

# **A Modular Robotic Workcell for Coagulation Analysis**

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## Abstract

**Background:** Total laboratory automation (TLA) has been shown to increase laboratory efficiency and quality. However, modular automation is smaller, requires less initial capital, and requires less planning than total laboratory automation. We engineered and performed clinical trials on a modular robotic pre-analytical workcell for coagulation analysis.

**Methods:** Our robotic modular workcell was engineered to allow a choice of specimen introduction manually, by conveyor, or by mobile robot. Timing studies were used to quantitate the efficiency of the manual processes and to identify areas in the processing of coagulation specimens where bottlenecks and long wait periods were encountered. We then designed our modular robotic system to eliminate these bottlenecks. Additional timing studies were performed during clinical trials of the robotic system.

**Results:** *Automation reduced the time required for pre-analytical processing time from a range of 18 to 107 minutes to approximately one minute.* Further improvements in workcell efficiency could be realized when high quality, pre-labeled specimens are introduced into the system.

**Conclusion:** Modular automation provides more predictable variation in specimen processing when compared to manual methods.

### Abbreviations:

Total Laboratory Automation - TLA

## Introduction

TLA has been introduced into a number of laboratories. In North America, payback periods of three years or less for laboratory automation are generally considered acceptable. Laboratories that have installed automation are reporting favorable payback periods (**1-3**). Factors such as the number of specimens entering the laboratory, renovations of the physical plant, and the quality of specimen labeling, play an important role in determining the final efficiency of the automation system (**4**). Two of the major costs associated with TLA are the cost of the system itself, and renovation costs associated with accommodating the large size of most TLA devices. However, the installation of TLA can be justified when consolidating several laboratories (**5,6**). *Modular automation is an alternative to TLA (7)*. *Modular automation* can be defined as a dedicated mechanical device capable of performing a selective laboratory task. For example, a pre-analytical modular device will generally stock samples, pre-sort specimens, decap, aliquot, label, and sort specimens into take out racks. In general, modular automation requires less room and requires a smaller investment than TLA. Modular systems designed for selective analytical tasks may better suit the needs of medium sized laboratories with modest specimen loads. In our studies, reported here, we examine the efficiency of modular automation relative to the manual process it is intended to supplement or replace.

Coagulation analysis is used to elucidate defects in biochemical pathways associated with hemostasis. Automated coagulation analysis usually requires the availability of specimens that have been previously centrifuged and sorted. Centrifugation of specimens, sorting, and transportation into the analyzer are essential pre-analytical tasks which need to be addressed by laboratory automation with a potential for significant labor savings and quality improvement.

The justification for the purchase of laboratory automation must be based on demonstrable improvements in efficiency and calculated payback. However, there is little data quantitating process improvement following the installation of laboratory automation using robotics. Therefore, we performed a study to determine the throughput and turnaround time of specimen processing of coagulation specimens in a clinical laboratory before and after the installation of a robotic system developed in our laboratory.

## Methods and Materials

Clinical studies were conducted at the University of Virginia Health System (Charlottesville, Virginia) core clinical laboratory. The Core Clinical Laboratories houses chemistry, hematology, microbiology (sample preparation and blood bacteria testing), and coagulation analysis. The Core laboratory performs approximately 1,600,000 billable stat and routine laboratory tests per year. Coagulation testing consists of approximately 300,000 tests per year. The daily census for coagulation specimens varied by about two-fold. The highest numbers of specimens were received on days when the renal dialysis unit was treating patients. During a two-week period, the lowest number of specimens in a 24-hour period was 265 tubes on a Sunday and 470 tubes on a Monday,

which included specimens from the renal dialysis clinic. The mean was 378 specimens per day during the two-week period. Processing times were determined for both high and normal specimen loads.

