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White Paper

Successfully Automating the Microbiology Laboratory

Validation of the Copan WASP: Walk-Away Specimen Processor

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Successfully Automating the Microbiology Laboratory

Validation of the Copan WASP: Walk-Away Specimen Processor

Executive Overview

In the United States, as in most of the Western world, there is an increasing shortage of skilled clinical laboratorians and laboratory floor space. Alverno Clinical Laboratories (PCL Alverno), a leading reference laboratory with over 750 tests, launched an aggressive campaign in 2013 to improve our laboratory workflow via a comprehensive approach that focuses on people, processes, and technology. For example, our team has adopted Lean practices to root out hidden waste and implemented automation technologies across the spectrum of pre-analytical, analytical, and post-analytical processes.

The introduction of the Copan WASP®: Walk-Away Specimen Processor gave our organization the opportunity to apply automation to labor-intensive specimen-preparation activities. As part of a pre-analytical workflow assessment, we conducted a series of studies to measure the precision of the WASP processor and compare results from the WASP instrument to those achieved using manual methods. A method comparison study conducted in the first half of 2013 showed that the WASP system outperformed manual streaking processes in a majority of cases by delivering more isolated colonies.

The validation program confirmed that our two Copan WASP systems met, and in many cases exceeded, expectations in terms of precision and comparison with manual processes.

Successfully Automating the Microbiology Laboratory: Validation of the Copan WASP: Walk-Away Specimen Processor

"We are very impressed with the Copan WASP. It helps us standardize pre-analytical processes and offers a level of versatility that is very important to our future growth."

James Clark
Microbiology Department Manager
PCL Alverno

Introduction

PCL Alverno validated the Copan WASP: Walk-Away Specimen Processor, part of the Siemens Microbiology Automation Solution, by comparing WASP results to manual methods for clinical specimen types selected for automation. This paper explains the validation process and results.

PCL Alverno is a full-service, community-based medical laboratory offering more than 750 tests in both clinical and anatomic pathology. Founded in 1999, PCL Alverno is the core lab for two hospital systems (with a total of 25 hospitals) in the Hammond, Indiana, area and provides outreach services to more than 1000 physician offices. A 24/7 operation, our lab has a comprehensive microbiology department covering all aspects of bacteriology, mycology, mycobacteriology, parasitology, and some basic virology immunoassay tests. Alverno employees describe the laboratory as a highly reliable scientific organization building a culture of service.

Like every organization in the healthcare industry, PCL Alverno is challenged to provide high-quality services at competitive prices. Healthcare costs are under pressure across the board, and labs often play an important role in controlling costs by helping to speed diagnoses, which in turn can help to reduce the length of hospital stays and, in some cases, prevent admissions altogether.

More than ever, labs must make more-efficient use of resources, including real estate, equipment, and, most importantly, personnel. However, a well-documented and growing labor shortage is making it difficult to find and retain skilled personnel. In 2010, the American Society for Clinical Pathology (ASCP) put the average age of the laboratory workforce at 49.2 years, up from 43.6 years in 2006.[1] The potential gap created by impending retirements is made worse by two additional factors: Labs need to hire 12,000 employees per year to keep pace with the growing volume of tests ordered, but only 5000 lab professionals graduate annually. What's more, about 70% of lab-technician education programs closed between 1970 and 2007.[2] In the face of these challenges, our organization must look for ways to streamline manual workflows.

PCL Alverno is expanding our outreach business, increasing the volume of tests performed. Because lab floor space is at a premium, we need to find ways to increase throughput without expanding physical space or significantly increasing staff.

1. American Society for Clinical Pathology [Internet]. ASCP Announces Clinton Global Initiative Commitment to Fill Healthcare Jobs in New York; 2012 Feb 23 [cited 2013 Aug 15]. Available from: http://www.ascp.org/Newsroom/ASCP-Announces-Clinton-Global-Initiative-Commitment-to-Fill-Healthcare-Jobs-in-New-York.html
2. Times Union [Internet]. Crowley, Cathleen F. High Demand, Low Supply; 2012 Sep 5 [cited 2013 Aug 15]. Available from: http://www.timesunion.com/business/article/High-demand-low-supply-3839665.php.

