# Create a Safe, Effective, Efficient AP Lab

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## Objectives

The objectives of this presentation will be to:

1. Describe the fundamental elements of Lean Six Sigma methodology
2. Learn how the practical tools and insights of LSS can help improve the safety, productivity, and quality in the lab, and assist with cost reduction
3. Review real life case study examples of Lean in the lab and provide takeaway ideas that can be applied to your laboratory

***During this presentation, please feel free to ask questions and think about how these tools might apply to your lab.***

# AP Industry Challenges



## Global crisis

- There will be an estimated 12.9 million new cancer cases globally in 2009.
- By 2020, the number of new cancer cases worldwide is anticipated to rise to 16.8 million.
- By 2030, the number of new cancer cases is expected to rise to 27 million, with 17 million cancer deaths.

## Industry trends

- Growth in lab automation and critical shortage in lab technicians continues
- TAT demands accelerate despite increasing regulatory pressure to safeguard patient samples
- Patients' needs, healthcare costs drive equipment for better diagnosis and prognosis
- Pharma companies' shift from blockbuster model to targeted therapy and personalized health care
- New technologies enable prognostic and predictive cancer information



## Media Reporting

United Kingdom National Health Service states that **one-third of lab tests are repeated unnecessarily**, because results were misplaced, often in the paper "jungle."
May 2009

Hospitals Move to Cut Dangerous Lab Errors – **Improved specimen collection and efficiency** help increase accuracy of medical testing.

Laura Landro
June 14, 2006

In reviewing 427,255 cases, the study **found mislabeled rates** of 1.1 per 1,000 cases, 1.0 per 1,000 specimens, 1.7 per 1,000 blocks, and 1.1 per 1,000 slides.
June 2010

According to Susan G. Komen report, "For all cancer specimens, the **frequency of AP errors** ranges from 1 to 43%.
June 2006

Up to **90,000 U.S. women** living with breast cancer may have diagnoses that are not entirely accurate.
November, 10, 2006

## The future of cancer care changes when you view it through the patient's eyes…



## One Error Changes a Future for a Lifetime

*Darrie is a single mother of a 15 year old son (at the time of the incident). She works in the accounts receivable department at a local community newspaper.*

*Source: Health on Today (MSNBC Interactive), October 4, 2007.*

A 35-year old woman, Darrie Eason (pictured), from New York was told she had cancer and had a double mastectomy done on her, only to find out she really didn't have cancer. The AP lab switched two patient specimens. The woman who really had cancer didn't find out right away; her cancer treatment was delayed.

# One Error Changes a Future for a Lifetime

Personal trainer Scott Aprile, (pictured), age 28, had a radical mastectomy when he was misdiagnosed with cancer. Aprile was told two weeks after surgery that there was a horrible mix up – his biopsy had been switched with that of a woman who underwent tests the same day.

*"When I saw the stitches and my mangled chest, I almost passed out for the first time in my life," he said. "They mutilated my body."*

*Source: NYDailyNews.com, "Cruelest cut of all: 28-year-old man gets mastectomy, then finds out he didn't have breast cancer" May13, 2009.*



# Workflow Consulting Solutions

## Streamline your lab

**Lean Workflow Strategies for Patient-Focused, Streamlined Labs**

# Workflow Consulting Solutions

Workflow works




# Workflow Consulting Solutions

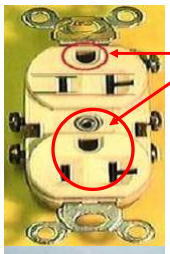
Evaluate patient safety and productivity opportunities with Lean Six Sigma tools

## Workflow Assessment Glossary

- Value-added (VA) work transforms a product or provides a service the customer is willing to pay for
- Non-value-added (NVA) work uses resources but creates no value
- Business-value-added (BVA) work does not create value but is still necessary to the business
- Takt time is the pace of the lab operation based on the daily demand (= total available time / daily demand)
- Lead time is the total amount of time for one piece to pass through the process
- Cycle time (CT) is the total time for one piece to pass through the process minus the wait times in between steps (i.e. workstations)
- Wait time (or Inventory time) is the time one piece sits in between steps



## Mistake Proofing or “Poka Yoke"



1. An electrical outlet designed to allow the plug to fit only one way
2. Newer outlets such as this one also have a fitting for grounding which adds a 6th S, Safety

1. Filling pipe insert keeps larger, leaded-fuel nozzle from being inserted
2. Gas cap tether does not allow the motorist to drive off without the cap
3. Gas cap is fitted with ratchet to signal proper tightness and prevent over-tightening.

