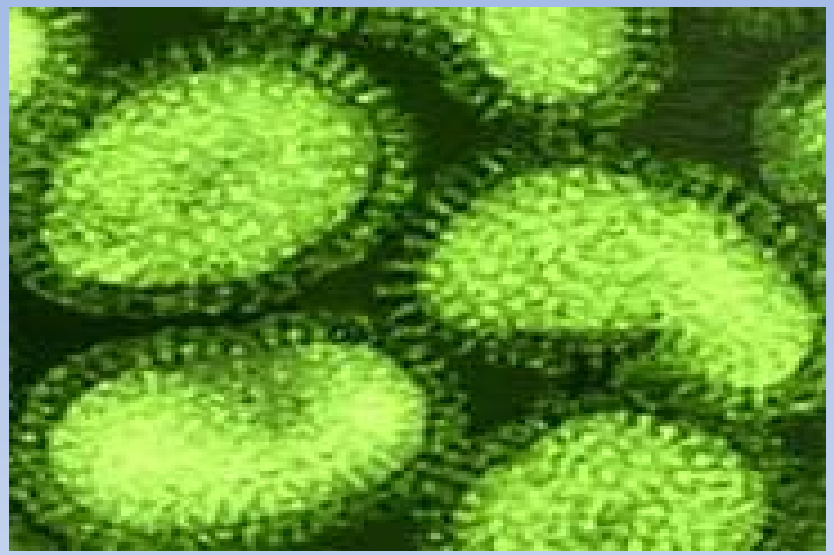


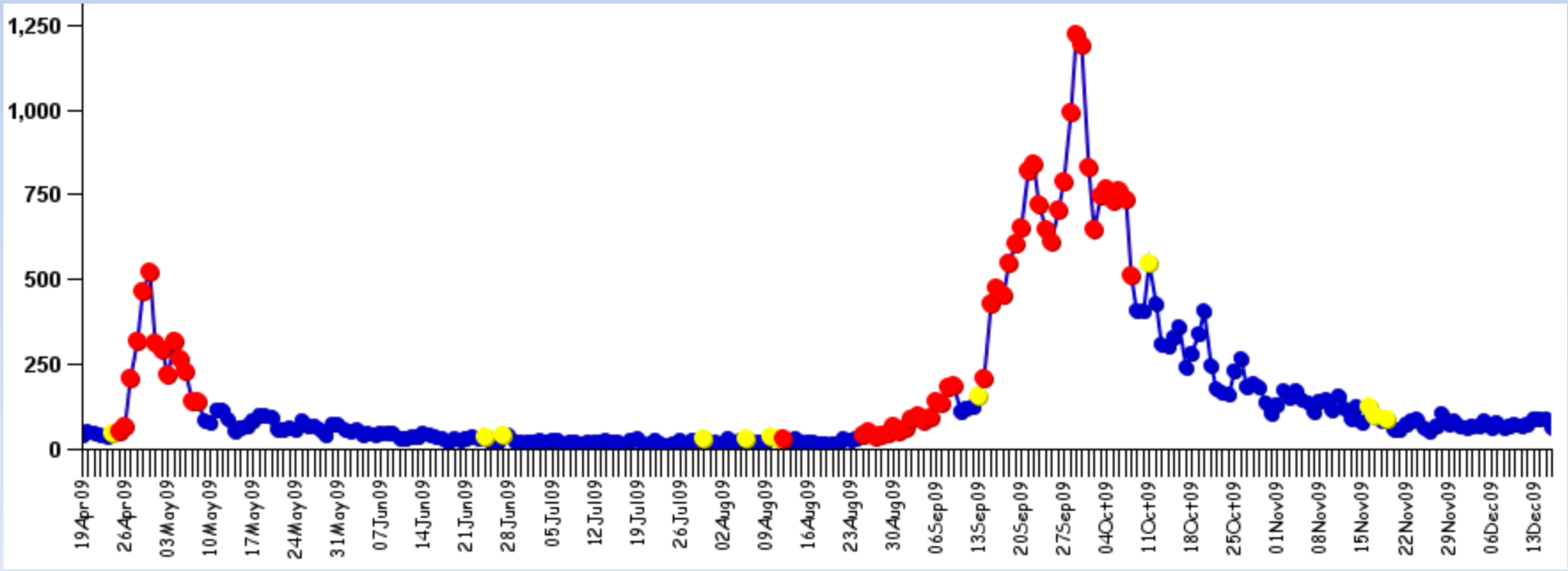
Process Improvement and Surge Capacity Impact:

DCHHS Influenza Surveillance 2013-2015

Daniel Serinaldi mbASCP

Syndromic Surveillance for Influenza-like Illness: Dallas County, April 19, 2009 – December 16, 2009

- The bulk of H1N1 cases occurred from August to November in 2009. A relatively early beginning to an Influenza season.



Dallas County LRN Influenza A PCR Test Results: 4/23/09 – 12/12/09

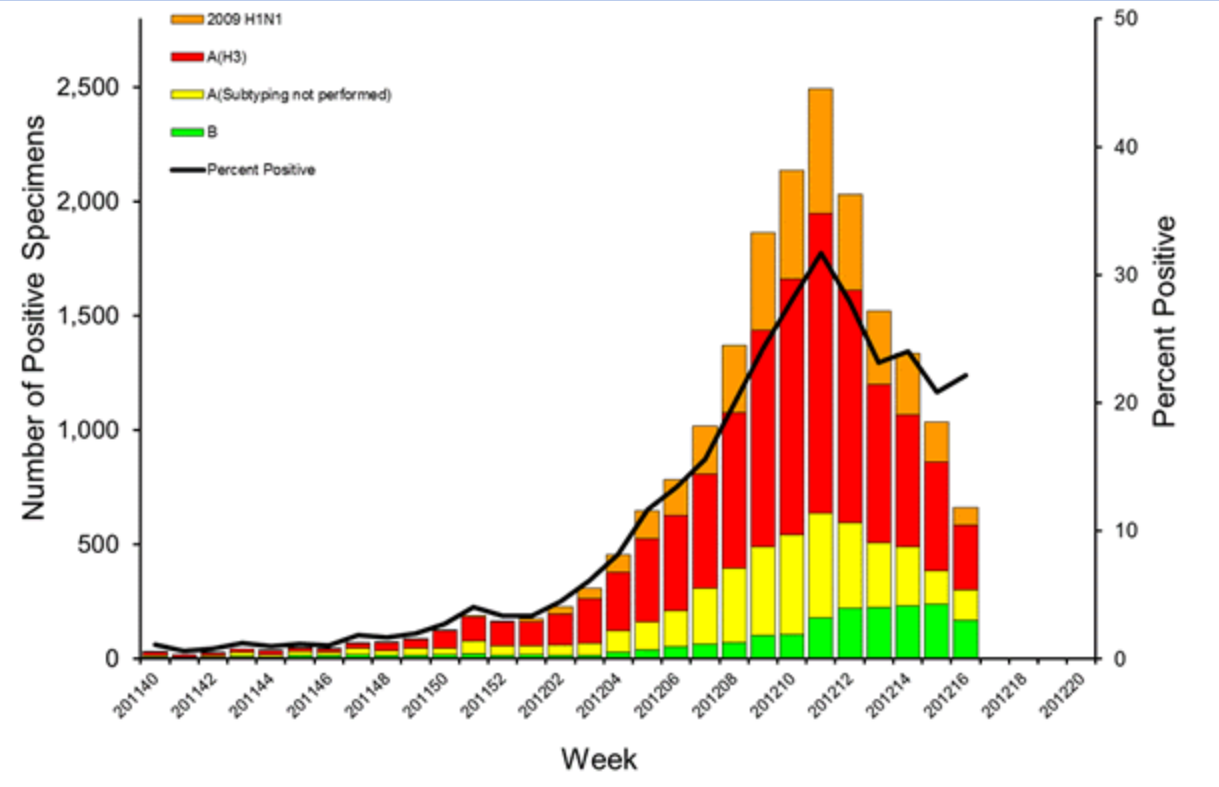
- A one-sided diagnostic season

Week Ending		April 24-Jun 27	June 28-Aug 29	Aug 30-Oct 31	Nov 1-Dec 12
CDC Week		16-25	26-34	35-43	44-49
Influenza A (Total Positive PCR Tests)		322	181	586	111
Subtype	Seasonal H1N1	16 (4.9%)	0	0	0
	Seasonal H3N2	32 (9.9%)	1* (0.5%)	0	0
	2009 H1N1	274 (85%)	180 (100%)	586 (100%)	111 (100%)
PCR-Negative Specimens		745	16	189	149

U.S. Virologic Surveillance

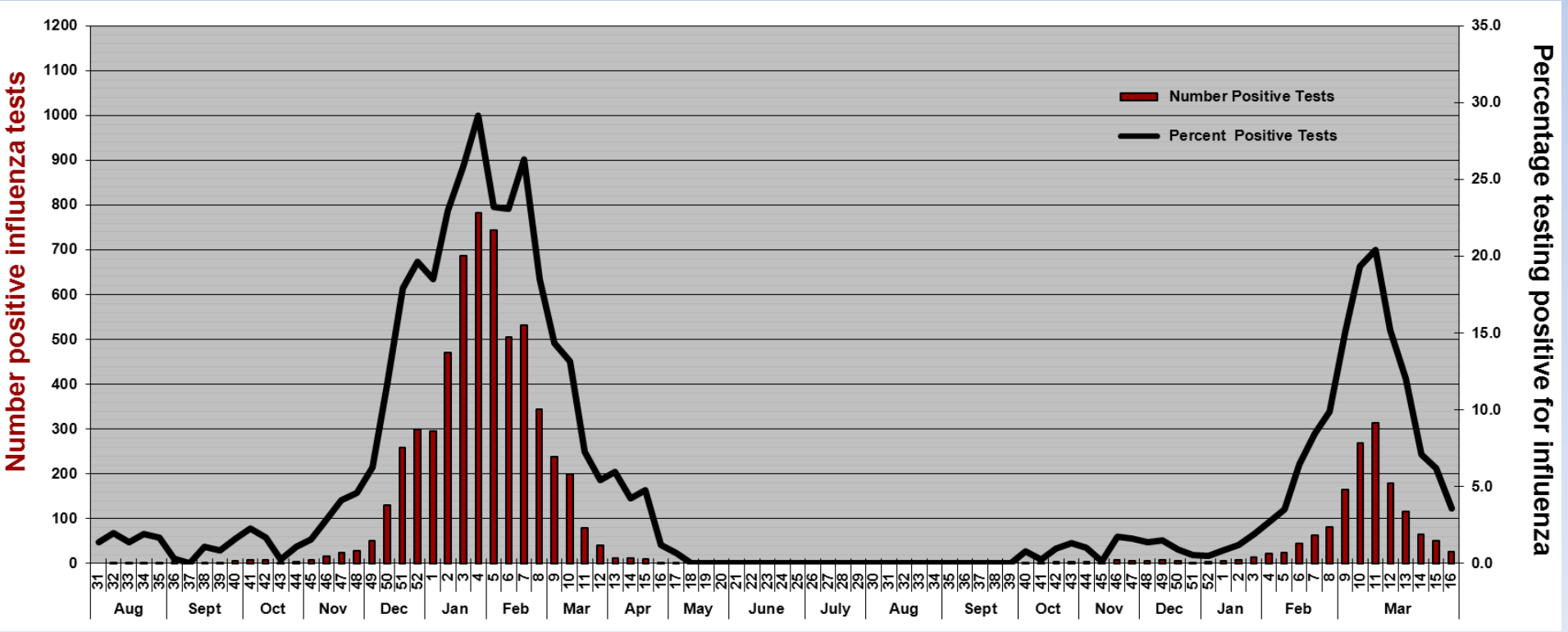
Influenza Positive Tests by Type and Subtype Reported to CDC during the week ending 4/21/2012

