



Using a LIMS to Solve Today's Most Common Laboratory Challenges



Laboratory Test Report

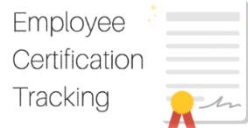
Patient Name: _____
Address: _____
Date: _____
Medical Center: _____
Test No.: _____

Temperature	PH	Protein	Albumin

Test Results Interpretation: _____

Signed By: _____

CALIBRATION RECORD		
DATE	BY	NEXT DUE



Presented by:
Ken Ochi
Manager of Global Marketing and Customer Relations

Agenda



- Today's Laboratory – An Environment of Challenges
- Using a LIMS to Solve These Challenges
 - Data Integrity
 - Traceability
 - Reporting
 - Achieving and maintaining regulatory and accreditation requirements
- Completing the Laboratory Automation Solution
 - Positive ID
 - Instrument Integration
 - Remote Environmental Monitoring
 - Mobile Technology for Field Environmental Testing
- Case Study: City of Naples, FL Central Laboratory
- Q & A

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Today's Laboratory – An Environment of Challenges



Laboratory Test Report

Patient Name: _____
 Address: _____
 Date: _____ Time: _____
 Medical Case: _____ Test No: _____

Laboratory Test Results

Time(minutes)	ES (cfu/ml)**	PSA (cfu/ml)**	SAU (cfu/ml)**

Test Results Interpretation: _____

Signed By: _____

CALIBRATION RECORD		
DATE	BY	NEXT DUE



Challenges in the Laboratory

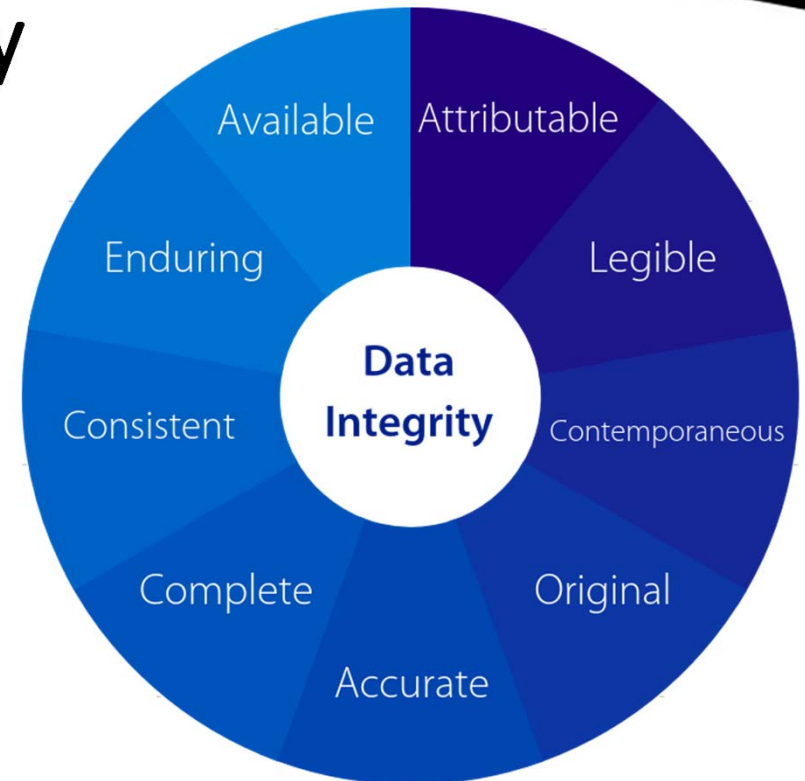
Data Integrity

Challenge
Accuracy of data is an ongoing issue for laboratories who have not invested in lab automation.
Data integrity is becoming an area of focus for regulatory agencies like the EPA.
Impact of inaccurate data could result in a loss of customer confidence in the laboratory's work or even worse.



Characteristics of Data Integrity

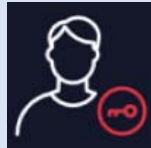
Laboratory's Job:
Produce **High Quality**, **Timely**, **Accurate** and **Affordable** data.