A Plan for Automation

Alverno has undertaken a thorough, comprehensive automation program. Through a range of process-automation approaches and supporting technologies, we are focused on improving accuracy, workflow, and, ultimately, patient care.

Standardization through automation is key to achieving these goals. When tasks are performed manually, even by the most seasoned lab personnel, there is always a certain level of variability in technique. Consider a basic culture technique such as streaking, which is the basis for microbiology work. The same individual can streak the same culture multiple times and end up with varying numbers and quality of isolation. When you multiply that by the person-to-person variability across all lab technicians, it can lead to longer turnaround times. This is particularly true when restreaking is required in order to obtain the necessary levels of isolation and volume of material.

Working in partnership with Siemens, key members of our PCL Alverno team performed a Lean analysis of our lab workflows to identify opportunities to reduce time and waste in pre-analytical, analytical, and post-analytical processes. Microbiology is an important target area for improvement, because its processes have historically been very manual and prone to inefficiency as technicians move from one station to another to perform different functions. Prior to implementing recommended personnel and process improvements, our organization invested in microbiology-testing systems and currently has 10 Siemens MicroScan® WalkAway® Systems in its laboratory.

Relatively recent advances in technology have allowed PCL Alverno to focus on automation at the pre-analytical process phase. Here the goal is to automate the processing of culture specimens as they enter the facility. We considered several technology options and ultimately selected the Copan WASP: Walk-Away Specimen Processor due to its range of features and versatility. For example, the WASP system has an extensive portfolio of classic streak patterns but also offers the option to build custom programs that match PCL Alverno's specific requirements. It uses wire loops, which lab personnel believe provide a more-standard spreading of bacteria than disposable plastic implements. Additionally, the WASP system is able to fully automate the inoculation of enrichment broths and preparation of slides for gram stain.

Validation

Our organization prepared for the WASP system implementation by conducting extensive personnel training, documenting new procedures, and updating quality-control practices. Most importantly, we conducted a validation of the WASP system under real-world lab conditions. Our study looked at two key areas: precision of the WASP system and comparison of the WASP processor to manual methods. It was important to understand both colony count and availability of isolated colonies. Over the course of a month, many studies were run to validate a range of common pre-analytical lab tasks and tests. (Details about the validation are covered in the following subsections of this report.)

Precision Studies

First and foremost, we wanted to confirm the accuracy of the two WASP systems. We prepared and tested 10 replicates of four known urine samples with concentration levels of less than 10,000; 10,000 to 50,000; 50,000 to 100,000; and greater than 100,000 cfu/cc. The acceptability criterion was set at two standard deviations for any data point.

Second, we conducted an instrument-to-instrument comparison of our two WASP systems to determine if they provided equivalent levels of performance and accuracy.

Finally, we looked at the potential for cross-contamination by running a heavily inoculated specimen followed by a sterile specimen with every instrument and loop scenario, increasing levels of spiked DBP in normal serum pools.

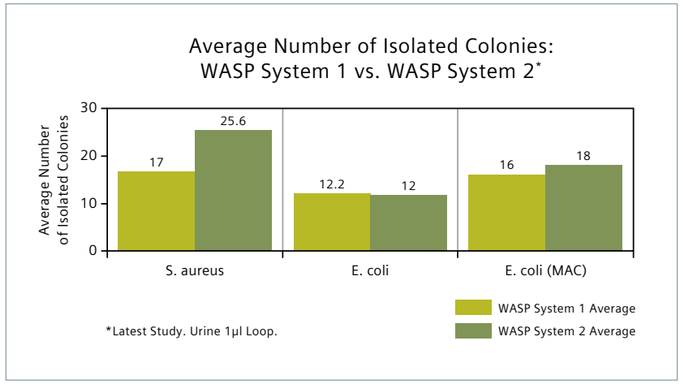
Findings

The known-urine-sample study confirmed the accuracy of the WASP instrument. All runs and colony counts were within two standard deviations of the expected results.

