Six Sigma Project # Hosp 001
Project Title:
Immunohistochemistry Laboratory Improvement
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Project Start Date: Jan 21, 2010

Team Members:
- **Team Member #1 Claudine Alexis**
- **Team Member #2 Danielle Lauth**
- **Team Member #3 Mike Ragnauth**

Project Description / Problem Statement:
Slides are sent for IHC from throughout the health system to a central location. Delays in the service greater than 72 hours happen 50% of the time, and the causes are not well defined. Additionally, the laboratory has been cited by the accrediting agency for inadequate resources. All of these issues culminate in increased turn-around-time for the cases, delayed diagnosis for the patients, loss of business opportunity outside of the health system, inappropriate utilization, and the possibility of errors in the laboratory.

Customer(s):
Referring Pathologists

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Potential Benefits

- Quality
  - Faster diagnosis → Timely reporting to Clinicians → Faster treatment for patients
- Employee Satisfaction
  - Staff retention
  - Improve physical work space
- Financial
  - 15% decrease in utilization
    - $30K savings to hospital lab operations
    - $50K loss in reimbursement to PAANS
  - Private courier savings $40K
  - Decreased utilization allows for increased capacity for new business

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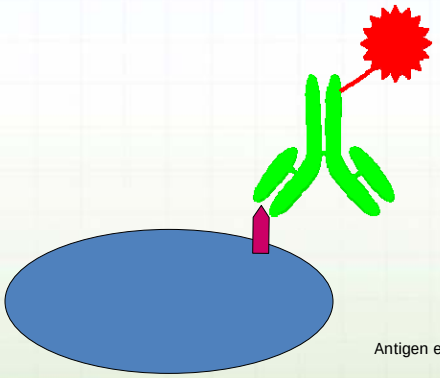
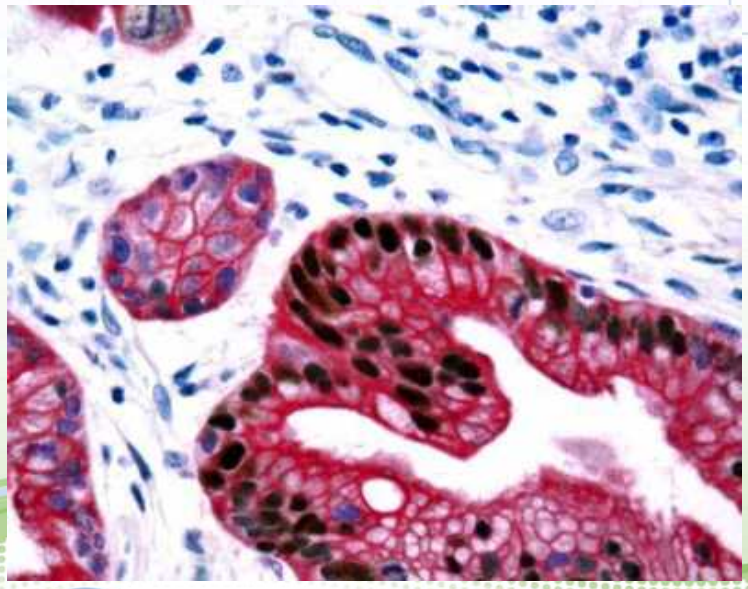
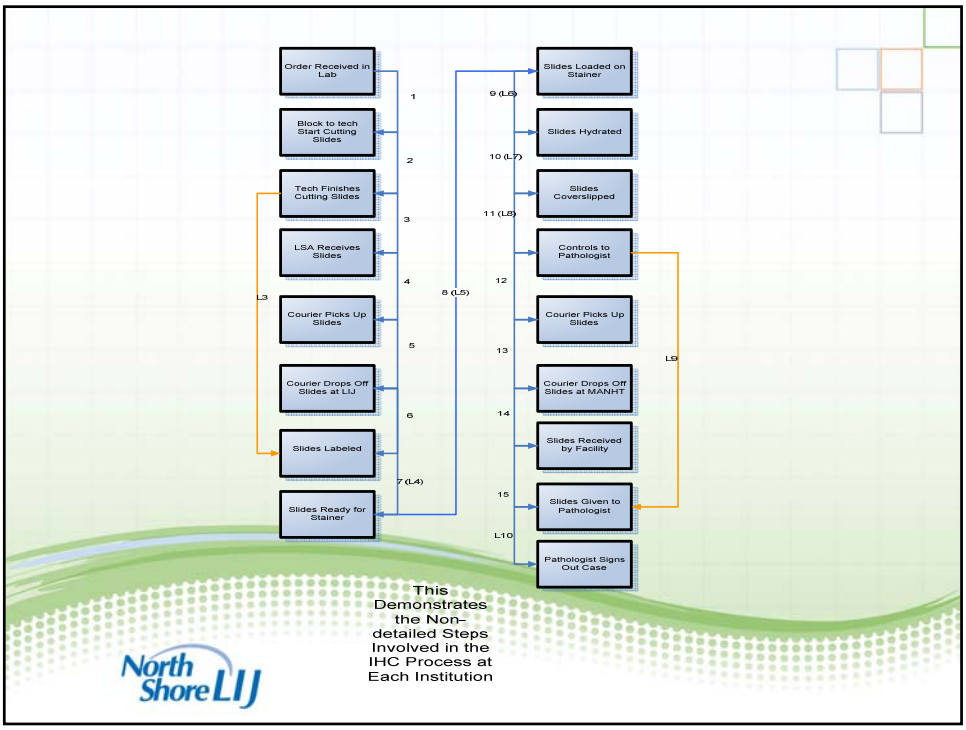
Outline of Procedure

