Implementing New Hematology System & Technology in TEN Hospital Labs

How We Incorporated Standardization, Automation and Middleware to Advance Patient Care

Objectives

- Understand the process for implementing a Six Sigma project with standardized tools.
- Describe how the project got launched for system implementation.
- Discuss how automation and new technology can be applied to improve workflow and patient care.

Who we are

Banner Health is one of the largest nonprofit health care systems in the country serving patients across seven states

- 25 hospitals
- Six long term care centers
- Family clinics
- Home care services
- Medical equipment services
- Research
- Surgery centers
- Urgent care
- Hospice
- Compounding Pharmacy

Banner Health Arizona Medical Centers

Banner Gateway

Banner Boswell

Banner Del Webb

Banner Desert

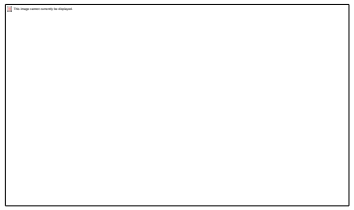
Banner Estrella

Banner Good Samaritan

Banner Baywood/ Banner Heart Hospital

Banner Thunderbird

Page Hospital



Banner Ironwood

2013: Banner Goldfield
2014: Banner Casa Grande

Laboratory Sciences of Arizona/ Sonora Quest Laboratories (LSA/SQL)

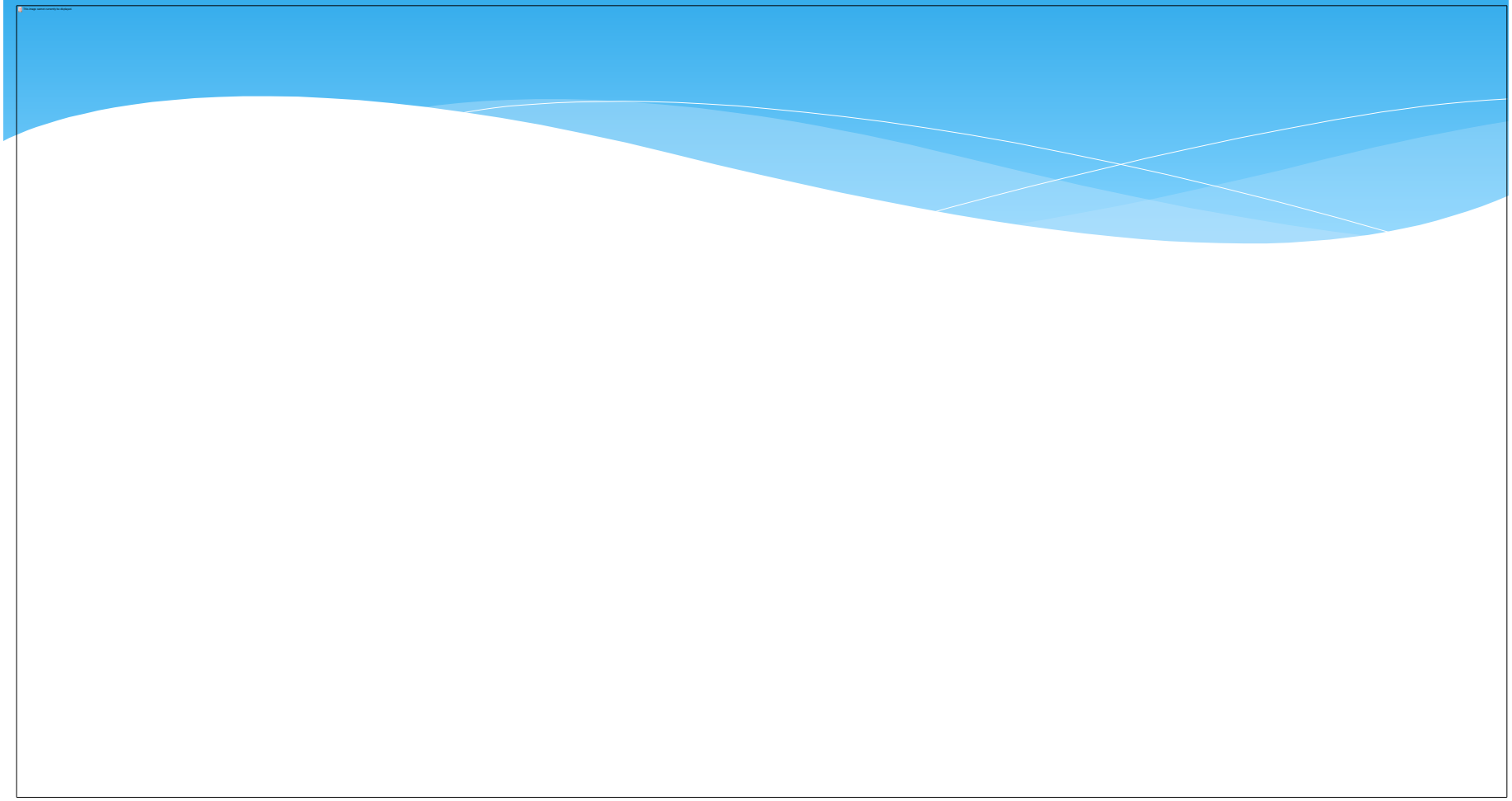
- LSA/SQL was formed by an integration of the hospital laboratories of Banner Health and Sonora Quest Laboratories
- 51% is owned by Banner Health System
- 49% is owned by Quest Diagnostics
- LSA/SQL manages Banner Health Arizona clinical laboratories

LSA/SQL ORG Chart

WHY IS THIS PROJECT IMPORTANT?

* **A System Implementation Team was created that included both quality and technical members to:**
  - ❑ Ensure System standardization of policies & procedures
  - ❑ Monitor consistency of site to site training and competency
  - ❑ Employ the Green Belt Six Sigma project process for the instrument implementation and IT systems
  - ❑ Utilize the results of the project to improve the Voice of the Customer outcomes

Project Team



The Team includes many LSA System Departments, Site Hospital Departments and Sysmex Technical personnel.

IMPROVE VOC (Voice of the Customer) OUTCOMES

* **The goal of the project is to reduce process defects that affect VOC results by:**
  - Reducing non-value added steps within the process
  - Decrease the scan/diff rate by 30%
  - Maintain in goal TAT* compliance through-out the implementation process and post implementation

Issues with Current Process

- **Not all Lab Sites use same instrumentation or procedures.**
- Variation in practices exist from site to site.
- The lack of standard practice creates difficulty in site to site comparisons.
- Numerous manual steps inherent in current instrumentation creates delays.
- No changes in hematology platform for over 25 years

