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

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ProMedica Laboratories

Lab Quality Confab

October 24,2017

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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
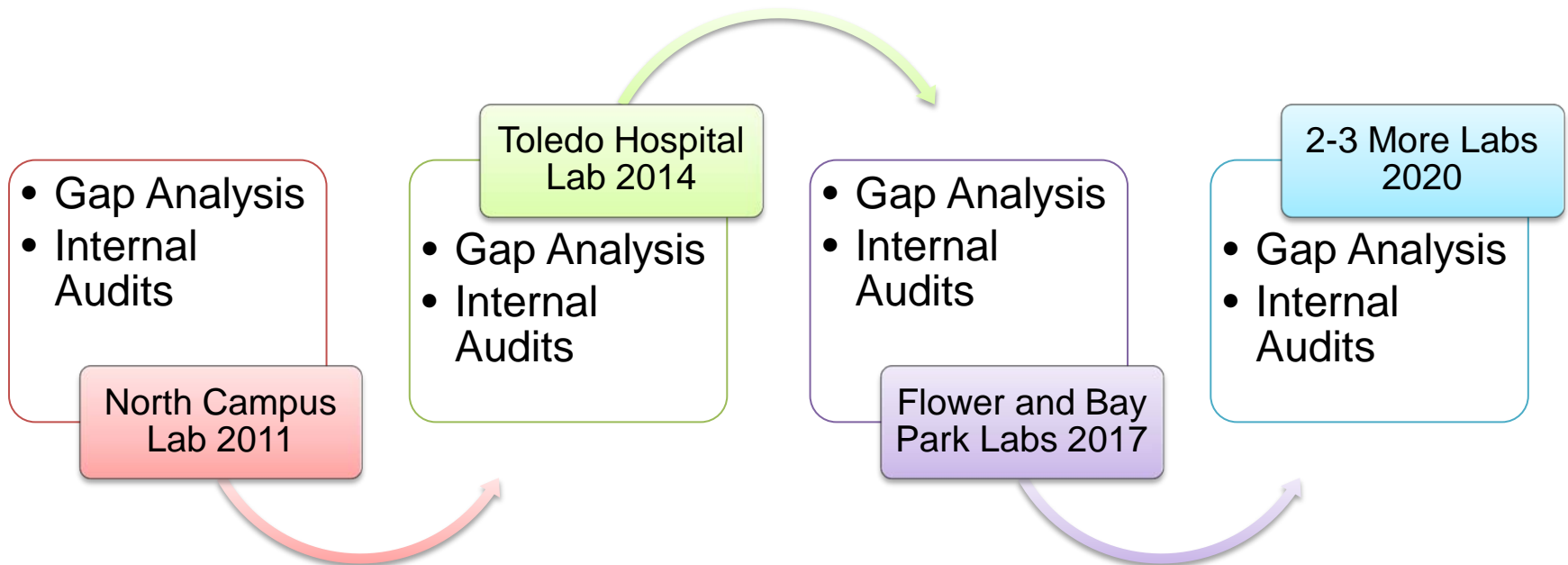- The 30 second rule

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 13th lab to achieve this certification – a point of pride

