#### "Inspection Readiness in a CAP15189 Laboratory: Lessons Learned from Standardization, Multi-Site Management, and Digitization of All Documentation and Checklists"

Bonnie Rashleigh C(ASCP) Chemistry Supervisor ProMedica Laboratories

Lab Quality Confab October 24,2017

#### **PROMEDICA HEALTH SYSTEM**

We serve 27 counties in northwest Ohio and southeast Michigan with 12 hospitals, numerous health care centers, and an extensive array of specialties.



#### **GETTING STARTED – THE LEAN WAY**

ProMedica Labs started our LEAN journey back in 2004, before it was popular in the laboratory.

- -Team approach, each team learned one of the LEAN Tools
- Bench Level techs were included and empowered, they know the work
- -Not just another new fad

#### **NO REAL OWNER- THE STORE ROOM STORY**

- The main lab storeroom was used by all but "owned" by none
- Our first project that was employee led without our LEAN Trainer
- Our project story was published in CAP Today in May 2006

#### THE STOREROOM STORY



Thirty seconds is all the ProMedica Laboratories staff needs to retrieve any item from the Lean-organized storerooms. Above (from left) preanalytic technician Karen Bonkowski and medical technologist Bonnie Rashleigh.

CAP Today – May 2006

- Cleared 20% of the space
- Found items that were ordered in duplicate
- Found unused & expired items
- Placement that made sense
- The 30 second rule

#### **CONTINUOUS PROCESS IMPROVEMENT**

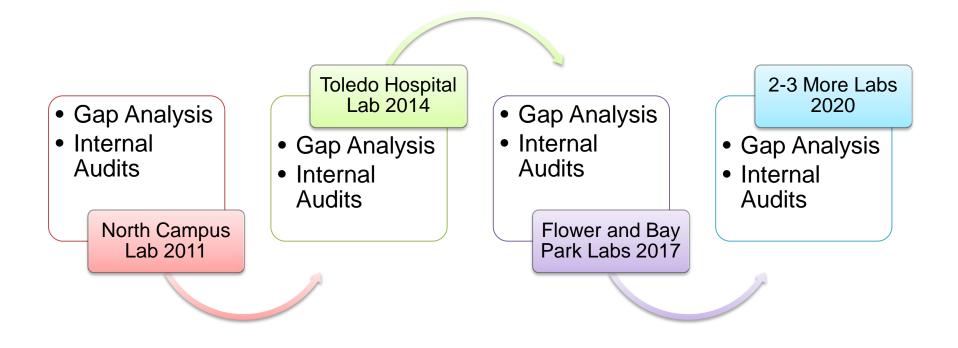
- ProMedica Labs now utilizes Process Engineers to incorporate LEAN training and tools into all of our projects
- "Boots on the ground" all employees have an understanding of value added, RCA, quality and process improvement.
- This has become part of all we do!

#### **INTRO TO ISO 15189**

- The next step was ISO 15189 certification
- This was not easy and was not initially embraced
- Once the improvements and processes were in place, the value became evident
- We were the 13<sup>th</sup> lab to achieve this certification a point of pride



#### WHAT IS NEXT – ISO 15189 PROGRESS





#### **STANDARDIZATION**

 How can you turn a diverse group of hospitals & labs into a cohesive group? It is NOT always a happy "marriage"

#### - The Lab formed FOCUS GROUPS for each discipline

- Subject matter experts from each lab came together once a month to work toward standard practices and procedures and solve problems
- Everyone had an equal say, not just the "big house" calling the shots
- Familiarity and friendship created cooperative teams, no longer us vs. them
- Standardized equipment increased support and troubleshooting experience

#### **WORKING SMARTER NOT HARDER**

- No matter how hard we worked and how much we improved, there were still some laborious tasks that had to be done.
- There were still some items that were found to be deficient by inspectors.
- A checklist to remind you to do your checklist???????



## There had to be a better way!

#### WHAT CAN TECHNOLOGY DO FOR US?

 Technology now is so advanced from what it was when we started (no matter when that was!)



– What kind of things could lend themselves to technology?



 How can we save time, money and do things that help with a green initiative?