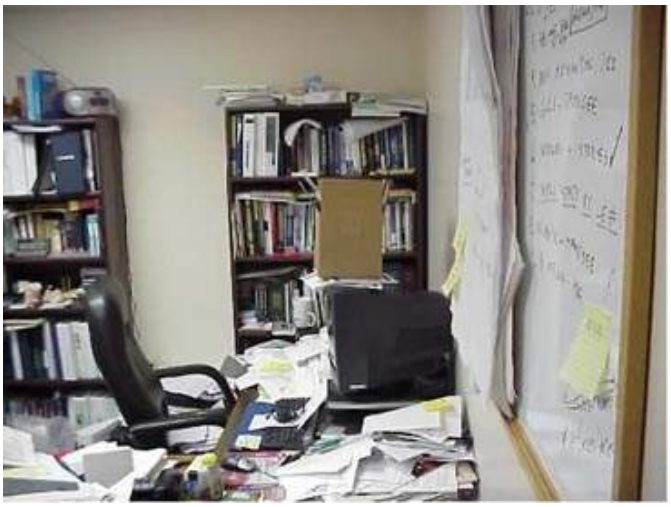
## The 5-Ss

- *Sort* – Put things in order, remove what is not needed and keep what is needed
- *Set in Order* – Proper arrangement, place things in such a way that they can be easily reached whenever needed
- *Sweep-Clean* – Keep things clean and polished; no trash or dirt in the workplace
- *Standardize* – Purity, maintain cleanliness after cleaning - perpetual cleaning
- *Sustain* – Commitment, practice 'Five S' daily to make it a way of life



## Examples of 5S (Before)

***What can we say about this photo?***



## Examples of 5S (After)

***What can we say about this photo?***



## Foundations of Lean

Waste ↓ ∀alue of Product ↑

= Value to Customer ↑

## Lean Defined

### Lean is:

- Value from the customer's point of view
- Eliminating waste or activities that don't add value
- Increasing operational velocity
- Continuous flow of value-adding activities
- Continuous process improvement
- Improving on-time performance
- Increasing productivity with the same resources
- Visual management

### Lean is *NOT*:

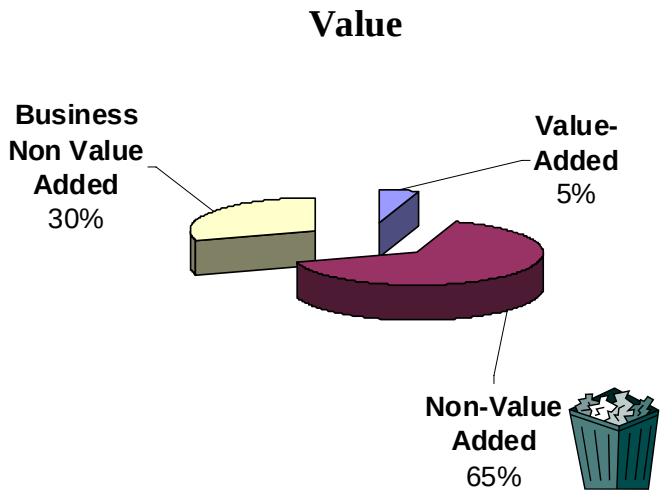
- Efficiency no matter what
- Cutting jobs or reducing workforce
- Less space
- Fewer people
- Limited resources
- Not enough supplies
- Giving the customer bare minimum
- Working harder
- Decreasing quality



## Characteristics of a Lean Process

- Involved and empowered employees
- Work stations in order of processes
- Visual performance board
- Cross-trained work force
- Streamlined workcell layout
- Process operations in-step with customer demands

## A Typical Workflow Process




***Before "Leaning" a process, most activities are NVA***



## Why it's time to implement a Lean workflow solution…

One data point from a 2-week study in histology [1]

- Close to 30% of cases had manual rework totaling 159 hours or 1.3 FTEs
- 89% of defects were made in the analytic phase
- Approx. 2% misidentification rate, 67% of those in slide labeling
- All misidentifications would have been addressed by an integrated identification system

Typical savings found in service businesses [2]

- 30–60% reductions in cost (over time)
- Cycle time improvements of up to 50%
- Capacity recapture of 20% (with no additional staff)

[1] Am J Clin Pathol 2007; 128 p423
[2] George Group results, Lean Six Sigma for Service

# Examples of Waste Opportunity

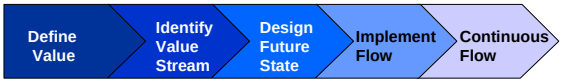
| Site 1 | Site 2 |
|---|---|
| ~ 1800 blocks per day | ~ 350 blocks per day |
| ~ 4000 slides per day | ~ 900 slides per day |
| $213/case etcher slides | $298/case color charged slides |
| $156/case charged slides | $183/case color uncharged slides |
| $105/case uncharged slides | $93/case white uncharged slides |
| $22.50/hr HT unburdened | $28/hr HT unburdened |
| $10.50/hr LA unburdened | $15/hr LA unburdened |