WHAT IS NEXT – ISO 15189 PROGRESS

- Gap Analysis
- Internal Audits

North Campus Lab 2011

Toledo Hospital Lab 2014

- Gap Analysis
- Internal Audits

- Gap Analysis
- Internal Audits

Flower and Bay Park Labs 2017

2-3 More Labs 2020

- Gap Analysis
- Internal Audits

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
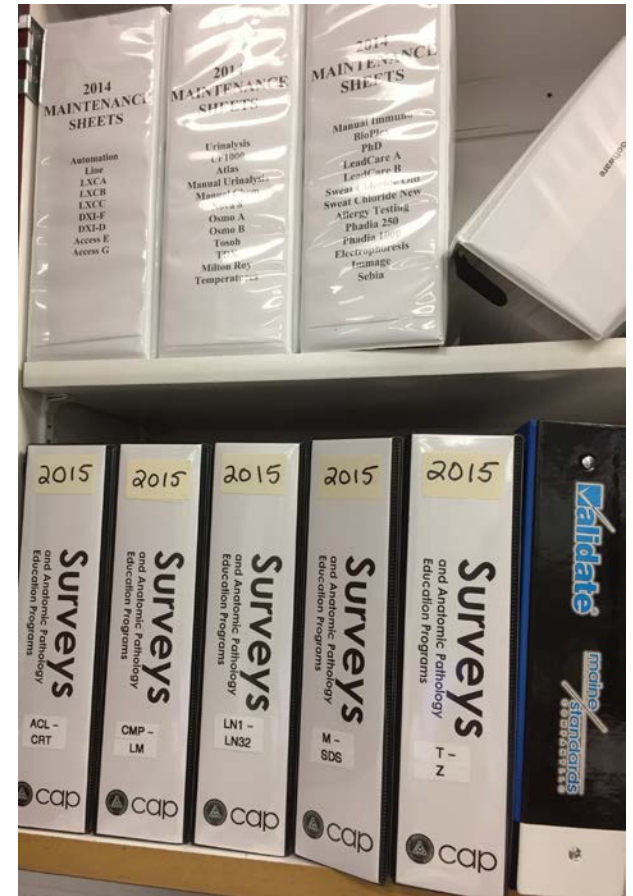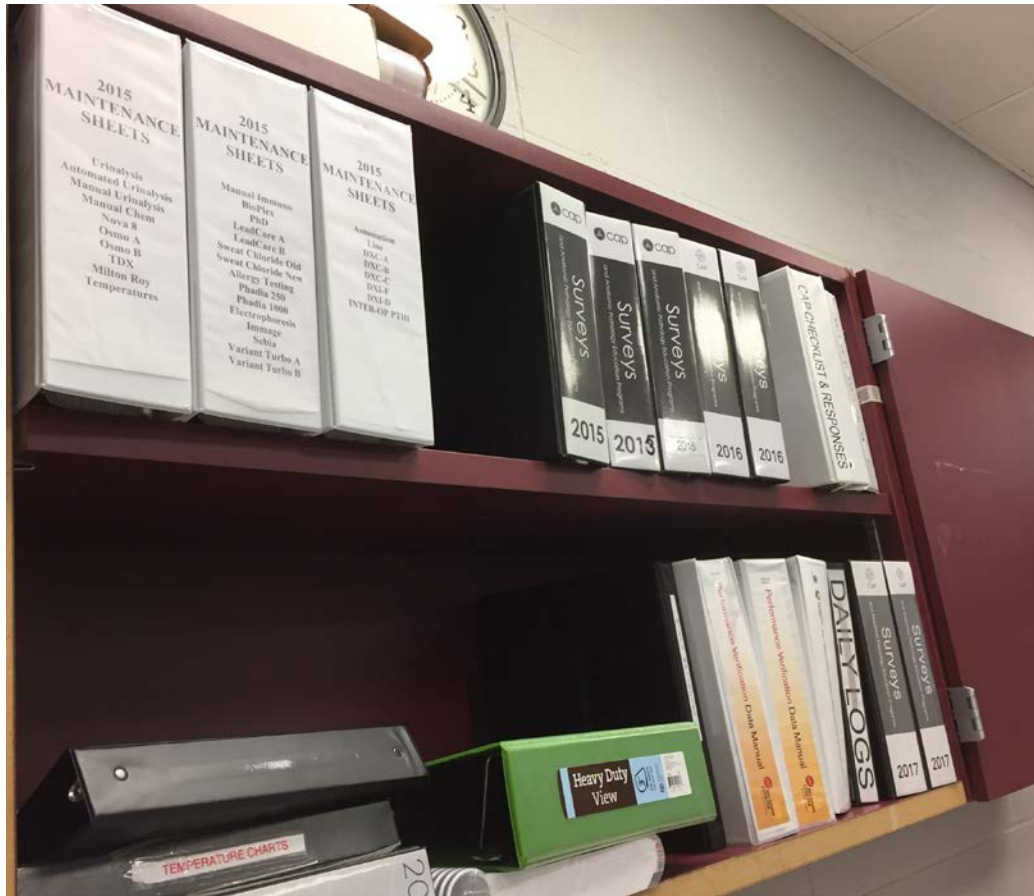
ELECTRONIC CAP SURVEY STORAGE

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

Unity TDM CONTROL ON AU-M

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

Please review your QC reports for June 2017.

Your tests are all within established parameters.

