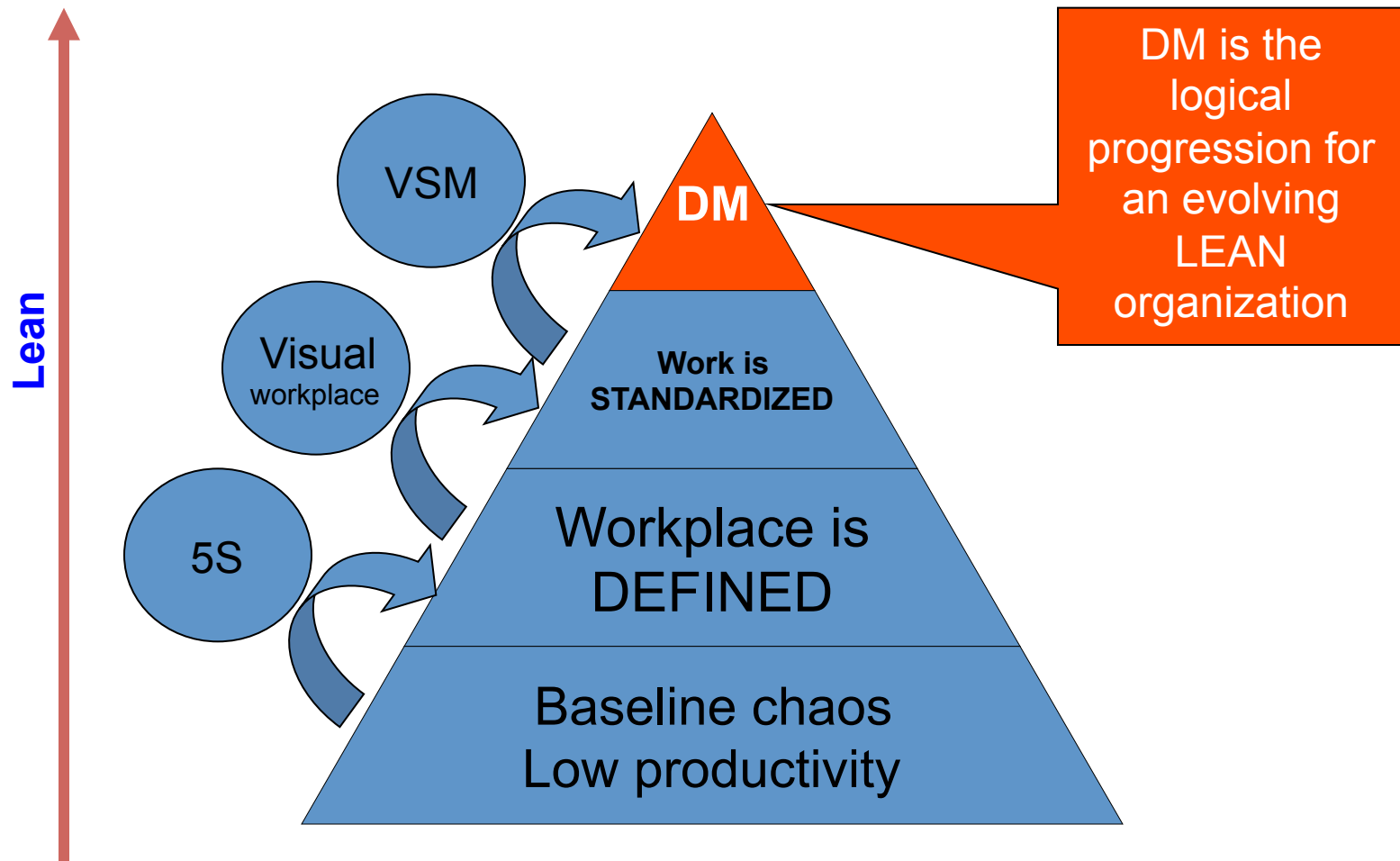
Peter F. Drucker



In-process variation
Defects
Deviations
Non-conformances

“The only things that evolve by themselves in an organization are disorder, friction and malperformance”

Chaos → Lean → Daily Management



What is Daily Management?

DM is the ultimate in true “visual management” in the workplace



**Did we
Win or Lose?**

- **Selected critical metrics define daily performance**
- **Info simple to collect, easy to understand**
- **Tells you at a glance in 3 seconds whether you are “winning” or “losing” today**
- **Is visible at a distance to all involved**
- **Is directed toward a group, not individuals**
- **Shows the standard and your performance toward it**
- **Involves all MD and admin managers, supervisors, tech leaders in the management process**
- **Focuses the team on few critical metrics for success today**
- **Is used to drive PDCA problem solving in a blameless environment**

Structure for Daily Management

Quality

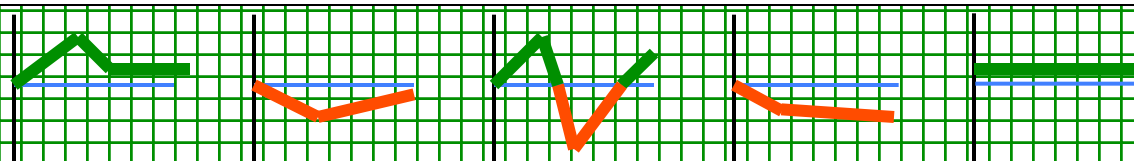
**Time
(Delivery)**

**Inventory or
WIP**

Productivity

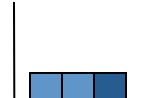
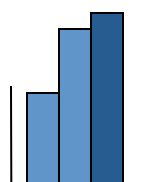
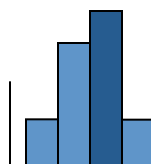
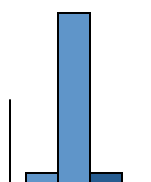
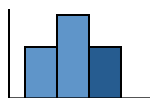
Safety