#### **THEN THERE WAS AN IDEA!**

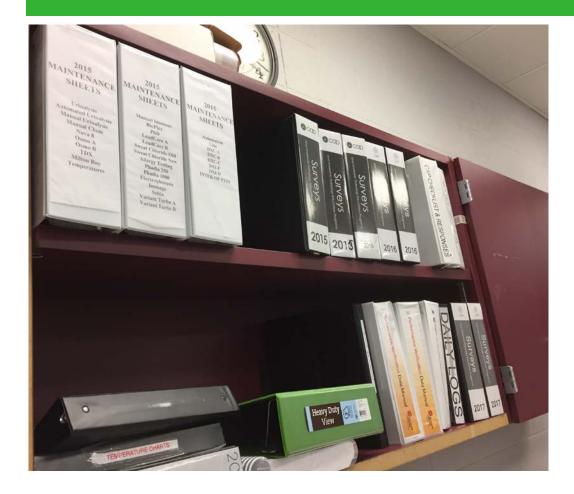




#### **INSPECTION READY & BETTER OUTCOMES**

- Electronic CAP Survey storage and approval routing
- Electronic monthly QC storage and routing
- Electronic LJ charts & detail for QC values
- Electronic Service reports & recalls
- ProMedica Innovations + KapiosHealth = Lab Assured Compliance Solution

#### **CAP SURVEY STORAGE**







#### **ELECTRONIC CAP SURVEY STORAGE**

N	D I IT
Name	Date modified
퉬 ACA-A	6/26/2017 8:08 PM
퉬 ACL-A	8/14/2017 7:51 AM
퉬 AL2-A	7/7/2017 10:13 AM
퉬 AL2-B	9/21/2017 2:50 PM
퉬 API - UDS-A	6/3/2017 2:48 PM
퉬 April 2017 Linearities	7/21/2017 7:53 AM
퉬 AQ-A	9/7/2017 10:33 AM
퉬 AQ-В	9/21/2017 9:19 AM
퉬 ARP-A	6/26/2017 8:16 PM
퉬 BL-A	4/28/2017 10:25 AM
퉬 BL-B	9/7/2017 9:03 AM
DNP5-A	6/8/2017 5:21 PM
퉬 BNP5-B	9/21/2017 9:50 AM
퉬 C-A	8/25/2017 9:21 AM
퉬 CAR-A	6/8/2017 8:22 AM
퉬 CAR-В	9/21/2017 9:47 AM
퉬 С-В	9/22/2017 11:46 AM
퉬 CM-A	6/8/2017 5:22 PM
퉬 CR-A	5/22/2017 2:43 PM
퉬 CRS-A	9/21/2017 3:26 PM
퉬 D6-A	6/2/2017 1:58 PM
퉬 D6-B 2017	9/21/2017 8:37 AM
퉬 ELP-A	6/13/2017 11:50 AM
퉬 ELP-B	9/22/2017 8:34 AM
퉬 FF-A	9/21/2017 3:17 PM
JFLD2-A	5/25/2017 10:39 AM
FLD2-B	9/25/2017 8:08 AM
퉬 FLD-A	4/19/2017 11:22 AM
퉬 FLD-B	9/22/2017 8:28 AM
🌗 FP-A	5/31/2017 8:36 AM
퉬 G-A	6/6/2017 3:33 PM
퉬 G-B	9/7/2017 8:46 AM
鷆 GH5-A	6/22/2017 3:30 PM
퉬 GH5-В	9/7/2017 3:13 PM
퉬 К-А	6/29/2017 3:21 PM
퉬 К-В	9/7/2017 8:49 AM
퉬 KET-A	9/21/2017 1:55 PM
퉬 LN3-A	7/3/2017 10:02 AM
퉬 LN6-A	8/25/2017 2:21 PM

Name	Date modified
🔁 BNP5-B 2017 Bixby Acceptable.pdf	7/17/2017 9:36 AM
🔁 BNP5-B 2017 FCH.pdf	8/22/2017 12:10 PM
🔁 BNP5-B 2017 FH Acceptable.pdf	9/21/2017 9:50 AM
🔁 BNP5-B 2017 FMH.pdf	8/29/2017 11:21 AM
🔁 BNP5-B 2017 Herrick Acceptable.pdf	7/17/2017 9:38 AM
🔁 BNP5-B 2017 NCL.pdf	7/17/2017 11:28 AM
🔁 BNP5-B 2017 Participant Summary.pdf	7/17/2017 10:58 AM
🔁 BNP-B 2017 PMRH Acceptable.pdf	7/28/2017 2:37 PM