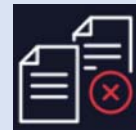
Preserving Data Integrity



Validate Input



Access Controls



Remove
Duplicate Data



Backup Data



Validate Data



Audit Trail



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Data Integrity – In LIMS

- Complete, consistent and accurate data
 - Sample Login – username and password
 - Date and Time Stamps – to the server that is controlled to be accurate
 - LIMS has controls in place to ensure Imported data from instrument (HPLC, ICP-MS, GC, IC, balance, etc) is correct
 - LIMS has controls for data Imported/Exported to Enterprise Applications
 - LIMS is designed for peer reviewing data for accuracy
 - Full history and audit trails
 - All QA and QC data are available along with supporting data
 - Audit trail data is readily available and accessible



Challenges in the Laboratory

Data Integrity

Challenge	Solution
Accuracy of data is an ongoing issue for laboratories who have not invested in lab automation.	Implement LIMS with barcode and scanning technology to eliminate data transcription errors.
Data integrity is becoming an area of focus for regulatory agencies like the FDA.	Positive ID – the ability to manage the chain of custody and instantly locate samples via barcoding within the lab is critical.
Impact of inaccurate data could result in a loss of customer confidence in the laboratory’s work or even worse.	Implement instrument integration to automate the transfer of testing results directly to the LIMS.



Challenges in the Laboratory

Traceability

Challenge
Not having an effective traceability solution in place can be costly as the result could be a product recall and damage to a company's reputation.
Achieving accreditation to programs like NELAP or standards like ISO 17025 requires traceability and the ability to generate an audit trail.
In water testing, traceability is important when dealing with a possible contamination issue.

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Traceability – Water

Biological Contamination and Chemical

LOCAL

State health department orders Delray Beach to test city water for level of 'forever' chemicals

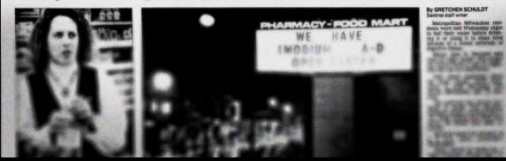
City officials said the order does not mean city water is contaminated with PFAs.

Mike Diamond Special to The Palm Beach Post
Published 3:54 p.m. ET Nov. 25, 2020 | Updated 2:26 p.m. ET Dec. 1, 2020

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Boil water, mayor says


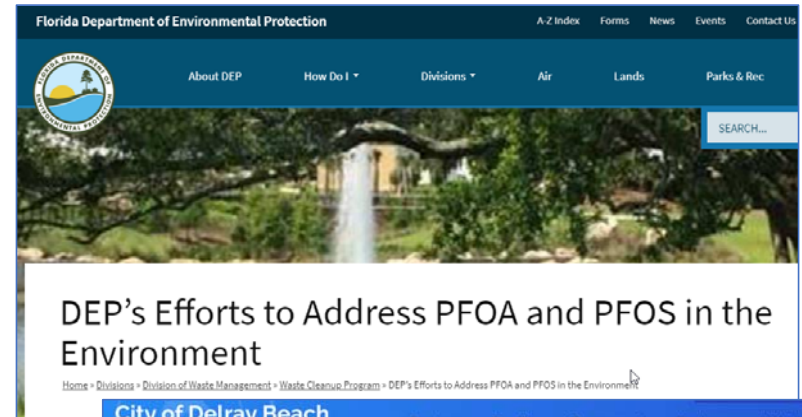
Safety of drinking supply probed in wake of mystery epidemic



Toxin taints CFPWA drinking water

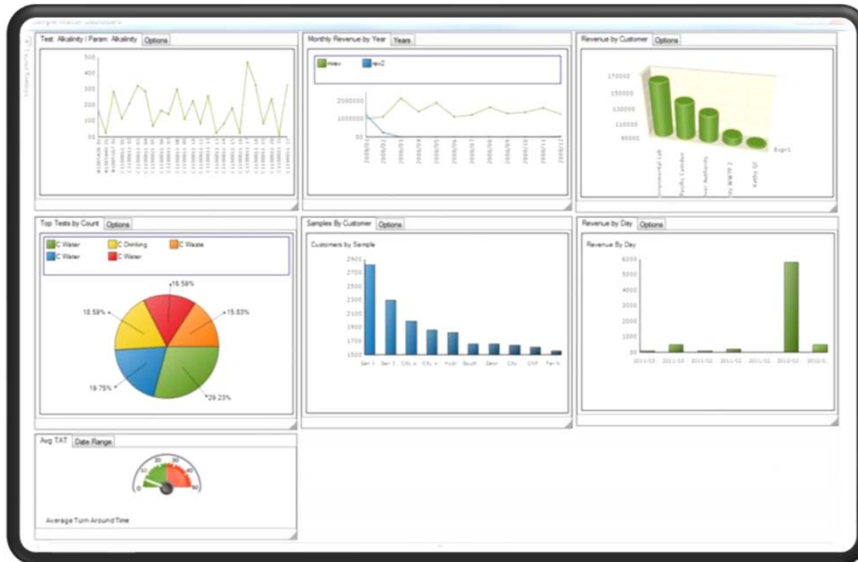
Wilmington, N.C. StarNews, June 8, 2017

From plant to pipes
Researchers have found chemicals made at the Fayetteville Works plant and used to make Teflon in the pipes of CFPWA's water system.