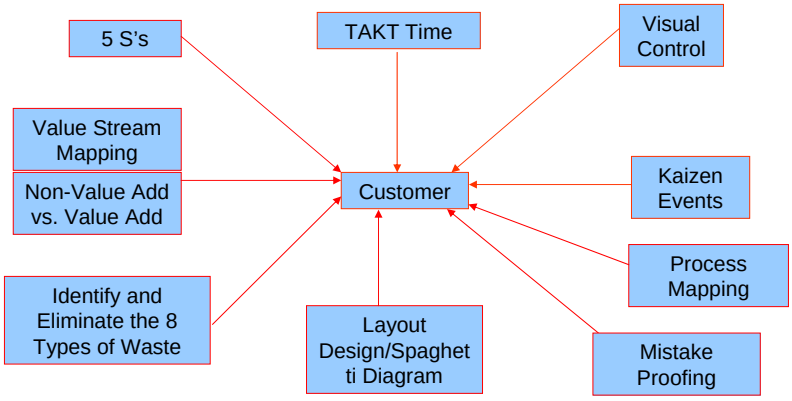
| Facility | Annual Opportunity (Hours) |
|---|---|
| 1 | ~ 12,500 hrs |
| 2 | ~ 5100 hrs |
| Total | ~ 17,600 hrs |

**Based on reduction or elimination of cutting preparation, production logs, IHC slide labeling, slide drying for IHC/SS, manual cassette marking, etcher management*



# Lean Concept Guidelines



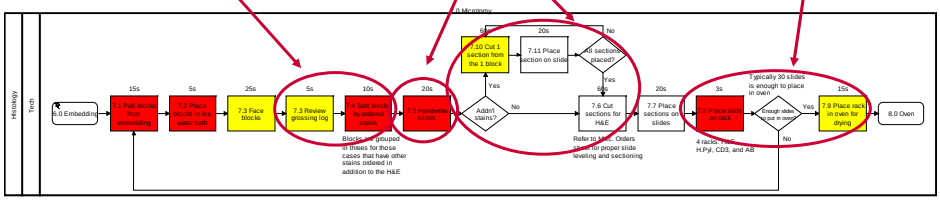
# Workflow Consulting Solutions

## New Lean workflow processes boost productivity, efficiency

Supply and process opportunity to eliminate unnecessary sorting by pre-grouping blocks at embedding

Technology process impact and patient safety issue

Supply and transport opportunity to designate a runner/spiderman to drive the "beat" of the production day



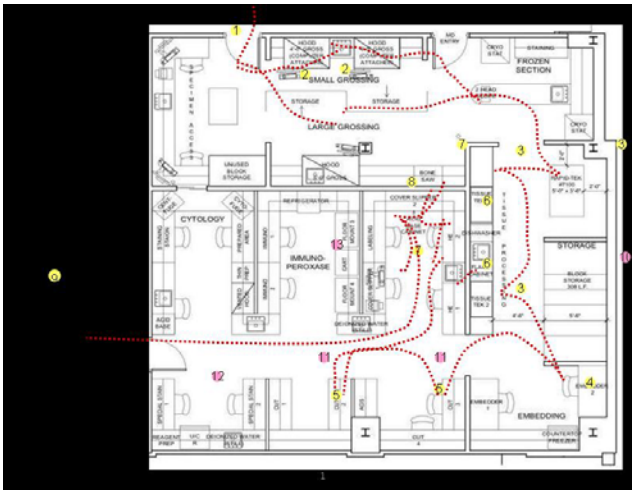

Boxes Shaded in **Red** are Non-Value Add Value Add

Boxes Shaded in Yellow are Business



# Workflow Consulting Solutions

## Re-design your lab to reduce bottlenecks and improve turnaround times



# Workflow Consulting Solutions

Gain immediate improvements, use Lean Six Sigma roadmaps to position for growth

| No. | Process Improvement | Workbench | Term | Lean or Quality? | Priority | Feasibility | Duration (in Months) 1 2 3 4 5 6 7 8 9 10 11 12 |
|---|---|---|---|---|---|---|---|
| 1 | VANTAGE Workflow and Workshop | Global | Short | Both | High | Medium | |
| 2 | Lab Runner - Continuous Flow and Increased Utilization | Global | Short | Lean | High | Medium | |
| 3 | Receiving and Accessioning Physical Flow | 1.0 Receiving and 2.0 Accessioning | Medium | Lean | High | Medium | |
| 4 | Case Assembly Cubby Hole - Supermarket Pull System | 11.0 Case Assembly | Medium | Lean | Medium | Medium | |
| 5 | Visual Controls and 5S | Global | Short | Lean | Medium | Easy | |
| 6 | IHC Inventory Management | 9.0 Staining | Short | Lean | Medium | Easy | |
| 7 | Transcription Improvements | Support Services | Short | Both | Medium | Easy | |
| 8 | Replace the Coverslipper | 10.0 Coverslipping | Long | Both | Low | Easy | |
| 9 | Work Schedule | Global | Long | Lean | Low | Medium | |
| 10 | Use Separate Bins for Each Case | 1.0 Receiving, 2.0 Accessioning, and 4.0 Grossing | Medium | Quality | Low | Easy | |
| 11 | Discontinue Three Patient Tissue on IHC Stains | 7.0 Microtomy | Short | Quality | High | Easy | TODAY |