Coagulation testing is performed on one of two MDS 180s, a commercially available instrument (Organon Teknika, Durham, NC). Instrument one was alternated on a daily basis. The second analyzer also served as a back up instrument in case of instrument failure, and to provide backup while the primary analyzer was undergoing routine maintenance. Coagulation processing was subdivided into a number of discrete steps. Each step was timed by watching a time stamped videotape. A Sony (model CCD-TRV70) 8mm video camera was mounted in the clinical laboratory to record all of the processing steps except pre-centrifugation. The camera had a time stamp in seconds that was recorded on the tape. The camera was placed at locations in the laboratory that allowed the reviewer simultaneous views of several processing steps.

Based on the data obtained from our time and motion studies, we designed a preliminary version analytical processing robot **(10)**. In developing the prototype, we determined that the essential components of an automated workcell (automated device dedicated to a single analytical area) should include a specimen storage area, a centrifugation device, a robot for specimen manipulation, and an output storage area. Both the input and output storage areas were designed to buffer the influx and output of specimens during the time that technologists were not available to add or remove specimens. In order to maximize the flexibility of the automated workcell, we designed the automated workcell to accept a variety of specimen input mechanisms. Specimens may be presented individually (e.g. for stat samples), in racks by a technologist, via conveyor as part of a TLA system, or via mobile robot. Automated centrifuge loading and unloading addressed the analytical time bottleneck that we observed in the manual time and motion studies. Automated specimen bar code scanning and specimen loading into the instrument streamlined the mundane task of assuring that the specimen bar code was properly aligned in the coagulation analyzer.

We present here the results of our examining two recent versions of our pre-analytical system, named coagAutoLink, interfaced to either one or two MDA 180 instruments (Organon Teknika, Durham, NC) **(Figure 1)**. We designed the system to include a CRS A255 anthropomorphic robot arm, a CRS C500C controller running the RAPL-3 language (CRS Inc., Burlington, Ontario, Canada), a modified Jouan C422 (Jouan Inc., Cedex, France), and a workcell enclosure. The enclosure was designed to restrict human access to the robot's workspace, both to protect the operator and to prevent objects from being accidentally moved or placed into the robot's environment. The enclosure had two electrically operated door locks, which prevented the robot from moving when the operator was accessing the sample racks. During our clinical trials, these safety measures were successful in ensuring operator safety.

The first version of the automated workcell, coagAutoLink SPIN, operated with a single MDA180 and a centrifuge. The second version, coagAutoLink 2CST, mechanically and electronically interfaced to dual MDA 180's and a Labotix specimen

transportation conveyor (Labotix, Ontario, Canada). The coagAutoLink 2CST does not include a centrifuge because specimens are separated prior to arrival at the coagulation station by the TLA system.

Additionally, we implemented and tested delivery of specimens using a mobile robot (RoboCart model 2110, CCRI, Lake Arrowhead, CA). The RoboCart is an autonomous guided vehicle that follows a guide path consisting of reflective tape adhered to the floor. Specimens were contained in input racks that were manually placed on the top of the RoboCart. The RoboCart was then programmed to follow a reflective tape path directly into a specially designed docking station on the coagAutoLink. The arrival of the robot was announced by a sensor that prompted the CRS robot arm to automatically unload the full specimen racks. Racks of tubes that had previously been analyzed were loaded onto the RoboCart for delivery to the specimen storage area of the laboratory.

For development and optimization of the control code for the coagAutoLink 2CST, we developed a discrete-event model of the laboratory sample flow, single and dual MDA 180 behavior, and conveyor and robot activities. The simulation was developed and validated according to methods previously used in our laboratory **(11)**. This discrete-event model was used to simulate a variety of design concepts and to maximize system throughput. After the simulation showed the desired performance characteristics, the actual robot control software was generated directly from the simulated robot control software.

The timing and throughput studies were designed to determine the performance of coagAutoLink, and to compare its performance with a manual process. Before installation of coagAutoLink, we identified each of the steps that are performed for manual processing of coagulation samples at the University of Virginia Health System Core laboratory. These steps included: 1) receiving-centrifugation-loading (sample reception including accessioning, labeling, transportation to the centrifuge, and loading of the centrifuge), 2) centrifugation-idle (includes idle time after the centrifugation cycle has completed), 3) sample transport to MDA (loading of spun samples into MDA racks and taking the racks to the coagulation testing area), and 4) sample placement into the MDA 180 (includes time the sample waits in the coagulation testing area for medical technologist to load it into the MDA). Each of these steps was observed and timing measurements were taken.