Work Group Specific Metrics



Daily, Weekly, Monthly, Annual Trends






Root Cause Analysis





URGENT TEMPORARY COUNTERMEASURES


[illegible]


PROJECTS AT THIS WORK STATION

Date	Test Instrument	Issue	Corrective Action	Responsible Staff	Due Date	Status
						
						
						
						
						

 ~Supervisor Review

 ~Initial Resolution or Contact

 ~Intervention Complete

 ~Defect Resolved

Visual Management At-a-Glance

DAILY Gemba Rounds with workers

- Each square has all days of month
- Color each per performance
- **RED: METRIC FAILED THRESHOLD**
- **GREEN: METRIC MET THRESHOLD**

Trendlines

- Trend challenging metrics
- Day, week, month, year...
- **BLUE: THRESHOLD**
- **RED: TIME OF FAILURE**
- **GREEN: TIME PASSING THRESHOLD**

Pareto Charts, RCA etc.

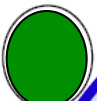















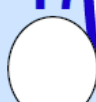




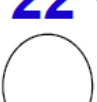









What	When
Why	How

Countermeasures:

Corrective & Preventive Actions
Assign responsibility and
Accountability for completion

Associated PDCA - A3 Projects

Quality

1 	2 	3 	4 	5 	6 	7 
8 	9 	10 	11 	12 	13 	14 
15 	16 	17 	18 	19 	20 	21 
22 	23 	24 	25 	26 	27 	28 
29 	30 	31 				

Owners: Jane Doe

John Smith

Month: May 2013

Meeting Time: 11 am

Metric:

of amended reports
of result modifications

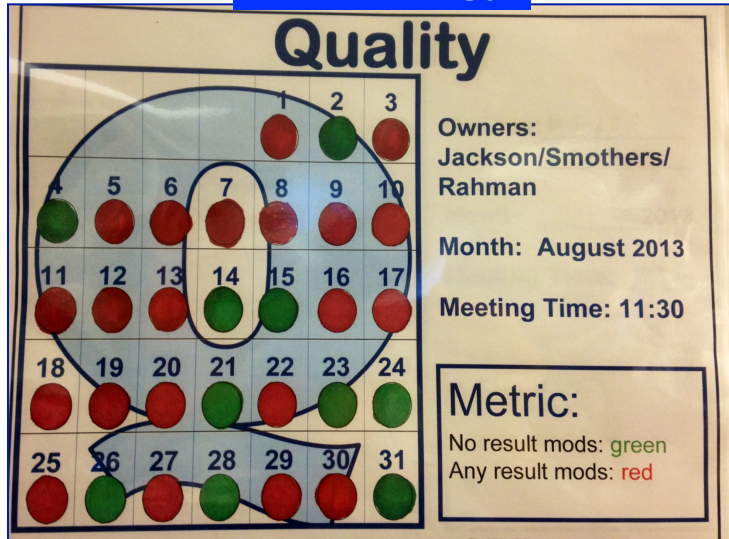
So Honey, How's Your Day Goin'?



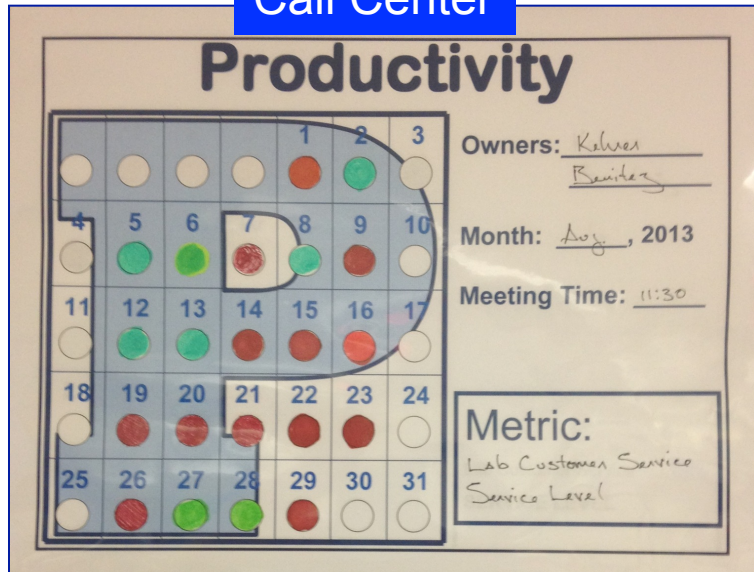
*Note: YMMV
(Your actual mileage may vary)