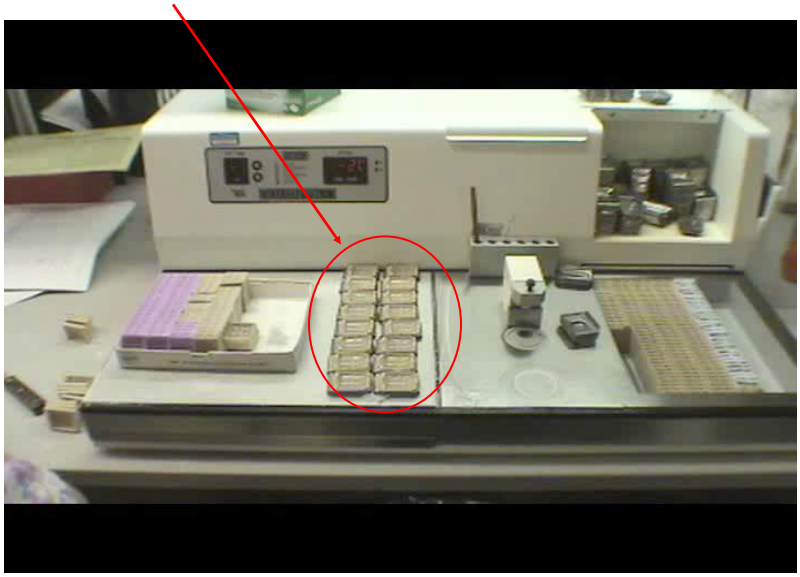


# 8 Types of Waste or “Muda”

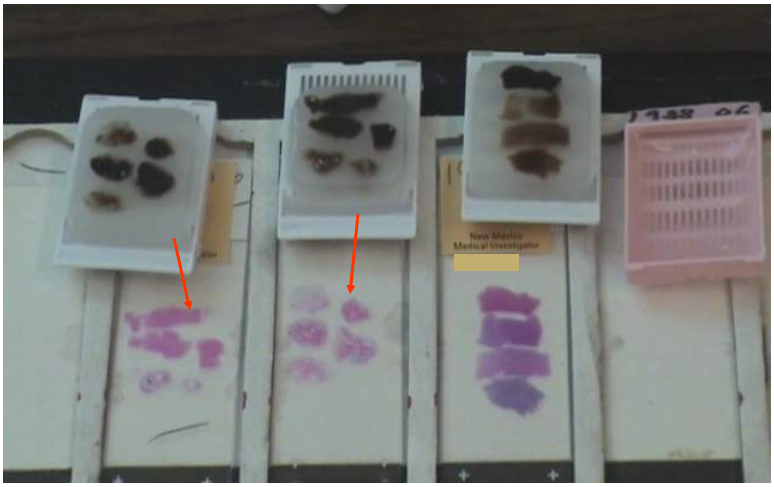
**Lean**: What do we look for in labs?



## Waste in Action



## Mislabeled Slides: Errors and Rework





## Sorting Through Materials

## Manual Coverslipping



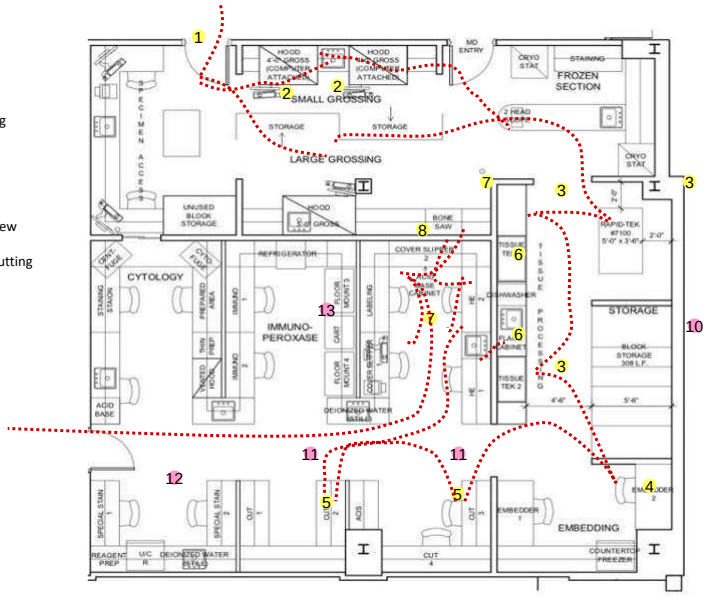


## Waiting Delays Turnaround Times

# Transportation

1. Receiving
2. Grossing
3. Tissue processing
4. Embedding
5. Cutting
6. H&E staining
7. Coverslipping
8. Labeling
9. Investigator review
10. Block retrieval
11. Special testing cutting
12. Special Stains
13. IHC

