Application of the Toyota Production System Improves Core Laboratory Operations

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Abstract

To meet the increased clinical demands of our hospital expansion, improve quality, and reduce costs, our tertiary care, pediatric core laboratory used the Toyota Production System lean processing to reorganize our 24-hour, 7 d/wk core laboratory. A 4-month, consultant-driven process removed waste, led to a physical reset of the space to match the work flow, and developed a work cell for our random access analyzers. In addition, visual controls, single piece flow, standard work, and “5S” were instituted.

The new design met our goals as reflected by achieving and maintaining improved turnaround time (TAT; mean for creatinine reduced from 54 to 23 minutes) with increased testing volume (20%), monetary savings (4 full-time equivalents), decreased variability in TAT, and better space utilization (25% gain). The project had the unanticipated consequence of eliminating STAT testing because our in-laboratory TAT for routine testing was less than our prior STAT turnaround goal.

The viability of this approach is demonstrated by sustained gains and further PDCA (Plan, Do, Check, Act) improvements during the 4 years after completion of the project.

The clinical laboratory, like the US health care industry in general, is under pressure to improve quality and provide test results faster while decreasing costs. This is an ever-increasing and difficult task owing to rising test volume, increased test complexity, space constraints, and shortage of medical technologists. Our laboratory was faced with a similar mandate but also saw pressures to provide better service to a growing emergency department patient load, to accommodate the addition of 40 new hospital beds, and to provide not only faster results but also improved quality.

A bottleneck for our multidisciplinary laboratory was its central processing area and core laboratory (routine chemistry, hematology, coagulation, and urinalysis), which stood to be most affected by this increased demand and most susceptible to making mistakes under pressure. From past experience, our usual response to increased volume was to add technologists to the core laboratory; our core laboratory space would not easily accommodate more technologists. Moreover, our core service consisted of a large number of technologists trained to perform a broad spectrum of cross-disciplinary testing, predisposing to a lack of standardization. We sought to address these issues by the application of the Toyota Production System management principles.1 This system has been proposed as one that, if applied to health care, could reduce errors and waste.2 The Toyota Production System results in “lean” manufacturing, a system by which value to the customer is achieved with less work expenditure.

In The Toyota Way, production principles are outlined by Liker.2 Table I.1 These principles embrace the totality of the Toyota management style and go far beyond the transfer of lean manufacturing principles into the clinical laboratory. Some of these principles are just beginning to be
applied to hospitals,3–5 a few clinical laboratories,6 and, more recently, anatomic pathology.7–9 We used a consulting firm (ValuMetrix, Ortho-Clinical Diagnostics, Raritan, NJ) with experience in clinical laboratory operations to conduct a lean “overhaul” of our core laboratory. Selection of this method coincided with our hospital’s adoption of similar methods as a new management philosophy; we, therefore, did not investigate other methods for our work. This report covers the project applied to our core laboratory and provides outcome measures 4 years after completion.

Materials and Methods

This project was accomplished in Seattle Children’s Hospital (Seattle, WA), a tertiary care pediatric facility and a clinical affiliate of the University of Washington School of Medicine, Seattle. Now, our 250-bed hospital has an 11,000-square-foot clinical laboratory staffed by 130 full-time equivalents (FTEs), including 10 doctoral staff, and has full services with the exception of a blood bank laboratory. Our entire laboratory performs 850,000 billable tests annually. A 24-h/d, 7-d/wk, 2,150-sq-ft core laboratory is staffed by 50 FTEs and encompasses specimen receipt and processing, blood product dispensing, automated chemistry, blood gas analysis, coagulation, hematology, urinalysis, selected therapeutic drug monitoring, and individual manual tests such as pregnancy tests and heterophil antibodies. While specimen processing is staffed primarily by laboratory assistants, the core is staffed by medical technologists. The hospital has a high penetrance of point-of-care testing for blood gases and electrolytes administered by the laboratory, but outside this core environment.

The pre-lean instrumentation layout is shown in Figure 1. All technologists were cross-trained for testing and rotated through those positions before the project. Approximately 70% of the samples arriving in the laboratory were obtained by nursing staff and sent by pneumatic tube into the core laboratory. Outpatient specimens were delivered to a receiving window at the processing area. Computerized physician order entry preceded this project by approximately 6 months. Autoverification and robotic specimen handling were not in place.