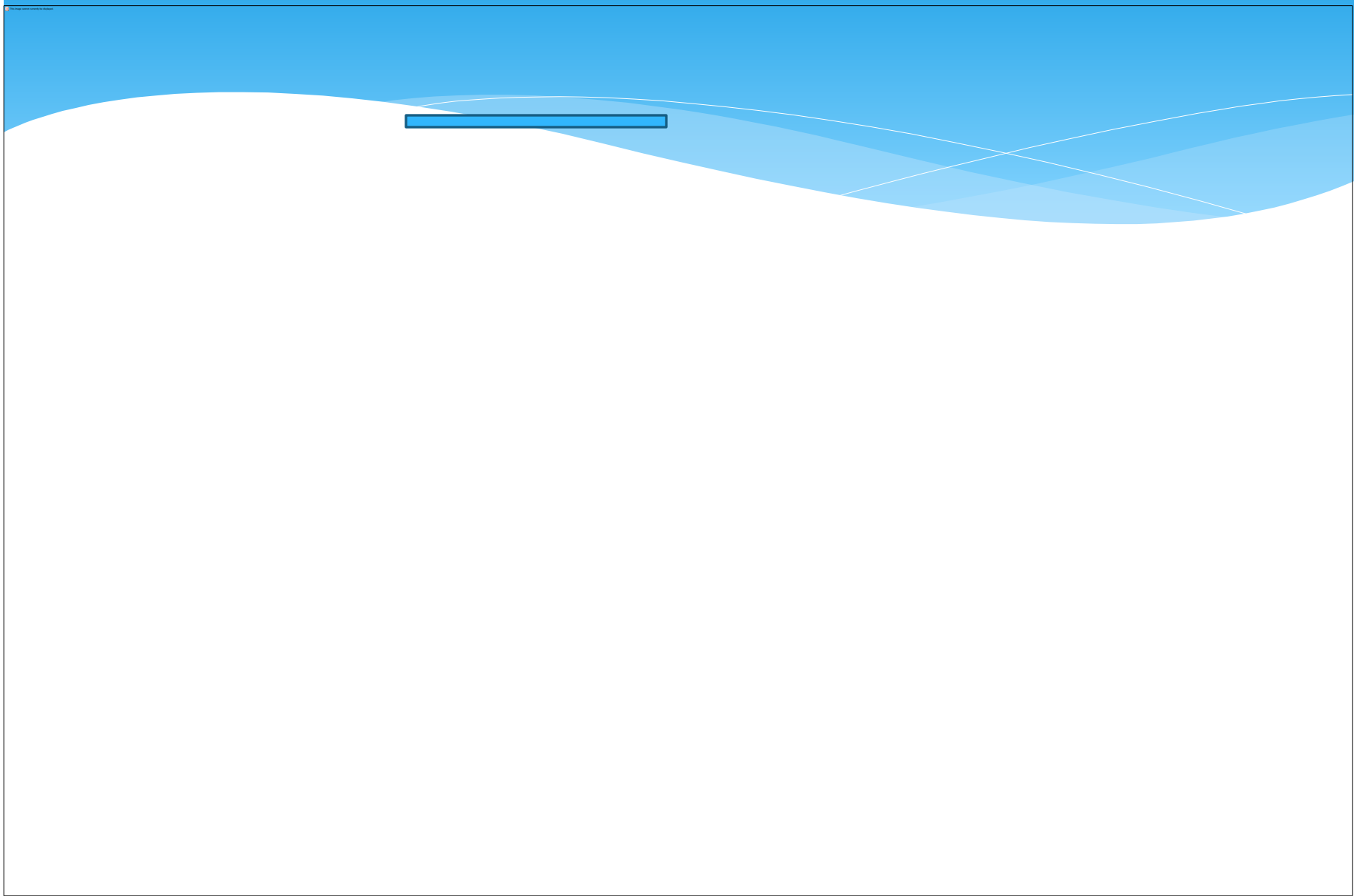
Our Goals

- Standardization of instrumentation and procedures provide comparisons from Hospital Lab Site to Site.
- Continued learning in Lean and Six Sigma.
- Identify improvement opportunities for the VOC.
- Report parameters from new technology to improve patient care.

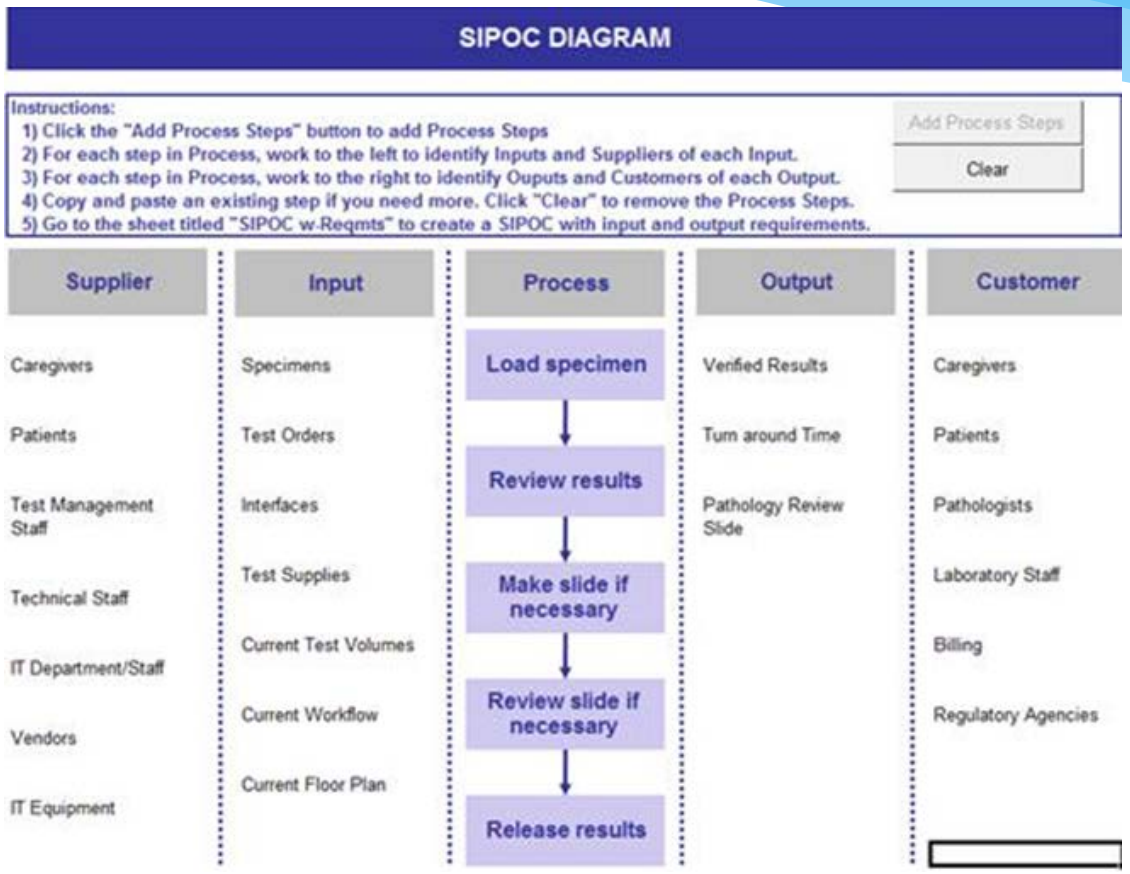
DMAIIC Methodology

- Define
- Measure
- Analyze
- Innovative Improvement
- Control

DMAIIC - Define



Define - SIPOC



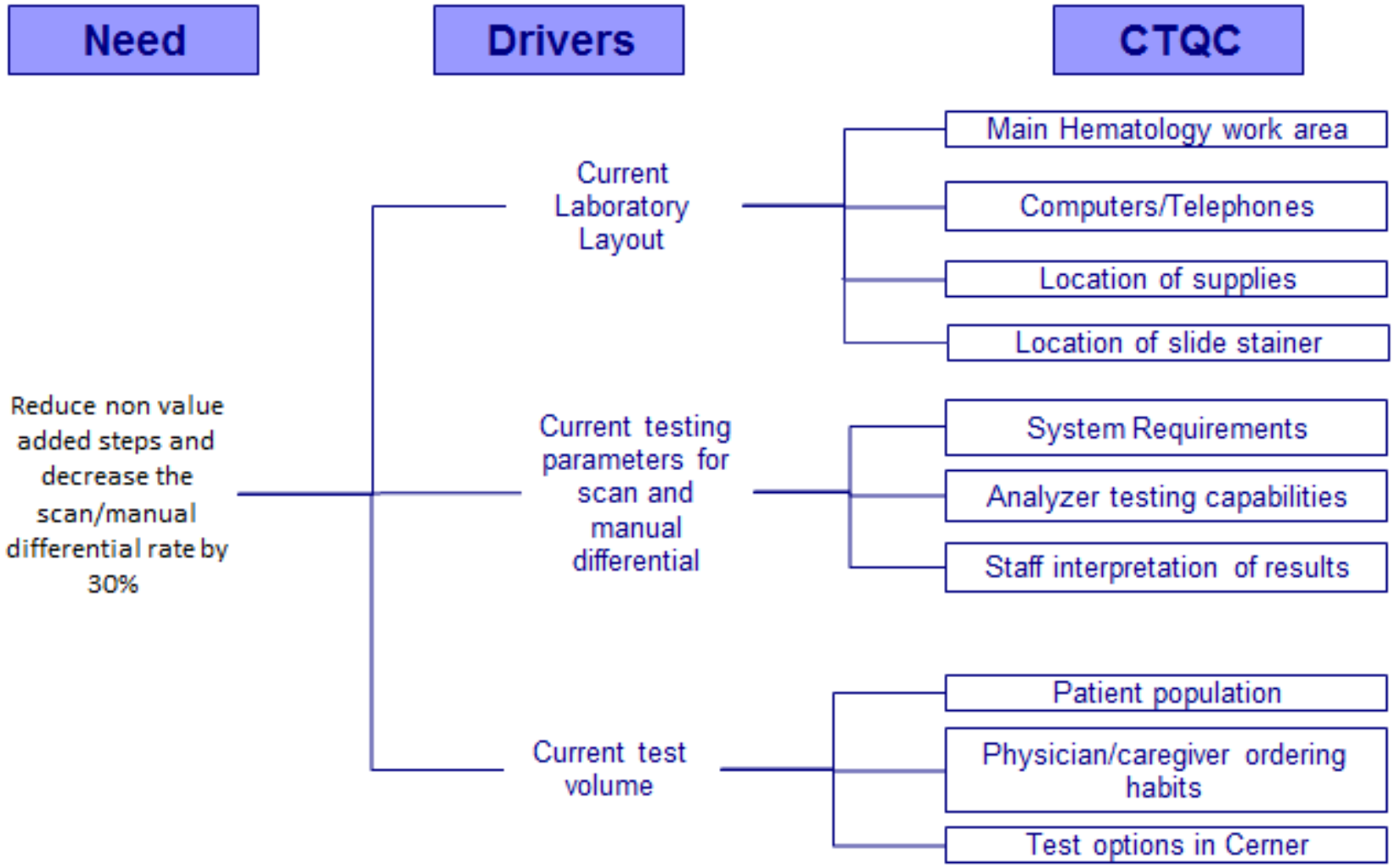
Variations Identified:

- ❑ Pre analytical workflow
  - ✓ Labelling
  - ✓ Transportation
- ❑ Analytical workflow
  - ✓ Specimen drop area
  - ✓ Loading analyzers
  - ✓ Middleware
  - ✓ Action Limits
  - ✓ Lack of middleware
  - ✓ Manual sampling handling
  - ✓ Manual slide making/staining
- ❑ Post Analytical
  - ✓ Criticals
  - ✓ Reference ranges

Define - VOC

- **Instrumentation**
  - Ease of use
  - Reliable
  - Hands off
  - New technology
- **IT**
  - Auto-verification
  - Downtime
- **Results**
  - Improve or maintain TAT for ER and In-patients
  - Report Clinical Advance Parameters (ACP's)
  - ***Improve patient outcome***

Define - CTQ



Identify what is critical to Quality

Measure – Data Collection

Measurement System Analysis	
Data Type:	Discrete; Time
Data Source:	Banner Health Computer System - Cerner Millennium
Data Collection System Description:	Computer - System Instrument - System
Measurement Process description:	Timing of the Current Hematology process began with specimen receipt in department and ended with specimen verification into Cerner.
Tools Used:	Excel Spreadsheet, Banner Health Computers, and timer/clocks.
Known Measurement Errors:	None
Suspected Measurement Problems:	Invidual timer/clocks may not have matched other clocks exactly, but the measured time a task took to complete was found to match.
Rationale for not performing a Gage R&R:	Not needed. Verified time with a group audit. Audit performed 11/29/2011.
Results of performing a MSA:	Manual measurements were within acceptable ranges for variation.

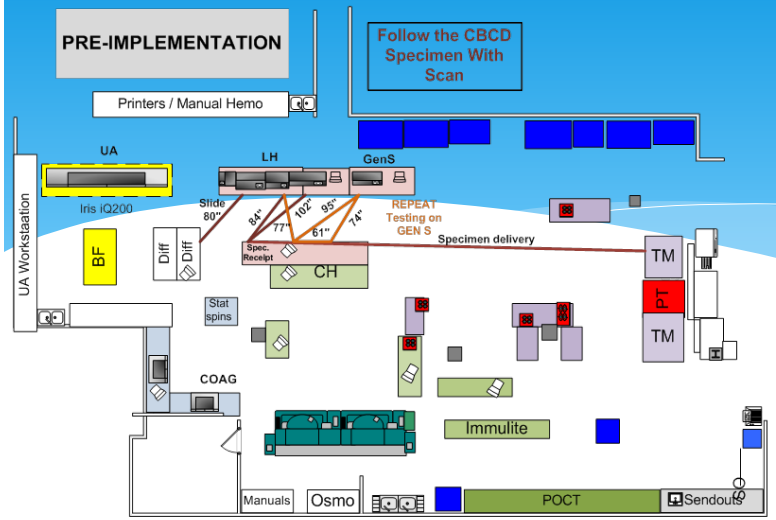
Measurement system is adequate

Measure

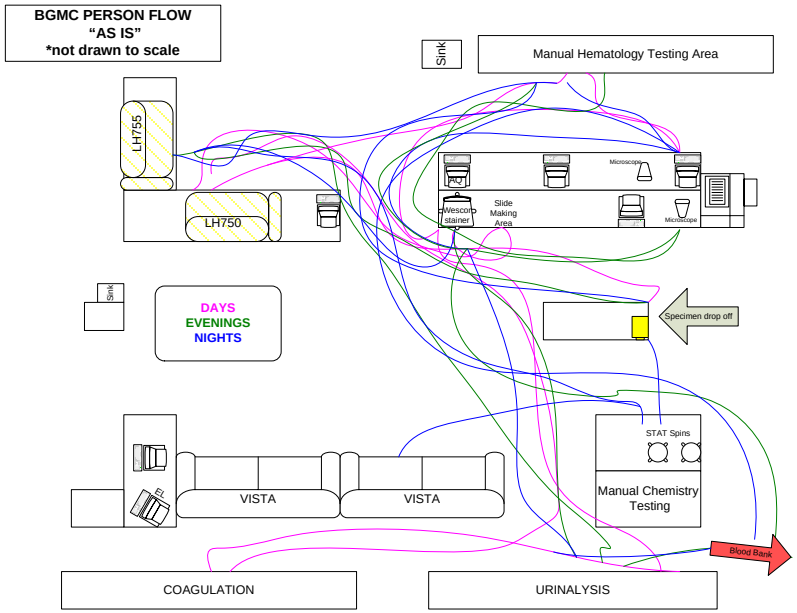
- (1) Reduce non added value steps
- (2) Rate of SCANS/MDIFF performed
- (3) CBC ED TAT DPMO

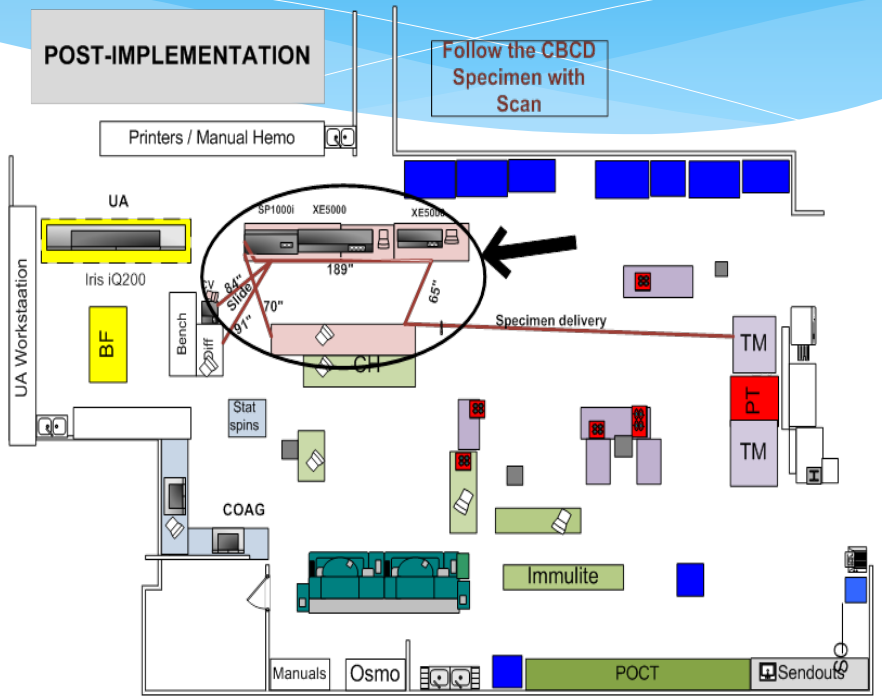
Project Y	Site	Baseline Metric	Target metric
Reduce non-value added specimen travel distance	A	97 feet	29 feet **(63% improvement)**
	B	8509 feet	3886 feet **(54%)**
	C	96 feet	67 feet **(26%)**
Current review rate of scans/manual differentials	A	21.8%	14.5% **(32%)**
	B	21.7%	14.6% **(7.1%)**
	C	18.7%	13.1% **(5.6%)**
Meet ED CBC TAT DPMO goal	A	100,000 DPMO (90%)	$\leq$ 100,000 DPMO **(90%)**
	B	100,000 DPMO (90%)	$\leq$ 100,000 DPMO **(90%)**
	C	100,000 DPMO (90%)	$\leq$ 100,000 DPMO **(90%)**