- In Contrast, 2012 revealed a greater variety of Influenza subtypes



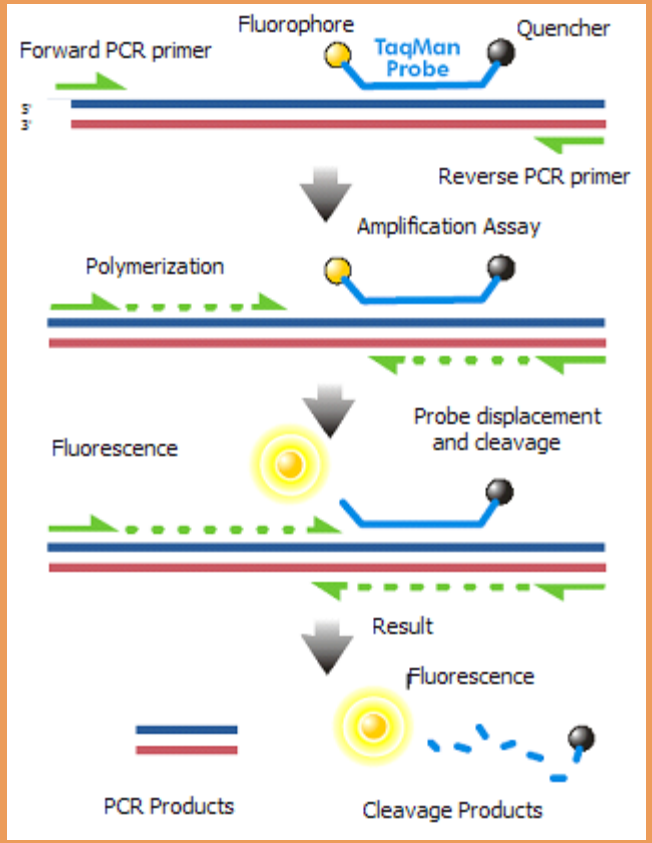
Number and Percentage Positive Influenza Tests by Week, Dallas County*: 2010-11 and 2011-12 Seasons

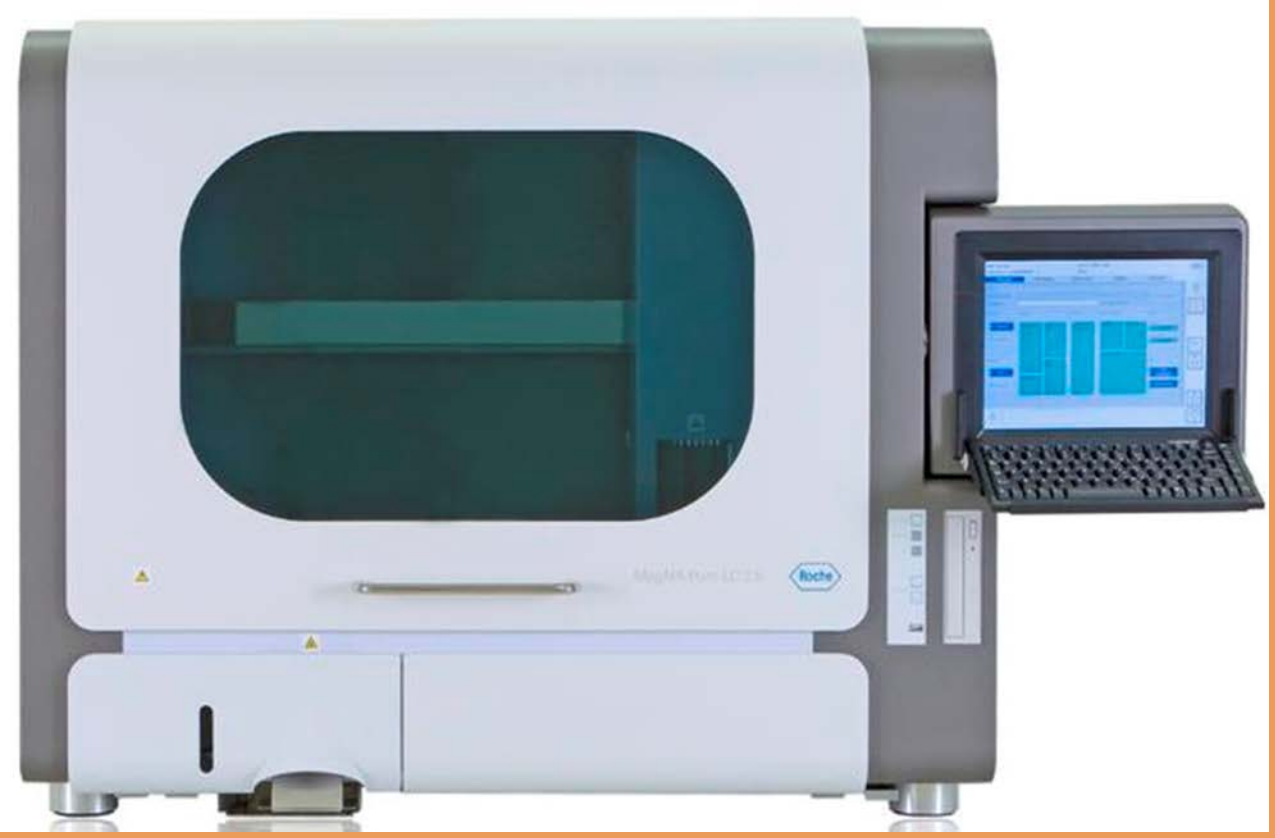
- An example of inter-season variability from the 2010-11 and 2011-12 seasons.



CDC Influenza Surveillance: Laboratory Diagnostics

- The CDC employs and provides a Reverse Transcriptase real time PCR method
- It is validated to amplify RNA that has been extracted using the Roche Magnapure LC, the Roche MagnaPure Compact, or RNeasy Qiagen manual kits.
- DCHHS has chosen the ABI 7500 standard as a PCR platform and the Invitrogen Superscript III Taq Polymerase.
- The PCR probe sets are designed for the detection of Influenza types A and B and further subtypes A/H1, A/H1 pdm09, A/H3, A/H5, A/H7



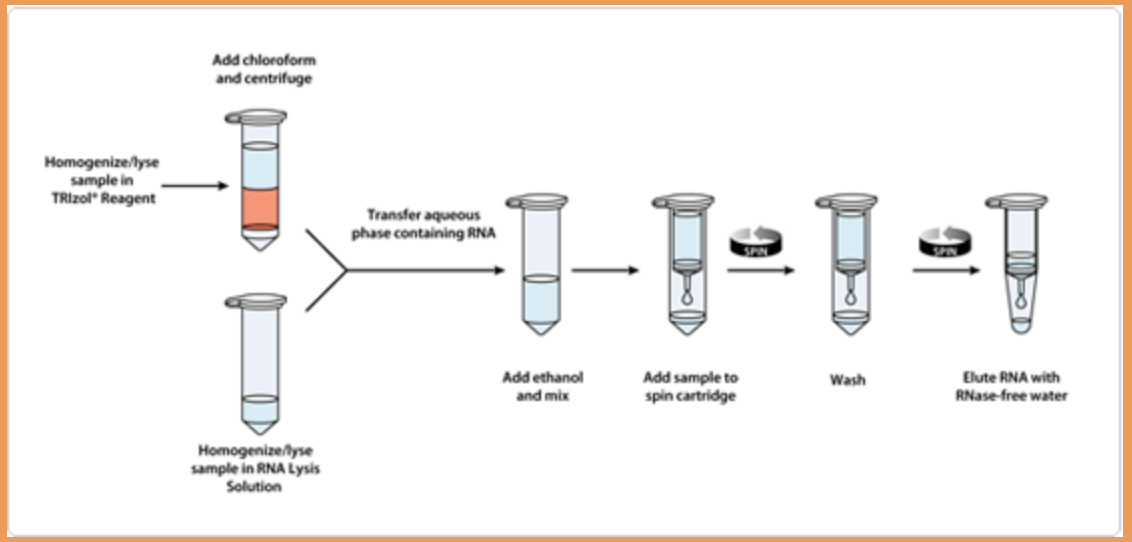


Roche Magnapure LC

- Fully Automated
- 32 samples in 1hr 45min
- Less specimens = Less time
- All Reagents are manually pipetted to tubs

Qiagen RNeasy Manual Extraction

- Provides greatest yield of possible RNA
- Manual Process contains many steps and is Tech intensive.
- Use of Centrifuge increases foot traffic in laboratory.