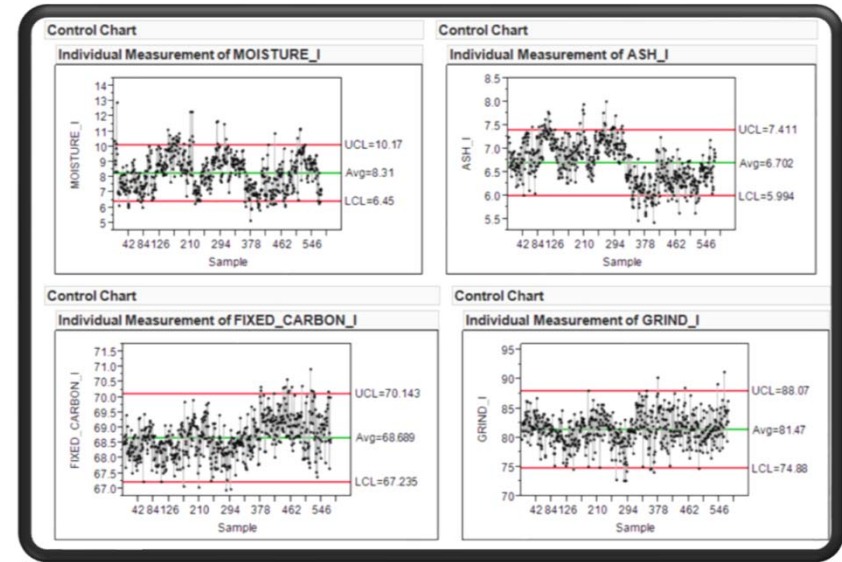



Real-Time Traceability

Dashboards & SAS JMP Statistical Analysis



**Dashboards for Business (KPIs),
Production and improved
communication**



**Leverage Statistical Software to
view trends**



Challenges in the Laboratory

Traceability

Challenge	Solution
Not having an effective traceability solution in place can be costly as the result could be a product recall and damage to a company's reputation.	Implement a LIMS that has strong traceability capabilities and the ability to generate an audit trail.
Achieving accreditation to programs like NELAP or standards like ISO 17025 requires traceability and the ability to generate an audit trail.	
In manufacturing, traceability is important when looking to track production and match replacement parts.	



Challenges in the Laboratory Reporting



Challenge
Need for comprehensive reporting and ability to modify reports quickly.
Want ability to alert lab personnel to possible out of compliance situations.
Communicating testing results to customers is time consuming.

Laboratory Test Report

Patient Name: _____
 Address: _____
 Date: _____ Time: _____
 Medical Case: _____ Test No: _____

Laboratory Test Results

Time(minutes)	ESC(cfu/ml)**	PSA(cfu/ml)**	SAU(cfu/ml)**

Test Results Interpretation: _____

Signed By: _____



Challenges in the Laboratory Reporting



Challenge	Solution
Need for comprehensive reporting and ability to modify reports quickly.	Implement a LIMS that has the ability to create a wide variety of reports as well modifying existing reports.
Want ability to alert lab personnel to possible out of compliance situations.	Use automated alerts (email and SMS texts) and dashboards as tools to avoid possible out of compliance scenarios.
Communicating testing results to customers is time consuming.	<p>Ability to communicate the reporting in a variety of ways including email, fax and web portal.</p> <p>Ability to generate reporting that can be delivered in a variety of EDD formats required by government or industry organizations.</p>

Laboratory Test Report

Patient Name: _____
 Address: _____
 Date: _____ Time: _____
 Medical Case: _____ Test No: _____

Laboratory Test Results

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Challenges in the Laboratory

Achieving/maintaining laboratory accreditation

Challenge
Achieving and maintaining laboratory accreditation (ISO 17025, NELAP) requires managing hundreds of data points on lab supplies, instrument calibration records and employee training records.
Quality standards like ISO 17025 requires the ability to track/document customer complaints as well as documenting Corrective Actions / Preventative Actions (CAPA)