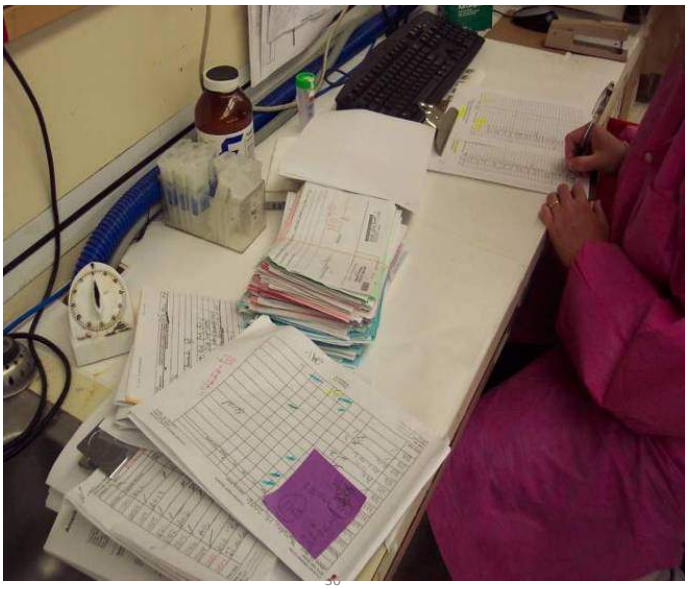
9 Pathologist office



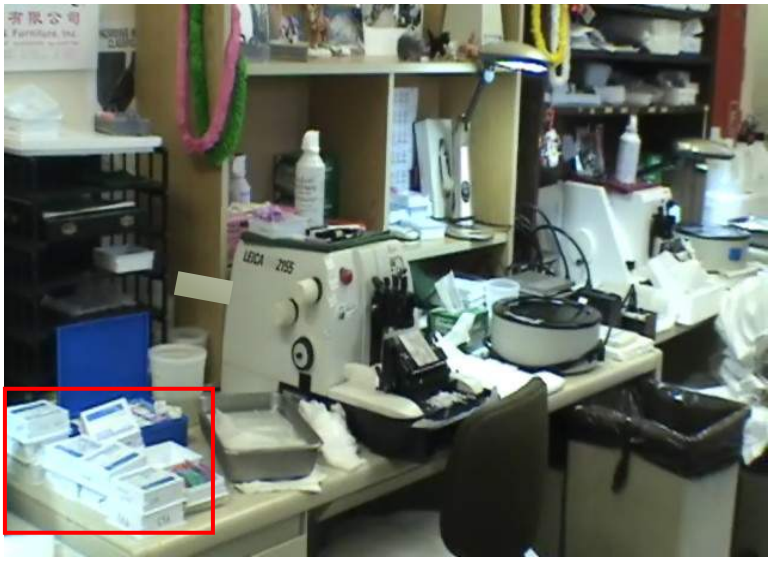





# Over-Processing



# Inventory at Cutting Station





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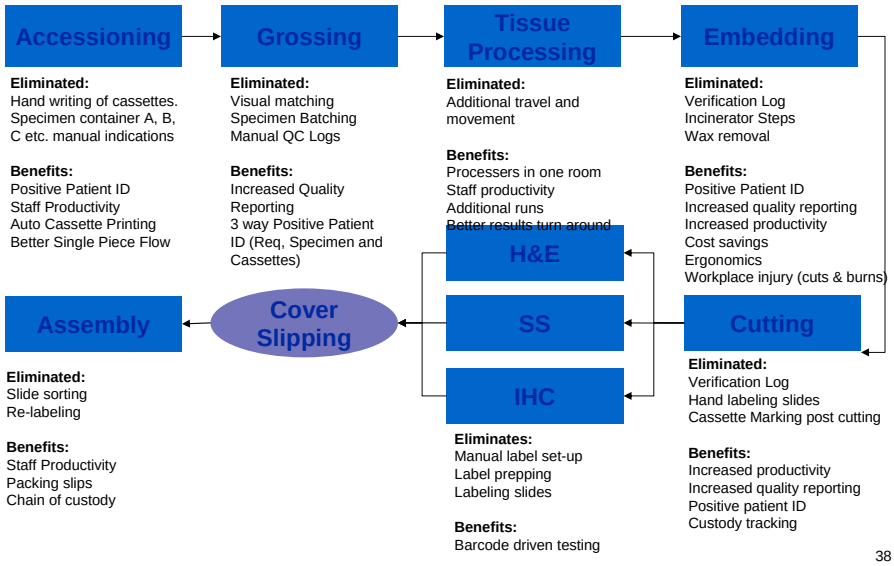
# Benefits of Lean Workflow



# Global best practices for a safe, effective, efficient



Accessioning

Grossing

Embedding

Workflow Efficiency

Tissue Processing

Microtomy

Staining

Case Assembly

Archiving

## Gain Efficiency in Grossing

- 5-S workstation eliminates time wasted looking for tools, supplies

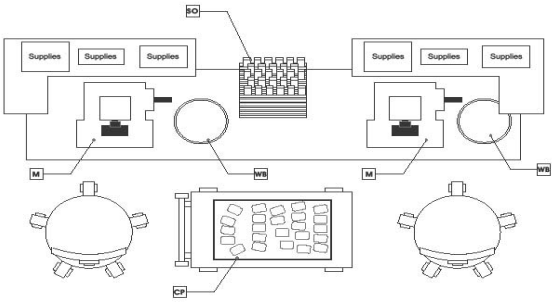


## Speed Processing Time

- Microwave rapid tissue processing promotes continuous flow
- Reduces routine processing time: 55 min. vs. 4.2 hr.