Roche Magnapure Compact

- Fully automated
- Runs 1-8 samples in 30 min
- Amendable to small specimen loads
- Easy load strips with premeasured reagents for each specimen

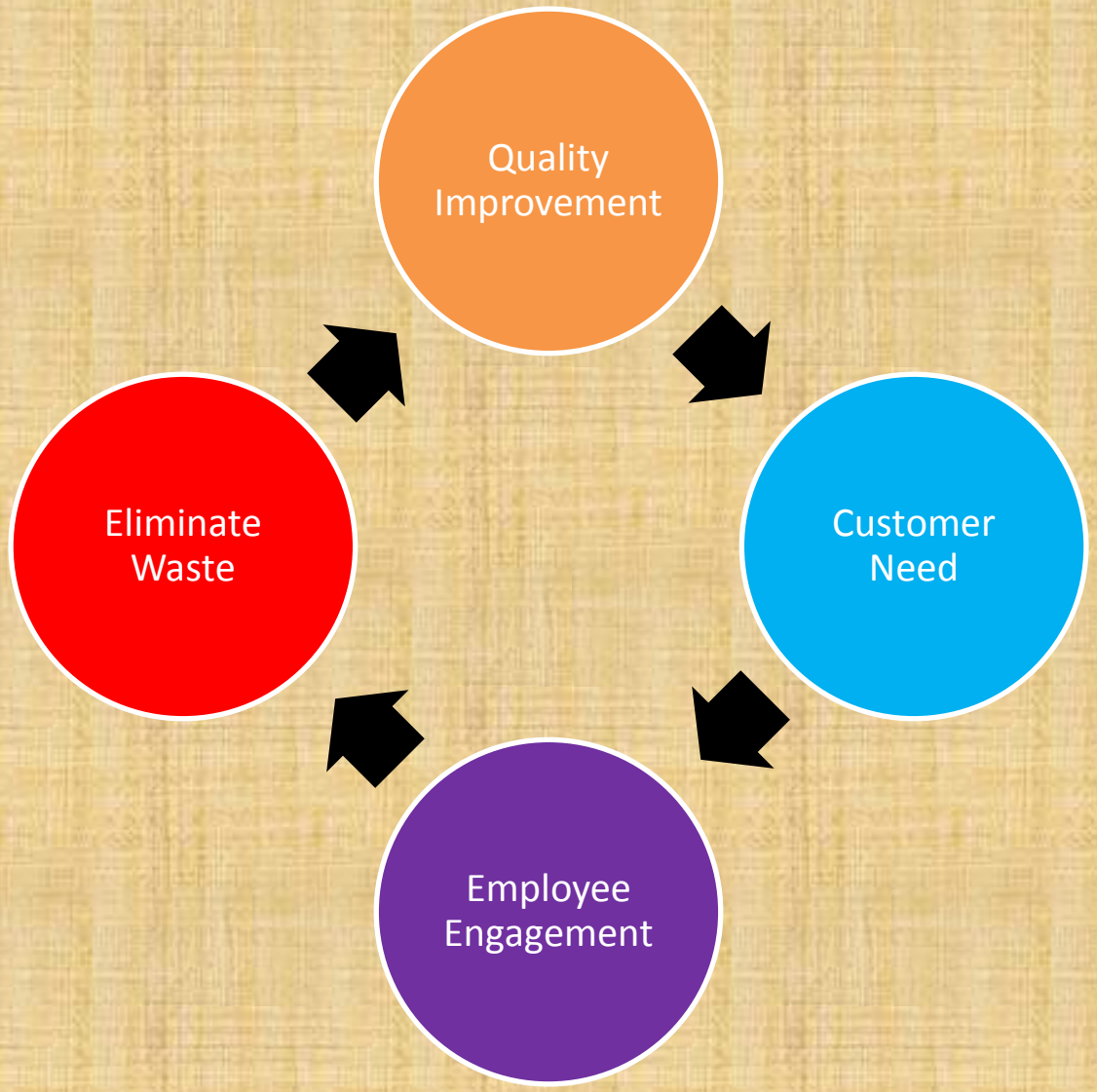
Invitrogen RT-PCR Superscript III Kit

- Master Mix includes: 2X buffer, Water, Primer Probes, Taq.
- 500 RXN kit

ABI 7500

- Real Time PCR capabilities on an open platform
- 96 Well Plate
- 3 platforms can run 9 specimens on full panel plates each in 1 Hr 40min

LEAN Process Management



Data Collection

Specify Value

- Reporting of results to the community, Sate health department, and CDC in a quick and orderly process

Map the Value Stream

- Value Added – FMEA, SIPOC Diagram, Work Flow Diagram
- Value Enabling – 5S, Set-up Preparation,
- Non-Value added – Waste, Rework, Contamination

Establish Flow

- Continuum of product movement, services, and information – SIPOC diagram, Spaghetti Graph
- Eliminate batch testing adopt a continuous process

Implement Pull

- Eliminate unnecessary inventory build up while efficiently feeding the Laboratory with necessary supplies

Pursue Perfection

- Complete elimination of waste
- Added value for the customer
- Continuous improvement

FMEA and Evaluating the Process

Failure Mode and Effects Analysis (FMEA) Worksheet

Page:		of	

System, Product, or Process:		Owner:		Date:	

Background				Rating				Countermeasure			Results			
Description	Potential Failure Mode	Potential Effect of Failure	Root Causes	SEV	OCC	DET	RPN	Owner	Due / Done	Action	SEV	OCC	DET	RPN

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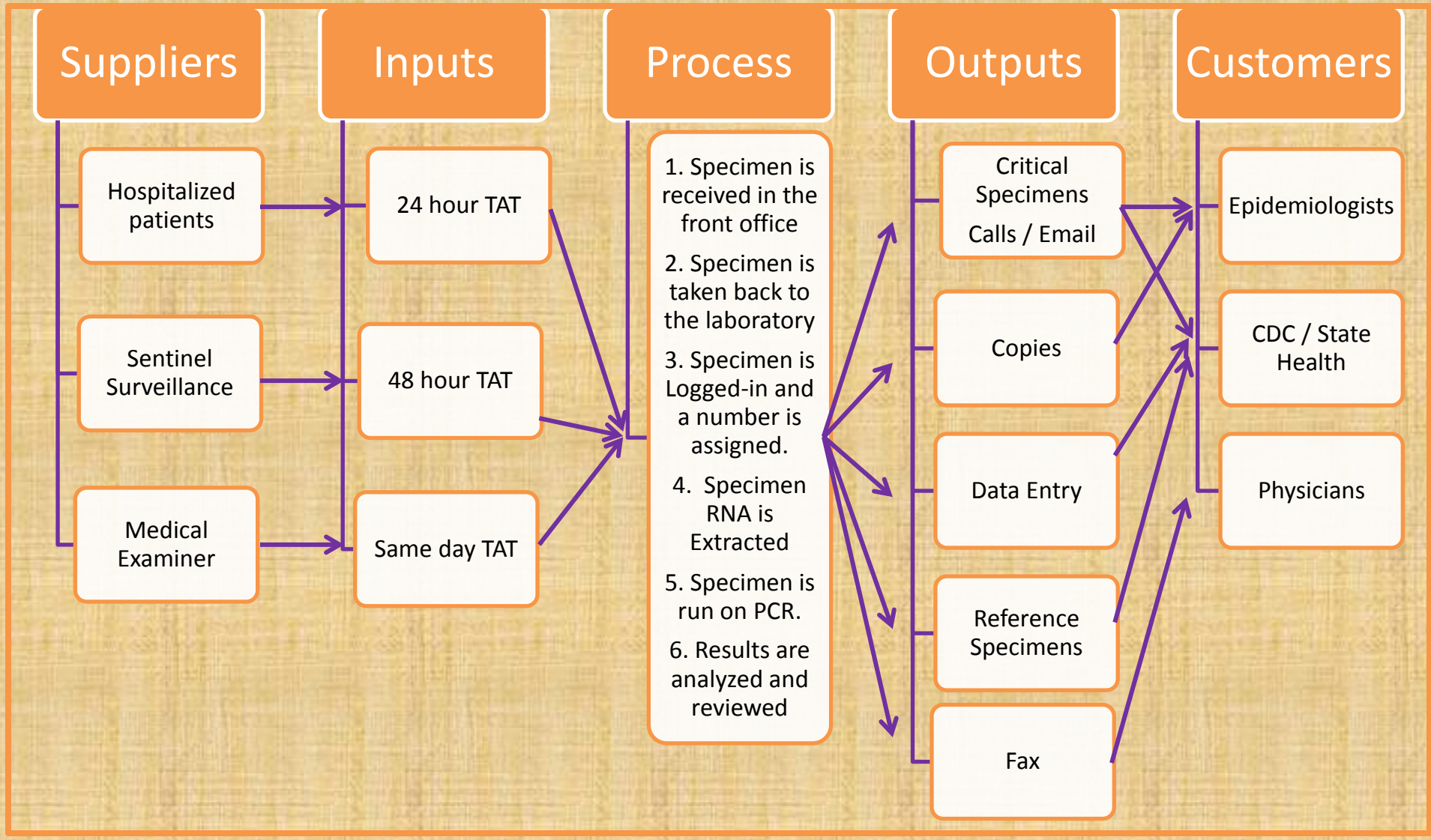
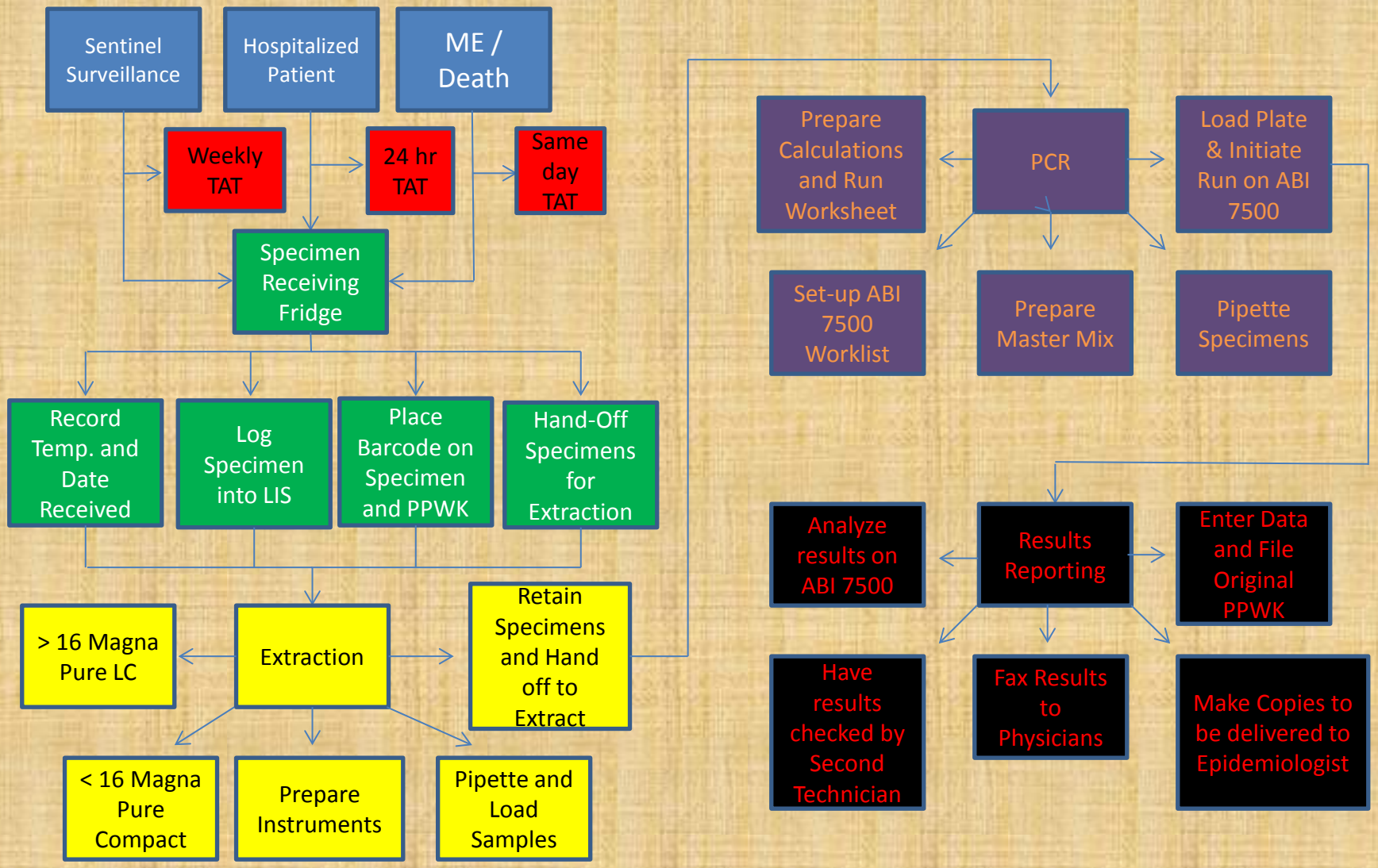
SIPOC Diagram