June 2017 • Lab 109002
TOLEDO HOSPITAL LABORATORY
2141 GIANT STREET
TOLEDO OH 43606
Attention: LONI MASON
BIOCHEMICAL PATHOLOGY

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

Corrective Action
I changed 6 reagent syringes on 7-16-17, did 6 month maintenance on unit 2, and changed the lamps on both units. Recal and new reagent should correct.
Christopher Emerson C(ASCP)CM 07/21/2017

Reviewed by Nicole Hubbard, M.D.   Date 9/27/17

```
   OSMOLALITY BY MANUAL CHEM , TTH-C1AA LOT #: 31811
 >342.6
 ------------------------------------------------------------
  340.5
  338.4
 ------------------------------------------------------------
  336.3
 C334.2
  332.1            X
 *330.0    X
 M327.9        X        X
  325.8            X
 C323.7
 ------------------------------------------------------------
  321.6
  319.5
 ------------------------------------------------------------
 <317.4
 DATE      2  4  6  9 10
  2017    JUL
 Type <cr> to continue

 QC SUMMARY           MEAN    S.D.    C.V.  # OBS     ACCEPTANCE RANGE

 EXPECTED            330.000  4.000                      2 SD

 ACTUAL              328.400  2.510   0.76    5
                                                  *   * * *  ASSAY  * * *
 PREVIOUS MONTH      329.400  2.798   0.85   15   *   MEAN        RANGE
 2ND PREVIOUS MONTH  328.929  2.165   0.66   14   *
 3RD PREVIOUS MONTH  331.214  2.486   0.75   14   *

 Type <cr> to continue

   OSMOLALITY BY MANUAL CHEM , TTH-C1AB LOT #: 31811
 >342.6
 ------------------------------------------------------------
  340.5
 C338.4
 ------------------------------------------------------------
  336.3            X
  334.2
  332.1
 M*330.0       X        X
  327.9           X
  325.8    X
  323.7
 ------------------------------------------------------------
 C321.6
  319.5
 ------------------------------------------------------------
 <317.4
 DATE      1  3  5  7  8
  2017    JUL
 Type <cr> to continue

 QC SUMMARY           MEAN    S.D.    C.V.  # OBS     ACCEPTANCE RANGE

 EXPECTED            330.000  4.000                      2 SD

 ACTUAL              329.800  4.324   1.31    5
                                                  *   * * *  ASSAY  * * *
 PREVIOUS MONTH      330.471  2.294   0.69   17   *   MEAN        RANGE
 2ND PREVIOUS MONTH  330.000  3.047   0.92   15   *
 3RD PREVIOUS MONTH  331.722  2.761   0.83   18   *
```

> Captured in real time

ELECTRONIC SERVICE REPORTS

One place to look for your instrument records -

Easily spot trends and issues

Name	Date modified
AU 5812	9/12/2017 10:14 AM
AU 5822	8/31/2017 8:08 AM
Automation Line	9/22/2017 11:42 AM
AUWi	8/7/2017 8:04 AM
BIO-PLEX	9/28/2017 9:07 AM
DXI-D	
DXI-F	
Immage	
Nova8	6/23/2017 1:51 PM
Phadia 250	9/25/2017 1:51 PM
PHADIA 1000	6/23/2017 1:50 PM
Turbos	3/29/2017 2:29 PM
Vidas	7/19/2017 11:25 AM

Type: File folder
Date modified: 9/28/2017 9:07 AM
Size: 8.48 MB
Files: Bar Code scanner and key board.pd

- 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
- Stockyard 082517.pdf
- Stockyard Gripper 060217.pdf
- 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