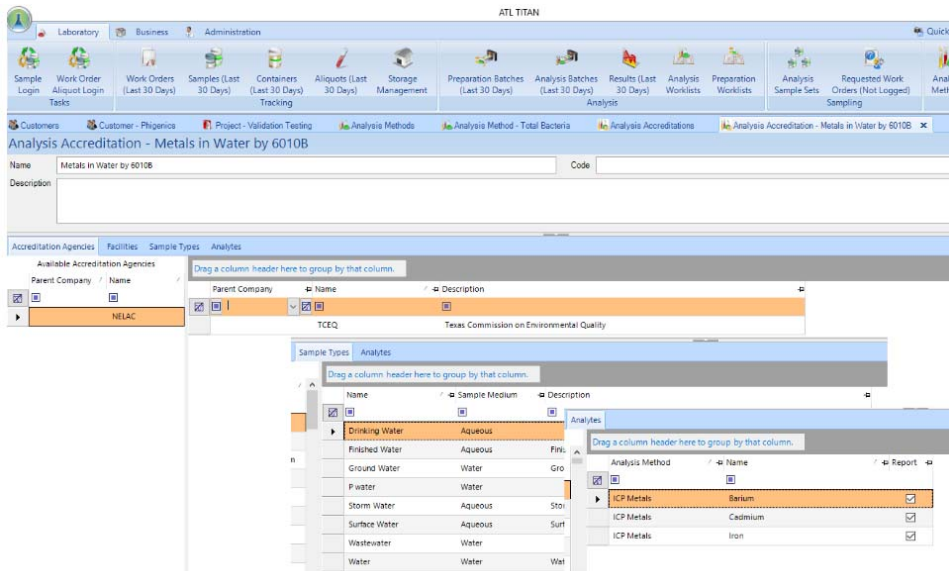
Challenges in the Laboratory

Achieving/maintaining laboratory accreditation

Challenge	Solution
Achieving and maintaining laboratory accreditation (ISO 17025, NELAP) requires managing hundreds of data points on lab supplies, instrument calibration records and employee training records.	Implementing a LIMS will provide a convenient and efficient means of satisfying the following accreditation requirements: <ul style="list-style-type: none"> • Personnel training records • Instrument calibration/maintenance • Inventory management • Document customer complaints • Corrective Action / Preventative Action (CAPA) • Full traceability and ability to generate an audit trail
Quality standards like ISO 17025 requires the ability to track/document customer complaints as well as documenting Corrective Actions / Preventative Actions (CAPA)	
Need to have a strong traceability solution for many accreditation programs like ISO 17025 and NELAP.	



Attaining/maintaining laboratory certifications



- ✓ Easily view what certifications are active for which tests
- ✓ Manage certifications and expiration dates
- ✓ Also manage instrument calibration certification
- ✓ And employee training certification, renewal dates with automated reminders
- ✓ Drag and drop certificates for quick access

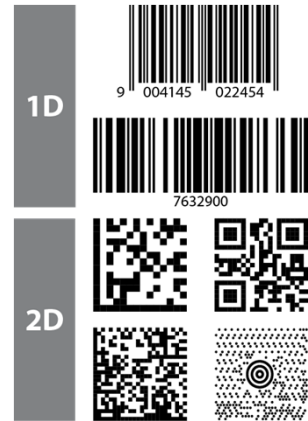






Impact of Automation



Positive ID: Barcoding and RFID

- Increased speed, accuracy and efficiency
- Sample login
- Inventory tracking
- Chain of custody



Chain of Custody Record and Analysis Request Form						
		Accelerated Technology Laboratories, Inc. 438 Holly Grove School Rd. Wood End, NC 27376 Phone: 800-555-0555 Fax: 800-555-0556		Customer: <input type="text"/> Work Order #: <input type="text"/> Requester: <input type="text"/> Project: <input type="text"/>		
		Customer: <input type="text"/> Work Order #: <input type="text"/> Requester: <input type="text"/> Project: <input type="text"/>		Phone: <input type="text"/> Fax: <input type="text"/> Email: <input type="text"/>		
Collection Information						
LIMS Sample #	Sample #	Date	Time	Collector	Analysis Methods	Container
00-1000000-01-01		02/20/2019	00:00		Ammonia (NH3)	00-1000000-01-01
00-1000000-01-02		02/20/2019	00:00		Ammonia (NH3)	00-1000000-01-01
Customer to sign & date below						
Prepared By:	Date/Time:	Accepted By:	Date/Time:	Total Samples: 2 Priority: Normal 10.00 day Date Results Requested: 10/7/2019		
Prepared By:	Date/Time:	Accepted By:	Date/Time:			
Prepared By:	Date/Time:	Accepted By:	Date/Time:			
Prepared By:	Date/Time:	Accepted By:	Date/Time:			
Prepared By:	Date/Time:	Accepted By:	Date/Time:			
Prepared By:	Date/Time:	Accepted By:	Date/Time:			
Prepared By:	Date/Time:	Accepted By:	Date/Time:			
Prepared By:	Date/Time:	Accepted By:	Date/Time:			
Prepared By:	Date/Time:	Accepted By:	Date/Time:			
Prepared By:	Date/Time:	Accepted By:	Date/Time:			



























