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In-House Pipette Calibration: The Lean Way

Sorenson Genomics of Salt Lake City focuses on DNA testing, with its expertise in quality, high-throughput testing that spans several diverse business units and highly accredited laboratories. The company's Identigene division offers direct-to-consumer paternity and relationship DNA testing, while the Sorenson Forensics division provides DNA-related services to law enforcement for a range of needs. Patient samples for pharmacogenetic and STD testing and tumor biopsies are processed by the company's clinical laboratories. Each division of Sorenson Genomics operates nationwide as well as internationally. The company recently conducted a detailed internal audit of its pipette calibration processes, which suggested that bringing the process in-house would result in savings of both time and money and improve reliability and record-keeping.

"A good portion of our testing involves liquid handling," explained Breeann Bryan, Identigene's laboratory manager. As with any lab, maintaining equipment—from the most sophisticated instruments to ubiquitous handheld tools—is crucial. Proper maintenance of liquid handling equipment requires regular testing and calibration, which in turn ensures that Sorenson laboratories are delivering accurate test results—results on which life-changing decisions are based.

Sorenson is highly accredited, with certifications from ISO 17025, the College of American Pathologists/Clinical Laboratory Improvement Amendments, American Society of Crime Lab Directors, the American Association of Blood Banks and the New York State Department of Health. For certified and regulated labs, instruments such as handheld pipettes need to be calibrated regularly and the process needs to be both transparent and documented. The company was sending many of its pipettes to an external service provider for calibration. But after undertaking a Lean Six Sigma project that examined this practice, the company found a way to transform what was once a lengthy, wasteful and burdensome process into one that is both cost- and time-efficient.

The Lean Project

When Bryan became Identigene's lab manager—and Sorenson's QC supervisor—each of six different labs had its own sets of pipettes. The higher-volume pipettes were gravimetrically calibrated in-house. But gravimetric testing becomes increasingly problematic with lower-volume calibrations, particularly those of less than 2 μ L. These lower-volume pipettes were therefore being sent to an external service provider.

Bryan and Sorenson's lead quality control technician, Natalie Taylor, both certified in Lean Six Sigma, began discussing all that was involved in outsourcing pipette calibrations. "The more we talked about it, the more I started picking up on things that were very wasteful," Bryan explained. This included the time spent on the plentiful individual steps required in sending out pipettes, which required cleaning, decontamination, packing and shipping, as well as generating all necessary paperwork.

Costs were incurred for shipping and the calibration service, as well as for maintaining a second set of pipettes to use in place of those out for calibration. "So we decided we should make a project out of it, using the principles and tools of Lean," she said.

"The foundational principle with Lean is that you're looking at your process and trying to eliminate waste to make the process flow more efficiently," says Bryan. "So we set out to collect data to show how calibrating all pipettes in-house would simplify our process and cut out waste. Doing so would be more cost-efficient and solidify our commitment to Lean principles." Sorenson expected that calibrating both the low- and high-volume pipettes in-house would consolidate and streamline the process, and that uncertainties about pipette damage caused by shipping and delays at the service provider would be eliminated.

Taylor was familiar with Artel and its benchtop PCS Pipette Calibration System, which can be used right where pipettes are used. "I liked working with the PCS because I trusted its accuracy at even very low volumes and because it was easy to use. It recorded data, calculated results and produced reports automatically," Taylor said. She suggested that Sorenson use the PCS instrument as a comparison alternative to outsourcing in its project (see *Figure 1*).

To send it out?

Sorenson would send pipettes used for volumes less than 2 μ L out for calibration every six months. This was done in batches to minimize shipping and administrative outlays, with a second set of pipettes



Figure 1 – Artel PCS Pipette Calibration System.

maintained and rotated in to allow work to continue. Each rotation cycle required a great deal of time and coordination (locating/gathering, logging, cleaning/disinfecting, packing, shipping, tracking, waiting, and finally all required steps in receiving the pipettes back into the lab's workflow). A detailed Lean evaluation of the time spent on each step in the process was the first item to address, followed by an analysis and identification of the "wasted" time.

The team determined that, in a given year, 10 batches of pipettes were sent out, requiring a total of 30 hours of a QC technician's time and 22 hours in the shipping department. Outsourcing costs were running about \$5000 per year, including packaging, shipping and vendor fees.