- Fix, embed and section tissue (or treat as "wholemount" preparation-small specimens only, such as cultured cells)
- Wash sections in physiological buffer
- Incubate with protein solution to reduce non-specific binding of antibody to specimen
- Incubate with antibody specific to antigen in question
- Wash in physiological buffer
- Apply suitable detection system
- Mount specimens and analyze microscopically

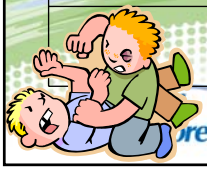





Order Received in Lab
Block to tech Start Cutting Slides
Tech Finishes Cutting Slides
LSA Receives Slides
Courier Picks Up Slides
Courier Drops Off Slides at LIJ
Slides Labeled
Slides Ready for Stainer
Slides Loaded on Stainer
Slides Hydrated
Slides Coverslipped
Controls to Pathologist
Courier Picks Up Slides
Courier Drops Off Slides at MANHT
Slides Received by Facility
Slides Given to Pathologist
Pathologist Signs Out Case
1
2
3
4
5
6
7 (L4)
8 (L5)
9 (L6)
10 (L7)
11 (L8)
12
13
14
15
L3
L9
L10
This Demonstrates the Non-detailed Steps Involved in the IHC Process at Each Institution

Stakeholder Analysis

Stakeholder Name	Strongly Against	Moderately Against	Neutral	Support	Strongly Support	Resistant Type	Plan to Address
A			x		0	P	Key person needs to be strongly supportive & engaged. Keep informed about feedback from pathologists
B		x			o	C,T,P	Address, educational needs. Include in decisions, Extended team member.
C		o					
D		x			o	C,T,P	
E			x		o	P,C	Same as techs, will be team members.
F		0					Key person. Needs to be strongly supportive and engaged. Keep informed about feedback from pathologists
G							
H					o		
	x				o	P,T	Encourage communication with user pathologists. Obtain data & expectations.



It is essential that the sponsor is supportive!

What is the Right Y (CTQ) to Measure? How will it be measured?

Y_1 = TAT defined as time of order to time slides are given to Pathologist, per site.

Y_2 = Number of defective slides per total number of slides processed.
Reason 1 Problem with staining
Reason 2 Problem with slide/tissue preparation

What are the data sources? How will the data be collected?

•Cerner Millennium can capture certain parameters on the tracking log. Specifically it can capture time of order and time of sign out.
•EVERYTHING ELSE MUST BE CAPTURED MANUALLY VIA TIME CLOCKS.
•Laboratory keeps track of number of repeats. Manual procedure. May be informative to keep track by stain type and originating facility.