Q-T-I-P-S

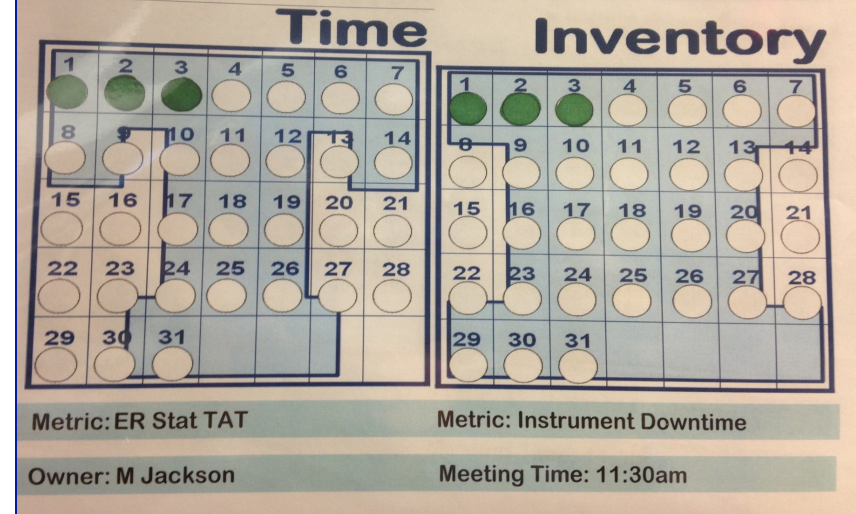
Hematology



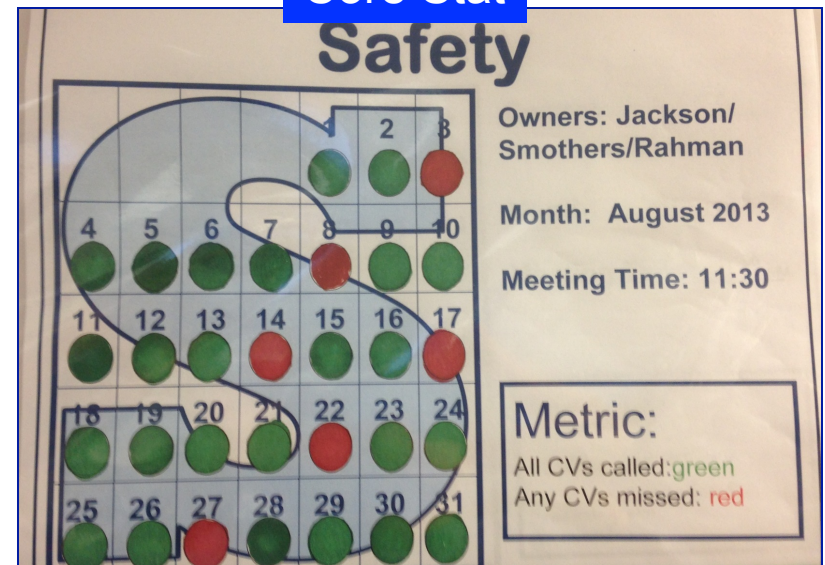
Call Center



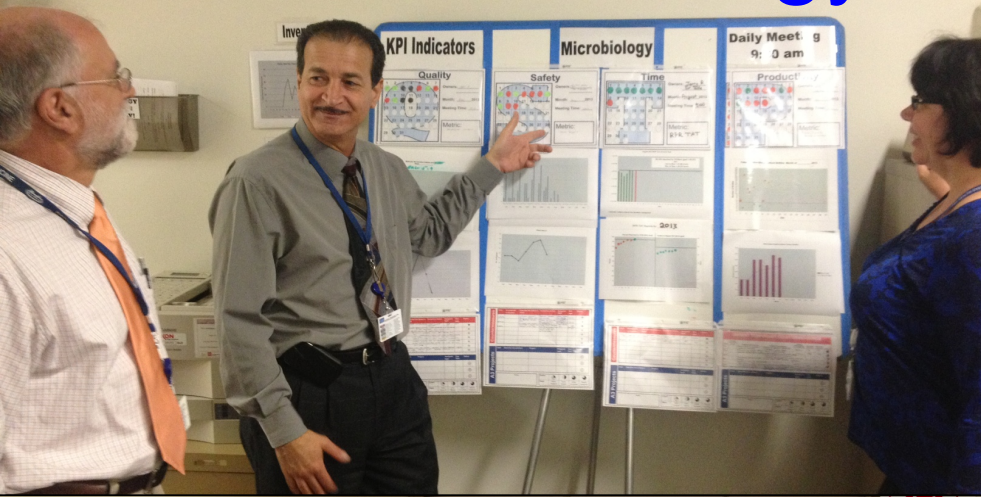
Coagulation



Core Stat



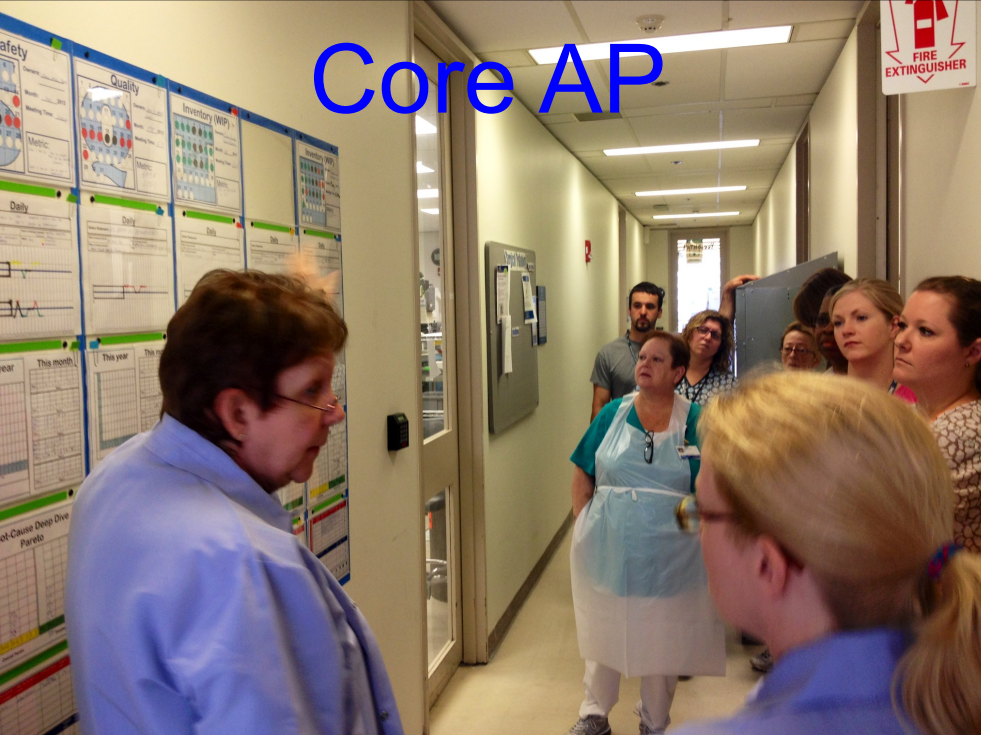
Core Microbiology



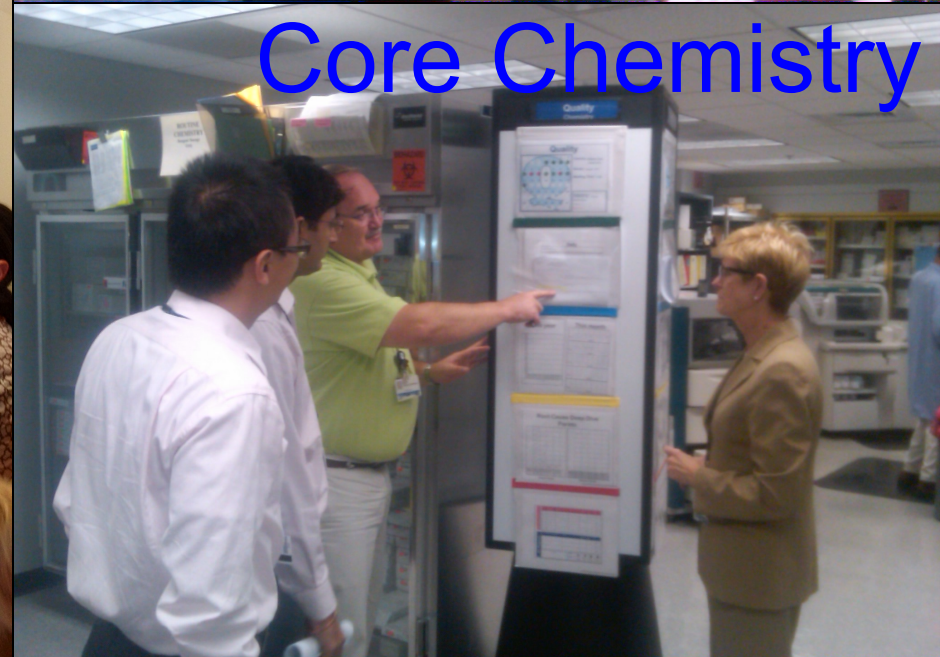
Core/Stat



Core AP



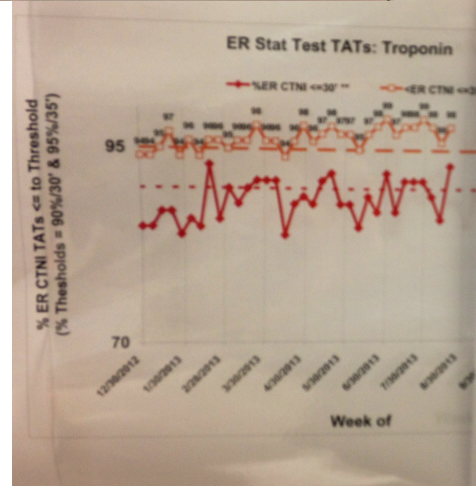
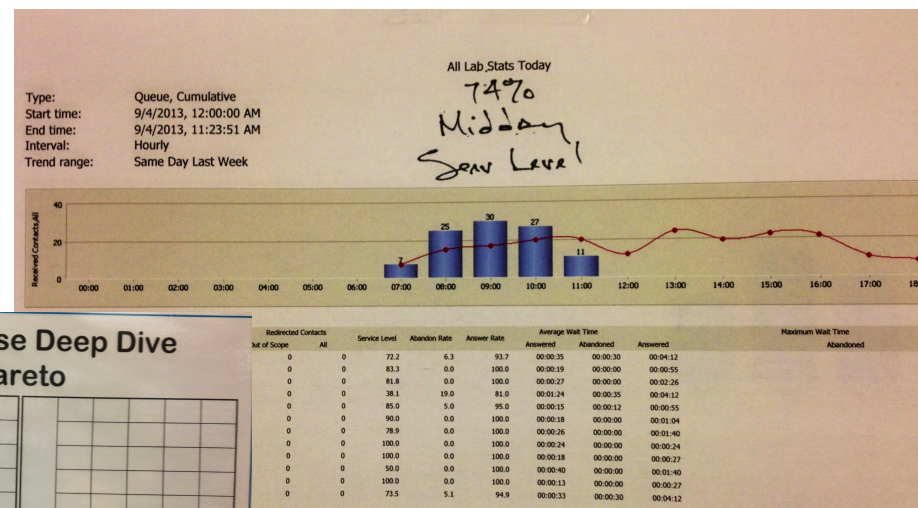
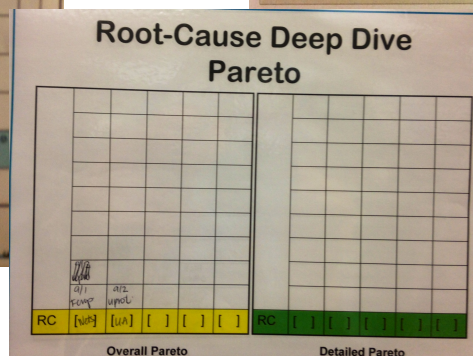
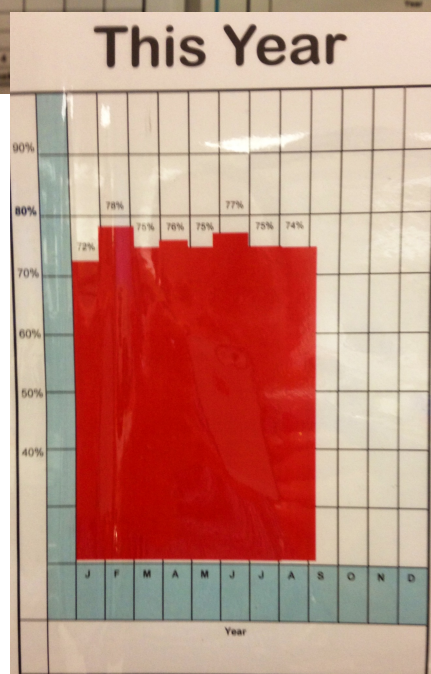
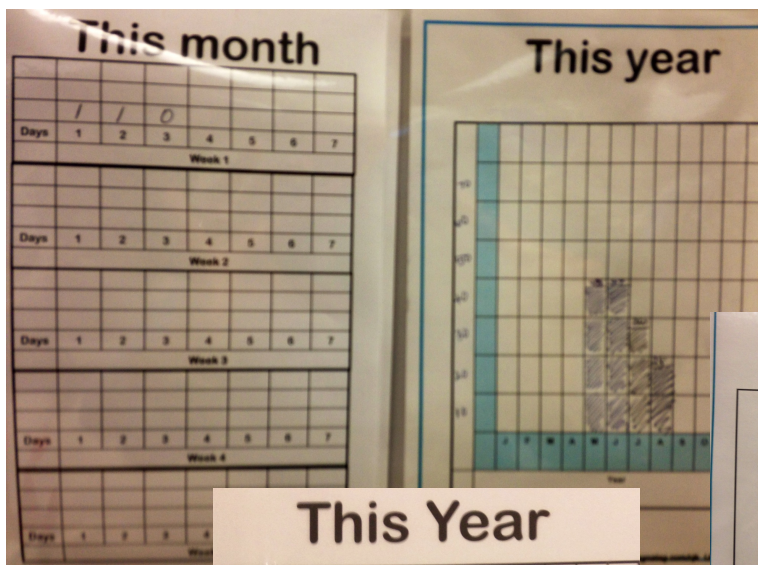
Core Chemistry



Daily Continuous Metrics