## Results

### Timing studies of the manual process

On days with a normal workload, processing time of a routine coagulation specimen ranged from a minimum time of 18.2 minutes to a maximum time of 107.6 minutes before the analyzer aspirated the specimen. The area presenting the largest time range was in receiving/centrifuge loading. This pre-centrifuge processing time ranged from 8 minutes to 65 minutes with an average time of 29.6 +/- 14.7 (1 SD) minutes, N=69 minutes (**Figure 2**). The next-largest variation of time was during centrifugation. All specimens were spun for a fixed time of 10 minutes, but the specimens were rarely removed from the centrifuge as soon as the centrifuge stopped because technologists were occupied with other tasks. Processing times at this step ranged from 10 minutes (when specimens were immediately removed from the centrifuge) to 28 minutes (18 minutes spent idle in the centrifuge) (mean=15.86 +/- 5.58 (1 S.D.) minutes, N=27).

Routine coagulation specimens were removed from a centrifuge and placed into a MDA rack by processing clerk. Racks then had to be placed on the MDA instrument for analysis by a medical technologist. These racks waited a range of 1 second to 11 minutes for loading by the MT (mean=1.97 +/- 3.15 (1 S.D.), N=28. One day a week a large volume of specimens were sent to the laboratory from the dialysis unit. Due to specimen queues on dialysis day, the largest variation of time was encountered in the pre-centrifuge processing step. The minimum time on those days with a high number of specimens was 38.50 minutes to a maximum of 106.00 minutes (mean = 81.24 +/- 18.17, N=44). The average total processing time on a normal day was 48.65 minutes and on a busy day was 100.33 minutes.

Stat processing time of coagulation specimens had a much faster throughput, but showed similar bottlenecks. The average receiving/centrifuge loading time was 3.23 +/- 3.78 (1 S.D.) minutes, N = 29. Processing times during centrifugation varied from 10.00 minutes when specimens were immediately removed from the centrifuge to 23.75 minutes, (mean = 12.98 +/- 3.43 (1 S.D.) minutes, N=55). The specimens are placed in the centrifuge by processing clerks, but are removed by the medical technologist in the coagulation area. Even with a stat specimen, the removal from the centrifuge was sometimes delayed for over 13 minutes after centrifugation was complete. Once the stat specimens have been removed from the centrifuge, final processing usually took under a minute to check for problems, load into MDA sample racks and be placed on the analyzer.

As shown in Figure 2, large variations existed in the amount of time spent in the manual process. In particular, the Receiving step varied from 8 minutes to over one hour. Clearly, reducing process time variability was a reasonable goal of coagAutoLink, which was subsequently installed in the University of Virginia core clinical laboratory.

### Timing studies following automation

Following installation of our coagAutoLink automation module, we repeated our timing studies. Three timelines in **figure 3** summarize the data from timing

measurements made following the installation of coagAutoLink. Note that figure 3 depicts the *average* times used for steps in the manual process so that it may be compared to the average time in the automated process. The coagAutoLink processing and centrifugation steps are shorter than their manual counterparts, and have predictable ranges. The process still required manual sample receiving and labeling. Each of the timelines is labeled to indicate the time required to aspirate the specimen, i.e. the time that the MDA actually begins analysis. The average times to complete the manual process, the process performed with coagAutoLink using manually labeled samples, and fully automated coagAutoLink (pre-labeled samples) are 50 minutes, 48.5 minutes, and 26.5 minutes, respectively.