## Improve Throughput

- Tandem microtomists sit in mirror image of each other
- Single case flow improves case-specific TAT, quality




| | |
|---|---|
| M | Microtome |
| SO | Slide Organizer |
| CP | Chill Plates |
| WB | Water Bath |

VENTANA
A Member of the Roche Group

Microtomy Station Design
Tandem Approach

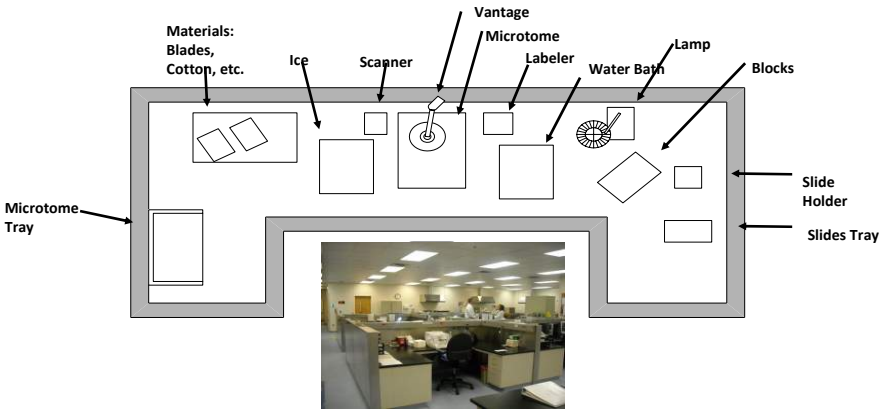


## Organize Workstations

- Save time and reduce errors associated with stopping and starting work at Embedding and Microtomy workstations

## Improve Ergonomics

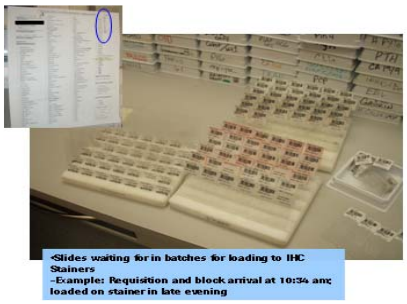
- 5S – Microtome layout and cutting station design improves workflow efficiency






## Improve Turn Around Time

- Process for automated stainers eliminates batches at preparation bench, removes manual process steps



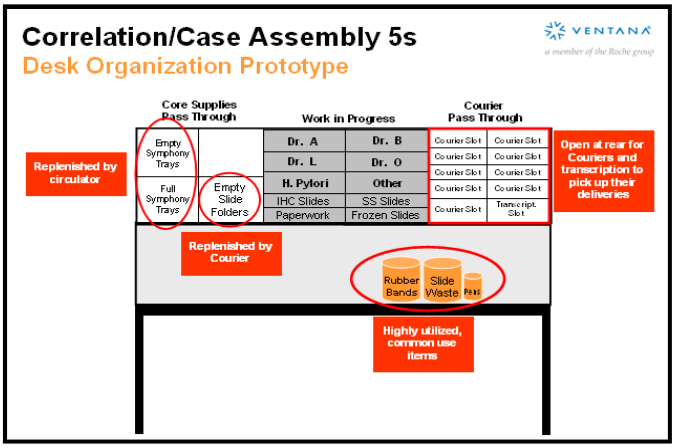

## Improve Turn Around Time

- Automated stainers and workflow improvements reduce TAT and increase standardization




## Improve Case Assembly

- 5-S case assembly bench reduces manual logs and improves tracking
- Reduces waiting time before slides reach PA



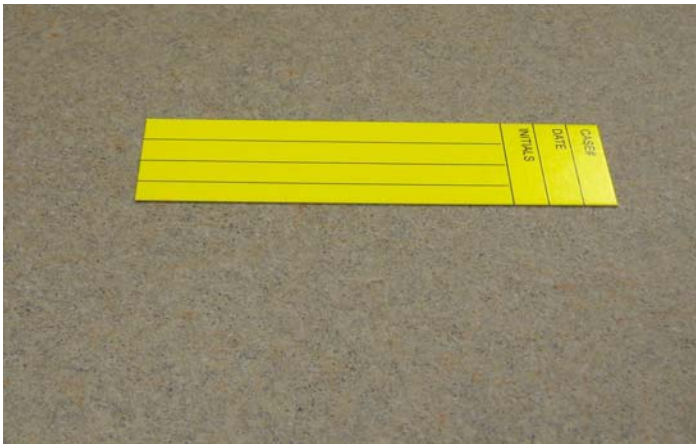
## Improve Visual Controls

- Reduce case set-up and preparation by 2 hrs/day



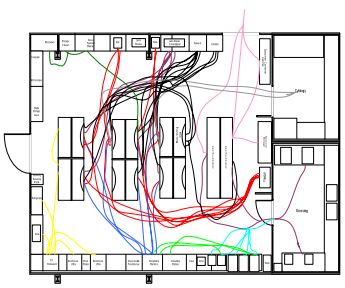

## Reduce Lost Slides in Archiving

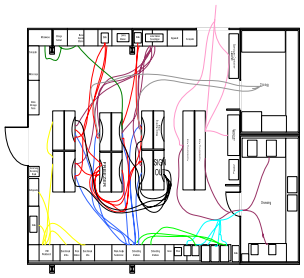
- Visual slide marker marks spot where slide was removed; facilitates faster, accurate slide replacement