- Survey data & Participant Summaries are all stored in one common location – no more paper and books to go from desk to desk, easy overview & comparison
- Reports are uploaded to our Document Control system to follow our approval procedure

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#### **QC RECORD STORAGE**



#### **ELECTRONIC QC**



TDM CONTROL ON AU-M

#### Monthly Evaluation TDM 1,2,3 • Lot 27720 • Exp 30-Nov-2019

TOLEDO HOSPITAL LABORATORY 2141 GIANT STREET TOLEDO OH 43606 Attention: LONI MASON BIOCHEMICAL PATHOL OGY

June 2017 • Lab 109002

Please review your QC reports for June 2017.

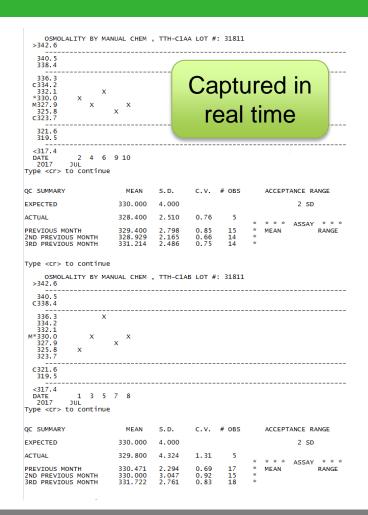
Your tests are all within established parameters.

CHRIS 1. DIGOXIN LVL 1 CVR IS AT 1.6

> Everything can be done and viewed remotely from anywhere – no more waiting for papers to travel from place to place – easy overview

Reviewed by Joseph shackelford MLS(ASCP) 07/19/2017 Bonnie Rashleigh C(ASCP) 7/19/17

the lam	os on both units. Recal and new r	reagent should correct
Marria		Christopher Emerson C(ASCP)CM 07/21/21
		•
	Nicole Hubbard, M.D.	P-t- 9/27/17
eviewed by	interest interest in the second	Date



#### **ELECTRONIC SERVICE REPORTS**

## One place to look for your instrument records -

Name	Date modified
퉬 AU 5812	9/12/2017 10:14 AM
퉬 AU 5822	8/31/2017 8:08 AM
퉬 Automation Line	9/22/2017 11:42 AM
퉬 AUWi	8/7/2017 8:04 AM
BIO-PLEX	9/28/2017 9:07 AM
🐌 DXI-D	Type: File folder
🌗 DXI-F	Date modified: 9/28/2017 9:07 AM
퉬 DXI-F 퉬 Immage	Date modified: 9/28/2017 9:07 AM Size: 8.48 MB Files: Bar Code scanner and key board.pd
	Size: 8.48 MB
]] Immage	Size: 8.48 MB Files: Bar Code scanner and key board.pd
Immage Nova8	Size: 8.48 MB Files: Bar Code scanner and key board.pd 6/23/2017 1:51 PM
Immage Nova8 Phadia 250	Size: 8.48 MB Files: Bar Code scanner and key board.pd 6/23/2017 1:51 PM 9/25/2017 1:51 PM