After visiting 1 local laboratory that had successfully instituted lean principles, we contracted for a several day assessment by a consultant from ValuMetrix. This assessment was congruent with our own intuition that these principles would likely result in better quality and cost savings. We did not attempt other solutions to this impending problem before this decision. We employed a consultant from ValuMetrix for a 4-month project to lead and coach a team of 6 “lean”
neophytes, which included the core team supervisor, phlebotomy supervisor, laboratory quality manager, evening shift technologist, billing supervisor, and a non–laboratory professional from the hospital education and training department.

This group commandeered our conference room for the duration of the project, and the project encumbered all of the 6 team members’ time. The project progressed through a series of steps outlined by ValuMetrix, although the principles and many of the techniques have been applied by others.10 In addition to guiding the 6 team members, a portion of the ValuMetrix philosophy was to train each of the team members to repeat a similar project elsewhere in the laboratory using the same tools.

The project’s aim was the elimination of waste. The team members instituted changes driven by data collected during direct observation and measurement of the work (eg, stop watches and video analysis). Process redesigns were proposed to the core technologists at weekly meetings and to the laboratory and hospital administrators at additional weekly briefings. After input, a redesign plan was formulated, implemented, and monitored by continued measurements and audits. This project was accomplished with a simultaneous initiative in the phlebotomy area that will be reported separately.

The new work flow required a physical reset (remodel) of the core laboratory, an unanticipated factor that delayed the overall completion of the project, increased the cost, and contributed to increased stress owing to the necessity to construct in the middle of an operating laboratory. Construction was further complicated by the rapid time line and having a variety of construction trades and vendors required. After the construction of the work cell, we had an extensive training period to the new standard work (the flow of specimens and people in the core laboratory) and the reasons why each change was implemented.

In addition to the metrics obtained to design the core laboratory, we collected data on test turnaround time (TAT) and corrected reports. TAT data were extracted from our laboratory information system and then adjusted to remove outliers associated with add-on tests and those requiring pathologist review.

### Results

Three major changes to our core laboratory resulted from this project: institution of “5S,” building an automated work cell, and establishment of standard work.

An integral component of this work was “5S-ing,” outlined in Table 2. The overriding result of 5S was to allow everyone to visualize the work area optimally by removing unnecessary equipment and supplies and transferring those needed to a place where they could be seen. Maintaining such a system in a shared workspace remains a challenge requiring continuous audits and visual controls.

The work cell was based on principles used in manufacturing.11 In our case, we physically colocated our random access analyzers into a linear array that matched the flow of specimens from the processing area through analysis. The technologist in the cell moved sequentially to the various analyzers. Specimens were loaded, and results from the previous specimens were verified before moving to the next instrument. When optimized, this resulted in a continuous flow for specimens and the operator, which achieved efficiency in movement and time.

The new physical layout is depicted in Figure 1 and Figure 2, along with the changes in the technologists’ work flow. The technologists walking distance and specimen travel distance were markedly reduced. The physical reset enabled one technologist to load samples and results from a chemistry analyzer, coagulation analyzer, and hematology analyzer. To accomplish these tasks, parameters were set so that a technologist’s cycle time through the instruments on the day shift was 12 minutes performed by 1 technologist. High demand could be accommodated by 2 technologists, in tandem, cycling through the cell in a load-verify-load-verify sequence.

**Standard work** prescribed the detailed steps to the operation of the work cell to achieve consistent work while minimizing wait time. Standard work was well received by some technologists, while others thought that existing practices were better. The more recently hired technologists were quicker to embrace the standard work, and, with time, it became more accepted. We developed a less rigid definition of standard work that would neither produce errors nor change the work flow of the cell. This softened approach was more acceptable to staff. In retrospect, we found it advantageous to restrict standard work to elements that made a difference in operations.