Increase speed, accuracy and efficiency

Sample Accessioning Positive ID

- Track – Great for tracking samples through the laboratory
 - Barcoding allows samples to be logged in rapidly.
 - Date/time stamp anytime you scan a barcode – good for auditing.
 - Check in and out of fridges for internal chain of custody.
 - Instrument tracking sheet to load instrument with details.
- Trace – A nice timesaver especially if you need info ASAP
 - Pull a sample and scan it to see it's history and look up any results that may be available.
 - Can trace any aliquots back to the original sample.
 - Trace forward to Trace back from raw materials to finished product – valuable if dealing with outbreak or recall.



JMC Laboratories VIDAS Instrument Tracking Sheet 5/21/2012 4:22:50 PM

Section A			Section A		
#	Plant Code	Sample	#	Plant Code	Sample
1	003		31	003	
2	003		32	003	
3	003		33	003	
4	003		34	003	
5	003		35	003	
6	003		36	003	
Section B			Section B		
#	Plant Code	Sample	#	Plant Code	Sample
7	003		37	003	
8	003		38	003	
9	003		39	003	
10	003		40	003	
11	003		41	003	
12	003		42	003	

Instrument Integration

- ✓ Increases accuracy and throughput
- ✓ Avoids duplication
- ✓ Enhances productivity
- ✓ Achieves ROI typically within one year



Instrument Integration

How does it work?



Inputs:

.csv
.xls(Excel)
Text(ASCII)
XML
Web Services
Database

Parser imports data:
On demand
On a schedule – automatically

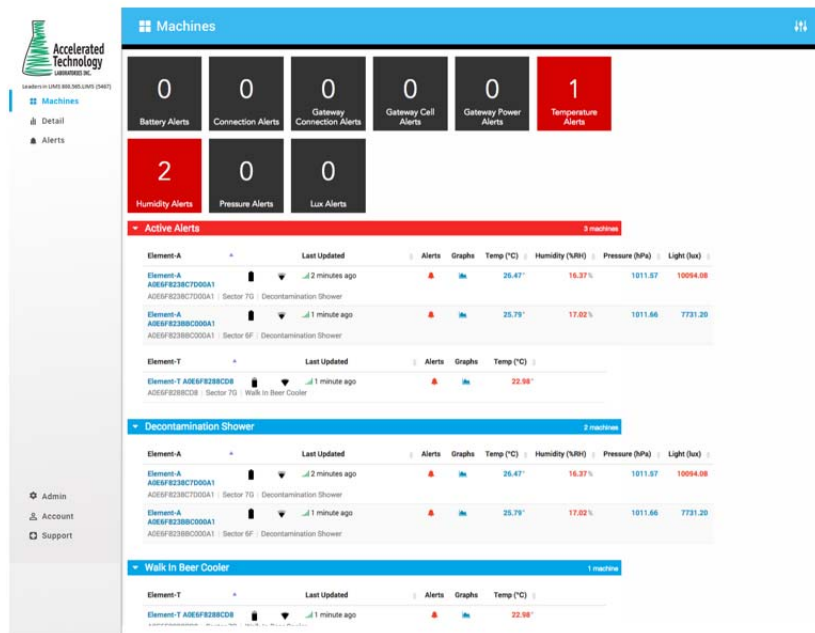


Contract lab data

Error Log for anything
not imported or if there
was an issue

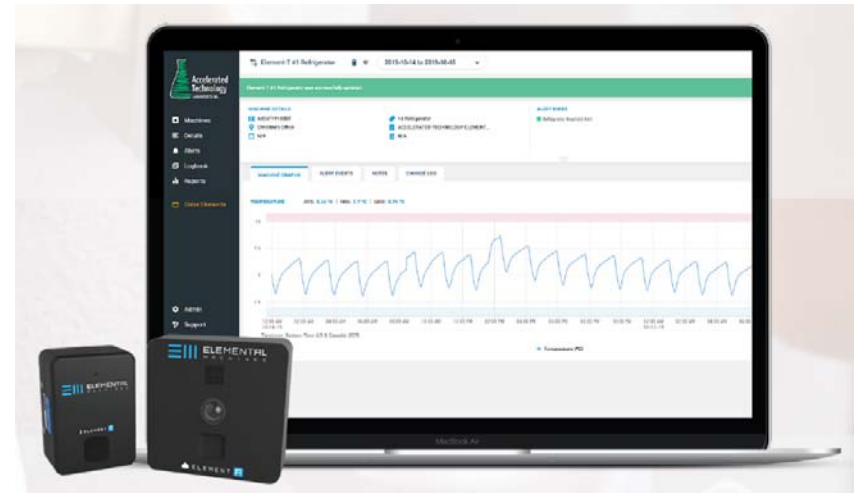


Remote Environmental Monitoring



Monitor:

- Fridges
- Freezers
- Incubators
- Humidity chambers



NIST
National Institute of Standards and Technology
U.S. Department of Commerce



Fridges



Freezers



Incubators

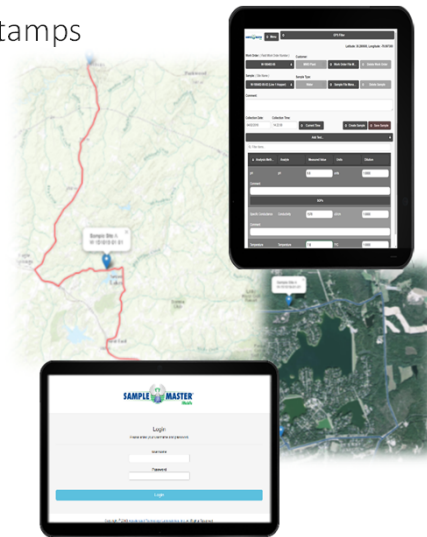
Mobile Technology for Field Environmental Testing

- ✓ Capture data in real time, **upload data** as it is collected (4G, 5G, WiFi, Hotspot)
- ✓ **Eliminate manual re-entry** of field measurements
- ✓ Synchronize data to LIMS including:

- Electronic chain of custody/Collector/Date and time stamps
- Location information/GIS coordinates
- Results/Comments

Additional Benefits

- Defines the fastest route for the collections
- Eliminates transcription errors
- Higher quality data



Before



After

Mobile Technology Return on Investment (ROI)

- Resource savings (avg. 60 min per day per person) x 6 field personnel = 6 hours/day time saved.
- Client recouped cost of Mobile solution within 6 months on labor savings alone.
- That includes cost of software, hardware, implementation.

Leveraging Mobile Technology to Improve Water Quality Data

Joe Yorke, Jojean Bolton, Melissa Billman and Dr. Christine Paszko*
Fairfax County Water Authority and Accelerated Technology Laboratories, Inc.*


ABSTRACT

Fairfax County Water Authority, like other utilities across the country, are continually looking for ways to manage their operations more effectively, maximize their productivity and reduce costs. A key element to operational efficiency is automation, which allows utilities to maximize existing resources, generate high quality data and promote communication, at while controlling costs. Fairfax County Water Authority, which is within the National Capital Region, is Virginia's largest water utility, serving one out of every five Virginians who obtain their water from public utilities. Two million people in the Northern Virginia communities of Fairfax, Loudoun, Prince William, Falls Church and Alexandria depend on Fairfax Water for superior drinking water.

The Water Quality Laboratory at Fairfax Water employs 24 full time staff including six field collectors that collect over 1,000 samples every year and the number is increasing as they expand. A major challenge was the lag time for field test data to be entered into Sample Master™ LIMS (Laboratory Information Management System). The presentation will cover the process of conducting a mobile technology needs assessment, gathering requirements, selecting the components, providing field training, and gradual testing through final deployment, culminating in successfully going live. The presentation will also look at the benefits of the automation, in terms of ROI, integration with the LIMS and end user experience.

INTRODUCTION

The laboratory struggled with a cumbersome manual process that required the field collectors to re-enter the field test data into the LIMS and deal with site of paperwork, transcription errors and the time lag associated with the manual transcribing of field data into their LIMS. As the volume and sample volume grew, the team knew it was time to investigate LIMS mobile technology.




The Fairfax County Water Authority is the main water company in northern Virginia, and one of the three major water providers in the Washington, DC metropolitan area. Nearly two million people depend on Fairfax Water for drinking water. The laboratory is constantly evaluating new technologies to enhance efficiency, increase data accuracy, and maximize resources while furthering green solutions.


The laboratory supports two treatment plants with a 200 MGD average production and 300 MGD capacity. The laboratory holds multiple certifications and analyzes 21 full time analysts, chemists, microbiologists, field collectors and managers that analyze the water for over 350 different analytes. A challenge facing the field collection team was the increasing amount of paperwork that was required to manage water samples collected in the field. Once the data was collected on the forms and returned to the laboratory, the collectors were responsible for entering the data into the laboratory's legacy, Master™ Laboratory Information Management System from Accelerated Technology Laboratories (ATI).

