Microbiology Lab Handles 900,000 specimens yearly

Combining Lean with Lab Automation to Get Impressive Results

➤➤ *CEO SUMMARY: By combining total lab automation with Lean techniques in a comprehensive makeover of its microbiology lab, one of the largest labs providing hospital acute care and community microbiology services in North America achieved major benefits. Benefits ranged from improvements in lab result turnaround time and reduced errors to significant gains in staff productivity and the quality of lab test results. Productivity improvements allowed the micro lab to absorb a 15% increase in specimen volume while staff levels were reduced by six full-time equivalent MLTs.*

PROBABLY NO AREA OF CLINICAL LABORATORY MEDICINE is experiencing the dramatic transformation happening in microbiology. From rapid molecular testing to the full automation of traditional manual processes, significant changes are happening in microbiology labs.

Moreover, the smart use of Lean and quality management techniques magnify the positive effects of these new diagnostic technologies and automation in microbiology.

One early-adopter laboratory leveraging all of these trends to deliver more value with microbiology testing services is **DynaLIFEDx Diagnostic Laboratory Services** in Edmonton, Alberta, Canada. DynaLIFEDx was one of the first two labs in North America to implement total lab automation (TLA) in its microbiology lab and the first to go live in September 2013 with patient specimens being processed on the BD Kiestra TLA system from **Becton Dickinson** (BD). The DynaLIFEDx microbiology team concurrently used Lean to optimize processes in its microbiology department and obtain added productivity from automation.

Another notable aspect about this microbiology lab makeover is that it involves one of the largest microbiology laboratories providing hospital acute care and community patient services in Canada and the United States. DynaLIFEDx processes 900,000 microbiology specimens annually for more than 120 hospitals and health centers across Alberta, Saskatchewan, and the Northwest Territories.

Among the benefits DynaLIFEDx realized were improved turnaround time, reduced errors, standardization of specimen handling and processing, streamlined operating procedures, improved patient and staff safety, and enhanced antibiotic stewardship.

The metrics from the combined use of Lean and total lab automation are impressive. Productivity gains supported a specimen volume increase of 15%, in addition to MLT staffing reductions of six full-time equivalent positions over 18 months. Also, workflow in microbiology has become much more efficient. DynaLIFEDx expects to realize further staff reductions as the lab continues to optimize the TLA system, further improve workflows, and implement new features and components.

"We are a private laboratory within an integrated laboratory service and work closely with **Alberta Health Services,** the public health system," stated Norma Page, the laboratory's Vice President of Clinical Operations. "We provide anatomic pathology, microbiology, and a wide array of other lab testing, including referrals, consultation, and support services.

"From our large referral laboratory in Edmonton, and from labs we operate in regional and rural hospitals within Alberta, we service an area about the size of California," she continued. "We employ 1,200 professional laboratory staff, including 40 pathologists, medical microbiologists, biochemists and other medical laboratory specialists."

➤ Improving Quality and TAT

"We provide microbiology testing for dozens of hospitals including large acute-care facilities, and regional, community, and rural hospitals and health centers," she added. "Those hospitals don't have microbiology departments, but they do have rapid response or stat labs."

"Over the years, DynaLIFEDx has consistently had a forward-looking approach toward innovation," commented Page. "Consequently, we look first for opportunities to use new tools rather than increase the number of hands needed to handle the steady expansion in specimen volume along with increases in our scope of service. Because of our focus on innovation, we often realize big leaps forward when there are new opportunities in technology, automation, systems, or internal innovation.

"These management philosophies supported the major changes implemented in the microbiology lab. Late in 2012 we recognized a need to automate our microbiology department," stated Page. "Over 40% of the 900,000 microbiology specimens we test each year are for acute care patients. We saw the opportunity to combine automation

and new technologies with Lean to improve turnaround time, quality, and productivity.

"Our team started with a thorough analysis of the available automation options," explained Page. "We chose the BD Kiestra system because it had a multi-year track record in various labs in Europe and it offered more flexibility in terms of handling different specimen types. By comparison, other automated systems we considered were early in their development at that time.

"Our business case was approved in early 2013 and by September of that year we installed one of the first two BD Kiestra TLA systems in North America," she recalled. "Two months later, in November 2013, it was fully implemented."

"This microbiology automation system has changed—or facilitated changes—to almost every component of our Microbiology laboratory," said Page. "It does automatic plate barcoding, automated processing of liquid specimens, semi-automated processing of non-liquid specimens, and automated incubation and imaging.

Benefit Of Standardization

"One major benefit that came with this total laboratory automation solution is standardization," added Page. "For us, it allowed us to standardize many aspects of microbiology. This was important to us because our previous traditional microbiology processes were manual with significant differences from person to person and specimen to specimen. We had variations in operating procedures affecting everything from the size of the inoculum to how the plates were streaked and how long culture plates were actually in incubators.