Measure - Spaghetti Map



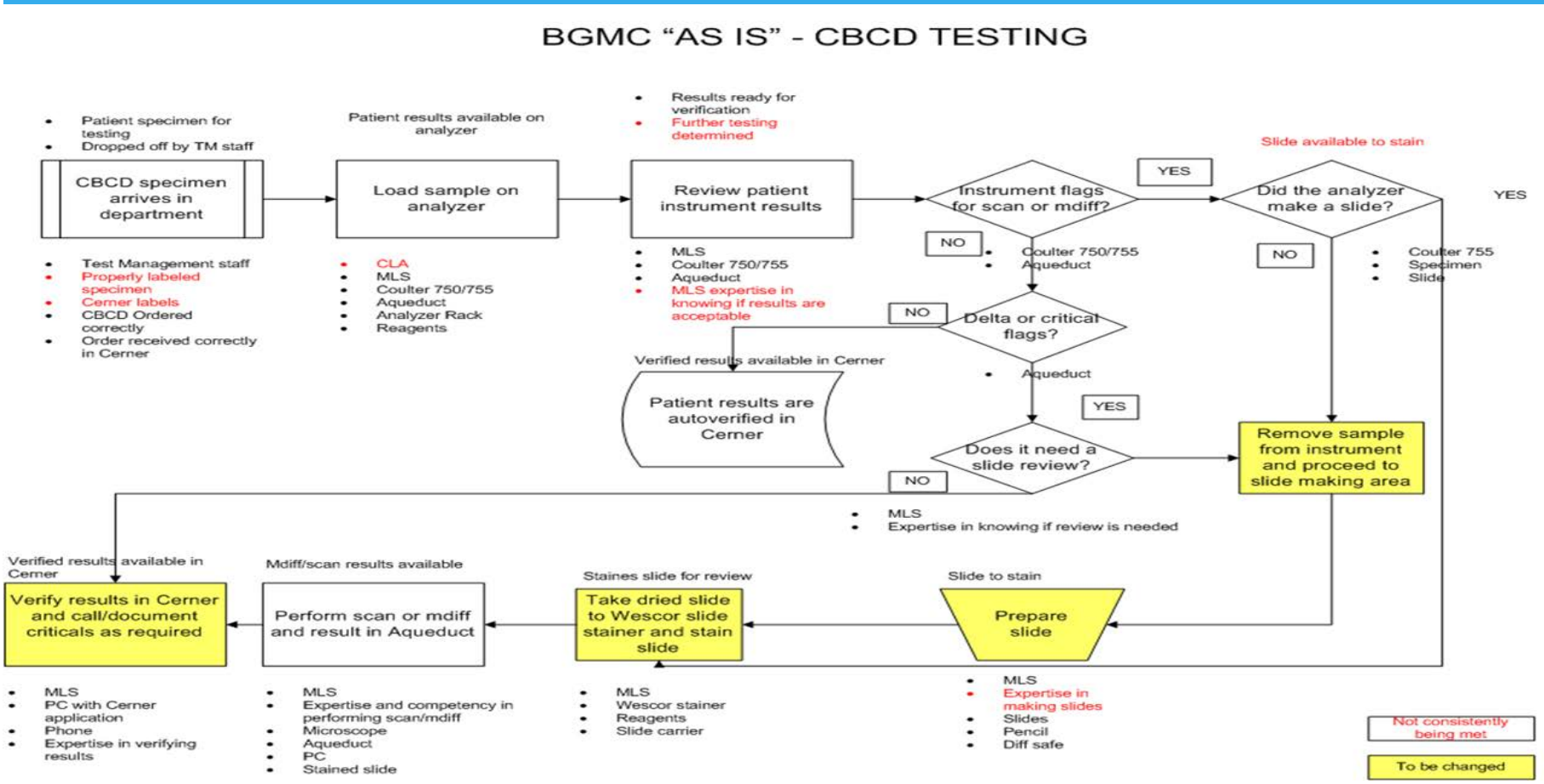
Reruns required additional handling & physical steps





Post Implementation showed physical steps due to reruns and additional handling were reduced within the process.

Measure – Process Maps

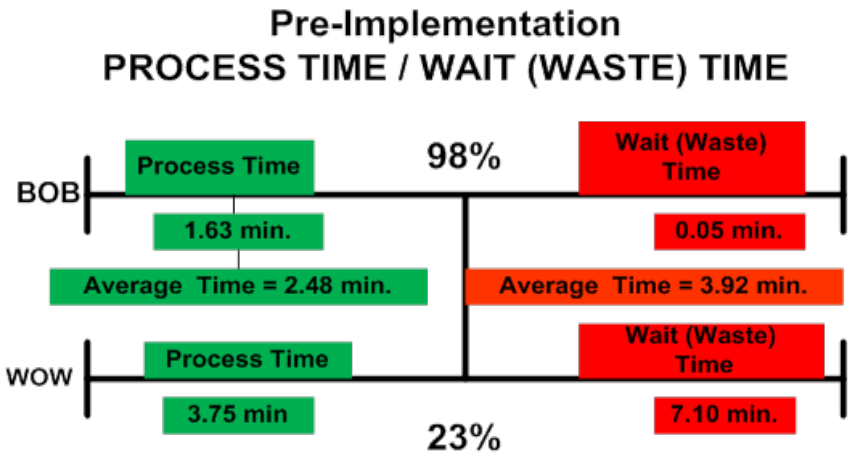


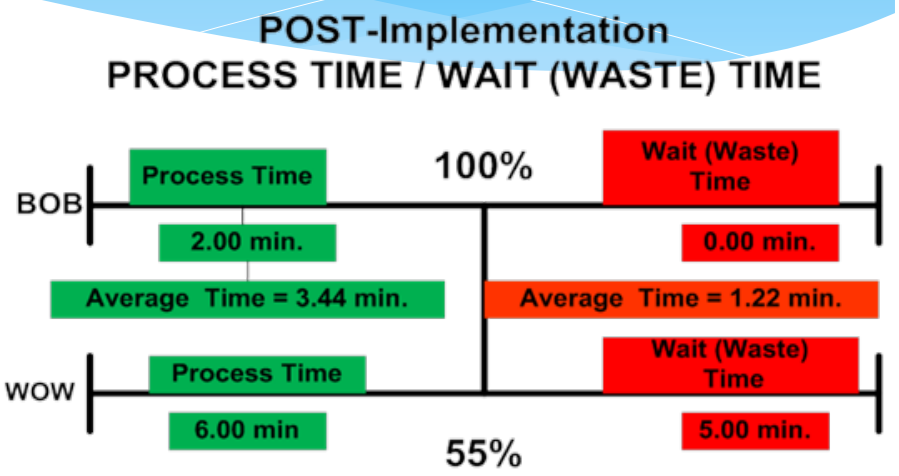
- Start = Specimen arrives in department
- Inputs and outputs listed for each step with indication of what is not being met
- Steps to be changed are highlighted
- Stop = Result verified in Cerner

Measure – Benefits of Mapping

- Determine loopbacks and where the process is stalled/delayed
- Shows which significant factors can be addressed
- Time and distance can be a factor
- May help to determine a better location for equipment or process steps
- Can show variation of the same process between different shifts
- Able to be used to re-evaluate staffing needs

Measure – Process Time

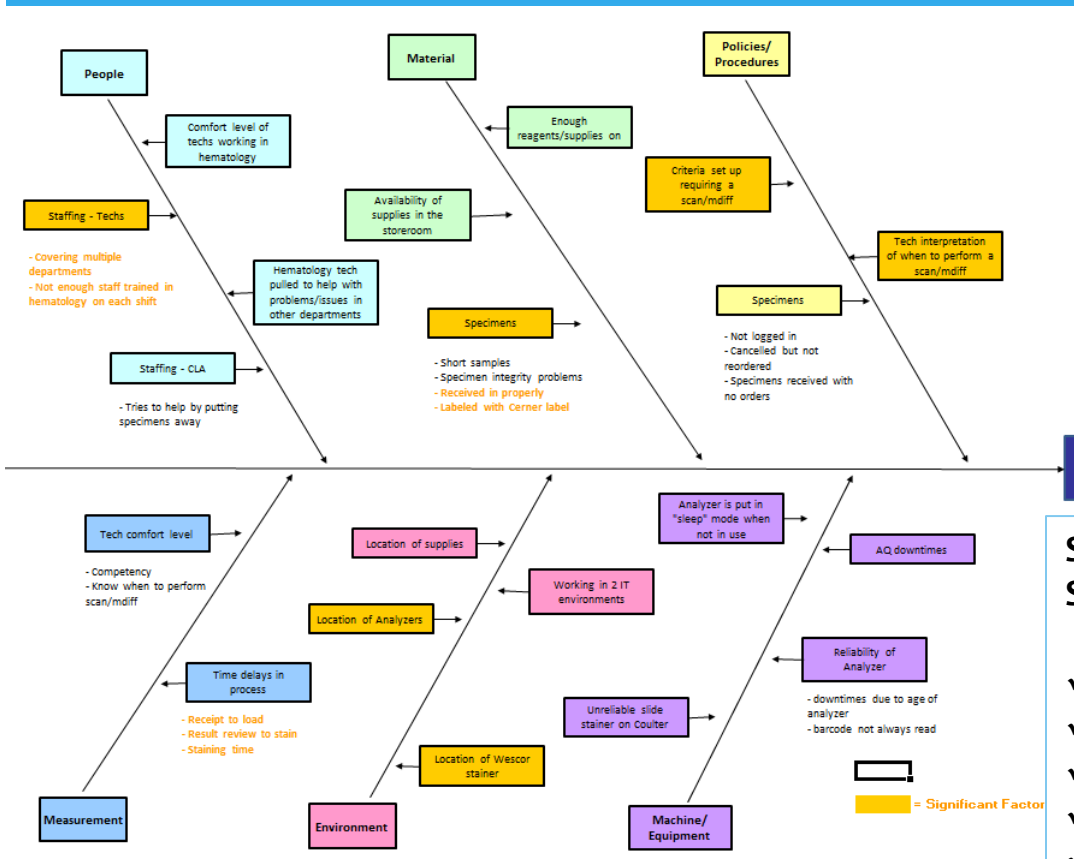




Time Value Charts: Average Wait (Waste) Time is 3.92 minutes. No middle-ware was utilized in the pre-implementation process.

