Using the SMS as a Tool to Enhance Productivity in Immunoassay Processing

Sample Management System Case Study
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Increasing workloads and decreasing qualified staff are major concerns for any laboratory manager today. Because of the need to "do more with less" and to get more work done faster, laboratory personnel are seeking instrumentation to help handle their workloads more efficiently. In this respect (and others), Siemens Diagnostics’ IMMULITE® 2000 has proven itself to be a very successful system in the higher volume immunoassay laboratories. In a continuing effort to provide the best possible products, Siemens Diagnostics has designed the Sample Management System (SMS) to further enhance the user efficiency of the IMMULITE 2000 and IMMULITE™ 2500 systems by automating the front-end sample-handling process.

What is the SMS?
The SMS is a robotic device that can transfer sample tubes to and from the IMMULITE 2000 series. The system consists of a robotic framework that resembles the look and feel of the IMMULITE 2000 or IMMULITE 2500. Within the framework are four drawers containing removable sample rack carriers. Each drawer has the ability to hold 5 racks of 10 samples, giving the system a total capacity of 200 samples. This more than doubles the sample capacity of the IMMULITE 2000 series, and the rack carriers and racks may be removed and replaced at any time without interfering with sample processing.

In addition to the increased rack capacity and flexibility, an independent user interface has been developed which allows the operator to identify the status of all tubes within the SMS. The interface resides on a 15-inch flat-screen monitor attached to the front left corner of the SMS. The operator can access the SMS software via the touch screen, keyboard or touch ball. In future versions of the software, this interface will provide the ability to store and identify tubes for reflex testing and auto dilutions. Other future features will include the ability to link multiple IMMULITE 2000 series systems into an Immunoassay Workcell, and to link them to an automated track system.

SMS evaluation criteria
An evaluation was performed to assess the impact on productivity when the SMS was used in the routine operations of clinical laboratories. This study was also designed to determine how laboratory processes might change as a result of integrating this device.

To evaluate the impact on laboratory dynamics, the following aspects of the SMS systems were assessed:

- IMMULITE 2000 SMS user interaction
- Intuitiveness of SMS operation
- Mechanical efficacy of the SMS
- Intuitiveness of the software user interface
- Changes in sample-loading dynamics
- Impact on workflow from increased front-end sample-loading capacity
- Impact on workflow by eliminating front-end pauses when loading and unloading samples
- Operator interactions with SMS drawers and racks
- Process improvements/differences when searching for samples
- Process improvements/differences when archiving samples.

Study Protocol
The evaluation took place over a 3-week period in which the IMMULITE 2000 SMS was run in routine operation. During the evaluation, the operators were asked to exercise all of the existing mechanical and software functions of the system. The operators were required to note the number of samples added and removed from the system, as well as the time period associated with these interactions. They were also required to note any times in which the front-end sample processing was interrupted because of system intervention or instrument idle times. At the end of each day, the operators answered a series of questions to assess the ease of use, mechanical software efficacy, and effect on workflow patterns. This allowed both the laboratory and Siemens to obtain a diverse set of data to assess how the SMS affects laboratory productivity.

Throughout the 3-week period, the following features on the SMS were exercised:

- Startup and shutdown routines of the SMS and IMMULITE 2000
- Running controls and adjustors on the IMMULITE 2000
- Running the IMMULITE 2000 and SMS in conjunction with the LIS
- Loading tubes of varying heights and diameters onto the SMS
- Adding and removing SMS rack carriers
- Adding and removing SMS racks
- Accessing a rack during SMS processing
- Transitioning from STOP, PAUSE and RUN modes on both the SMS and IMMULITE 2000 systems
- Adding and removing reagents and beads from the IMMULITE 2000
- Adding samples directly onto the IMMULITE 2000 during SMS processing
- Searching for a sample by using the SMS user interface
- Tracking sample status on the IMMULITE 2000
- Modifying the rack configurations—trying combinations of input and output vs. input/output only
- Repeating samples
- Running microsamples on the IMMULITE 2000
- Tracking sample status on the SMS.

A checklist was provided to allow the operators to track the features that had been exercised each day.

To track system processing, the operators were required to maintain a log of how many samples were loaded onto, and removed from, the SMS and at what time those interactions occurred. The operators also noted in this log any other periods of downtime caused by instrument interventions or system idle time. Additionally, all observations during the testing period were noted. These included workflow suggestions, and questions and concerns that occurred (or might occur) while running the system. Finally, a separate error log was maintained for tracking error conditions on the IMMULITE 2000 and SMS each time an error occurred on either system.

Taking screen captures from the SMS
Throughout the evaluation period, the operators were asked to take several screen captures of the SMS user interface to assist in training and troubleshooting.