A variety of lean principles were used to maximize the efficiency of the work cell Table 3. The cycle time allowed the work cell in the core laboratory to receive samples in a single-piece flow or standardized small batches. Specimens

### Table 2

<table>
<thead>
<tr>
<th>5S Technique</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sort</td>
<td>Removal of all unnecessary materials and paper</td>
</tr>
<tr>
<td>Simplify</td>
<td>Taping workplace with labels for all objects, all objects in place, visual clue to missing or misplaced items needed for work</td>
</tr>
<tr>
<td>Sweep</td>
<td>General cleaning, especially where extraneous materials were stored</td>
</tr>
<tr>
<td>Standardize</td>
<td>Wrote standard procedures, and trained to detailed standard work</td>
</tr>
<tr>
<td>Sustain</td>
<td>Reinforced use of standard work via audits</td>
</tr>
</tbody>
</table>
not needing to be divided into aliquots went from the central processing bench directly to the cell for centrifuging. Other technologists could enter the core laboratory for specialized coagulation testing on the reserve instrument. Technologists rotating in the cell also made peripheral smears and passed them through to the manual differential area. All phone calls, dilution, sample problems, and restocking, which previously interrupted the technologist, were handled by a person outside the cell so that a technologist in the cell could maintain the cycle time unimpeded. Duplicated backup instruments were incorporated into the cell, providing continuous operation in case of malfunction.

It would be too complex to monitor, on a daily basis, the time-motion studies used to establish the necessary changes, so daily TAT was used as a surrogate performance measure. The measures chosen encompassed several representative but different areas of the core laboratory, including the work cell as outlined in Table 4. The mean TAT decreased by more than 50% for all except the prothrombin time. While mean or median TATs may be important, a much more useful measure was the percentage of specimens with results available within a specific time goal. Deviations for the specimens exceeding the defined limit of 1 hour were investigated in an attempt to understand why the theoretical performance of the cell was not achieved. Follow-up of outliers and eliminating their causes reduced not just the mean TAT, but more dramatically, the variability as depicted using creatinine measurement as a monitor for chemistry testing Figure 3. This reduction in variability has enabled the laboratory to completely eliminate prioritization of STAT testing (which before this project was promised with a 1-hour TAT). Now, more than 95% of our core tests, whether routine or STAT, are turned out in less than 1 hour. The daily audit system was a positive outcome of the project.

Several other objective measures demonstrated additional improvements without sacrificing quality. Efficiency and productivity of staff improved by 20.3%, ie, the same number of FTEs performed 20% more tests with improved

Table 3
Toyota Production Principles Used

<table>
<thead>
<tr>
<th>Principle</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visual management control</td>
<td>Places for items labeled, cabinet doors removed to see supplies; cell pathway visible to all; arriving specimens are seen</td>
</tr>
<tr>
<td>One-piece flow</td>
<td>One specimen (or a batch of up to 3) done at a time regardless of the number of specimens waiting</td>
</tr>
<tr>
<td>First in, first out for specimens</td>
<td>Elimination of trying to decide which gets priority</td>
</tr>
<tr>
<td>Balanced distribution of work</td>
<td>Staffing adjusted to meet peak demands; balancing work to the technologists so each has equitable volume of work</td>
</tr>
<tr>
<td>Task time paced</td>
<td>Cell cycle time set to accommodate batch size and the time it took to perform the tasks during the circuit</td>
</tr>
<tr>
<td>Standard work</td>
<td>Every step specified to be performed one and only one way</td>
</tr>
<tr>
<td>Reliable methods</td>
<td>Consocringly developed, easy-to-follow procedures</td>
</tr>
<tr>
<td>Moving and standing operations</td>
<td>In specimen processing and the cell, the operating technologist is standing or moving</td>
</tr>
</tbody>
</table>
The laboratory avoided hiring 4.2 additional FTEs for new patient activity. In addition, the core laboratory footprint was reduced by 25%, creating new space for specialty laboratory expansion. Corrected reports as documented in our laboratory information system for this area of the laboratory were unchanged immediately after the project; they remained between 0.27% and 0.23%.

Our return on investment (ROI) was 24 months vs a projected ROI of 18 months; the increase above projection related to higher construction costs than initially projected. This ROI included the consultant, materials, and construction costs, but not the team members’ or managers’ hours. Labor reductions were achieved in part by reduced overtime and flex-time payments. The ROI did not include the cost avoidance of the technologists we anticipated hiring to meet the increased demand. We continue to benefit from the savings achieved with the project.