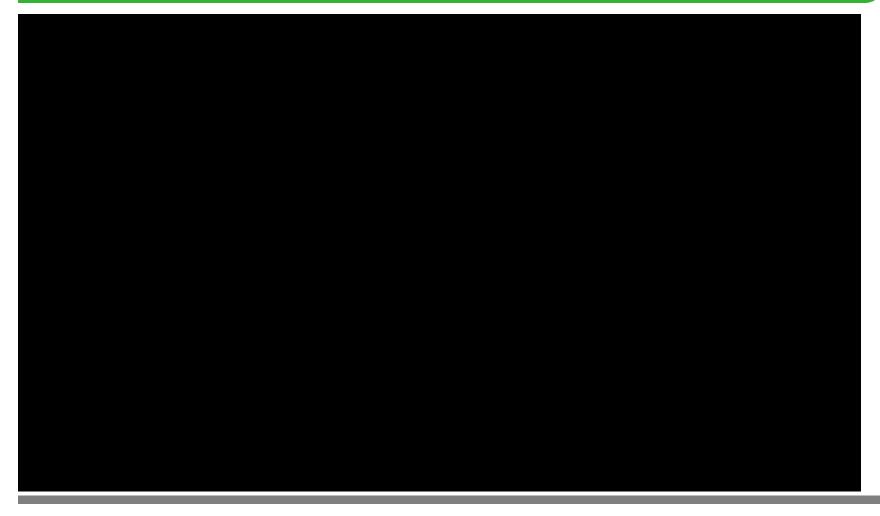
#### Easily spot trends and issues

🔁 Pwer Processor 022817.pdf 🔁 recapper 051117.pdf 🔁 Recapper 062517.pdf 🔁 Recapper 080117.pdf 🔁 Recapper 082317.pdf 🔁 Stockyard 022717.pdf 🔁 Stockyard 030917.pdf 🔁 Stockyard 082317.pdf Line of the stockyard State of the stockyard Stockyard State of the stocky and the stocky are stocky and the stocky are s 🔁 Stockyard Gripper 060217.pdf Line for the stockyard PM 032117.pdf

#### **MICROSOFT VIDEO - LACS**



#### **MICROSOFT CASE STUDY - LACS**



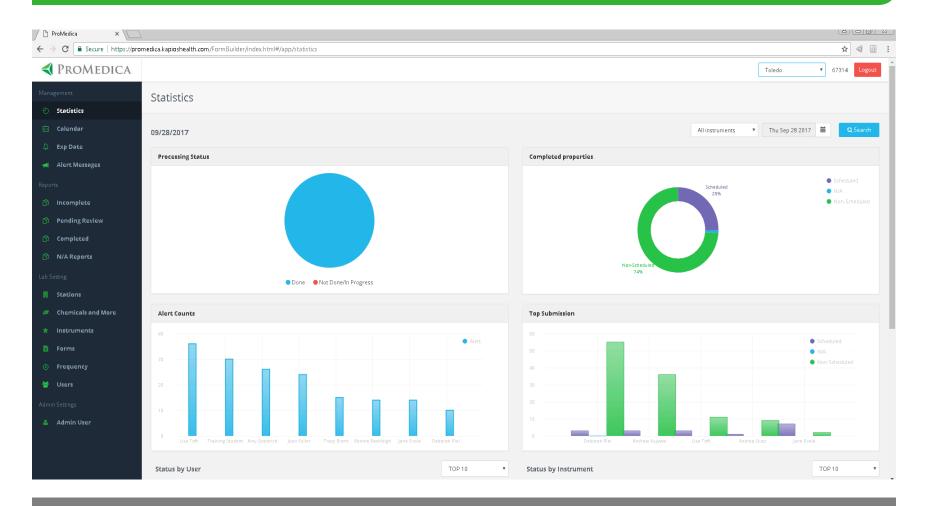


#### LACS - LABORATORY ASSURED COMPLIANCE SOLUTION – WHAT IT CAN DO

- BOOSTS THE PRODUCTIVITY OF THE LAB TECHNOLOGISTS AND TECHNICIANS
- MAINTAINS THE INTEGRITY OF THE DOCUMENTATION
- REPLACES COMPLIANCE DEFICIENCIES
   AND PERFORMANCE FAILURES