"Perhaps the most interesting technology in the BD Kiestra system is how it uses magnetic beads to streak the plates," she stated. "Underneath where the culture plate sits, there's a magnet that drives the streaking pattern. A magnetic ball rolls across the media in various patterns spreading the specimen on the culture medium. We spent a lot of time determining which pattern was best for each specimen type. This streaking system optimizes colony isolation.

No Need For Subculture

"This is clinically important because when the colonies are isolated, our lab team can go directly to pathogen identification and then to susceptibility testing," continued Page. "Thus, it is not necessary to do a subculture, which reduces turnaround time and supports better patient care.

"That's the first key advantage: standardized culture plates," emphasized Page. "The module that does this process is BD Kiestra's InoqulA automated specimen handling system. It delivers standardized inoculum size, standardized streaking patterns by specimen type, and isolated colonies which support immediate pathogen identification.

"There are two sides to the InoqulA module," she explained. "The automated side takes any liquid specimen, removes the lid, picks up a defined volume of the specimen, inoculates the plates, sends the plates to the streaking system, and then transports them along the track to the incubator.

"The other side is the semi-automated section," stated Page. "We currently do not use this side because in Canada, as in the United States, microbiologists don't manually handle specimens except in a biological safety cabinet.

"We worked with BD to develop a biological safety cabinet (BSC) version, of the InoqulA," she noted. "The first one was installed at the **Royal Jubilee Hospital** in Victoria, British Columbia, and we will install ours in a few months. This customized BSC module gives us the same benefits of the standardized system but it can be used for plating as many as five specimens at one time or doing five plates on the same specimen.

"The second key advantage is improved plate management, and we consider this to

Combining Total Lab Automation with Lean Helps Microbiology Lab Reduce TAT and Errors

Traditional Microbiology	Primary Culture	Sub-Culture	Pathogen Identification	Antibiotic Susceptibility	Total time to Report
	1 – 2 days	1 day	1 day	1 day	4 - 5 days
Microbiology Automation	Primary Culture	Path ID and Susceptibility	Total time to Report		
	18-25 hours	20-24 hours	1.5 to 2 days		

Greater than 50% reduction in TAT

TWO TABLES ARE PRESENTED which show the improvements in turnaround time and error rates at the microbiology laboratory at DynaLIFEDx in Edmonton Alberta, after a new total laboratory automation system was installed and Lean methods were used to improve workflow. The table above shows how, with automation, DynaLIFEDx was able to reduce average microbiology test TAT from four to five days to under two days. The table at right shows the reduction in error rates for different processes due to automation.

Pre- and Post-Lean Error Rates	March 2012	March 2014
Labelling Error	28	0
Media Missed	18	1
Missed Information	16	5
Missed Order	14	0
Specimen Mix	14	4
Wrong Media Labelled	10	3
Plates Not Labelled	6	0
Total # Errors	**106**	**13**
Total # Specimens Processed	70,523	77,951
Total Error Rate	**0.150%**	**0.017%**

Source: DynaLIFEDx Diagnostic Laboratories, Edmonton, Alberta.

be a significant benefit of this automated system," said Page. "Prior to installing this automation, our microbiology lab had an average of 5,000-plus culture plates in motion on any given day. And multiple people handled many of those 5,000 plates. That's a lot of non-value added handling.

"Now our automated system does it all," she explained. "It barcodes the media, matches the specific specimen when it arrives, sends the inoculated media to the correct incubator (CO2 or O2), accurately times the incubation of the culture media, sends the plates for imaging at the ideal time, and pulls the plates out of the incubators when the specimen is completed and ready to be discarded. These processes are fully-automated and specimens are transported via the track system.

"The third key advantage is smart incubators," she said. "For each specimen type, we define standard incubation times to eliminate over-incubation and under-incubation. Both over- and under-incubation can interfere with colony isolation and pathogen ID. Moreover, the system tracks precisely how long every plate was incubated. We now know how old every colony is before we send it for susceptibility testing.

Incubators Get Smart

"Before we made these improvements, we ran a traditional microbiology lab," explained Page. "That meant the staff arrived in the morning and pulled that day's plates out of the incubators onto the bench. A substantial number of the plates were either underdone or overdone. This lack of standardization complicates processing as specimens move through the lab each day.

"In traditional microbiology labs, there are times when a pathogen may not be incubated optimally," noted Page. "Possibly it incubated for 13 or 14 hours when it

should have had 18 or 20 hours. Or maybe susceptibility testing was performed on an isolate without accurately knowing how many hours those colonies had been growing. Our automation and Lean workflow improvements have greatly reduced that source of error.

"Another benefit of our new automated workflow is that we no longer have cultures sitting on the bench instead of being incubated at the right temperature and in the right environment," she added. "With the TLA, plates are kept in the incubators—except for the brief periods when imaging or follow-up work is being performed. This adds a further layer of standardization and quality compared with previous processes.

"The fourth key advantage is digital imaging of the plates," explained Page. "Digital imaging enhances plate reading and provides a detailed audit of follow-up testing.