Daily Continuous Metrics



Core Hematology

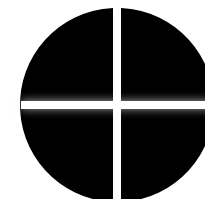
Root-Cause Deep Dive Pareto

	7/18 precision failed									
	7/16 H+H							7/24 unable to fill bath	7/27 agitator + gripper	
	7/11 BKGD failures	7/18 precision failed						7/21 arm jam	7/20 gripper	
	7/10/13 noise	7/16 H+H						7/20 unable to draw bath 5	7/16 gripper	
	7/9/13 BKGD noise	7/11+7/12 probe wire					7/19 washing smeared off	7/16 gripper	7/12-7/14 gripper	
	7/2/13 clogged aperture	7/12/13 tear read low	7/27 lotion failed				7/19 arm issues	7/5/13 gripper	7/5/13 gripper	LIS-Auto file Hemo not auto filling 7/16
RC	LHA	LHB	LHC	SMA	SMB	SMC	SSA	SSB	SSC	Other
	Analyzers			Slide Makers			Slide Stainers			

Immediate Countermeasures

Critical Values Core Lab

Date	Accession# or location	Describe the defect or issue	Corrective Action	Assigned Staff	Due date	Status
5/17/13	Core Lab	CV Cell Back	need 6 elements before escalated	DS/JZ	6/17/13	●
5/23/13	Home (Auto)	Babies (cltd) critical info being missed	Testing - will discuss w/ DI	MJ/RM	5/31/13	●
6/13/13	Cong	PI entered as OVNTF	discussed w/ tech	MA	6/13/13	●
						⊕
						⊕
						⊕
						⊕