Time Value Charts: Average Wait (Waste) Time is 1.22 minutes. With the addition of middle-ware the process time increased to 3.44 minutes which is demonstrated as required quality time.

Analyze – Fishbone

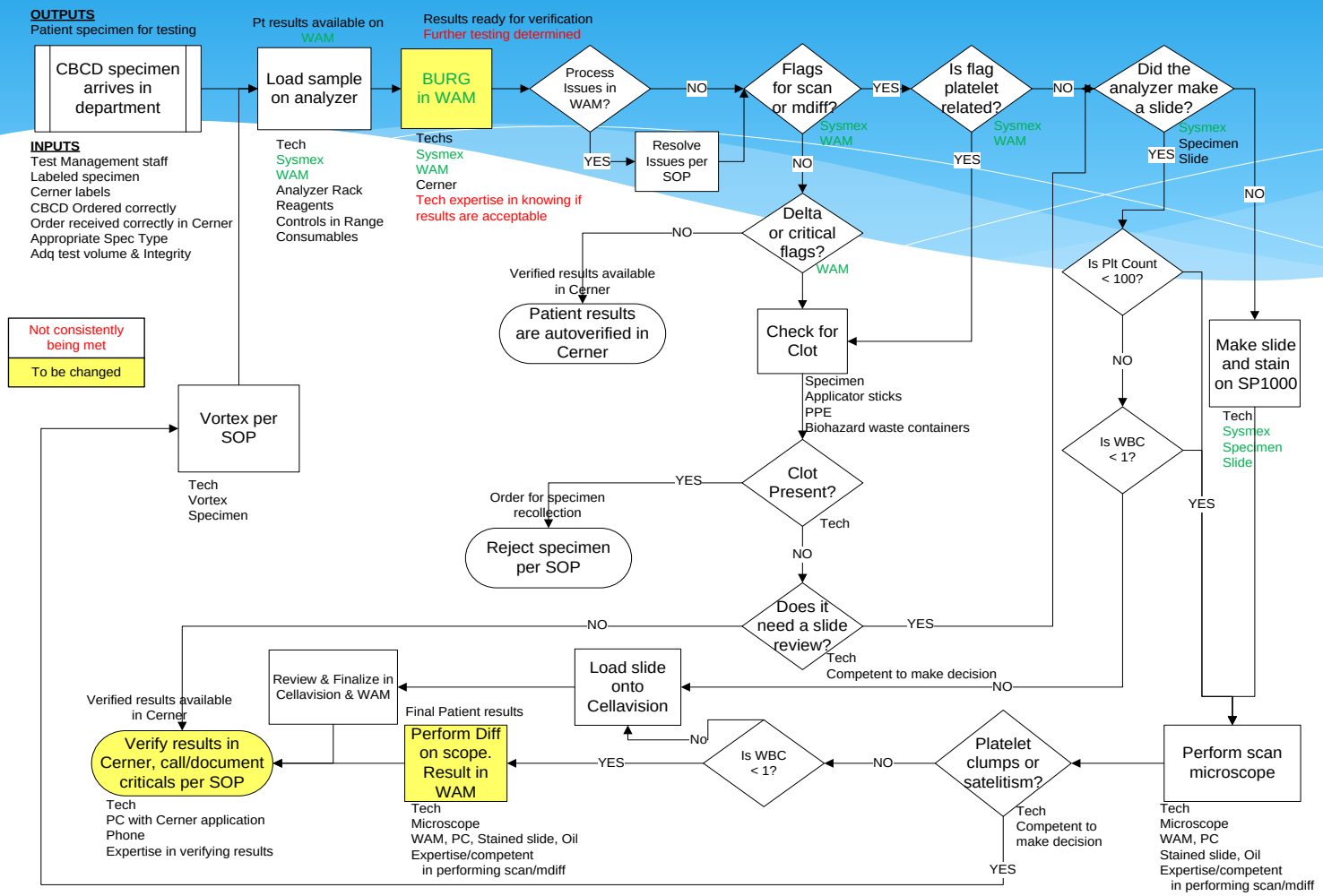


Significant factors which would decrease the SCAN/MDIFF rate and non value added steps:

- ✓ Multi-tasking
- ✓ Multi-step process
- ✓ Location of the analyzers
- ✓ Location of the backup stainer
- ✓ Current rules defined for performing a SCAN/MDIFF
- ✓ Tech interpretation of when to perform a SCAN/MDIFF
- ✓ Current rules defined for ordering a To Path

Identifies Effects (Symptoms, Customer Impact, Rework, Loopback)

Analyze – Process Map



Steps may be more consistently met. Rules in WAM:

- Help ensure consistent process steps
- Help ensure techs know if results are acceptable

Improvements – solution Matrix

Number	2) Solution Description	3) Rating 1 - 5: Ease of Implementation	Useful as volume increases	Additional product/reagent needed	Additional training time required	Development Time	Development & Implementation Cost	4) Total Σ(Weight x Rating)
1	**Use the slidemaker/stainer on the analyzer**	5	5	1	5	5	5	87
2	**locate the analyzer closer to the receiving site of specimens**	5	5	1	5	5	5	87
3	Educate staff about the correct way to put the barcode	2	5	1	3	5	5	65
4	**Check for the availability of supplies at the beginning of shift**	5	5	1	5	5	5	87
5	**Train more people in hematology (Sysmex)**	5	5	1	5	5	5	87

	DAY SHIFT		EVE SHIFT		NITE SHIFT		All Shifts
SOLUTIONS	score	ranking	score	ranking	score	ranking	ranking
All or most UA techs cross-trained in parts of Hemo	3.714	2	4.167	3	4.60	1	1
Cellavision physically located near the analyzer	3.429	3	5.000	1	3.40	4	2
Primary Triage station is at high desk height	3.286	5	4.667	2	3.80	2	3
Locate Wescor stainer in Manual Test area	3.286	4	3.667	4	2.40	5	4
~~Secondary Triage station in the Hemo area~~	2.000	6	2.833	6	3.60	3	5
Secondary Triage station in the Manual Test area	3.857	1	2.667	5	1.60	6	6

Site A Improvements:

- ✓ Automated slidemaker/stainer.
- ✓ HST placed closer to testing are. Decrease from 76 feet to 16 feet.
- ✓ Additional staff trained in hematology for off-shift hours allowing less need to work in multiple departments.