In **figure 4**, four scenarios are compared: manually processed routine samples, manually processed stat samples, coagAutoLink SPIN as observed after installation, and projected figures for coagAutoLink SPIN when pre-labeled samples are used. *Our data demonstrate that manual processes have a larger variation in processing time when compared to the automated process.* In the manual process, the longest wait periods were experienced during the removal of specimens from the centrifuge. In the routine area, the mean wait time from when the centrifuge stopped until the specimens were removed was 5.86 minutes and in the stat coagulation centrifuge area, the mean wait time was 2.98 minutes. In both the stat and routine centrifuge areas efficiency was lost when specimens waited for the next processing step to begin. Often, technologists were preoccupied with other more pressing tasks and thus were not available at the precise time the centrifuge was finished. Pre-analytical systems such as coagAutoLink reduce sample idle time, thereby improving overall throughput.

We measured the throughput of coagAutoLink SPIN (**figure 5**). The *measured* maximum throughput of the coagAutoLink SPIN is 99 samples/hour. Thus, coagAutoLink's throughput exceeds the analytical throughput (assuming 2 assays per sample) and will not present a throughput bottleneck to the process. *In separate experiments, prototype system testing of coagAutoLink 2CST has shown that sustained throughput will be approximately 135 samples/hour. This increased throughput is a result of the lack of need for a centrifuge in the 2CST model.*

## Discussion

We demonstrated that the routine testing of specimens for coagulation disorders could be automated in a clinical laboratory using a modular robotic system. The versatility of the system was enhanced by providing specimen input via a mobile robot, manually by technologist, or by conveyor belt. The modularity of the coagAutoLink *suggests* its use in a relatively small laboratory with coagulation specimen demands of greater than approximately 350 specimens per day. Smaller number of coagulation specimens may not justify the expense of the purchase of the robotic device. Significantly greater number of specimens (greater than the 135 specimens per hour throughput) may justify multiple robotic systems.

We demonstrated in clinical trials of our automated pre-analytical device that the automation was sufficiently efficient to keep pace with the analytical hardware. In other words, we matched our automation to the clinical need. The major benefit of the automated pre-analytical device was a reduction in the variability in turnaround time for coagulation specimens. In a similar clinical trial, we demonstrated that centrifugation alone was able to reduce the turnaround time and labor required for pre-analytical processing [12]. By adding additional components to pre-analytical processing (e.g. sample stocking, aliquotting, and sorting), the process became even more efficient. Versatile pre-analytical processors that can accommodate a wide variety of specimen sizes and shapes are becoming commercially available [13]. There are no reports that describe the return on investment for modular pre-analytical automation. This study focused on the ability of our system to reduce the time associated with pre-analytical tasks. However, it did not address the issues related specifically to return on investment.

The efficiency of any robotic system, including the coagAutoLink, may be improved by providing specimens that are correctly filled, labeled, and transported. Our timing studies determined that significant delays were experienced in dealing with improperly labeled specimens. During one ten-hour period, 32 out of 193 specimens (17%) were mislabeled or had incorrectly applied labels and required one or more minutes of corrective measures by a technologist. Pre-analytical variables can also cause significant deviations from expected coagulation results. For example, improper tube filling can render some specimens virtually unusable for routine coagulation analysis. Underfilling tubes will result in a larger specimen to anticoagulant (3.2 % citrate) ratio and can cause prolonged prothrombin time (PT) and activated partial thromboplastin time (APTT). Siegel et al (14) found that partially filled heparinized coagulation specimens resulted in shorted APTT times. Short draw coagulation tubes that have their original labels obscured by multiple institutional labels are particularly problematic. It is necessary to remove the labels before one can determine if the tube has been designed for a short draw, or is simply under filled. Excessive waiting during the pre-analytical phase can cause in vitro neutralization of heparin. In our institution, we found that an average of 2.52% of the tubes had compromised quality (1.25% for incorrect blood to anticoagulant ratio and 1.27% were hemolyzed). A significant improvement in pre-analytical processing efficiency in coagulation testing can be realized simply by improving specimen quality.

In summary, we characterized the steps involved in routine and stat coagulation processing. We found a wide variation in wait periods for coagulation specimens, which include a delay in loading the centrifuge, time to verify correct specimen container, time to address improperly labeled tubes. We developed an automated pre-analytical processor to reduce these delays. Improvements in task time variability and overall task time were shown.