### WITH SIMPLE, FAST AND SUCCESSFUL AUDITS AND INSPECTIONS

#### LACS-WHAT IT CAN DO - DASHBOARD



#### LACS-WHAT IT CAN DO - CALENDAR VIEW

•	medica.kapioshealth.com/FormBuild	der/index.html#/app/app_calendar					☆ ≪ 〔
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Statistics							
Calendar	<			SEPTEMBER 2017			
Exp Date							
Alert Messages	Sun	27 Mon	28	29 Wed	Thu	Fri 31	Sat
	(55/55)	(71/71)	(60/60)	(54/54)	(66/66)	(53/53)	(62/62)
	100% Completed	100% Completed	100% Completed	100% Completed	100% Completed	100% Completed	100% Completed
Incomplete				-		-	
Pending Review	(53/53)	3 (69/69)	4 (62/62)	5 (75/75)	6 (53/53)	7 (53/53)	8 (60/60)
Completed	100% Completed	100% Completed	100% Completed	100% Completed	100% Completed	100% Completed	100% Completed
N/A Reports		10		40			
N/A Reports	(55/55)	10 (70/70)	(60/60)	12 (54/54)	13 (55/55)	(51/51)	15 (62/62)
	100% Completed	100% Completed	100% Completed	100% Completed	100% Completed	100% Completed	100% Completed
Stations							
Chemicals and More	(53/53)	17 (69/69)	18 (59/59)	19 (55/55)	20 (52/52)	(52/52)	22 (59/59)
	100% Completed	100% Completed	100% Completed	100% Completed	100% Completed	100% Completed	100% Completed
Instruments							
Forms	(54/54)	(69/69)	(61/61)	26 (53/53)	(56/56)	28 (39/50)	29
Frequency	(54/54) 100% Completed	(09/09) 100% Completed	(01/01) 100% Completed	(55/55) 100% Completed	(56/56) 100% Completed	(39/50) 78% Completed	
Users							
			2		4		
	(1/53) 2% Completed						
Admin User	2.0 Completed						

#### LACS– WHAT IT CAN DO – PENDING REVIEW

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eports	19		Reagents/Controls/Calibrators(Chem)	AU5812	Creat		Andrew Kujawa	Non-Schedule	09/29/2017 08:21
🕅 Incomplete	18		Reagents/Controls/Calibrators(Chem)	AU5812	Barbiturates		Andrew Kujawa	Non-Schedule	09/29/2017 08:21
Pending Review	17		Reagents/Controls/Calibrators(Chem)	AU5812	Mag		Andrew Kujawa	Non-Schedule	09/29/2017 08:20
ා Completed	16		Reagents/Controls/Calibrators(Chem)	AU5812	BUN		Andrew Kujawa	Non-Schedule	09/29/2017 08:20
	15		Reagents/Controls/Calibrators(Chem)	AU5812	Trig		Andrew Kujawa	Non-Schedule	09/29/2017 08:20
) N/A Reports	14		Reagents/Controls/Calibrators(Chem)	AU5812	Glucose		Andrew Kujawa	Non-Schedule	09/29/2017 08:20
b Setting	13		Reagents/Controls/Calibrators(Chem)	AU5812	CO2 (Bicarb)		Andrew Kujawa	Non-Schedule	09/29/2017 08:20
Stations	12		Reagents/Controls/Calibrators(Chem)	AU5812	TRFN		Andrew Kujawa	Non-Schedule	09/29/2017 08:20
🖉 Chemicals and More	11		Reagents/Controls/Calibrators(Chem)	AU5812	Calcium		Andrew Kujawa	Non-Schedule	09/29/2017 08:19
	10		Reagents/Controls/Calibrators(Chem)	AU5812	ALT		Andrew Kujawa	Non-Schedule	09/29/2017 08:19
🖈 Instruments	9		Reagents/Controls/Calibrators(Chem)	AU5812	Albumin		Andrew Kujawa	Non-Schedule	09/29/2017 08:19
Forms	8		Reagents/Controls/Calibrators(Chem)	AU Calibrators	TCA		Andrew Kujawa	Non-Schedule	09/29/2017 08:13
S Frequency	7		Reagents/Controls/Calibrators(Chem)	AU Calibrators	TCA		Andrew Kujawa	Non-Schedule	09/29/2017 08:13
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	2		Hydrasis	HYDRASYS & HYDRASYS 2_Manual	Daily Maintenance	S/N 779	Jane Evola	General	09/29/2017 12:00
	1		Assist	Phoresis ASSIST	Daily Maintenance Log Sheet		Jane Evola	General	09/29/2017 12:00