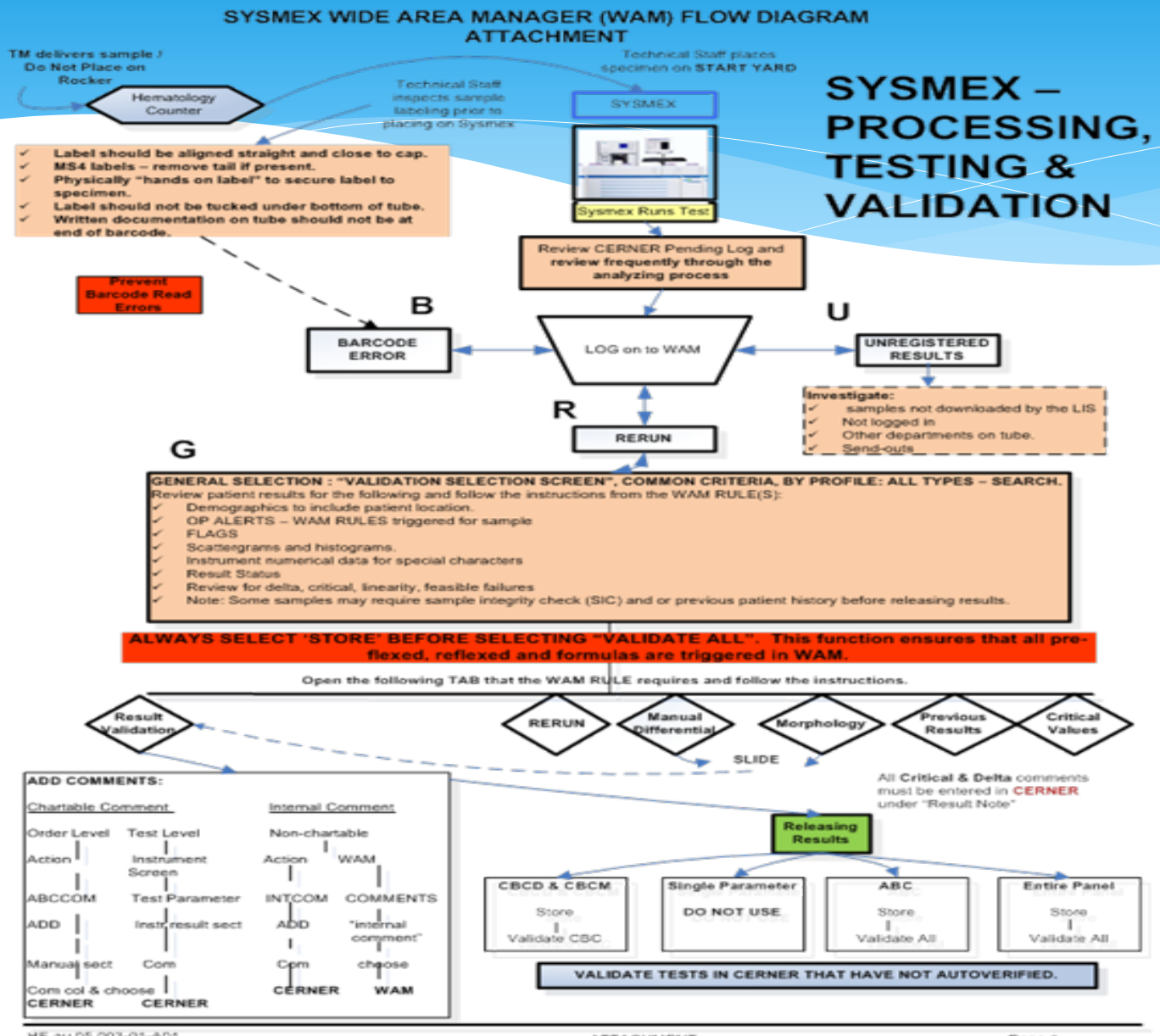
Site B Improvements:

1. Distance travelled by tech
   a. Baseline = 96 feet, Post = 41 feet

2. SCAN/MDIFF Rate
   b. Baseline = 19.8%, Post = 12.3%
   (Test of Proportions = 0.00000)

3. CBC ED TAT DPMO – maintained pre and post go live.

Innovative Improvement



Control

Time Value Charts : Comparison of old methodology (Previous Analyzer)- Pre with new methodology (Sysmex)-Post:
Improvement in decreasing the waste wait time.

- The addition of Test Management Staff placing the specimen on the instrument impacted the process.
- Auto-verification impacted the process.

F-Test & t-Test : The (F-Test) variances & (t-Test) means are different between the Previous Analyzer (PA) and Sysmex methodology.

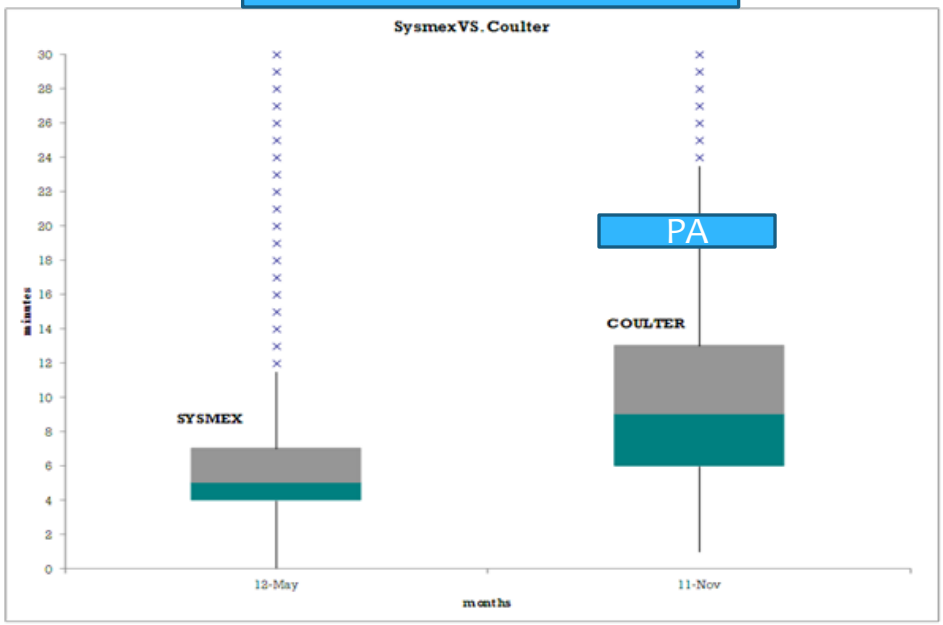
The percent compliance is about the same between the two methods. However the average monthly minutes have decreased with the Sysmex instrumentation. This is demonstrated on the Control Chart below.

- (Pre) Previous: 2011 data – Nov
- (Post) Sysmex: 2012 data – May

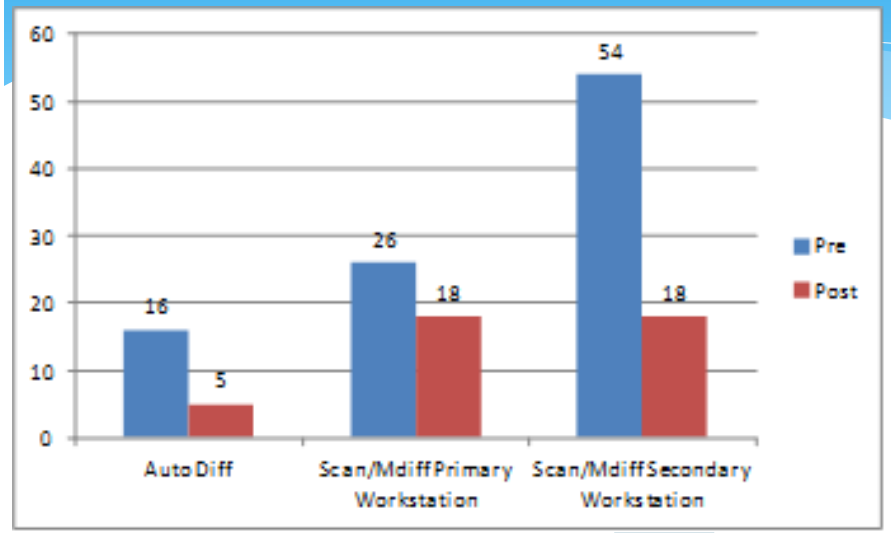
Box-Whisker Chart: Shows the differences in the placement of data and variation between the two instrumentation processes. The Sysmex process shows improvement from the PA process.

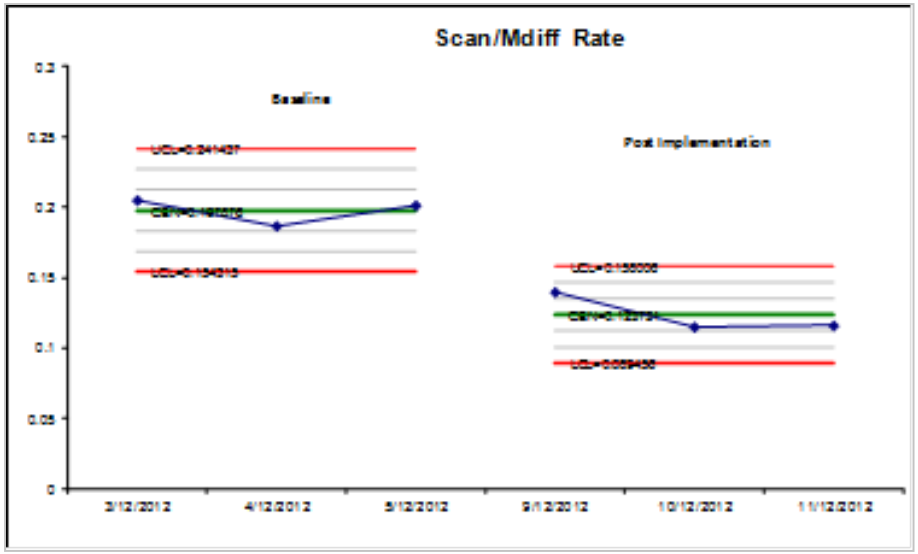
Metric	Pre	Post	% Change
Wait Time	3.9 min	1.2 min	69%
Percent Compliance	96.5%	96.8%	0.3%
Average Minutes	11.6 min	7.7 min	32.5%

Sysmex vs. Previous Analyzer(PA)