Work Process Diagram



Station 1

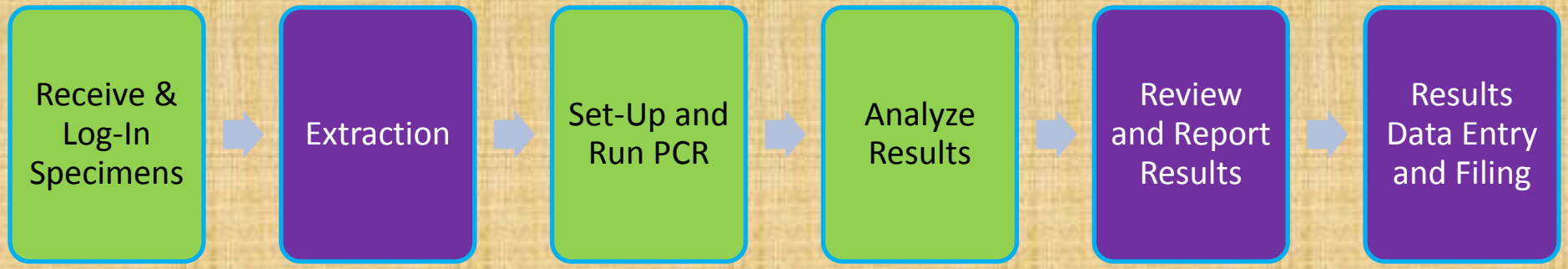
- Receive & Log-In Specimens
- Set Up & Run PCR
- Analyze Results

Station 2

- Extraction
- Review and Report Results
- Results Data Entry and Filing

Station 3

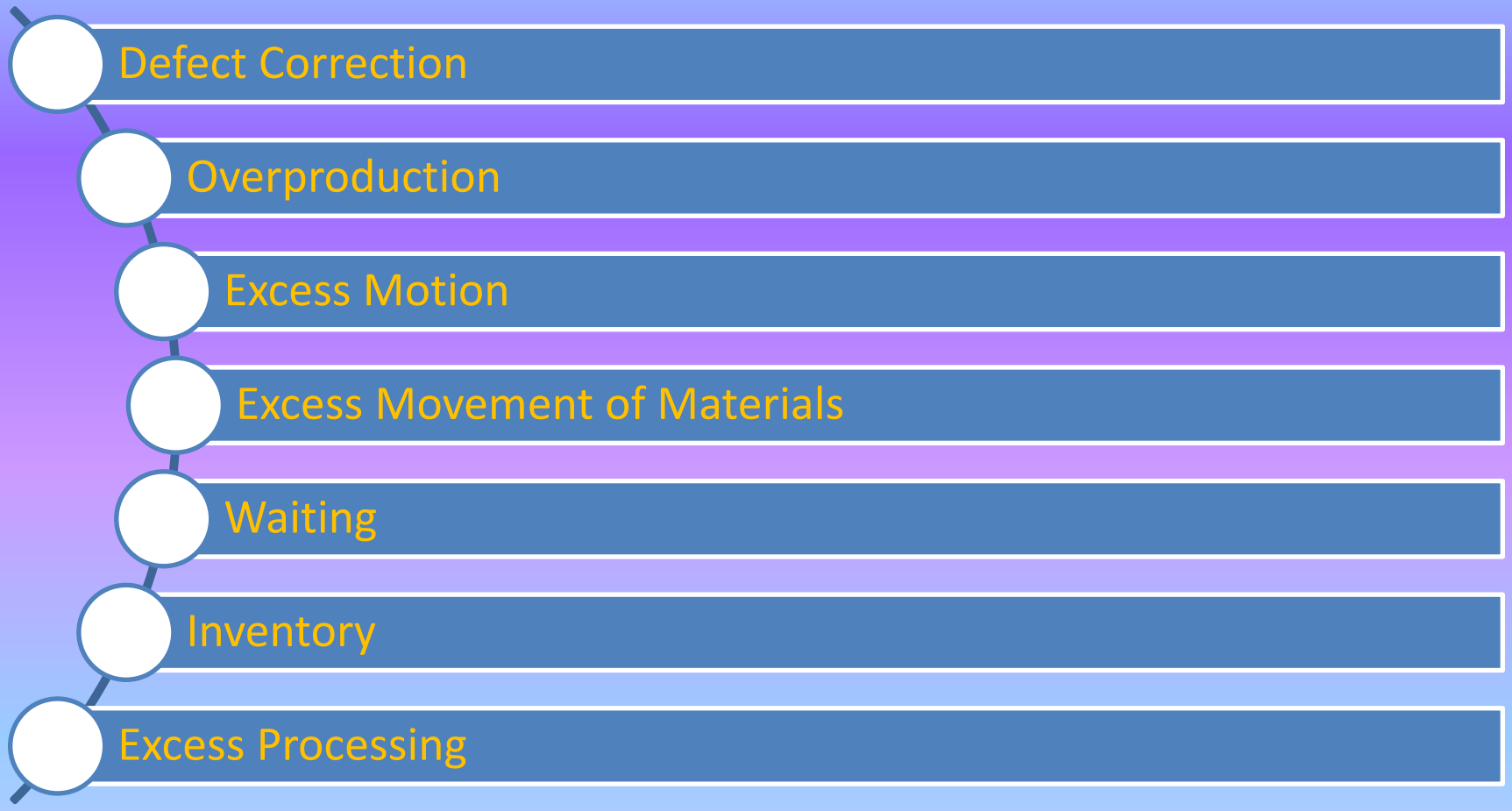
- Communicate & Lend Assistance
- Set-Up and Prep Materials
- Expedite Processes at Bottlenecks