#### LACS-WHAT IT CAN DO - VIEW FORMS

D	etail			×
	Station	Maintenance		v
	Instrument	Mimmu_Manual		v
	Form Title	Manual Immunology - Daily Task		
	Sub Title	Manual Immunology		
	Slide #1			
	* MI pending log		Yes No	
	* BioPlex Maintenance	2	🖲 Yes 🔘 No	
	* PhD Maintenance (T	uesday & Friday)	Yes No	
	* Ultra Maintenance (1	Thursday)	🔘 Yes 💿 No	
	* Log all reagent, calib	rators, QC	● Yes 🔘 No	
	* Run lot-to-lot on nev	v lot PhD slides	🔘 Yes 💿 No	
	* Enter controls into L	15	🖲 Yes 💿 No	
	* Worksheets initialed	& filed	🖲 Yes 🔘 No	
	* Inventory (Mon.)		🔘 Yes 💿 No	
			Delete	Update OK

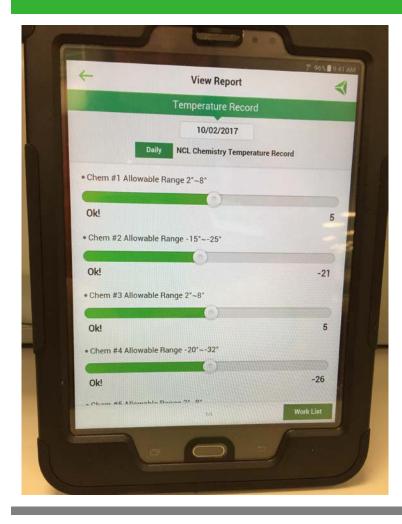
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#### LACS– WHAT IT CAN DO – TEMPERATURES

Station	3rd Shift	
Instrument	Temperature Record	
Form Title	NCL Chemistry Temperature Record	
Sub Title	Consolidated Measurements	

Slide #1	
Chem #1 Allowable Range 2°-8°	Ξ 5
Chem #2 Allowable Range -15°25°	
Chem #3 Allowable Range 2°-8°	
Chem #4 Allowable Range -20°32°	-26
Chem #5 Allowable Range 2°-8°	2
Chem #6 Allowable Range 2°-8°	б
Chem #7 Allowable Range -12°24°	
Chem #8 Allowable Range -60°70°	-69
Chem #9 Allowable Range 2°-8°	6
Chem #10 Allowable Range -1520	-15
Chem #11 Allowable Range 2°-8°	5
Chem #12 Allowable Range 2°-8°	6
Chem #13 Allowable Range 2°-8°	3
Chem #14 Allowable Range 2°-8°	4.5
Character Decision of	

#### LACS- WHAT IT CAN DO - TEMPERATURES



- One page for easy movement from fridge to fridge
- Allowable temps coded into form
- Easy slide bar adjustment no typing
- If out of acceptable range, bar turns red and forces a corrective action entry



#### LACS-WHAT IT CAN DO - FORM BUILDER

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Management	Station	1st Shift								T
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🛗 Calendar	Form Title	AUW Daily Maintenance	UF-1000 #15411							
🗘 Exp Date	Sub Title	FIRST SHIFT								
📹 🛛 Alert Messages	Doc ID	TTH-AUW-Daily Log-0001								
Reports	Frequency	Daily Shift 1								¥
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D) N/A Reports										
Lab Setting	Slide 1 🛞 🕀 Add New Slide	2				Question	Header			*
📕 Stations	× + Check	Reagents	🔵 Yes 🕘 No		# ×	Selected Type :	Header			
🧖 Chemicals and More		Fluid in Trap Chamber	○ Yes ○ No		/ ×	Title				
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#### LACS- WHAT IT CAN DO - DEFINE USERS

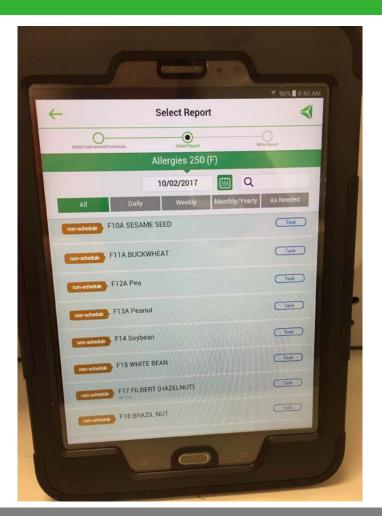
Jser List	ViewCount: 11	) V Search			
No	SecurityLevel	ID	FirstName	LastName	email
6	TECH3	89466	Lolanda	Mason	
5	Bench Tech	89235	Jane	Evola	
4	Supervisor	67314	Bonnie	Rashleigh	bonnie.rashleigh@promedica.org
3	TECH3	53371	Deborah	Piel	
2	Bench Tech	47910	Chris	Speier	
1	TECH3	33449	Gerald	Titkemeier	
				« ( 1 2 3 4 ) »	