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Containment Plan

Issue: No quality control data is being recorded for IHC

Data to Support Problem:

No data available

Stakeholders:

Pathologists, Administrators, Laboratory Staff, Clinician, Patients

What	Who	When
Reinstitute data collection log	Lab Administrator	Immediately
Train All personnel	Lab Supervisor	Immediately
Summarize data on a weekly basis	Lab Supervisor	Weekly
Analyze data for consistent issues	Six Sigma Team	Weekly until process improvement phase is over
Continue to collect and analyze data	Lab Supervisor	On-going

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Analytical Summary

What was tested	Target	Mean	P-Value	Test Method	Result
Order received to slides cut START	210	227	0.005	One Sample T-Test	Not at Target – Reject Ho Vital X
Blk cut END to slides labeled	60	618	0.000	One-Sample T-Test Test for Equal Variance (L vs. M)	Not at Target – Reject Ho Vital X
Slides labeled to slides ready for stainer	30	196	0.000	One Sample T-Test	Not at Target – Reject Ho Vital X
Slides ready for stainer to slides loaded	60	131	0.000	One Sample T-Test Test for Equal Variance (L vs. M) Mood Median (Rt vs FT)	Not at Target – Reject Ho Vital X
Slides coverslipped to control to pathologist	15	431	0.000	One Sample T-Test	Not at Target – Reject Ho Vital X
Ctrl to pathologist to courier PU	60	353	0.005	One Sample T-Test	Not at Target – Reject Ho Vital X

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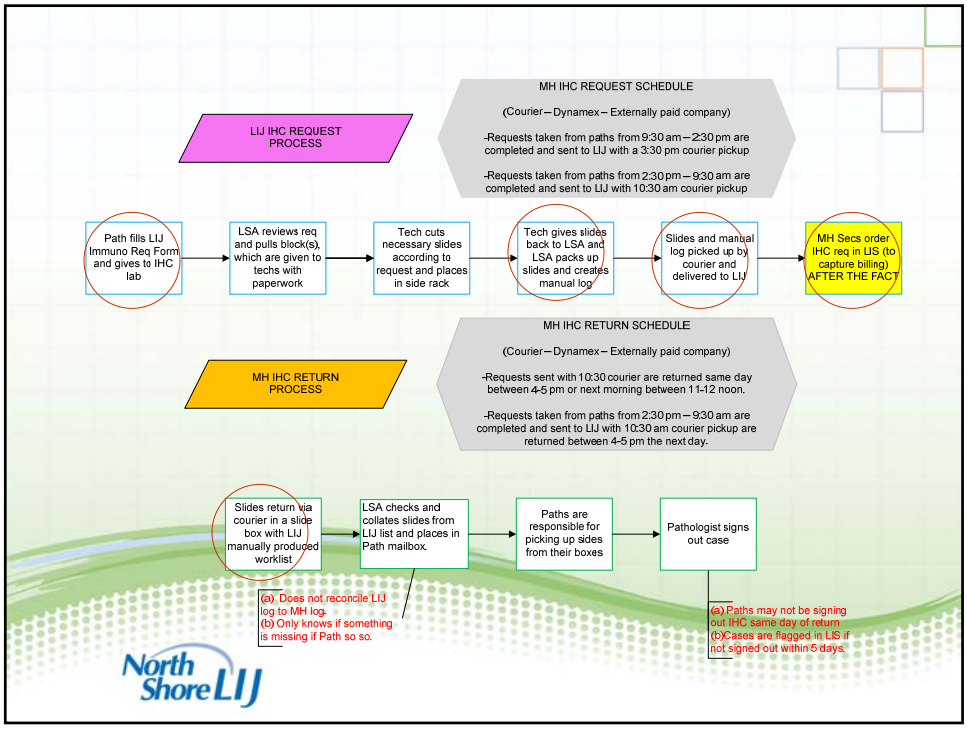
What X's (inputs) cause the most variation?
Order Received to Slides Cut

What are some potential solutions? How can we change the process?
Pathologist to enter order in Laboratory Information System

What is our improvement strategy? How will we implement the change?
Pathologists are reluctant to order in the system because they perceive the system is slow.
Plan: Enter panels in LIS to speed ordering.
Demo ordering process.
Train pathologists to enter orders.
Train technologists to receive orders.



I think that electronic ordering is the greatest thing since sliced bread!!

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What X's (inputs) cause the most variation?
Block Cut End to Slides Labeled
Slides labeled to slides ready for stainer.
Slides ready for stainer to slides loaded on stainer.

What are some potential solutions? How can we change the process?
Process Change-Currently, slides are being batched according to test type.
Limit the amount of slides batched to 30 slides or number of slides gathered in 1 hour.

What is our improvement strategy? How will we implement the change?
Run smaller batches.
Minimize instrument idle time.
Assign dedicated technologists. Possible re-scheduling of technologists.
Plan: Develop standard operating procedure for process flow.
Re-train technologists.