Files required from the IMMULITE 2000
Technical Services at the Instrument Systems Division obtained the LIS log, error log and Maindata.mdb files from the IMMULITE 2000 on a weekly basis, either via the RealTime Service™ connection, or via PC Anywhere modem access.

Files required from the SMS on a daily basis via the Remote Diagnostics modem
On a weekly basis, Technical Services downloaded all the files saved on the SMS computer. At the end of each day, the operators were asked to place the computer into the Remote Diagnostics mode to facilitate this transfer. A Technical Services Specialist dialed into the SMS PC and extracted the appropriate files between 7:00 and 9:00 AM EST.

Data compilation and questions
The information gathered during the evaluation period was submitted on a weekly basis. This included answered questions, instrument logs, and checklists of the features exercised. At the end of the study, reviewed all data generated from the instrument were reviewed and a focus group session was held with the evaluation sites to answer any outstanding questions or concerns.

Supporting Data
Results

Study 1
A US laboratory currently has three IMMULITE 2000s that run a wide variety of immunoassays across the systems. A single SMS was installed onto one of the systems, resulting in the following observations.

- During the laboratory’s peak sample-receipt and result-generating hours, an average of 35 percent more samples and tests were run on the IMMULITE 2000 with the SMS than without the SMS.
- Testing was completed an average of 45 minutes earlier with the SMS.
- The number of times that the operator was required to interface with the system to add samples decreased from about 8 times per day with the stand-alone IMMULITE 2000 to about 6 times per day with the SMS. This equated to about 15 minutes of free operator time.
- Instrument interventions for adding samples (sample pausing) accounted for approximately 40 minutes of downtime prior to the addition of the SMS, and zero downtime after its addition.
- The average number of samples loaded at one time (30 vs. 64) and tests loaded at one time (48 vs. 100) more than doubled with the addition of the SMS.
- An average of 40 percent more samples and tests were run through the IMMULITE 2000 SMS over a 2-week period. This is in part attributed to the increase in the laboratory workload that was directed to the IMMULITE 2000 SMS system. The increased productivity seen on the IMMULITE 2000 SMS indicates that substantially greater sample numbers can be handled more easily by this instrument than by a stand-alone IMMULITE 2000 system.
- The site was able to move its workload from three to two IMMULITE 2000 systems owing to the additional sample-handling capacity and increased productivity within 1 week of SMS integration. The resulting excess capacity allowed the laboratory to add more assays to its in-house testing menu, thereby increasing its ability to generate more revenue.

Labor Savings
Some of these data can be translated into direct labor savings for the laboratory. The following extrapolations can be made on the amount of time saved daily using the SMS:

1. The SMS saved 45 minutes of technician time per day.
   - 45 minutes saved per day, which is 270 minutes per week or 1,080 minutes per month or 12,960 minutes per year or 216 hours in annual labor savings and increased productivity

2. The number of times that the operator was required to interface with the system to add samples decreased from about 8 times per day with the stand-alone IMMULITE 2000 to about 6 times per day with the SMS. This resulted in an additional 10 minutes of free operator time.
   - 10 minutes saved per day, which is 60 minutes per week or 240 minutes per month or 2,880 minutes per year or 48 hours per year in labor savings and increased productivity

Total hours saved = 264 hours annually

Study 2
A second lab reported similar findings.

- An average of about 30 percent more samples and tests were run through the IMMULITE 2000 over a 2-week period.
- Instrument interventions for adding samples (sample pausing) accounted for approximately 50 minutes of downtime prior to using the SMS and zero downtime after the addition of the SMS, which decreases operator interaction with the system and increases operational efficiency.
- The average number of samples loaded at one time was increased by about 30 percent with the addition of the SMS.
- The average number of tests loaded at one time was increased by about 30 percent with the addition of the SMS.

Summary
With the addition of the SMS, the laboratory can complete its immunoassay workload more quickly and with less operator intervention than without the SMS.
- The ability to centralize all of the laboratory’s workload onto two systems (reduced from three) means that the lab now has spare capacity to bring in additional testing and can increase its opportunity to generate more revenue without adding additional systems or personnel.
- According to one study, the installation of a single SMS linked to one IMMULITE 2000 in the laboratory would save an estimated 264 hours of labor time per year and increase productivity.

Conclusions
The SMS increases usable operator walk-away time, improves productivity and provides the opportunity to generate more revenue by bringing additional testing in-house. It makes all of this possible by:

1) expanding the on-board sample capacity of the IMMULITE 2000, thereby allowing the IMMULITE 2000 to process more samples in a given amount of time. The SMS can hold up to 200 samples—a 120 percent increase over the 90-sample maximum of the IMMULITE 2000.
2) eliminating the need for the IMMULITE 2000 to pause when an operator adds or removes samples. The SMS can continue transferring samples between one of its drawers and the IMMULITE 2000 while the operator is loading and unloading samples in the other three drawers.