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LACS– WHAT IT CAN DO - DASHBOARD
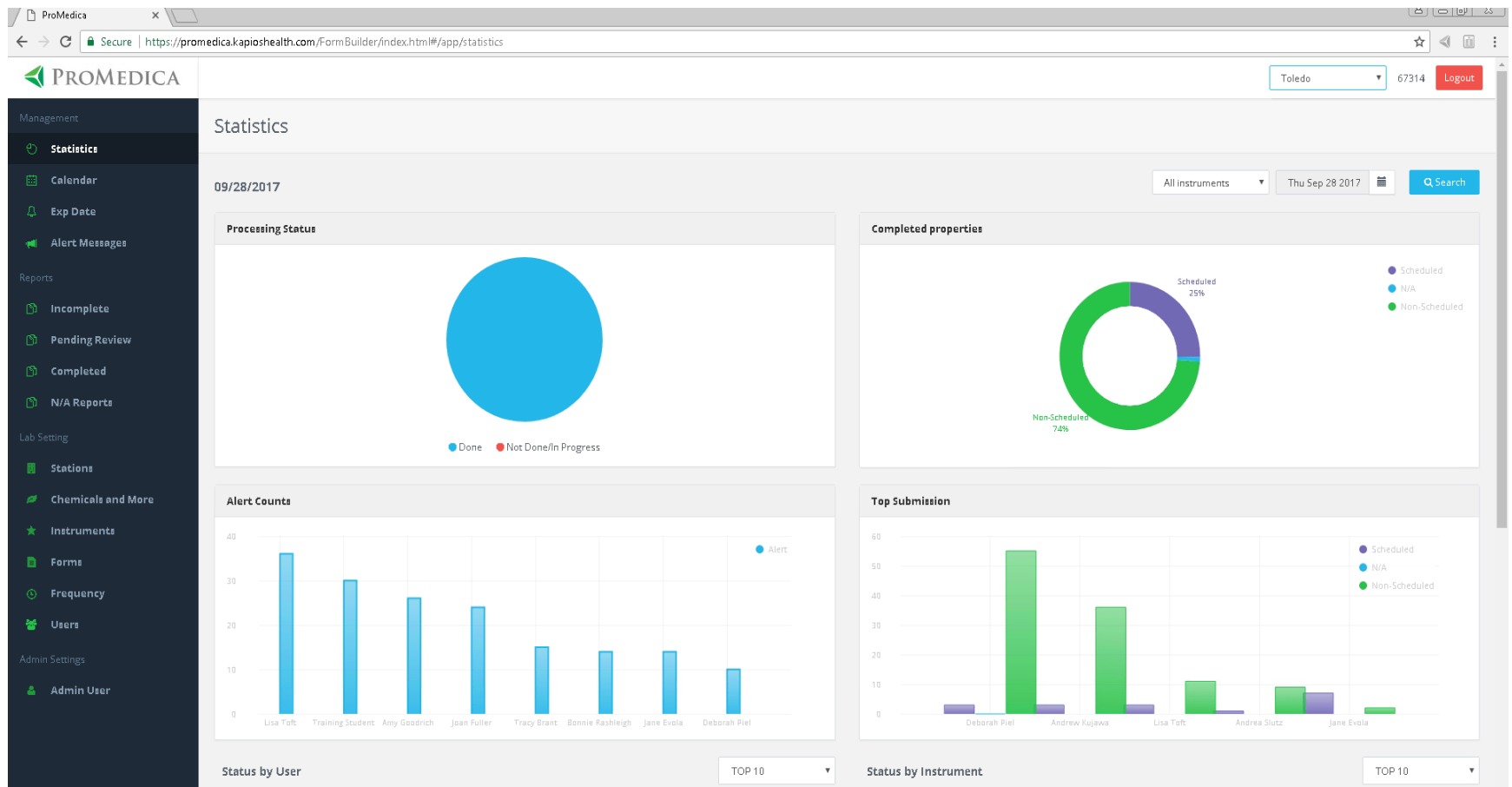
LACS– WHAT IT CAN DO – CALENDAR VIEW

LACS– WHAT IT CAN DO – PENDING REVIEW

LACS– WHAT IT CAN DO – VIEW FORMS

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°	5
Chem #2 Allowable Range -15°–-25°	-18
Chem #3 Allowable Range 2°–8°	4
Chem #4 Allowable Range -20°–-32°	-26
Chem #5 Allowable Range 2°–8°	2
Chem #6 Allowable Range 2°–8°	6
Chem #7 Allowable Range -12°–-24°	-12
Chem #8 Allowable Range -60°–-70°	-69
Chem #9 Allowable Range 2°–8°	6
Chem #10 Allowable Range -15–-20	-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
Chem #16 Allowable Range 2°-8°	4