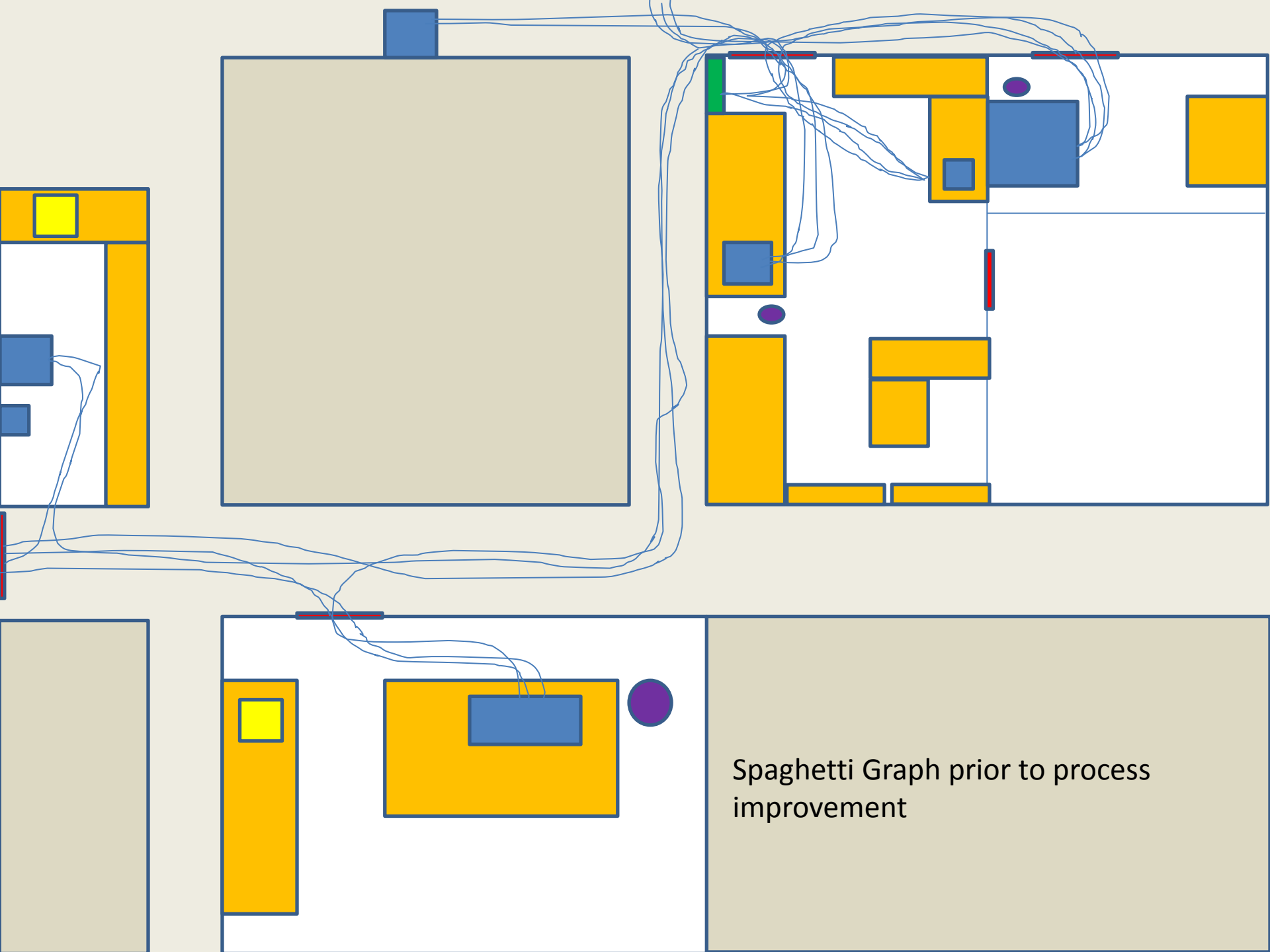


The 5S's

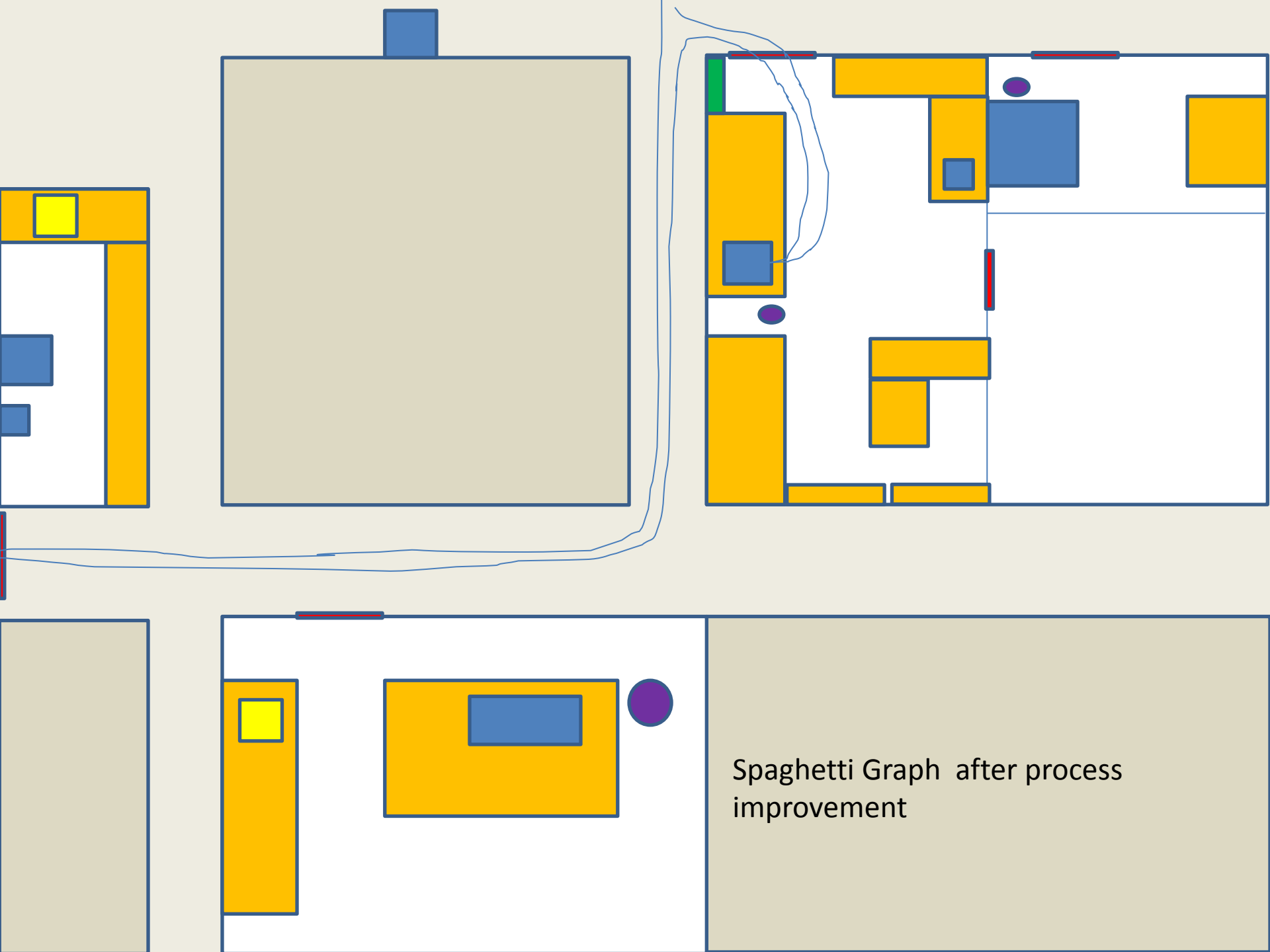
Sort	• Remove any obsolete, defective, or excess items. • Old equipment, pipettes, centrifuges, water bathes removed.
Straighten	• Set in order and Arrange items in easily accessible places. • Rearranged laboratory analyzers and supplies to cut down on foot traffic.
Shine	• Clean work surfaces, equipment and storage area, dispose of garbage and ensure safety. • Cleaned out PPWK from cabinets
Standardize	• Identify roles for keeping areas clean and orderly and establish responsibility for tasks. • Roles for cleaning, stocking material, and disposing of garbage for each section determined
Sustain	• Lend motivation and support to the members of the team. • Seeking to maintain a flexible and friendly work environment