# Document New Process in Workflow Maps

- WFC documents workflow before and after Lean, calculates savings from reduced time/steps traveled in lab:





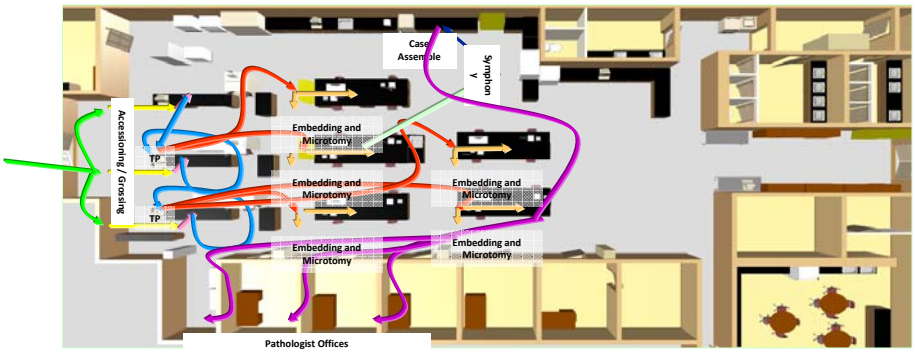
Here, we can reduce travel distance by 17.1 with relocation of freezer and sign out area

| Step | Dist. | Opp. | Lean |
|---|---|---|---|
| Accession 1 & 2 | 38 ft | 0 ft | 38 ft |
| Grossing | 5 ft | 0 ft | 5 ft |
| Tissue Processing | 20 ft | 0 ft | 20 ft |
| Embedding | 48 ft | 0 ft | 48 ft |
| Microtomy | 210 ft | 85 ft | 125 ft |
| H&E Staining | 40 ft | 0 ft | 40 ft |
| Case Assembly | 50 ft | 20 ft | 30 ft |
| IHC | 160 ft | 0 ft | 186 ft |
| **Total** | **616 ft** | **105ft** | **511 ft** |



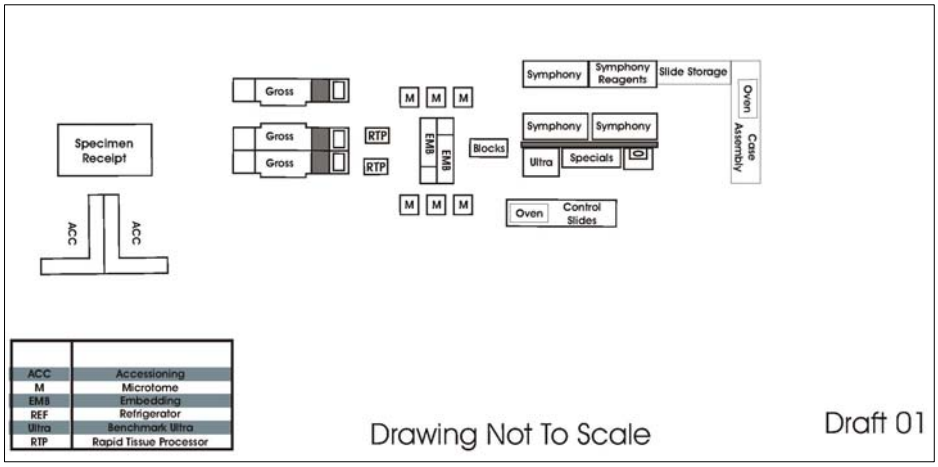
# Streamline the Flow within the Lab

- Specimens flow from embedded blocks to stained slides in a linear manner
- Reduces H&E TAT to 4.5 hours



## Lean Design for the Histology Lab

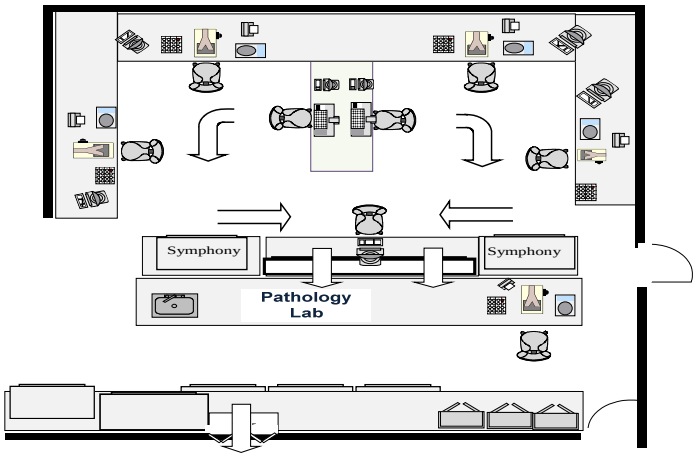
- Create linear workflow to maximize flow of specimen and staff