Action:

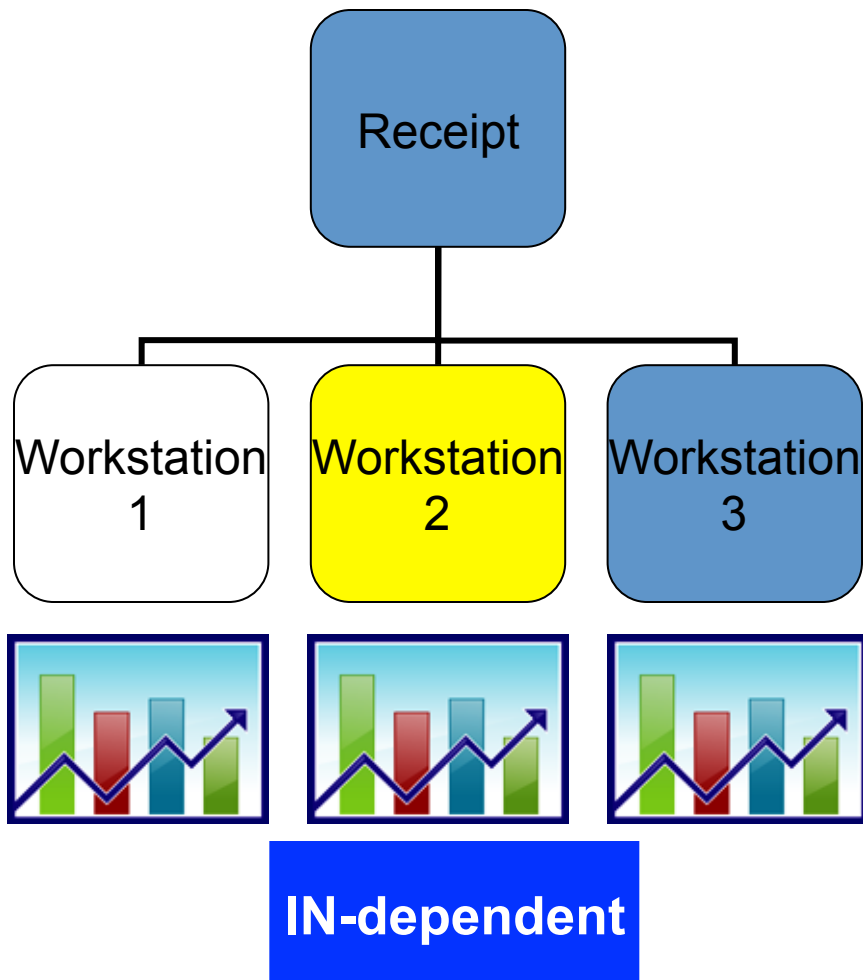
- Assigned
- Started
- Completed
- Sustained

Result Modifications Hematology Core Lab

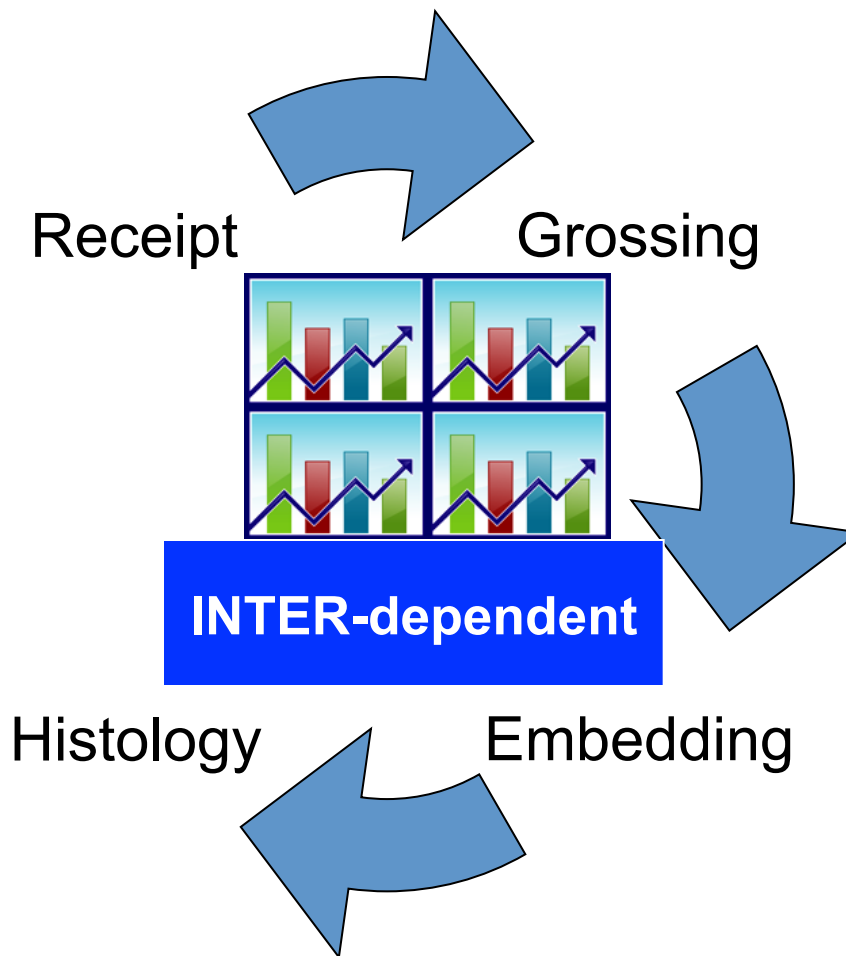
Date	Accession# or location	Describe the defect or issue	Corrective Action	Assigned Staff	Due date	Status
5/16	Auto Home	QNS samples (primarily EE)		R. Maise, M. Jackson		⊕
6/12	Auto/Manual Home	SIM entering diff that are sent here for manual review - have labels entered as normal	Emailled Ken 2.	M.J. /KZ	6/13/13	●
7/8/13	Cong	incorrect result entered Tech advised middleware	PI request submitted	M.J.	7/10/13	●
						⊕
						⊕
						⊕
						⊕