An unplanned activity not included in the aforementioned ROI was time for audits. For more than 6 months after implementation, members of the lean team and administrative and medical directors of the laboratory met daily for 30 minutes around an audit board to explore reasons why we were not meeting the theoretical goal. We made only small changes, but more important, we established a collaborative atmosphere, while jointly working with the technologists in the core laboratory, toward the common goal of quality improvement. We continue a virtual audit of the daily TAT and respond to exceptions to understand why deviations have occurred in order to institute corrective action.

The work cell and prescribed standard work for all constituted a huge change for a very experienced group of highly skilled technologists, and, at times, during the project and immediately afterward, emotions ran high. The responses and feelings of our technologists and colleagues were complex and necessitated a second project to address some of the issues. Outcomes of that workshop included more teaching on the fundamentals of the Toyota Production System and a visibility board to monitor the status of technologists, instruments, and patient activity. During a period of approximately 12 months, the technologists became more comfortable with the new work. One bench technologist elected early retirement. One member of the project team migrated to our hospital’s continuous performance improvement office as a charter member and worked on projects in other areas of the hospital. While many of us viewed our project as a success from the change management standpoint, our technologists suggest it was too much change too quickly.

Discussion
Clinical laboratories have been at the forefront of integrating managerial quality principles into their operations, the history of which is probably best seen by the increasing

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**Table 4**

<table>
<thead>
<tr>
<th>Test</th>
<th>Minimum</th>
<th>Median</th>
<th>Average</th>
<th>Maximum</th>
<th>% ≤60 min</th>
<th>% ≤80 min</th>
<th>No. of Tests</th>
<th>Baseline 2004 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Creatinine</td>
<td>12</td>
<td>21</td>
<td>23</td>
<td>73</td>
<td>99</td>
<td>100</td>
<td>104</td>
<td>71</td>
</tr>
<tr>
<td>CBC</td>
<td>3</td>
<td>9</td>
<td>15</td>
<td>102</td>
<td>99</td>
<td>99</td>
<td>175</td>
<td>87</td>
</tr>
<tr>
<td>Differential</td>
<td>3</td>
<td>30</td>
<td>30</td>
<td>197</td>
<td>94</td>
<td>95</td>
<td>115</td>
<td>69</td>
</tr>
<tr>
<td>Prothrombin time</td>
<td>13</td>
<td>21</td>
<td>24</td>
<td>71</td>
<td>96</td>
<td>100</td>
<td>25</td>
<td>88</td>
</tr>
<tr>
<td>Urinalysis</td>
<td>4</td>
<td>12</td>
<td>13</td>
<td>37</td>
<td>100</td>
<td>—</td>
<td>30</td>
<td>86</td>
</tr>
<tr>
<td>Ionized calcium</td>
<td>1</td>
<td>4</td>
<td>5</td>
<td>13</td>
<td>100</td>
<td>15</td>
<td>15</td>
<td>99</td>
</tr>
</tbody>
</table>

* For April 10, 2009, with a hospital census of 210. The original monitors were selected to measure 1 aspect of the core laboratory in and outside the work cell. Bold type indicates meeting the target results, and italics, failure. This display is posted in the laboratory and e-mailed to supervisors, the laboratory director, and pathologists daily.

† % ≤30 min for ionized calcium.

‡ % ≤40 min for ionized calcium.
requirements to institute quality systems in the College of American Pathologists’ laboratory accreditation process. While clinical laboratories have realized that they are not manufacturing plants, they have made the journey from quality control to quality assurance and now are pushing through quality improvement toward total quality management systems.

One managerial technique now being extended to health care is the Toyota Production System. Several medical centers are already publishing their successes with the institution of quality improvements in patient care using such techniques. Likewise, clinical laboratories and consulting industries are migrating these same attempts to improve quality in an increasingly complex system and at the same time reduce cost. One does not have to consult business journals to realize that US manufacturing has also embraced some of these philosophies in an attempt to remain competitive (or even viable), particularly as exemplified in the automotive industry. Because of the clinical laboratories’ leadership roles in quality innovation, it seems reasonable that they should be the “laboratory” for applying these techniques to health care. While the goals of our project were not so lofty, the results demonstrate success in one area of the laboratory and in one area of our medical center. The positive outcome of our project has stimulated ongoing applications of these techniques in other areas of our hospital. The success in our laboratory was one factor stimulating Seattle Children’s Hospital to adopt these techniques as its management system, now termed Continuous Performance Improvement. Our current goal in the laboratory and our hospital is to use this system to achieve quality improvement as reported by others.  