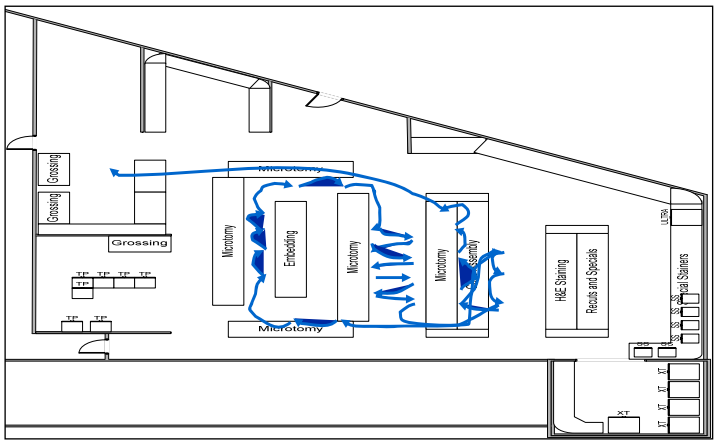

## Improve Specimen Flow

- Create linear histology workflow to increase TAT



## Reduce Bottlenecks, Increase TAT

- Lab runner, water spider establishes continuous flow
- Reduces 356 ft/case or 38% of total distance traveled





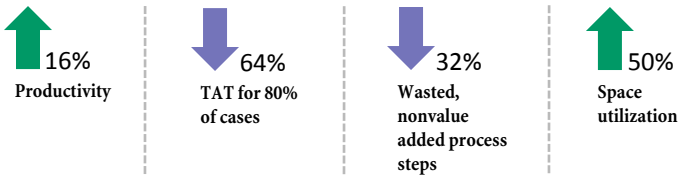

## Lean: How does it impact Patient Safety?

"I need to **reduce errors** and mitigate risk."



# Improve Patient Safety

## Case Study: Multi-center Health System




**& virtually eliminates labeling errors**

## Sites 1 & 2 Opportunity Summary

*VANTAGE Estimated Payback Time*

Based on VANTAGE's:

- Labor Savings
  - 11,205 hours > Site 1
  - 4,000 hours > Site 2
- Improved Patient Safety
  - Reduction of mislabeled slides and cassettes
- Administrative costs
  - Slides waste
  - Label waste

**Site 1**
**< 1 Yr.**

**Site 2**
**2+ Yrs.**



## Lean Benefits

- Lean supports patient safety with:
  - Specimen integrity
  - Specimen chain of custody throughout the process
  - Visibility into training opportunities with staff
  - Less opportunity for human error
  - Visual checks and balances
  - "Freed up" technician time for a more focused staff
  - Less stressful environment

# Closing Remarks



## Closing Remarks

- What have we learned?
- What are the 3 key takeaways from this presentation?
- What can I immediately apply to my lab?
  - Where is the waste?
  - Where are the possible patient safety risks?
  - What can I do about it?
- Where can I get more information/mentoring on LSS and my lab?

## Workflow Consulting Solutions




## Contact Information

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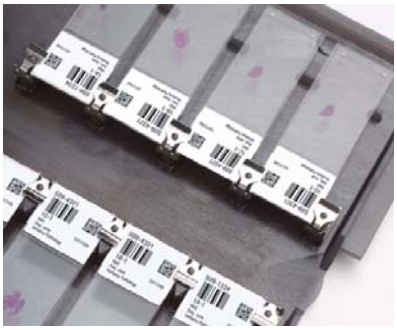
# Appendix





## **SYMPHONY** system

- Empowering labs to enhance quality and improve productivity
- SYMPHONY automated H&E slide staining system enables discreet slide staining to help prevent cross-contamination between patient samples

## BenchMark **ULTRA**

- Delivering “any test, any time” technology to labs worldwide, the BenchMark ULTRA system offers total automation and multiple technologies on a single platform
- With 30 individual slide processors, patient-focused continuous workflow and STAT processing

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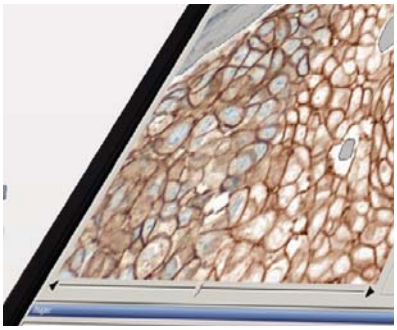

## VIAS

- The VIAS image analysis system is the market-leading image analyzer, providing pathologists with a precise view of every patient’s test, plus customized patient reports
- Optimized for use with the Ventana breast panel (HER-2, ER, PR, KI67, P53) tests

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