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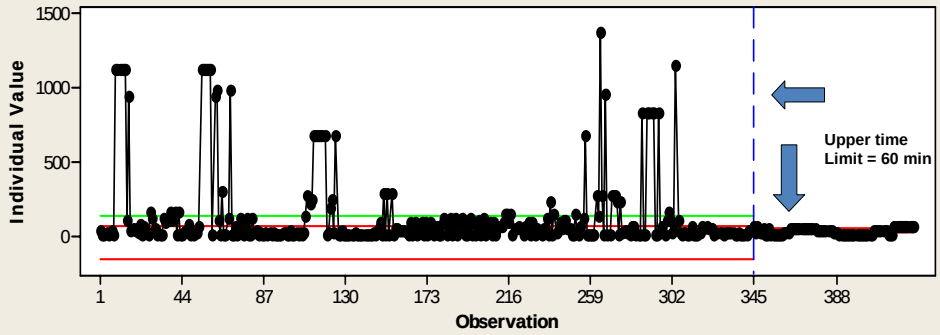
Slides Labeled to Slides put on Stainer Step



Before

N=344
Mean = 134.7 min
2.25 hours

After

N=85
Mean= 27.6 min

What X's (inputs) cause the most variation?
Slides coverslipped to controls to pathologist
Control to pathologist to courier pick-up

What are some potential solutions? How can we change the process?
Assign more than one pathologist so work is prioritized.
Direct communication with pathologist when slides are ready.
Put control on actual case slides.
Teach technologists how to read controls.

What is our improvement strategy? How will we implement the change?
Sponsor to assign pathologists.
Set up standard operating procedure for contacting pathologists when controls are ready.
Set up control bank.
Need buy in from pathologists and training of technologists.

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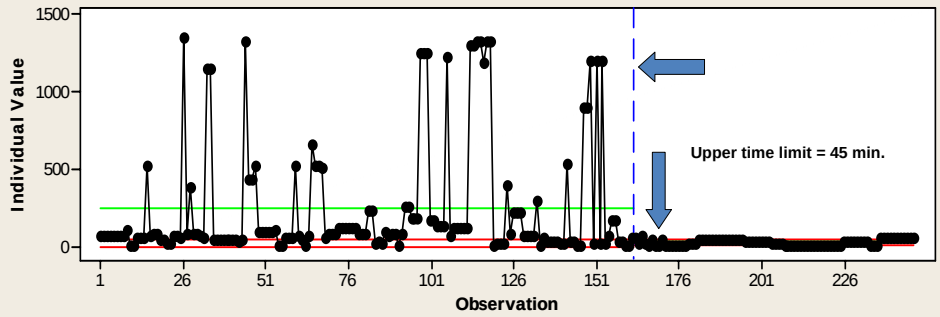
Pathologist Views Control Step

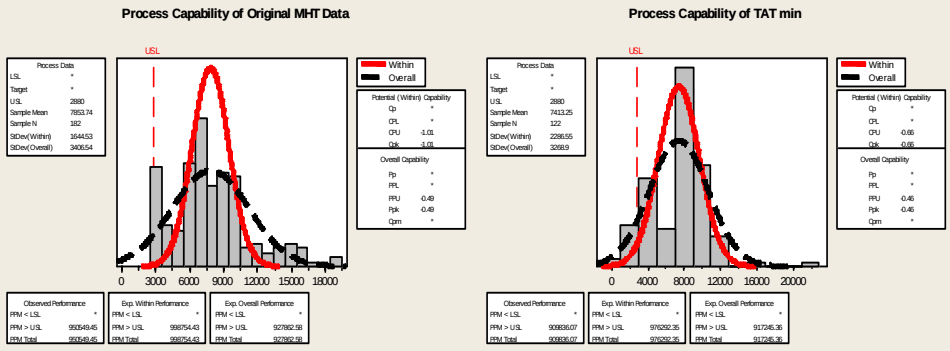


Before

N=162
Mean = 248.6 Minutes
4.14 hours

After

N=85
Mean = 27.6 Minutes



Defects per Million Opportunities

950,549 **909,836**

Yield of Good Product

4.95% **9.02%**

Sigma Score

1.500 **1.500**

Decrease of Mean by 440 Minutes (7.5 hours)

The Team chose to implement the improvements in phases.

Phase I Ordering process — *DONE*
Phase II New SOP — *IN PROGRESS*
Achieving buy-in of all parties
Training for new process
Go live with new process
Phase III Long term improvements such as control bank
Cerner Millennium ABT System — *LONG TERM*
TAT Metric for PICG — *IMPROVEMENTS*

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Questions for the Team?

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