Control - Charts

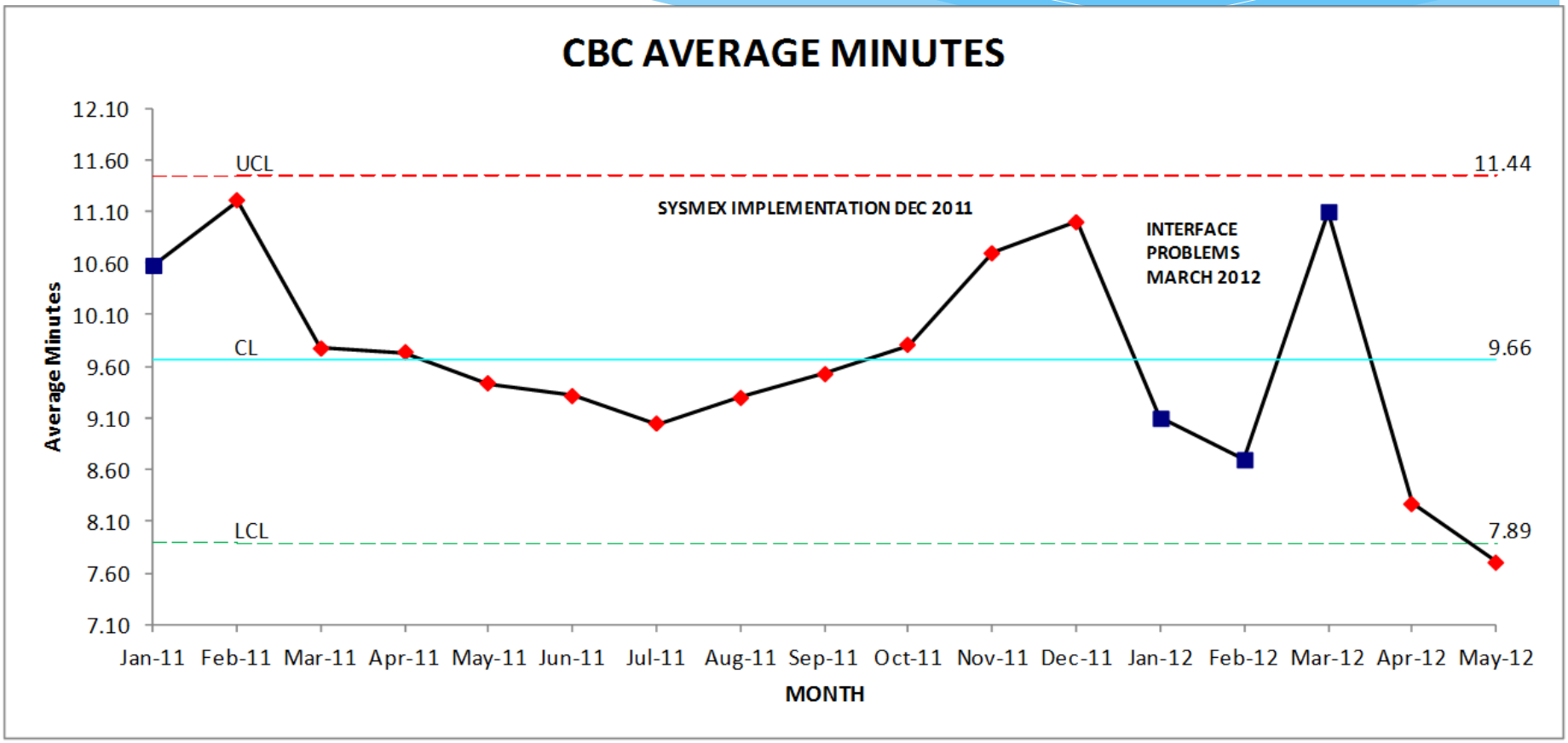




Decreased by 38%

Goal: Decrease by 30%

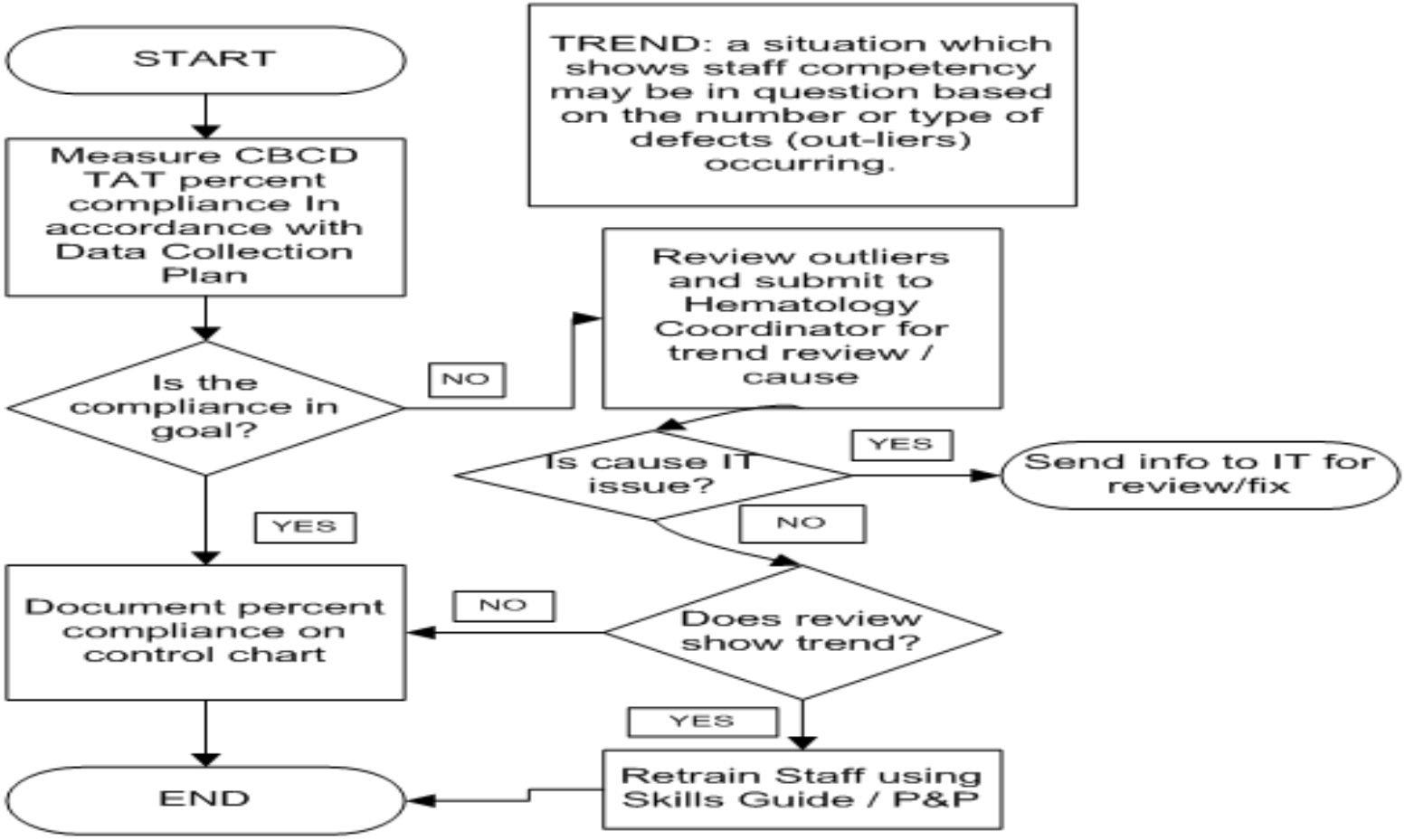
Control Plan - results



Control Plan

PLAN/DO	CHECK				ACT
Process Steps (example – replace)	What & How to Check	Target	When	Who	Action Required
CBCD specimens delivered to the Hem dept → Specimen loaded onto coulter rack then on analyzer → Specimen analyzed → Review slide if necessary → CBCD verified in Cerner	CBC ED TAT DPMO	≤100,000 DPMO	Monthly	Quality Specialist	Process owner review & identify causes of failures
	Scan/diff rate for one month	13.9%	Every 6 months or as needed	Quality Specialist	Process owner review & identify causes of failures

Reaction Plan



Advance Clinical Parameters (ACP)

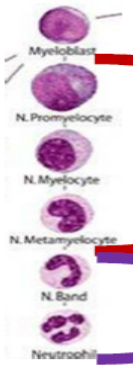
NEW! AUTOMATED!