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LACS– WHAT IT CAN DO – TEMPERATURES
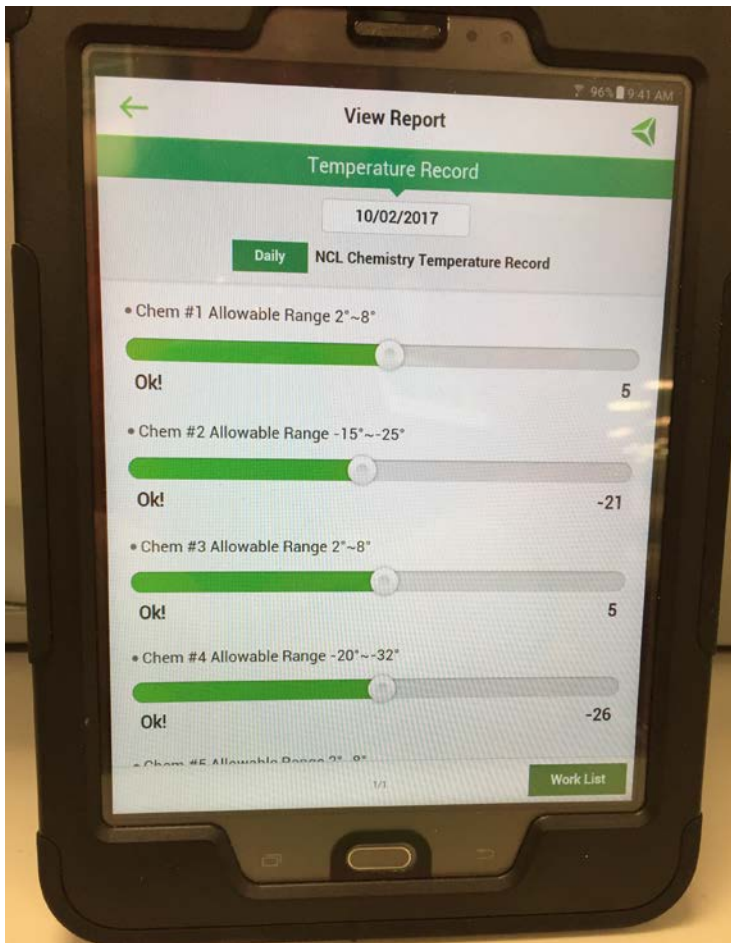
- One page for easy movement from fridge to fridge

- 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

LACS– WHAT IT CAN DO – DEFINE USERS

User List

| Name ▼ | [   ] | ViewCount: 10 ▼ | 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

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LACS– WHAT IT CAN DO – REAGENT LOGGING
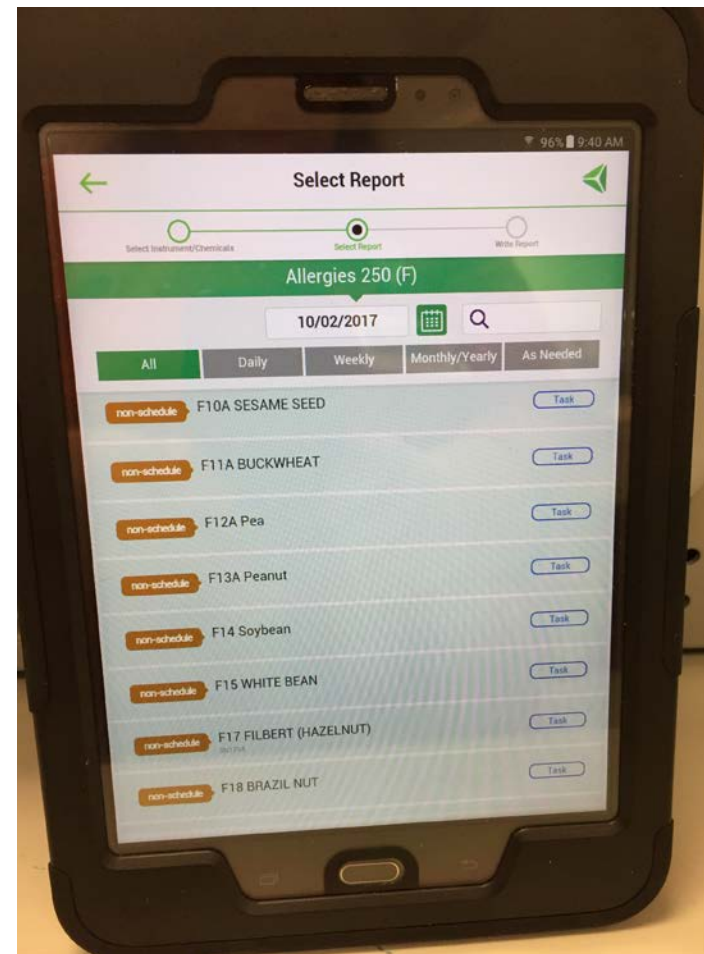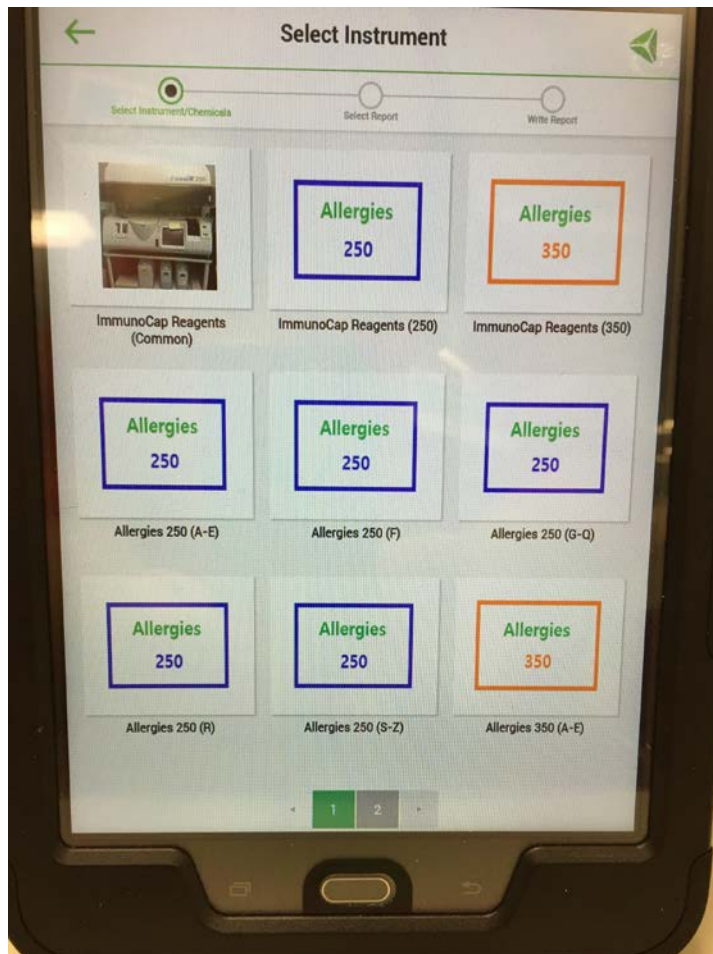
ROI FOR LACS FOR JUST ONE DEPARTMENT