Elimination of Waste

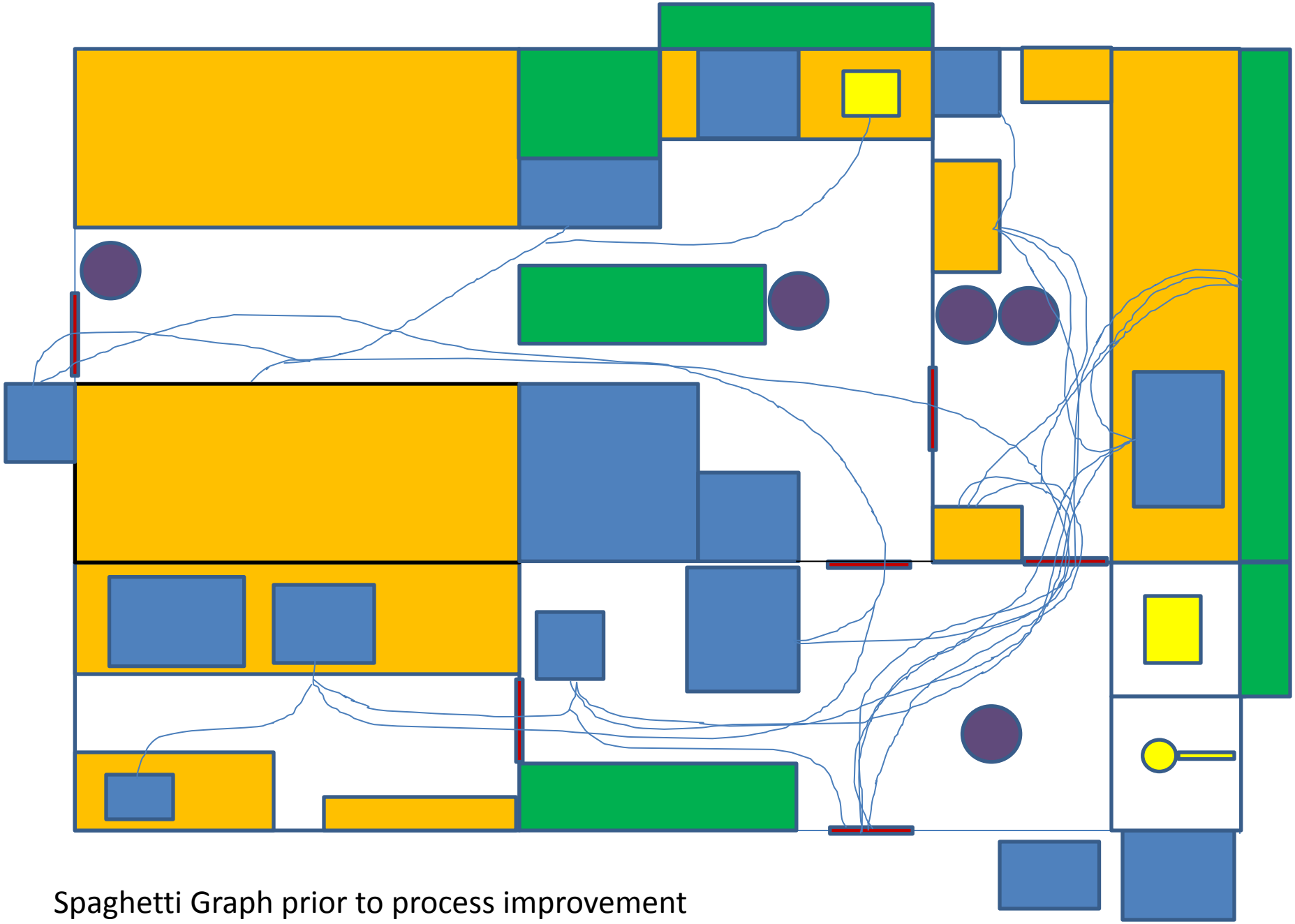




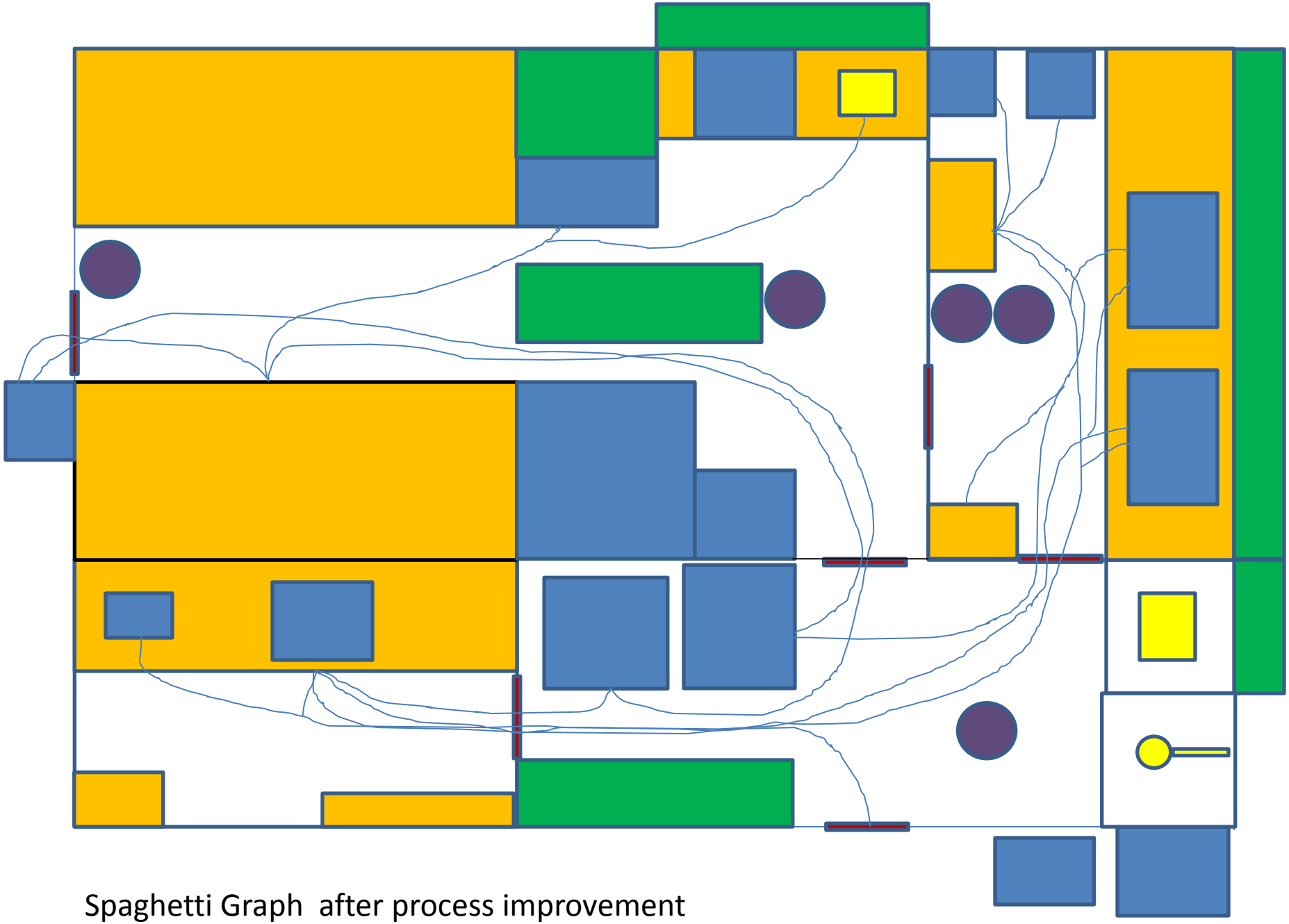
Spaghetti Graph prior to process improvement



Spaghetti Graph after process improvement



Spaghetti Graph prior to process improvement



Spaghetti Graph after process improvement

Path To Process Improvement

Continuous Flow

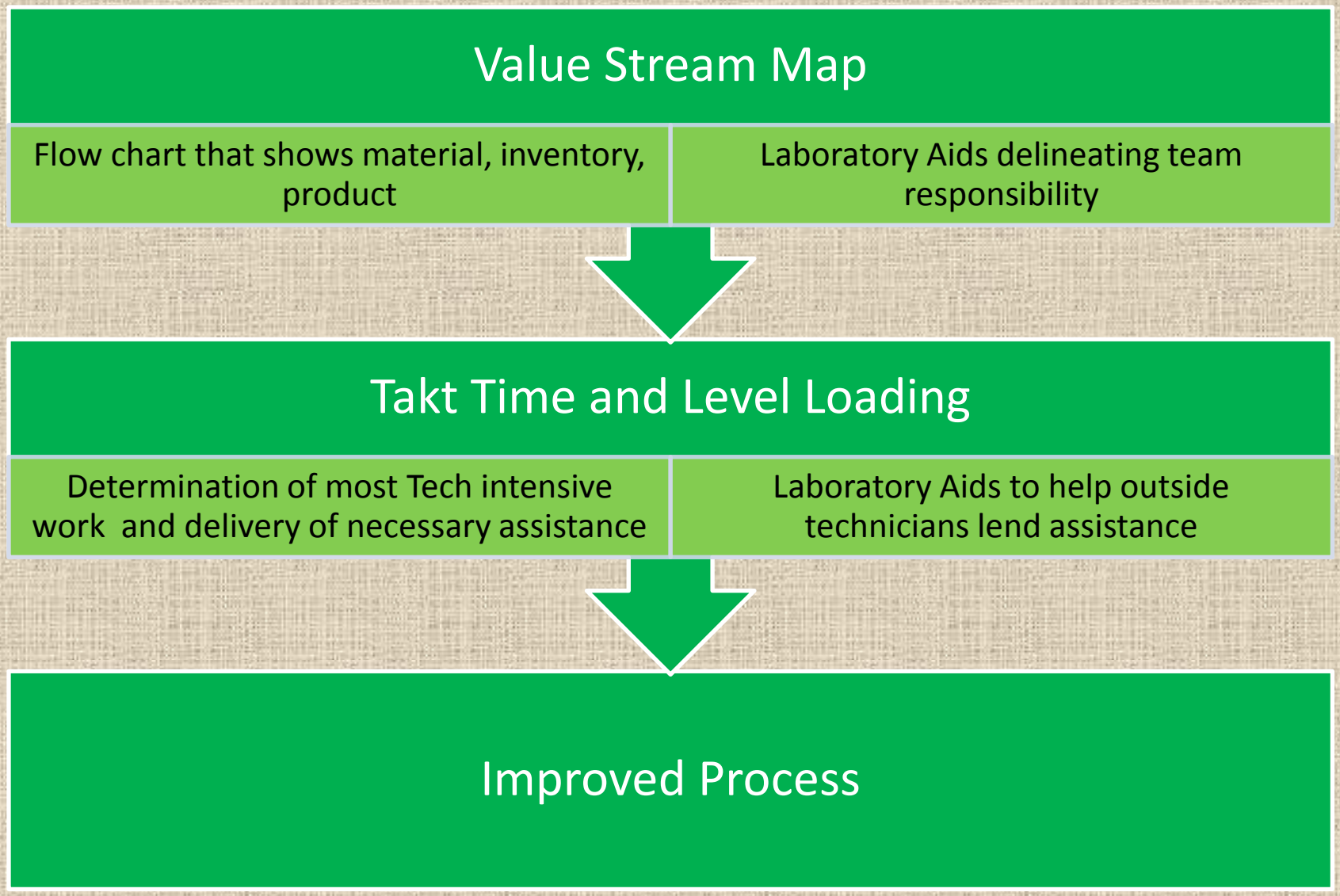
One for One Process, No Waiting, Demand = Production	Two Person “Leap Frog” process with available “Bottleneck” assistance

Set-up Reduction

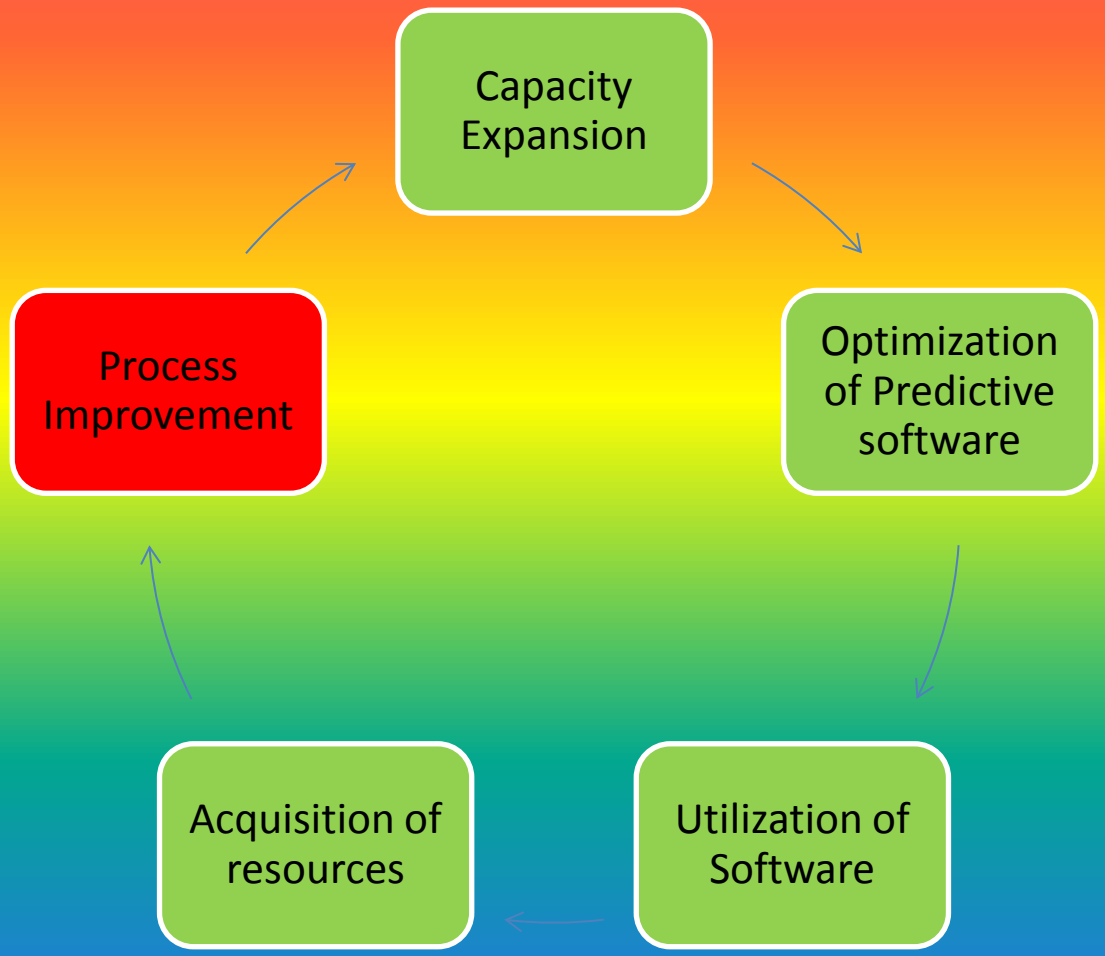
Preparation of work area and supplies	Add lysis buffer to extraction tubes Prepared Fax Cover sheets