As shown in the “Results” section, our project was highly successful, not only in reducing recurrent costs but also in reducing variability in test TATs. This success, we believe, is based in part on the techniques used, particularly those that were more scientifically than politically based, an excellent team, and an enthusiastic and experienced consultant who forced each of the participants to fulfill his or her role. While it was easier in our organization to “attack” the entire process, it is possible as practiced by others, to break the mission into multiple smaller, discrete projects. In our case, such an approach would not have given us the insights or the organizational support to change the layout of the physical space.

This was a large project for a laboratory of our size, and we have reflected on how we might have achieved the same productivity with less investment. While SS techniques that bring order to the workplace have advantages, we do not think the use of SS alone would have produced a substantial increase in productivity to meet the realized 20% volume increase. Likewise, standard work might well have improved quality and reduced some rework; its implementation would not have given large gains. The instrumentation layout changes, the most disruptive to concurrent laboratory operations, alone could have produced substantial gains, but not without a detailed analysis of which tests should be in the work cell and the institution of new standard work to accommodate the altered layout. Moreover, the layout, owing to construction costs, was the most expensive part of the project. In retrospect, we cannot point to components of the project that would have produced a majority of the results for substantially less investment.

The concept of the work cell can be adapted to other laboratories. The more challenging aspects of the project involve application of other Toyota Production System principles to the function of the work cell and the flow of specimens throughout the laboratory. Those design principles should optimally be coupled with defined work and work that is related to time of performance. The long-term success of our project required considerable education around the fundamental principles and the experience of a consultant. With this learning, we have been able to apply these improvements to other sections of our laboratory with less expense and no consultants.

A key component of the lean process is single-piece rather than batch flow. In many areas of the laboratory, we still must operate with batch analysis, but for commonly ordered tests, particularly those on random access platforms, single-piece flow is a good match. One of the more difficult challenges for a technologist was to no longer prioritize emergency department and intensive care unit samples, but to accept the samples in the order they were received. With time, the staff developed trust in their ability to produce the results without having to change prioritization and interrupt flow.

We failed to document a reduction in errors because we did not measure errors in a meaningful way before the changes were instituted. While we track many errors in the laboratory for our own metrics and incident report system, we found that we were tracking so many different indicators it was difficult to pick out which was most meaningful and, hence, useful. Moreover, our error measurement systems did not meet the rigor needed to support scientific documentation owing to reporting biases.

Before this project, we had the impression of an increasing number of errors and increasing customization of work by individual technologists; many of these reached the medical director. Corrected report analysis was diluted by many clerical additions rather than errors such as specimen mix-ups and analytic failures. Our hospital incident reporting system combined all reported laboratory errors from all sections of the laboratory, making it less useful to measure effects. We have been careful for the life of the project to retain the same TAT measurement method but have made alterations in collecting longitudinal quality data. While we did not document measured error reduction, we continue...
to believe it is a by-product (or primary product, depending on one’s focus) of this type of work. The power of the lean method to reduce errors was nicely shown by Zarbo et al13 with a two-thirds reduction in histology misidentification while achieving a 125% increase in throughput in the histology laboratory. In retrospect, we should have had more robust measures of quality for this project.

While the Toyota Production System has as a foundational principle continued improvement, we have been slow to make additional changes in our core laboratory, even though we have identified additional areas for improvement. Part of our hesitation was a desire to reach stability within the current design and to gain experience for the technologists using this new system. As demonstrated in Figure 3, we had a longitudinal decrease in TATs and decreased variability without substantial additional changes. The length of time required to train the staff in new work methods and stabilize processes was surprising, but nevertheless, we have reached a stable environment that is now amenable to additional improvements. During the course of more than 4 years, we have successfully replaced the chemistry and hematology analyzers in the work cell.

The concept of the physical space being aligned with the flow of work is the basis for a work cell. Raab et al8 nicely demonstrated a change in process flow in the histology laboratory without having to resort to remodel. The work cell in the clinical laboratory has demands not seen in some industries. For example, in a 24-h/d, 7-d/wk operation, instrument maintenance and repair must be accomplished while the cell is fully functioning. Since the laboratory may not govern when specimens arrive, the cell has to accommodate varying demand. This inconstant flow of specimens complicates having only one set of standard work for all hours of operations. Four years after this project, we are examining what our next goals should be, and elimination of variation seems to emerge as a major step to reduce errors.