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## Figure legends

Figure 1. The coagAutoLink pre-analytical system. We engineered two versions of the robotic pre-analytical processor. The SPIN version (Panel A) includes a centrifuge and a robot for specimen manipulation. The 2CST version (Panel B) provides robotic movement of specimens to and from a conveyor belt. The centrifuge is not used in the 2CST version since specimen separation is normally accomplished by the total laboratory automation system.

Figure 2. Processing time of a routine coagulation specimen under normal workload, broken down into the component tasks. Average, maximum, and minimum times for each task are shown.

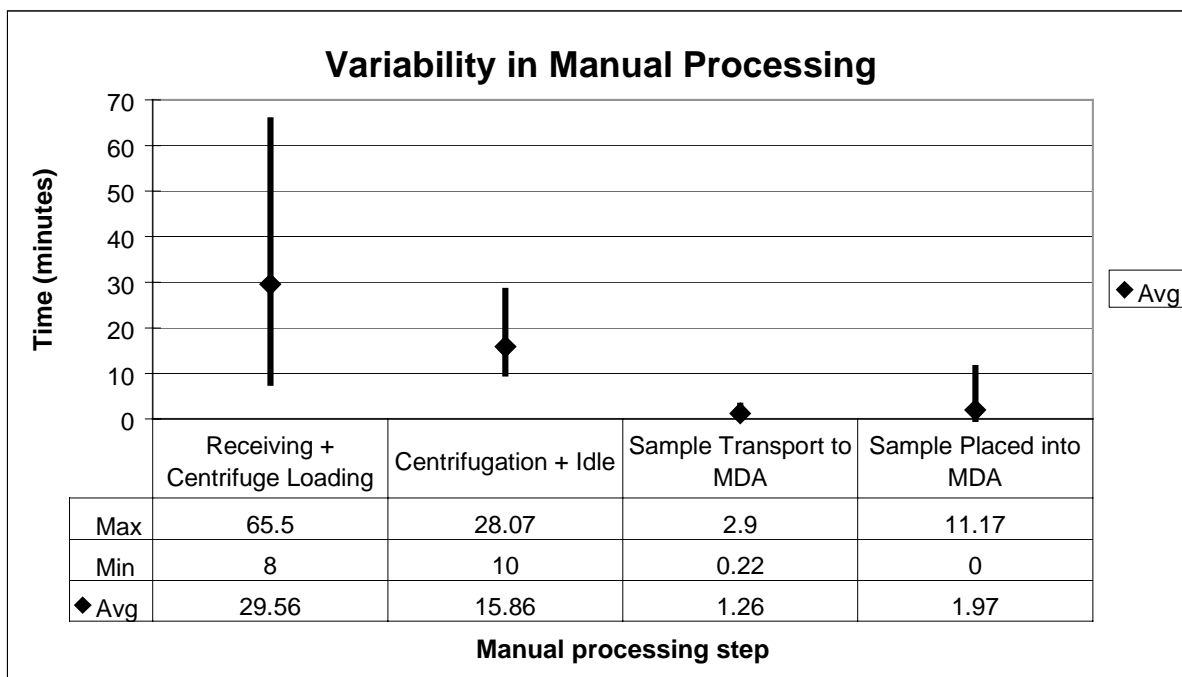
Figure 3. Timelines showing time-to-aspiration improvements resulting from the coagAutoLink SPIN workcell.

Figure 4. Range of measured times, from sample arrival at Central Receiving to sample aspiration in the MDA180. Note that the range was smaller for the automated system as compared to the manual method. Mean, standard deviation and number of data points are shown in the results section for each measurement.