Making Good Alphabet Soup DM, CAPA, PDCA, A3

Parallel Lab



Serial Lab



Daily Management Board- Surg Pathology



Core Surgical Pathology

Quality

Owners: Dr. [Name]
 Month: September 2013
 Meeting Time: 1:30pm

Batch log case discrepancies Residents/PAs

Inventory (WIP)

Owners: Dr. [Name]
 Month: September 2013
 Meeting Time: 1:30pm

Specimen site unlabeled Threshold=0

Inventory (WIP)

Owners: Dr. [Name]
 Month: September 2013
 Meeting Time: 1:30pm

**Biopsies leftover
 Not acc by 9:15pm
 Not gross by 10:15pm
 Not cut by end shift**

Quality

Owners: Dr. [Name]
 Month: September 2013
 Meeting Time: 1:30pm

IHC slides retained Threshold=0

Daily

Defect Statement: Batch Log Discrepancies

What is being tracked? Batch Log Discrepancies

How is it being tracked? Batch Log Discrepancies

Why is it being tracked? Batch Log Discrepancies

Knowledge: Batch Log Discrepancies

Daily

Defect Statement: Specimen site unlabeled

What is being tracked? Specimen site unlabeled

How is it being tracked? Specimen site unlabeled

Why is it being tracked? Specimen site unlabeled

Knowledge: Specimen site unlabeled

Daily

Defect Statement: Biopsies leftover

What is being tracked? Biopsies leftover

How is it being tracked? Biopsies leftover

Why is it being tracked? Biopsies leftover

Knowledge: Biopsies leftover

Daily

Defect Statement: IHC slides retained

What is being tracked? IHC slides retained

How is it being tracked? IHC slides retained

Why is it being tracked? IHC slides retained

Knowledge: IHC slides retained

This year

Week 1

Week 2

Week 3

Week 4

Week 5

This month

Week 1

Week 2

Week 3

Week 4

Week 5

This year

Week 1

Week 2

Week 3

Week 4

Week 5

This month

Week 1

Week 2

Week 3

Week 4

Week 5

This year

Week 1

Week 2

Week 3

Week 4

Week 5

This month

Week 1

Week 2

Week 3

Week 4

Week 5

This year

Week 1

Week 2

Week 3

Week 4

Week 5

This month

Week 1

Week 2

Week 3

Week 4

Week 5

Root-Cause Deep Dive Pareto

Overall Pareto

Detailed Pareto

Root-Cause Deep Dive Pareto

Overall Pareto

Detailed Pareto

Root-Cause Deep Dive Pareto

Overall Pareto

Detailed Pareto

Root-Cause Deep Dive Pareto

Overall Pareto

Detailed Pareto

Countmeasures

Overall Pareto

Detailed Pareto

Countmeasures

Overall Pareto

Detailed Pareto

Countmeasures

Overall Pareto

Detailed Pareto

Countmeasures

Overall Pareto

Detailed Pareto

A3 Projects

Overall Pareto

Detailed Pareto

A3 Projects

Overall Pareto

Detailed Pareto

A3 Projects

Overall Pareto

Detailed Pareto

A3 Projects

Overall Pareto

Detailed Pareto

Process Stability Patterns



Aligned PDCA Process Improvement

Core Surgical Pathology Lab Accession-Gross-Histology Workstations

Countermeasures	Date	Accession# or location	Describe the defect or issue	Corrective Action	Assigned Staff	Due date	Status
	6-2-13	Histo pm shift	disorganized workforce	smooth workflow, pair strong/weak emb. hist. techs - no work load issues	Nataliya		●
	6-12-13	PA pm shift	prostate bxs set aside till later in shift	late day shift pm shift put prostate cases thru as early as possible to hist field	pm pairs		●
	6-12-13	Acc - pm	large, late batches	work & courier off site hosp. to send bxs (lgs) ASP - don't hold	Cheryl		●
				will do onsite visit at Macomb to examine workflow			⊕
	6-26-13	Histo pm shift	one tech leaving - plus vacat - replacement position not started	one - temporary hire - pm's suspended pm's to replace - temporary			●
		Acc - pm	late midcom batch, bxs done much earlier in day	about midcom batch taking batch out back to show out & range ceps	Cheryl, ACC, Madeline		●
	7-13	Acc - PM	Macomb / acc cases still exceeding 7 bxs, cases from early am on	Dr. Lucy called; batch of < 7 to meet expectations; no more early am case	Cheryl, Dr. Lucy		⊕
	8-19	Histo	last number starting	on last batch - waiting on approval to direct			