This initiative was not easy. First, it required temporarily removing 6 staff members from the work pool and backfilling their roles for more than 16 weeks. While we had not anticipated as much construction, once the design became more visible, it was clear that we would have the maximum improvement if we invested in changes to the physical layout. One of our greatest concerns by juxtaposing our instruments closer together was that of heat generation. That became a reality in the summer months and required additional cooling in this area of the laboratory. Moving the pneumatic tube system required outside engineers. Rapid change and adaptation on the part of a large cadre of technologists resulted in considerable unhappiness and job dissatisfaction, which was addressed with a second project and is a source of ongoing efforts. We were fortunate that our project coincided with a hospital initiative to embrace the Toyota Production System because the foundation for using these techniques was being laid throughout the hospital; we did not have the burden of using these tools in an isolated system.14 It is unclear if we could have accomplished and sustained the gains without support from colleagues outside the department.

Not every change was optimal. The numeric modeling performed as a prelude to implementation suggested we should bring our random access Vitros ECi automated instrument (Ortho-Clinical Diagnostics), which performs ferritin, thyroid and other hormones, hepatitis, and α-fetoprotein testing into the work cell. We abandoned the idea because it required even more training on the part of technologists, there was not a clinical need for rapid TAT for those tests, and we were consuming considerably more quality control and standards to run individual samples in single-piece flow rather than batching several times per week. Obviously, decisions like this hinge on the volume of testing that will vary among laboratories. Despite the shortcomings, the project overall was, and remains, a success. The ability to recognize suboptimal decisions and make necessary changes is foundational to the Plan-Do-Check-Act cycle that is the basis of quality improvement in most systems.

Certain aspects of the improvements were impossible to accomplish, for example, inventory management. Just-in-time instrument reagent supplies were not instituted owing to seasonal volume fluctuations and economies of batch and lot purchasing. We instituted a kanban system for core-specific supplies, but we have shared inventory among all sections of the laboratory and were not able to institute a just-in-time inventory for all core supplies. That project remains to be accomplished on a more global laboratory basis.

An unanticipated consequence was the increased amount of managerial time the postproject environment required to sustain the improvement gains and make further improvements. All of the input from consultants and from our own observations in several manufacturing plants suggested that sustaining the changes was most likely to occur if top management was involved. Hospital-based training in lean processing poured the conceptual foundation at the management level, insuring vertical buy-in. We found this to be true. We continue to monitor the project metrics daily. Nevertheless, this took time that had to be diverted from other activities and was not anticipated. In retrospect, the audit time investment was essential to sustaining the project. Over the years, we have continued to refine and standardize the system. This continuous attention and improvement has been necessary to maintain the system.

In fact, the audit system is integral to the sustainability and improvement of the core laboratory. TAT was chosen, not because that was a goal, but rather it was a time-sensitive metric that our laboratory information system could provide raw data to collate in about 20 minutes of manipulation. It
is seen daily by the medical and administrative directors, the clinical pathologist for the core laboratory, and the managers and supervisors and is posted for all the technologists. The percentage of tests that fail the goal and the maximum TAT have proved to be very sensitive indicators that can detect unanticipated short staffing and variances from standard work (or reveal processes that need standard work). It has proved laborious to communicate to the technologists that the indicator is not about working faster or even producing results faster, but rather, is an easy method to monitor the system. Sensitive monitors allow incremental changes to be made and assessed to determine if they worked as planned. Examples are centrifuge replacement in September 2008, which reduced the mean TAT, and the more recent implementation or normal value chemistry autoverification (Figure 3). The proper audit system is the key element to continued process improvement and sustaining the improvements made. Audits alone would not produce higher productivity and quality. We have learned from this experience that audits are necessary to maintain improvements and form the basis for longitudinal improvement.

Our experience highlights some of the factors contributing to sustained success. The improved performance in the core laboratory has proved beneficial as demands on the laboratory have grown. Based on this experience, we can recommend this system to other laboratories as a tool for quality improvement.

References


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