THE CHALLENGE

The challenges facing the field collection team were numerous. They had a high volume of paper forms to complete in the field, including the means of recording, then they had to transport all of the samples and associated forms back to the laboratory. Once back in the lab, they would manually key in all of the handwritten data into the LIMS, check the data, deliver the samples and file away the paper forms. As the sample volume increased so did the volume of paper. The results of samples were not scheduled.



When customer complaints were received into the laboratory, the field collectors would respond to these as well. Data was captured in the field on paper forms that were stored in 3 ring binders. Some of the issues encountered revolved around transcription errors that would occur when typing the handwritten data into the LIMS, when information was illegible or forms were lost. Another factor was the time required to have the field collectors perform dual entry, first on the paper forms and then again enter the information into the LIMS. There was also a time lag from the time a sample was delivered to the laboratory for analysis and when data of custody data was entered into the system. The laboratory knew that LIMS mobile technology could help address that time lag, transcription errors, and paper loss. Also, because the mobile technology could be tightly integrated with the LIMS, all of the sample scheduling information could be sent to the tablet and the collector would know exactly what to collect each day, as well as what tests and QC were required. The QC would then be generated electronically and QC data easily captured at each site.




THE SOLUTION

A needs analysis was conducted in which several factors were considered including network security/needs, LIMS mobile screen format, ease of use of the software and device, cost of the system including devices (tablets, smart phones, data plans), software updates and maintenance. The IT team reviewed network security/scans to ensure it was secure and that the laboratory team could leverage remote access to the LIMS on mobile. There were some concerns about network connectivity in remote locations that turned out to be non-issues.

RESULTS

The LIMS mobile software was purchased and installed on the web server, the tablets were purchased and the software was deployed. The solution was used for a trial period to evaluate the technology alongside the manual paper system. The time saving benefits were immediately obvious, the collectors had using the new technology and were connected to the laboratory, other benefits were enhanced operational efficiency, better data accuracy, improved staff efficiency, and a smaller carbon footprint. Once the field collectors had the tablets, not only were they able to access the Sample Master™ Mobile software, but they also had access to send the required camera and photo capturing.



SUMMARY

Performing a needs assessment of current operations and understanding the requirements for a field electronic data entry system and off in terms of understanding the various options to meet each requirement. Fairfax Water, working with ATI, successfully leveraged mobile technology to meet project objectives. In addition, significant cost savings were achieved, paper collection forms eliminated, electronic QC, increased communication within the laboratory and collection teams, and team members were provided with better tools. The benefits included:

- Resource savings (average 60 minutes per day per person) x 6 field personnel = 6 hours/day time saved by eliminating manual entry errors.
- Resources could be allocated for more useful work, a real labor cost savings, more samples can be collected with identical staff.
- Fairfax Water managed costs of mobile solution versus in months on labor savings alone (including, iPad, tablets and data plan).
- Transcription errors eliminated.
- Data captures and data files organized - providing real time data.
- QC controlled are automatically captured and recorded.
- Increased data availability - faster and better quality data.
- Chain of custody automatically printed upon return to the lab.
- Staff have access to LIMS (work instructions) in the field.
- GPS for navigation to sites and auto capturing coordinates.
- Email to send photos or other, lab on tablet, back to laboratory.

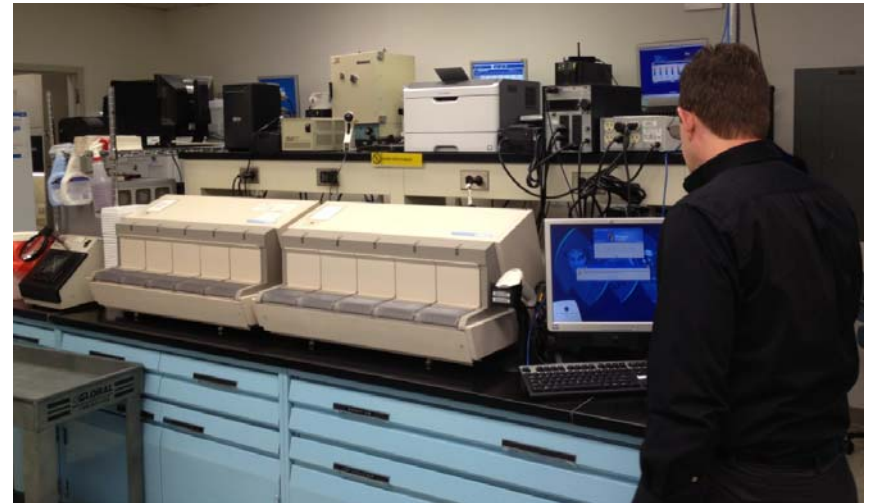
ACKNOWLEDGEMENTS

The authors would like to thank everyone that participated in the development and the analysis and analysis that led to the success of this project. Accelerated Technology Laboratories, Inc. for their support and expertise in providing the mobile solution. The authors would like to thank the following individuals for their support and expertise in providing the mobile solution: Joe Yorke, Jojean Bolton, Melissa Billman, and Dr. Christine Paszko.