The comparison of isolated colonies between the two WASP systems showed slightly more growth on one of the instruments. However, as indicated in Figure 1, the discrepancy was not statistically significant, and no medical decision points would be changed.

Successfully Automating the Microbiology Laboratory: Validation of the Copan WASP: Walk-Away Specimen Processor

Figure 1: Instrument-to-Instrument Method Comparison Finds No Statistically Significant Difference



The carryover study was completed with satisfactory results. No carryover was found.

Method Comparison Studies

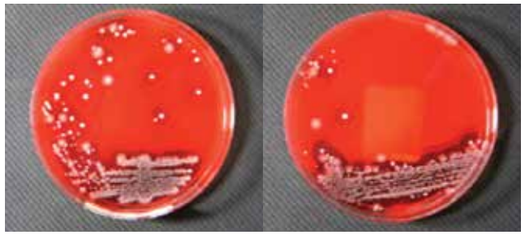
The method comparison studies evaluated the resulting number of isolated colonies for manual streaking versus the WASP system. Wound, body fluid, cerebrospinal fluid, urine, fecal, and sputum cultures were all studied, in many cases using more than one growth medium.

Findings

In all cases, the WASP system met our expectations. In the majority of cases, the WASP system outperformed manual streaking processes by delivering more isolated colonies. Figure 2 shows just one example of the superior WASP system results with a wound culture in two different mediums.

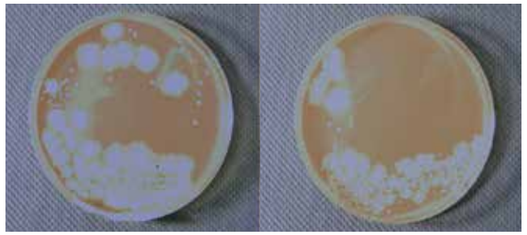
Figure 2: WASP System vs. Manual Method—Wound Culture (WND)

Method Comparison—WND (BAP)



WASP Manual

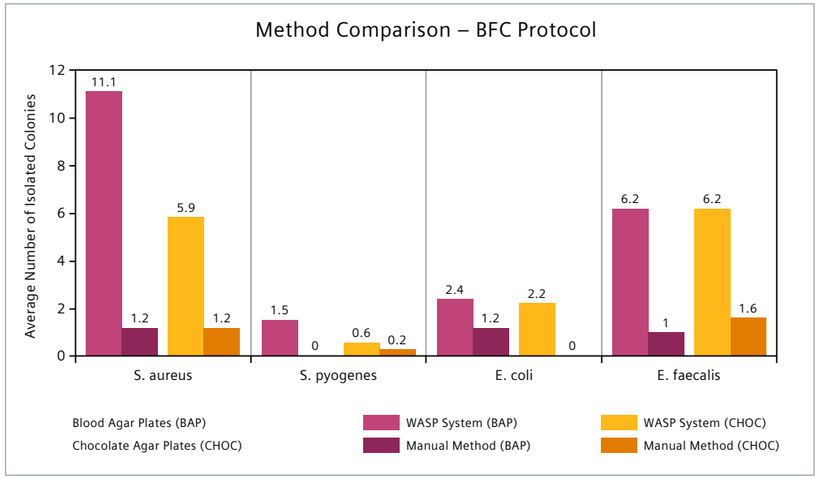
Method Comparison—WND (CHOC)



WASP Manual

Similar results were observed with other samples, as summarized in the charts in Figures 3 and 4. The results of the WASP system are indicated by the left bar and manual methods by the right bar of each column.

Figure 3: WASP System vs. Manual Method—Body Fluid Culture (BFC)



We also compared the WASP system to manual methods for enrichment broth inoculation and gram stain slide preparation. We found the results to be acceptable in both cases.