New Automated Hematology Tests

White Blood Cells

IG# (Immature Granulocyte Count)

IG% (Immature Granulocyte Percent)



Automated Immature Granulocytes ***IG***

- ✓ ***Identifies and Quantifies <u>Immature</u> Myeloid cells***
- ✓ ***Counts 32,000 cells*** – *More sensitive and more precise than manual differential*[1]
- **IG = Metas + Myelos + Pros**
- ✓ *Early screen for sepsis*
  - *Better indicator for infection than WBC*[2]
  - *Comparable to ANC*[2]
  - *IG% >1% indicates a left shift*
  - *IG% >3% may predict positive blood cultures with 98% specificity and 92% Positive Predictive Value*[2]
- ✓ *Detects myeloproliferative disorders*
- **Neutrophil count includes bands**
- ✓ Flags atypical cells and reflexes to manual review

Rapid! Accurate! Precise!

Platelets

IPF (Immature Platelet Fraction)

As fast as a CBC!

Automated Immature Platelet Fraction ***IPF***

- ✓ Evaluate mechanism causing thrombocytopenia[3]
- ✓ Determine need for platelet transfusion
- ✓ Predict platelet count recovery
- ✓ IPF recovers ~3 days earlier than platelet count[4]

↓ Plts + ↑ IPF → *Peripheral destruction or BM Recovery*

↓ Plts + ↓ IPF → *BM production disorder*

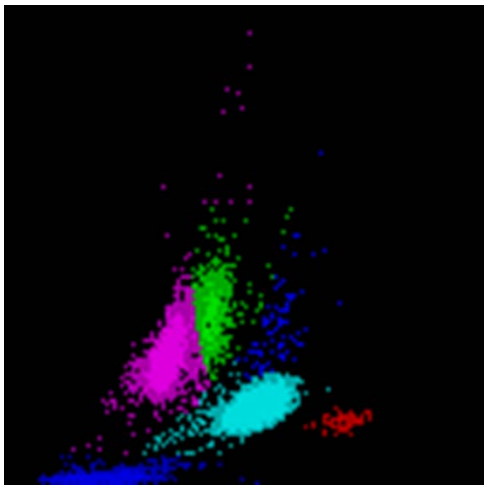
REFERENCES:

1. Immature granulocyte measurement using the Sysmex XE-2100. Am J of Clin Path; 2003;120(5):795 –799.
2. Automated Enumeration of Immature Granulocytes. Am J Clin Pathol 2007; 128; 454-463
3. Assessment of an immature platelet fraction (IPF) in peripheral thrombocytopenia. Br J of Haematology. 2004; Jul; 126(1): 93-9
4. Immature platelet fraction as a predictor of platelet recovery following hematopoietic progenitor cell transplantation. Lab Hematol; 2006; 12(3):125-30

Immature Granulocyte (IG%)

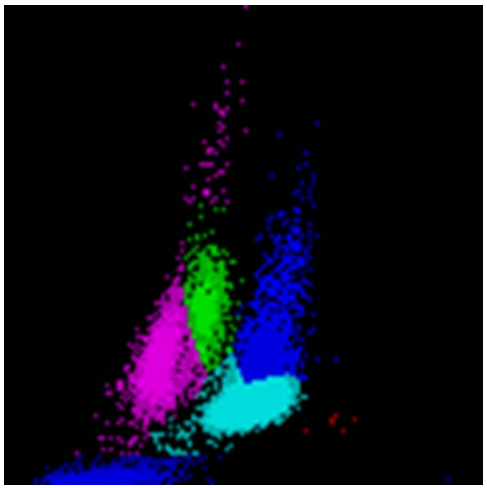
* **Case #1: Infection or Inflammation?**
- ✓ 25-year-old female with autoimmune disorder
- ✓ Admitted to hospital with severe hemolytic anemia
- ✓ Treated with steroids.
- ✓ Elevated WBC.

Day 1



IG% = 1.9

Day 5



IG% = 5.9

Immature Platelet Fraction (IPF)

* IPF ➔Thrombocytopenia Management
  * Differentiate Production vs. Destruction
  * Oncology
    * Evaluate bone marrow recovery
  * Pharmacy help identify patients with HIT
  * Platelet transfusions
  * Avoid unnecessary bone marrow aspirates
  * Avoid unnecessary expensive testing

Advanced Clinical Parameters (ACP)

New Automated Hematology Tests

NEW! AUTOMATED!

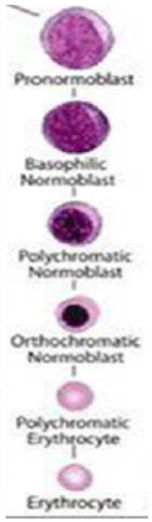
Red Blood Cells

NRBCs (Nucleated Red Blood Cells)

3-Part Retic

1) Retic # & Retic %
2) ***IRF*** (Immature Reticulocyte Fraction)
3) ***RET-He*** (Reticulated Hemoglobin Equivalent)

Rapid! Accurate! Precise!



Automated Nucleated Red Blood Cells ***NRBCs***

- Instrument checks for NRBCs on *every* patient
  - ✓ Up front for ICU, NICU, Oncology patients
  - ✓ Any CBC that flags possible NRBCs will reflex to rerun specimen for automated NRBC evaluation
- One NRBC in an adult is important finding[1]
- Study[2]: ICU Mortality rate 3X higher if NRBCs present when patient moved from ICU to floor, compared to ICU patients with no NRBCs

Automated 3-Part Retic ***Retic-Comprehensive***

1) Reticulocyte Count and Percent (Retic # & Retic %)

As fast as a CBC!

2) **IRF** (Immature Reticulocyte Fraction)
   - ✓ ***Quantitative*** measure of immature retics
   - ✓ Indicates bone marrow response to anemia
   - ✓ Elevated IRF indicates increased red blood cell response from bone marrow

3) **RET-He** (Reticulated Hb Equivalent)
   - ✓ ***Qualitative*** measure of Hb in reticulocytes.
   - ✓ ***Cellular evaluation of iron status***
   - ✓ Diagnose iron deficiency and monitor response to treatment
   - ✓ Not effected by inflammation or uremia
   - ✓ Used by **National Kidney Foundation** clinical practice guidelines to detect iron deficiency anemia in chronic kidney disease[3]
   - ✓ Adopted by **AHRQ** for management of patients with End Stage Renal Disease
   - ✓ Cited in **clinical guidelines** for the diagnosis of iron deficiency anemia in children 0-3 years old[4]
   - ✓ Study[5]: Preop evaluation of anemia in orthopedic patients → decreased red blood cell transfusions

REFERENCES:

1. The Clinical Relevance of Nucleated Red Blood Cell Counts. Sysmex Journal International, Vol. 10, No. 2 (2000).
2. Nucleated red blood cells in the blood of medical intensive care patients indicate increased mortality risk: a prospective cohort study. Critical Care 207, 11:R62. http://ccforum.com/content/11/3/R62
3. www.kidney.org/professional/KDOQI/guidelines_anemia/cpr12.htm
4. Diagnosis and Prevention of Iron Deficiency and Iron-Deficiency Anemia in Infants and Young Children (0-3 Years of Age). Pediatrics 2010;126;1040-1050.
5. Protocol for Transfusion-Free Major Orthopaedic Operations using RET-He. Sysmex Journal International 2009. Vol 19, No 1.

Reticulocyte Hemoglobin (RET-He) Immature Retic Fraction (IRF)

- **Early diagnosis of iron deficiency**
  - Helps monitor iron therapy
  - Monitor drug therapy in pharmacy. E.g. Erythropoietin Stimulating Agent (ESA) therapy.
  - Pre operative work for elective surgeries
  - Add to anemia care sets

- **Results:**
  - Decrease re-admission rate due to anemia as follow:
    - 2012: 13.2%
    - 2013: 10.9%
    - 2014 : 8.3% (YTD – Jan – June)
  - Incorporated RET-He in CORE Program at BDWMC. Improved patient outcome from elective surgery.

Summary - Workflow

- Consolidation of workstations with automation of sample handling.
- Standardized 10 hematology laboratories with one LIS System into one Sysmex WAM middleware system.
- Established standardized rules that will help the technologist follow the same procedures on flagged specimens.
- Improved capacity and throughput.
- Maximize existing work space.
- Automated peripheral blood smear review.
- Implemented auto-verification system wide with an average rate 85%.
- Decrease peripheral blood smear review by 30%
- Maintained ED CBC TAT goal throughout learning curve

Summary - Technology

- **Leveraged new technology to improve patient care, which includes the following:**
  - Immature Granulocyte (IG)
  - Immature Platelet Fraction (IPF)
  - Immature Retic Fraction (IRF)
  - Reticulocyte Hemoglobin (RET-He)

- **Improve coding and billing**
  - CPT code for IPF (85055)
  - Nosocomial infection vs. acquired – IG

- **Financial**
  - Decrease LOS
  - Decrease re-admission rate due to anemia
  - Decrease RBC / PLT transfusions

Questions