Add New



#### LACS– WHAT IT CAN DO – REAGENT LOGGING





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#### **ROI FOR LACS FOR JUST ONE DEPARTMENT**

#### So many ways to save and go green -

- Supervisor Time savings
- Tech 3 Time savings
- Paper Cost

- Copier / toner costs
- Storage Costs
- Inspection Ready Everyday!

# Think of what an ENTIRE Lab could Save each year !

Item	Quantity	Mont	hly Savings	Ex	tended	Monthly Savings Calculations
A review was conducted of 60 pages						
92 missing verifications out of 7050 checks						
Saves technologists approximately 13 hours each month in administrative tasks such as preparing,						
printing, distributing, managing, troubleshooting, and filing maintenance logs.	13	\$	30.00	\$	390.00	13 hour X \$30.00 = \$390.00
Saves supervisors approximately 3 hours per month in just reviewing and signing each page of						
documentation. (Overall LACS saves supervisors of each department 15 hours per month.)	1	\$	675.00	\$	675.00	15 hours X \$45.00 = \$675.00
Time savings with improved biennial CAP audits	1					
Time savings with improved biennial peer reviews	1					
In printing and document storage alone, it saves over \$45.00 each year. \$9.74 worth of paper and \$25.76 worth of ink plus three 2" binders.	1	\$	3.75	\$	3.75	\$45.00 divided by 12 months
Regulations dictate these documents must be stored for the life of the instrument plus 2 years. This leads to average external storage costs of approximately \$5.76 per year.	1	\$	0.48	\$	0.48	\$5.76 divided by 12 months
Labor to maintain and store documents.				j.		
Notes:			Aonthly s with LACS	\$ 1	1,069.23	
Estimated salary of a technologists is \$36,000 per year or \$3,000 per month. The burdened monthly rate					•	
is \$3,900 per month. The burdened hourly rate is \$30.						
Estimated salary of a lab supervisor is \$72,000 per year or \$6,000 per month. The burdened monthly						
rate is \$7,800 per month. The burdened hourly rate is \$45.00.				2		

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#### HOW DO WE KNOW HOW WE ARE DOING?

## METRICS & Daily Management

- Monitor crucial TAT
- Monitor instrument downtime
- Monitor defects (wrong orders, hemolyzed, labelling...)
- Monitor & measure specific pain points
- Improve in small steps immediately rather than waiting for the perfect solution

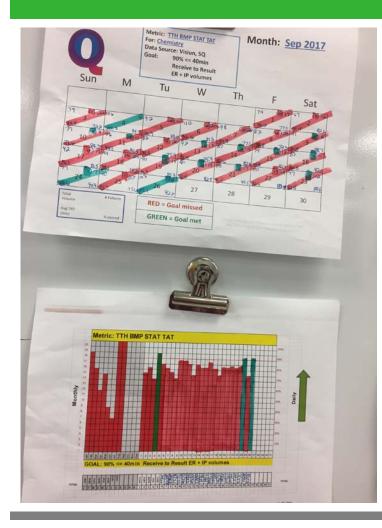
#### **SPREAD THE WORD - SUCCESS**

# We take every opportunity to celebrate our successes !

- Lab Week Activities
- Project Closeouts
- ISO Awareness Week
- 5S Competition
- Toledo Hospital Disaster Olympics



#### **LESSONS LEARNED**



- Make sure you have the correct data for your metrics
- You need to have the correct tools available to your techs
- COMMUNICATION –better to have MORE than less– we under communicate by a factor of 10

## Questions?



## Kapios HEALTH Todd Borowski - Sales Todd.Borowski@kapioshealth.com

### www.kapioshealth.com