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	Monthly Savings	Extended	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	$5.76 divided by 12 months
Labor to maintain and store documents.				
Notes:		**Total Monthly Savings with LACS**	**$ 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.				

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Kapios HEALTH

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***
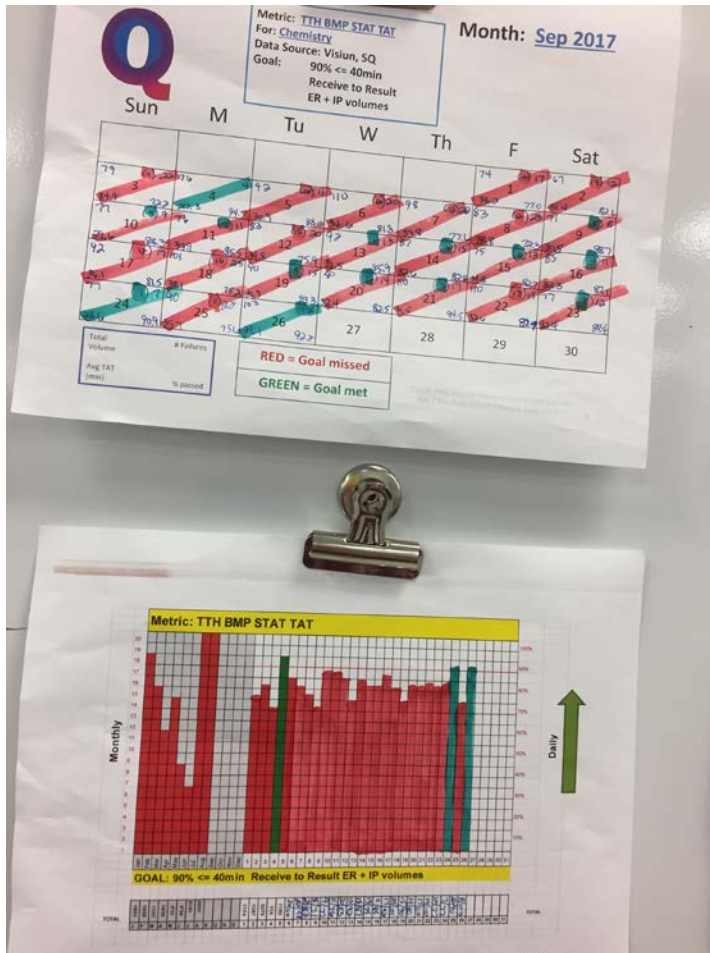
SPREAD THE WORD - SUCCESS

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

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Questions?

Todd Borowski - Sales

Todd.Borowski@kapioshealth.com

www.kapioshealth.com