Figure 4: WASP System vs. Manual Method—Cerebrospinal Fluid (CSF)

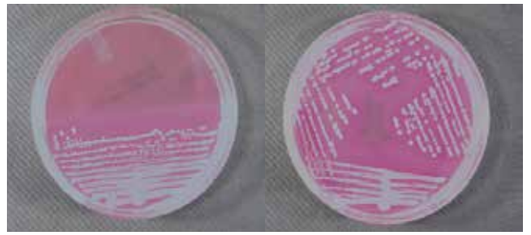
Lessons Learned

The value of the validation process was highlighted by two unexpected results, both of which led us to fine-tune the processes we now follow for the WASP system.

In the urine method comparison, our technicians observed that the blood agar plates (BAP) were only being inoculated halfway down. In consultation with Copan, we determined that a likely cause was insufficient loop depth related to drying/shrinking of the media on the plate. We found that a minor protocol adjustment to use a depth of 1 mm and a slight alteration of the urine dipping quota resulted in significant improvements. These changes were incorporated into our standard WASP system process. Since then, no further streaking issues have been observed on our blood agar plates. This is a testament to the flexibility of the WASP system and how easily it can accommodate different protocols, depending on specific needs.

Figure 5: Comparison of sterilization and nonsterilization

Sterilization After First Inoculum versus Nonsterilization



Sterilization Nonsterilization

We also found that eliminating the sterilization step and associated wait time for the loop to cool down improves workflow efficiency and reduces fecal-sample processing times.

In the fecal method comparison, the WASP system initially did not perform at the same level as manual streaking. A protocol change was made that eliminated the sterilization process after the first inoculum, which resolved the issue. Figure 5 illustrates the difference between sterilization and nonsterilization after first inoculum using the WASP system.

Conclusion and Next Steps

As of June 2013, PCL Alverno has two Copan WASP systems fully operational and is running all outreach specimens on the instruments. Physician offices, skilled nursing facilities, and other outreach customers use the Copan ESwab liquid-based, multi-purpose collection system and urine tubes, as well as the specialized collection transport containers, which further streamlines specimen processing using the WASP system.

The validation study and current day-to-day operations confirm that the Copan WASP: Walk-Away Specimen Processors meet, and in many cases exceed, our expectations in terms of precision and comparison with manual processes. The WASP systems are automating and standardizing labor-intensive, pre-analytical specimen-management tasks, which not only speeds throughput but also has allowed our technicians to assist with other, higher-value lab tasks. The productivity improvements from the WASP system provide a throughput boost without having to increase staff or floor space. In the future, we would like to conduct additional studies to quantify the significant time and/or material savings from the WASP system implementation.

As a next step in our ongoing continuous-improvement efforts, our organization plans to implement the Bruker MALDI Biotyper System for fast, accurate, and cost-effective microorganism identification. Furthermore, we will implement the Copan WASPLab System, a bar-code-driven conveyor system with smart incubators and digital culture readout.

An Overview of PCL Alverno's Lab Technology

As a designated Siemens Microbiology Innovation Center (MIC), PCL Alverno serves as a reference site for other laboratories interested in exploring the Siemens Microbiology Automation Solution.

PCL Alverno is currently using:

- Two Copan WASP: Walk-Away Specimen Processor Systems that automate pre-analytic specimen processing
- Ten Siemens MicroScan WalkAway *plus* Microbiology Systems that deliver comprehensive microbiology testing capabilities
- Siemens LabPro Connect software: a networking solution that enables technologists to manage nearly all aspects of specimen processing and reporting without leaving their benches

PCL Alverno plans to implement the Bruker MALDI Biotyper System for fast, accurate, and cost-effective microorganism identification and the Copan WASPLab System, a bar-code-driven specimen-processing system with smart incubators and digital culture readout.

For more information about PCL Alverno, please visit http://www.alvernoclinicallabs.org/.

To learn more about Siemens Microbiology Solutions, please visit www.usa.siemens.com/microbiology.