A3 Projects	Date	Describe Issue/Defect	Project	Assigned Staff	Due Date	Status
	8-19	Histo, Acc, PA	detailing improvements over 3 months		for Aug STE	⊕
						⊕
						⊕

Notes:	Symbol				
	Status	Action Assigned	Action Started	Action Completed	Results Sustained

A3 Process Improvement
Aligned Serial Path of Workflow
Share the Gain Presentation
Aug 29, 2013

Reducing XPress Biopsy Leftovers

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Problem Background

- Large XPress biopsy batches were placed on the processors late into the 2nd shift
- Histology 2nd shift hours were standardized to 4:00 PM until 12:30 AM
- **Histotechs were unable to finish cutting the XPress biopsies before the end of their shift**
- **1st shift histotechs had to finish cutting the leftover biopsies the next morning before they could begin to cut their morning workload of blocks**

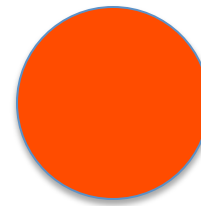
Hypothesis

- If we level the workload across Surgical Pathology (Accessioning, Grossing, Histology), the Histology 2nd shift will be able to cut all the XPress biopsies (except the last batch embedded) before the end of their shift

Current Condition

- Large specimen batches are received around 8:30 PM from the last courier pickups
- By the time Bx were accessioned, grossed and processed, the histology techs didn't have adequate time to cut them
- All employees – Accessioning, Grossing, Histology – felt pressured, overwhelmed and discouraged

Editorial comment- Lot of daily



Current Condition Data

- **Blocks Leftover = Red**
- Slides Leftover = Black

* Post Easter very light workloads

Dates	M	T	W	TH	F
4/8 – 4/12	-- -- *	-- --*	86 294	90 368	86 356
4/15 – 4/19	12 36	31 62	20 120	122 498	87 222

Problem Analysis- **Loads Large & Late**

- Root Causes identified using Daily Management Board Deep Dive Pareto analysis
 - **Large, late processed XPress biopsy batches**
 - 75 - 105 minute processing time until blocks are ready to be embedded
 - **Large volume of prostate biopsy cases (cut 6 slides per block; average 72 slides/case)**
 - Negative impact increased when they were on late batches
 - **Staffing shortages periodically on all shifts**
 - Resignations, LOA's, vacations

Target Condition- **Earlier**

- Accessioning: All XPress biopsies will be accessioned no later than 9:30 PM
- PA's (Grossing): All XPress biopsies will be grossed and taken to Histology for processing no later than 10:15 PM
- Histology: All XPress biopsies will be embedded and cut minus blocks on last batch

Corrective Action Plan

Lean Principles SW, Flow, Batch Size

- SW: Establish expectations for Accessioning, Grossing and Histology
- Flow: Extra attention to be given to the continuous flow of XPress biopsies to Histology throughout both shifts
- Batch Size: Prostate biopsy cases will no longer be set aside to accession, gross or cut at the end of the shift

Corrective Action Plan - Accessioning

- Work with HFH clinic to bring prostate biopsies to lab on more continuous basis
- Work with farthest community hospital courier to improve last arrival time
- Batch XPress biopies in same trays
- Work with community hospital leaders to reduce large, late batches

Corrective Action Plan – PA's

- Biopsies given top priority
- Log batch size/time to Histology
 - Note which batches contain prostate Bx cases
- Gross endometrial and breast needle core batches toward end of shift
 - Non XPress biopsy cases (next day processing)
 - Breast needle cores need pictures taken at gross

Corrective Action Plan - Histology

- Only one tech embeds (E1) when there are blocks ready to cut
 - E2 splits time between embedding and cutting
- All techs presort cut blocks by hospital/hundreds at shift's end to expedite search for recut blocks
- 2nd shift will run only RUSH special stains
 - Kidneys, livers, transplant lungs

Implementation Plan

- Expectations clearly communicated to all employees in Accessioning, Grossing and Histology
- Metrics posted to Daily Management Board and monitored daily
 - Accessioning, Grossing: # of leftover cases at cutoff time
 - Histology: # of blocks not cut, minus those in the last batch
- Pursue deeper dives as needed to establish additional root causes if expectations are not met

Results

- **Blocks Leftover = Red**
- Slides Leftover = Black

April

Day A T E S	M	T	W	TH	F
4/8 -4/1 2	0	0	86	90	86
	0	0	294	368	356
4/15 -4/1 9	12	31	20	122	87
	36	62	120	498	222

July

Day A T E S	M	T	W	TH	F
7-22 - 7-26	0	0	9	0	29
	0	0	15	0	55
7/29 - 8/2	0	12	0	0	0
	0	27	0	0	0

Types of Waste

- Waiting: Downstream process inactivity
- Inventory: Excessive WIP batches near end of shift

Rules of Work

- Standard Activities: Prioritizing XPress biopsy batches
- Standard Connections: PA batch time and volume log
- Making Improvements: Daily Management data incorporated into 3 monthly A3s using PDCA cycles

Continuous Flow Tools

- Load leveling across shifts/hours
- Batch size reduction
- Standardized priority for cases in biopsy stream
- Daily metrics to monitor performance variation

Am I in heaven?
If Lucy & Ethel could only see us now



Why ISO?

**“Learning is not compulsory,
neither is survival”**

W. Edwards Deming