Error – Proofing

Doesn’t allow mistakes to occur	System for numbering specimens Technicians PPWK Review


Value Stream Map
Flow chart that shows material, inventory, product
Laboratory Aids delineating team responsibility
Takt Time and Level Loading
Determination of most Tech intensive work and delivery of necessary assistance
Laboratory Aids to help outside technicians lend assistance
Improved Process

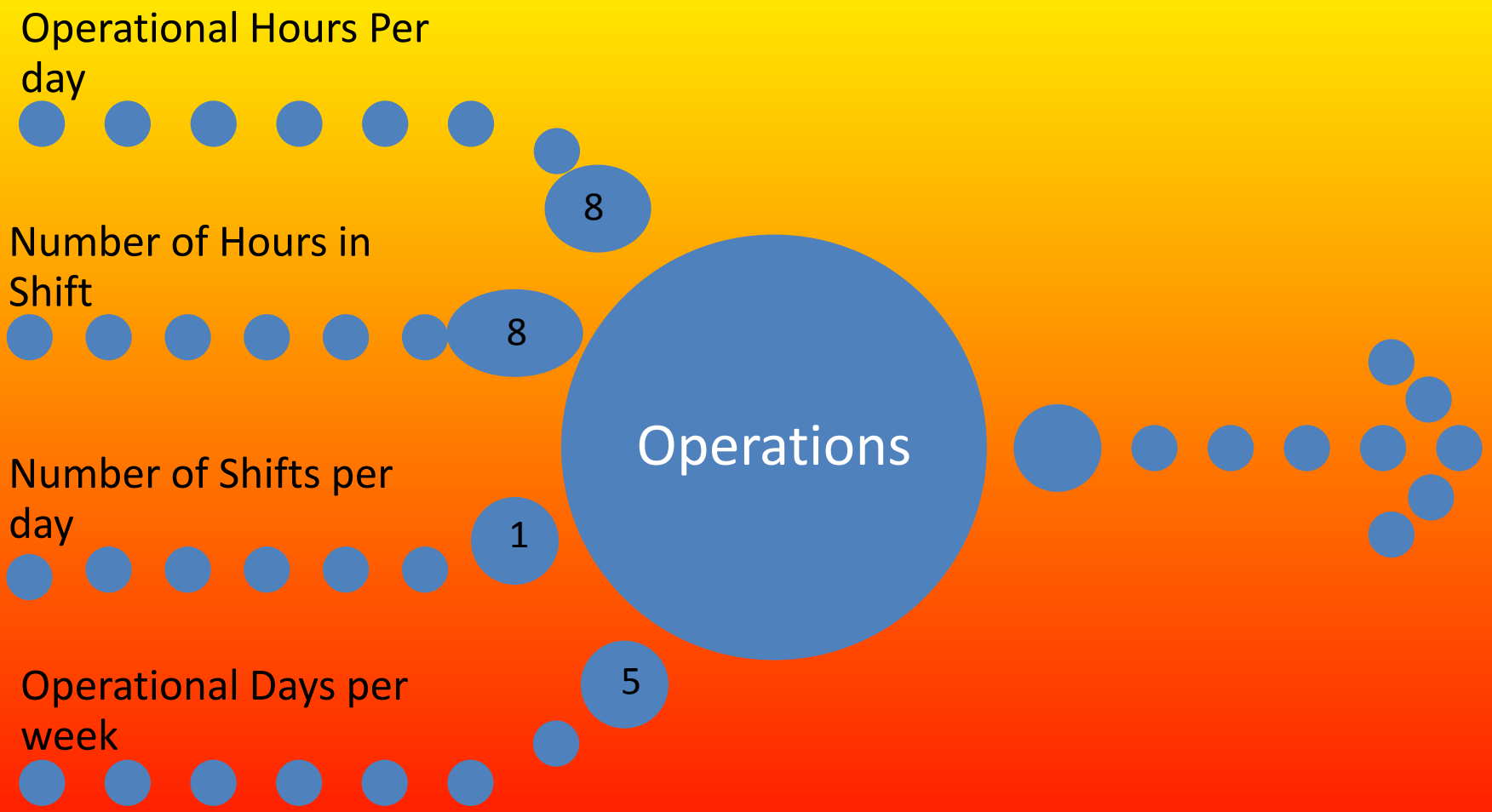
Surge Capacity



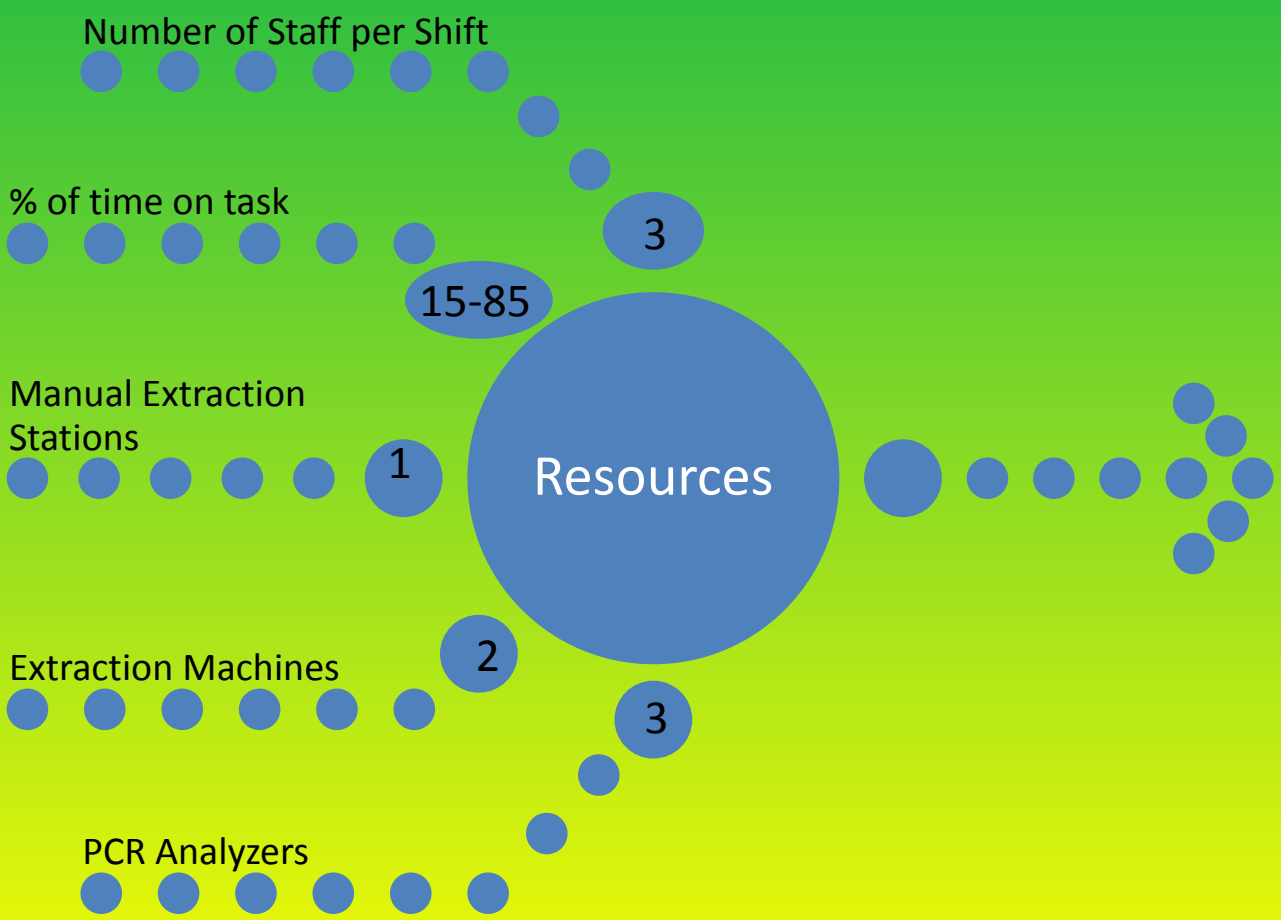
Surge Capacity Assessment

- Predictive Software flulabsurge 1.0
  - Excel based
  - Created by CDC
  - Designed for influenza molecular diagnostics
- Application of Software
  - List standard operations and available resources
  - Walk the process for one sample
  - Monitor time at each step
  - And in-between steps