The 52 logged hours and direct costs do not include significant amounts of additional time the Sorenson team had to spend regularly due to irregularities encountered with the calibration service provider. Often, Sorenson's QA group needed to follow up several times with the service provider as the pipettes were returned without proper calibration certificates. In other cases, additional time was required when the service provider would not return pipettes on the expected date but instead several weeks later. This resulted in delayed lab work and logistics, as the next batch of pipettes could not be sent out as scheduled, and further requiring all subsequent batches of pipettes to be rescheduled.

Delays in receiving calibration certificates on time from the service provider disrupts documentation storage and can lead to complications during audits, while frequent rescheduling of shipments of pipettes causes interruptions to the daily laboratory work.

Recurring challenges with calibration service providers required Sorenson to identify, qualify and test new vendors on a regular basis until a trusting relationship could be established.

All of the above-listed time commitments are significant, but are not easily reflected in the immediate cost for an outsourced pipette calibration since they are not part of the default workflow.

Bryan was also concerned about the pipettes being jostled and subjected to varying temperatures and barometric pressures during transit. There was little doubt that the pipettes were properly calibrated and conditioned when they left the service provider. However, she just had to assume that they were still within specifications when they arrived: there was no way to know what effect the return trip may have had, as the lab was not in a position to verify the calibration.

Bring it in (-house)

Conducting pipette calibrations in-house would immediately eliminate the time spent shipping, receiving and waiting for the pipettes and, most importantly, the need for outside vendors. The QA software would indicate the pipettes due for calibration, and these could be calibrated promptly. As soon as the QA database could be updated with the new calibration status, the pipettes could be returned to the labs for continued use.

Because the laboratory's entire pipette inventory and calibration plans could be stored in advance in the Artel PCS software database, a calibration would be started by simply scanning the pipette's barcode.

Following the PCS screen's step-by-step plan, which involves measuring the absorbance of two different dye solutions, a pipette calibration with 30 data points (three volumes, 10 replicates each) could be completed in less than five minutes. A detailed report is generated and a calibration label for the pipette is printed. This further reduces all of the post-calibration administrative tasks. For accredited facilities like the Sorenson family of laboratories, it is critical that all actions are auditable, with electronic signatures captured and data stored in secure databases. This functionality, built directly into the PCS software, provides important documentation for 21 CFR Part 11-compliant labs.

The economic cost/benefit analysis conducted by the QC team estimated that an Artel PCS instrument would pay for itself in less than three years. In addition, in-house calibration would afford other, less easily quantifiable benefits such as reduced disruption for the labs due to missing certificates or delayed return shipments and peace of mind as the potential hazards of shipping were eliminated. After the findings were presented to Sorenson's management, the company purchased and began using an Artel PCS.

Implementation

The QC staff found using the PCS to be faster and easier than either outsourcing or gravimetric calibration, and they now use the instrument for all 50 pipettes up to 30- μ L volumes, some of which were previously calibrated gravimetrically, because the photometric process of the PCS is "less subject to fluctuations if you're having an unusually dry or humid day," according to technician D.J. Nelson.

Before purchasing the PCS, Bryan estimated a total annual in-house calibration time for the 29 pipettes with <2 μ L nominal volume was between 63.5 and 90.5 hours. After using it for over a year, Bryan estimates that Sorenson actually only spent 33 to 38 hours to calibrate its 50 pipettes with <30 μ L nominal volume in-house. So the company is well ahead of schedule to recoup the capital investment. Additionally, Sorenson has since sold or donated many of its pipettes because it is no longer necessary to maintain a complete spare set. With a smaller pipette inventory, calibration time requirements are even further reduced. "After all," Bryan said, "pipettes are tools which need to be used to generate revenue. Any unused pipettes, or pipettes off-site for calibration, cannot be used for that purpose."

Sorenson has already seen the financial benefits of bringing all pipette calibrations in-house. With the PCS on-site, the lab can test a pipette at any point in time, whenever there is reason for doubting its correct performance, e.g., after it has suffered a drop. Instead of sending pipettes out in batches for calibration, the company now has a single-piece flow of pipettes through calibration, allowing for faster turnaround times and smaller inventories. Most importantly, greater control over its lab instruments has reinforced Sorenson Genomics' confidence in the critical test results that its laboratories produce every day.

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