Working Smarter

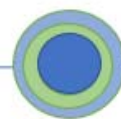
- Needs Assessment/Requirement gathering
- Requirements Documentation/Technology review
- Project Management and Configuration
- Implementation/Testing/Verification
- Superior Training
- Parallel Operations
- Go-Live
- Outstanding Support



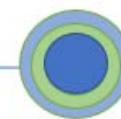
Plan



Define



Analyze/Configure



Deploy



Go Live

NEMC

Ideal LIMS Solutions Platform for Today's Laboratory

"A Laboratory Information Management System or LIMS is a software-based system with features that support a modern laboratory's operations."



Innovation.
Performance.
Success.

LIMS Case Study: City of Naples, FL

Organization Profile

- The City of Naples Utilities Department provides drinking water and wastewater services for a population of 62,000. The Water Treatment Plant handles 30 MGD and the Wastewater Treatment Plant (WWTP) treats 10 MGD.
- The Central Laboratory (CL) conducts testing for both the WTP and WWTP as well as ad-hoc testing for residential and commercial customers. Staff consists of a Laboratory Supervisor, two lab technicians and an industrial waste technician.

Their Challenges

- In 2013, the CL implemented a commercial LIMS. Over time, there were shortcomings that included the following:
 - Reports could not be created in the LIMS so the lab created them manually in Word and Excel.
 - Data from bench sheets or the Chain of Custody were manually transcribed into reports – this was time-consuming and prone to occasional errors.
 - The staff could not generate control charts, which is a requirement for NELAP-accredited labs. So the solution was to manually enter the data into Excel to create control charts – a very inefficient process.
 - The LIMS did not support data qualifiers so there was no way to immediately alert the lab if a sample result was below or above a certain control limit.
 - User access of the LIMS was becoming a frustrating situation for the lab; there was an ongoing debate between the LIMS provider and the city's IT department in trying to resolve it. And other issues requiring vendor support were not being resolved in a timely fashion.



City of
Naples Florida

LIMS Case Study: City of Naples, FL

The Solution

- The IT Administrator had started looking at moving some of the City’s software applications to a cloud or Software as a Service (SaaS) deployment model. When added to the ongoing issues with the LIMS provider, the decision was made to look at alternative LIMS solutions.
- The Laboratory Supervisor and staff put together a list of requirements for the new LIMS. These included:
 - LIMS should have ability to analyze QC data and create control charts
 - Provide functionality needed to continue maintaining NELAP accreditation
 - Ability to create and modify professional-looking reports in the LIMS
 - Ability to easily import results conducted by contract labs, eliminating need to re-key data
 - LIMS provider should offer outstanding and prompt technical support
 - Provide a cloud (or SaaS) deployment option that would eliminate the need for support from IT Dept.
- The City of Naples evaluated several LIMS providers before selecting ATL Sample Master LIMS. In addition to meeting the lab’s LIMS requirements, the evaluation team also selected ATL due to its understanding of water/wastewater/environmental laboratories, ISO certification, excellent support and the existing installed LIMS base in Florida.
- UPDATE: Janelle McClure, Laboratory Supervisor, provides this update on additional LIMS benefits:
 - The SaaS version of the LIMS makes it possible to use the LIMS from home –this was especially important during the first few months of the pandemic.
 - The LIMS provides powerful options for running queries – this makes it very easy to provide historical data upon request from internal clients and the public. This feature has been a huge timesaver.
 - Having this LIMS allowed us to add IDEXX methods to our scope of accreditation and we are now using the MPN calculator



summary

- Automation brings significant benefits for enforcing data quality, reducing errors, increasing throughput and productivity
- Instrument integration ensures accuracy
- Integrated calculations save time and reduce data errors
- Elimination of mundane tasks increases employee joy
- LIMS and laboratory automation helps to facilitate regulatory compliance
- Management excitement in having real-time data metrics, ability to identify issues quickly and mitigate risk
- QC team has the ability to mine data, discover trends



NEMC



THANK YOU!



- Thank you NEMC Organizers and Attendees!
- Special thanks to Robert Benz for moderating our session and to the great team at NEMC for putting together this “hybrid” version of their annual conference
- Feel free to contact me for any follow-up questions/feedback:
 - Ken Ochi (kochi@atlab.com)
 - C: (910) 315-3271
 - Website: atlab.com