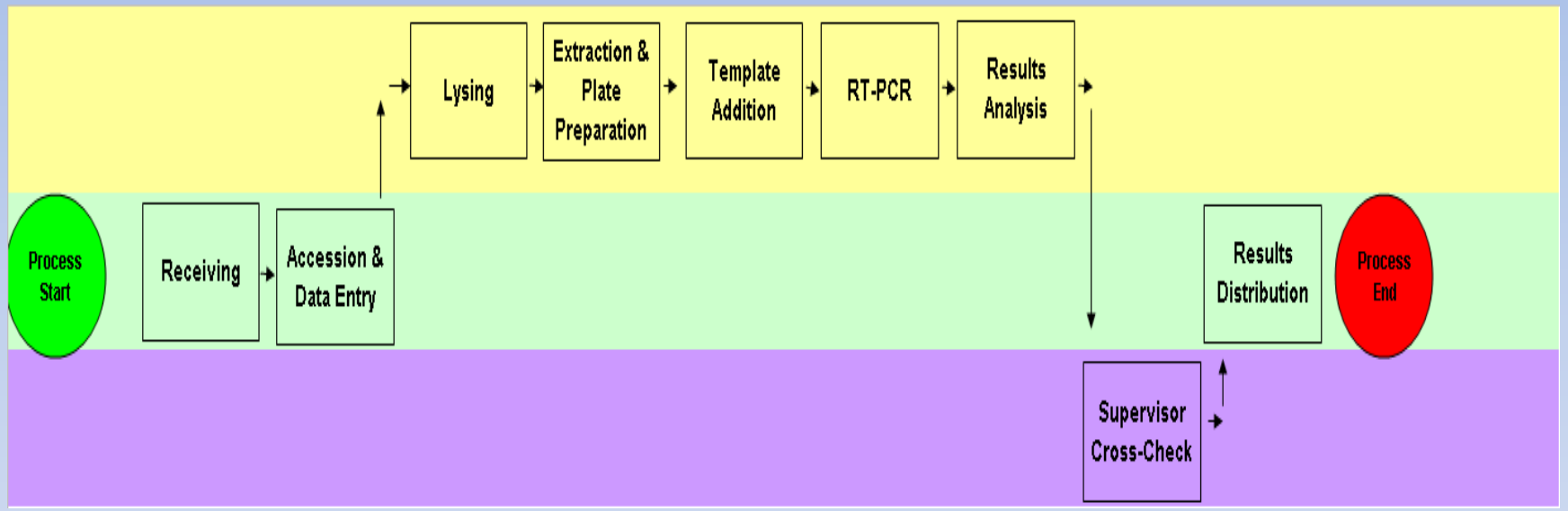
Operation Inputs



Resource Inputs



Laboratory Flow



Values are observed estimating minimum and maximum times for processing along with an average estimation of wait time before the sample begins the process

Capacity Prediction

			Benchmark Per Shift		54			
			Hours Per Shift		8			
			Shifts Per Day		1			
			Days Per Week		5			
	AVERAGE CAPACITY VALUES					MAXIMUM CAPACITY VALUES		
	Per Shift	Per Day	Per Week			Per Shift	Per Day	Per Week
Min:	7	7	35		Min:	7	7	35
Max:	29	29	145		Max:	32	32	160
	Can benchmark capacity be met with current resources and shifts?	NO				Can benchmark capacity be met with current resources and shifts?	NO	

Will these values work?

How can these predictions be optimized for accuracy?

Site Specific Predictions

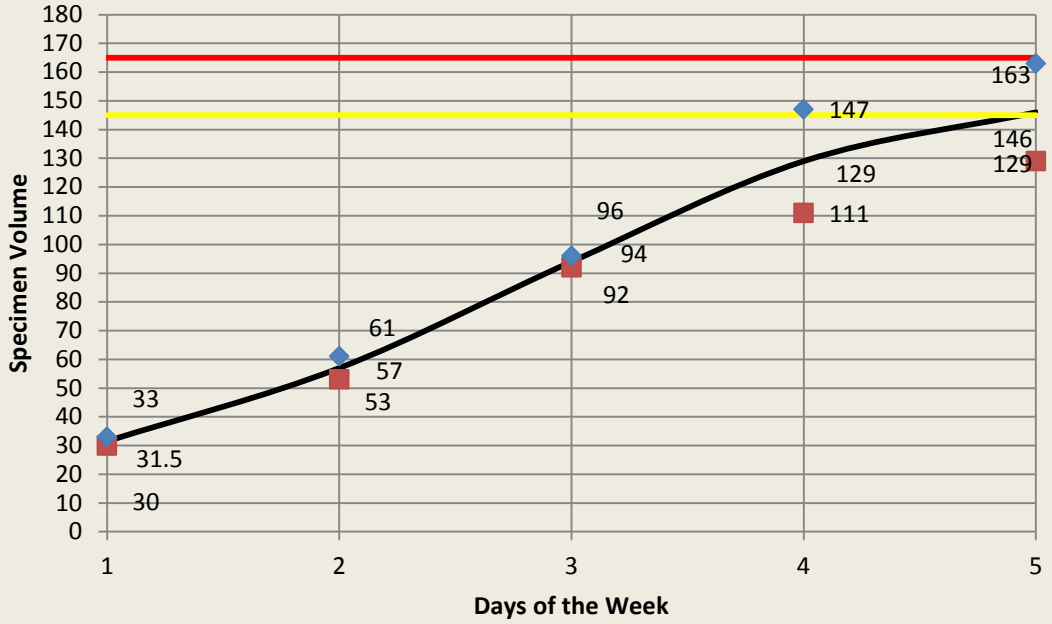
- Surge Capacity = Volume X Time X Complexity
  - Volume of samples
  - Turn-around times
  - Predictive software calculates Complexity
  - Although Error rates impacts cause increased complexity
  - Monitoring these on-site values can better optimize capacity predictions

Utilization of Software

- Site specific capacity estimates can be represented with a range
- Weekly ranges take into account a variable capacity with fluctuating TAT's and impact events that influence actual capacity
- Activation of surge assistant can be initiated when the positive range reaches the upper or lower range

	Predicted Upper Range	Predicted Lower Range			
	165	145			
DAY	Neg Range	Daily Volume	Errors TAT	Errors QA	POS Range
1	29	32	2	1	35
2	64	35	1	2	70
3	94	36	4	2	109
4	119	30	3	2	138
5	140	25	3	1	162
		158	13	8	
Weekly Values		Total Errors	21		
		Error Percent	13.29113924		

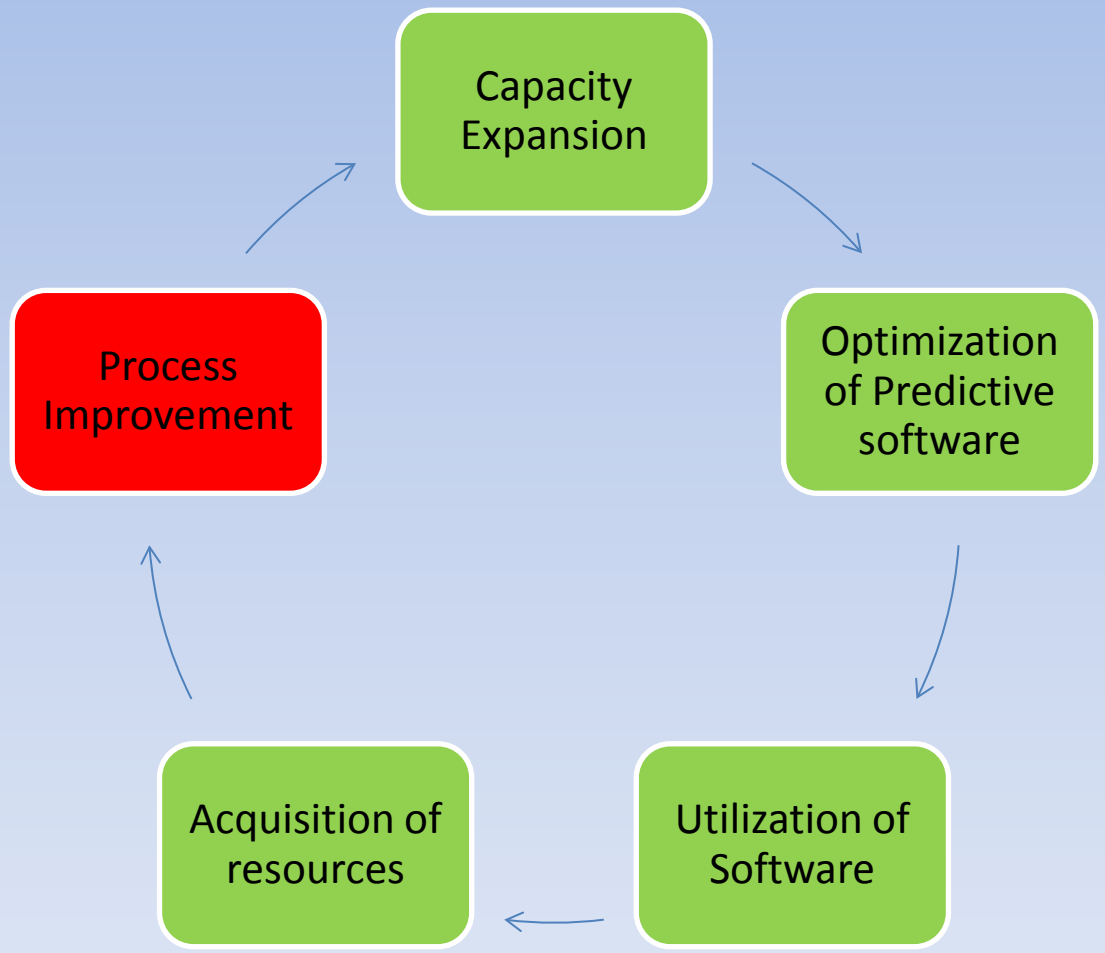
Surge Capacity



Acquisition of Resources

	Operations		Resources		% of shift time spent on task for testing flu		Extraction Methods		RT-PCR
1	Operational hours per day							**14**	RT-PCR Platforms
	8		Number of Staff per shift			**12**	Manual Extraction Stations		ABI 7500 Fast DX
2	Number of Hours in Shift 8	**6**	# Lab Staff 2	**9**	85%		Manual Extraction		ABI 7500 Fast DX
3	Number of Shifts per day 1	**7**	# Support Staff 1	**10**	25%				ABI 7500 Fast DX
4	Operational Days per week	**8**	# Management Staff 1	**11**	40%	**13**	Extraction Machines		
	5						roche magnapure LC		
5	Benchmark per shift						Compact		
	54								

Process Improvement



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CDC Week 49--Week ending December 12, 2009 Elizabeth Hull Smith, RN MHA, Epidemiology Surveillance Coordinator Joey Stringer, Ed Bannister PhD, LRN Laboratory Wendy Chung, MD, MSPH, Chief Epidemiologist Christopher Perkins, DO Health Authority, Medical Director Zachary Thompson, MA, Director

Dallas County Health and Human Services, 2011-2012 Influenza Surveillance Program *CDC Week 16 -- Week ending April 21, 2012.* Kristy Baumgart, MPH, Influenza Surveillance Coordinator Public Health Preparedness and Communicable Disease Division Staff Joey Stringer, Ed Bannister PhD, LRN Laboratory Ira Nemeth, MD, Public Health Preparedness Medical Director Wendy Chung, MD MSPH, Chief Epidemiologist John Carlo, MD MSE, Health Authority, Medical Director Zachary Thompson, MA, Director