"We have a reading room where the technologists read the images and interpret the plates," she continued. "When reading these high-resolution images, they can circle a colony to work up and then use a series of codes to indicate what further testing they want and why. On average, it takes 37 seconds to read a plate and put all the indications on it for what needs to be done next—whether further work-up or susceptibility testing.

Seeing Impressive Results

"Our lab is like many microbiology labs today in that we do pathogen ID with mass spectrometry using MALDI-ToF (matrix assisted laser desorption ionization time-of-flight) technology which is capable of accurately identifying more than 2,200 bacterial pathogens," stated Page. "We use the automated Vitek MS from **Biomerieux** to complete the identification of a recognized pathogen in minutes. We have two of these instruments that fit nicely into our microbiology automation system workflow.

"All these improvements in microbiology workflow and standardization have generated another major benefit: improved turnaround time. TAT in microbiology can be improved dramatically compared to the TAT in a traditional microbiology lab," declared Page. *(See sidebar on page 13.)*

Traditional Micro Lab

"In a traditional microbiology lab working from 8 am to 4 pm, it typically takes a day or two to do the primary culture, depending on when the specimen arrived; potentially a day to do the subculture; a day to do the pathogen ID by traditional methods; and then another day for antibiotic susceptibility," she noted. "Thus, the total TAT for a positive specimen in a traditional system could be four to five days. Or, with a complex organism, it could take even longer to produce a final result.

"But now we have automated systems and our lab operates 24/7," observed Page. "Those factors reduce turnaround time and we also save time by having accurate incubation times. Further, we have significantly reduced the need to do a subculture. That means we can go directly to pathogen ID and susceptibility testing from the primary culture plate. That can save up to two or three days, supporting more rapid patient treatment."

Page acknowledged that the microbiology laboratory operates much differently today because of the use of Lean and automation to streamline workflows. "So many of our processes are different from how we handled specimens in early 2013," she said. "At that time, we did batch processing, manual labeling of media, and mostly manual plating.

"Formerly, there were wide swings in workload, and the average elapsed time to process a specimen from the time it was received in the lab was 180 minutes," she recalled. "A significant amount of rework and photocopying took place every day.

"Compare that to how we handle specimens now," continued Page. "We have single-piece flow with automated plate labeling and positive specimen identifica-

tion. Throughout the day, workloads have been leveled and the average elapsed time to process a specimen fell to 56 minutes. There was a huge reduction in duplication and rework. The net result was a 69% reduction in process lead time."

The new workflow and automation has benefited the lab staff as well. "Now we schedule the right number of people for the volume of specimens arriving in the lab," stated Page. "That has made a huge difference because no longer is one person overwhelmed by incoming specimens. Staffing matches demand, which has improved our lead time. For example, from the arrival of an unaccessioned specimen in the microbiology lab to being inoculated used to take about three hours. Now, with automation and the other changes we made, it takes less than one hour, saving two hours of turnaround time.

Dashboard Management

"One more advantage of the BD Kiestra system is the ability to manage many aspects of testing in real time via the dashboards and reports," she observed. "As an example, from these sources, we learned that 30% of our specimens arrive from midnight to 6 am every day.

"Using this information, we staggered our staffing to more precisely match incoming specimen volumes at given times of the day," noted Page. "Steady distribution of work improves TAT. Even with the longer incubation times required for chromogenic agars that we have implemented, we have realized faster TAT. For example, we saw reductions in TAT for MRSA by 7 hours; superficial wounds by 10 hours; urine testing by 5 hours; and VRE by 31 hours compared with a traditional microbiology lab without advanced automation.

"Error reduction has been equally impressive," continued Page, "especially as a result of single-piece flow in specimen processing.

"Another significant result was improved antibiotic stewardship," she stated. "This happened partly because we reduced the turnaround time and partly because the results are more accurate (through use of the MALDI-ToF analyzers)." TDR

—Joseph Burns

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Lean Had Major Role in Planning for Automation

"IT WAS IMPORTANT TO USE LEAN TO STREAMLINE WORKFLOW IN MICROBIOLOGY as we implemented the total lab automation project at DynaLIFEDx," stated Norma Page, the lab's Vice President of Clinical Operations. "To accomplish this, we used Lean approaches and tools to design the layout and the workflow. That required our team to change from the traditional 'batch mentality' to single piece flow in our specimen handling.

"As a first step, we built a mock microbiology lab before we got the new Kiestra automation," noted Page. "We did a cardboard mock-up of where all the equipment would go. We also matched the mock-up to the spaghetti diagrams that came from our value stream maps. We know that technologists hate making mistakes and so we wanted them to be successful. By having them build workspaces out of cardboard, not only was it fun, but it helped our technical staff be more confident about the changes that would be made.

"In the mock lab, we worked through different layouts and designs," she added. "For example, one day the single piece team was working on one option for a layout to see how it would look and function. We discussed an idea about a conveyor system. Several variants to this idea were tried in the mock-up lab and it was determined that they all fell short of required performance. This helped us avoid purchasing and installing equipment that was not going to succeed."