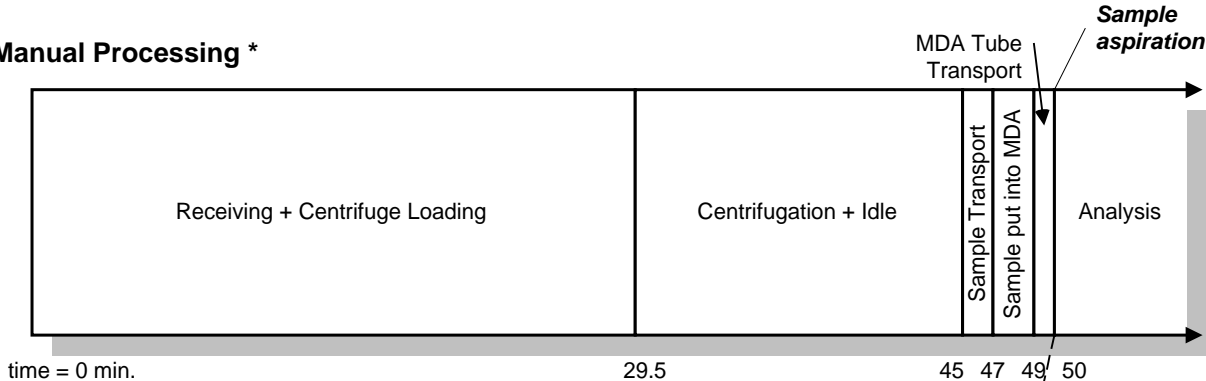
Figure 5. coagAutoLink SPIN throughput. System throughput is dependent on centrifuge cycle time. coagAutoLink is at least as fast as the throughput of the MDA when running a typical two assays per sample, with centrifuge cycle time below 10.6 minutes.



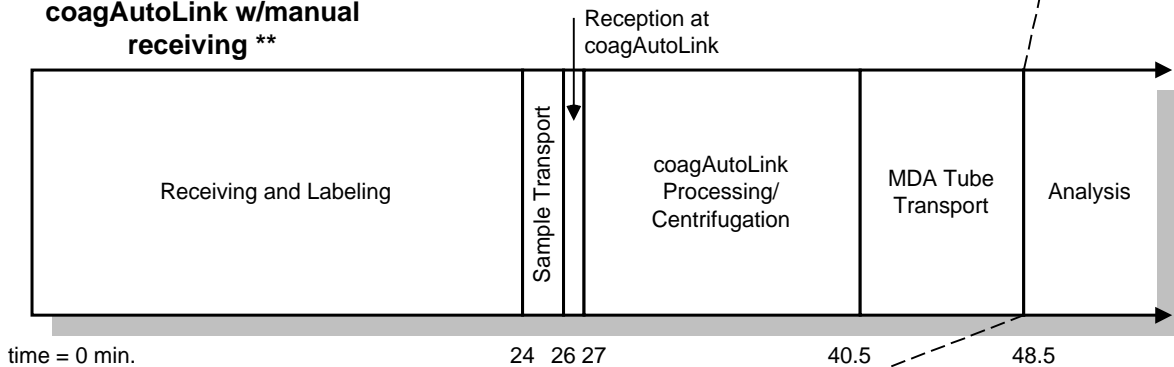




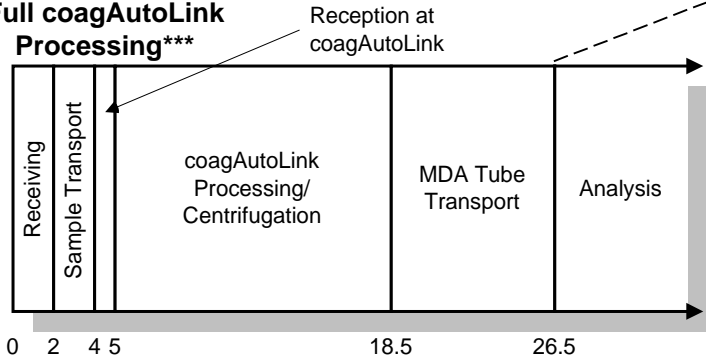
**Manual Processing \***



**coagAutoLink w/manual receiving \*\***



**Full coagAutoLink Processing\*\*\***



\* Average times measured at the University of Virginia Health System central lab

\*\* Times measured after installation of automation. Samples are still manually labeled and hand-delivered to workcell.

\*\*\* Projected time for labs where samples arrive already barcoded, and are automatically transported to automated workcell

