

RESEARCH ARTICLE

# Increased effectiveness of urinalysis testing via the integration of automated instrumentation, the lean management approach, and autoverification

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**Abstract**

**Background:** In 2014, the Department of Clinical Pathology, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand developed and implemented a new process that uses fully automated instrumentation, the lean management approach, and autoverification to improve the productivity and efficiency of the urinalysis workflow process. The aim of this study was to evaluate analytical turnaround time compared with our old urinalysis workflow process and our new urinalysis workflow process that was launched in 2014.

**Methods:** This study was performed at the Central Laboratory of our center during June 2017 using data collected from the July 2012 (old process) and July 2014 (new process) study periods. We used our laboratory information system to compute and analyze turnaround time of urinalysis tests, and those results were compared between processes.

**Results:** The 90th percentile turnaround time in overall data was dramatically decreased from approximately 60 minutes in 2012 to <50 minutes in 2014. The mean during both 6:00 AM to 9:00 AM and 9:00 AM to 12:00 PM was approximately 42 minutes in 2012; however, that duration was reduced to approximately 30 minutes for both of those time periods in 2014. Specimens within 60 minutes in both intervals increase from approximately 80% to more than 90%.

**Conclusion:** The results of this study revealed our new urinalysis workflow process that incorporates fully automated instrumentation, the lean management approach, and autoverification to be effective for significantly increasing productivity as measured by analytical turnaround time and removing 1 staff to another section.

**KEYWORDS**

automated urine analyzer, autoverification, lean, urinalysis

**Abbreviations:** LIS, laboratory information system; TAT, turnaround time.

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## 1 | INTRODUCTION

Urinalysis is a process that includes evaluation of physical characteristics, chemical analysis, and microscopic sediment examination. The manual method of examining urine is time-consuming, labor-intensive, and it requires well-trained technicians. The manual method is also associated with some inherent subjectivity, which can lead to staff-related variability. Automated urine analyzers were developed to improve laboratory productivity and to reduce interobserver inconsistency.<sup>1-3</sup>

Our center is a 2300-bed university-based national tertiary referral hospital that is located in Bangkok, Thailand. Our clinical pathology laboratory receives an average of 500 urine samples per day that must be processed by 7 staff technicians. This high workload was found to be associated with delayed reporting of urinalysis results, workload-related stress. In response, our department set forth to improve the urinalysis process in 2014 by integrating fully automated instrumentation, the lean management approach, and autoverification into the urinalysis workflow process.

The lean management approach or principle, which was first introduced by Toyota in 1990, is the foundation of the Toyota Production System.<sup>4,5</sup> The essence of lean management is the elimination of waste, and the elevation of value via reductions in error rates, waiting times, and other factors that reduce efficiency.<sup>6,7</sup> Although the concept of lean management and/or manufacturing found its start in the industrial sector, it has now been integrated into the healthcare sector where it was found to improve the quality of services and safety, to reduce turnaround times, and to reduce costs.<sup>5-9</sup>

Autoverification is a process by which laboratory results are released to a physician without manual intervention. This is accomplished by programming the laboratory information system (LIS) and/or instrument middleware software with the criteria that determines which information is released, when, and to whom. Autoverification in our laboratory facilitates the release of normal urinalysis result data to physicians automatically. Autoverification reduces the time and manpower needed to manually review results, and it also reduces the mental fatigue and potential for error that are associated with the verification of large volumes of laboratory result data.<sup>10-14</sup>

Since the sample collection and transportation components of the process are not managed by laboratory staff, we used analytical

turnaround time (TAT) as the parameter to measure laboratory performance. TAT is defined as the time duration between the time the specimen is received and the time the results of urinalysis are reported. Ninetieth (90th) percentile TAT was reported to be the best measure for summarizing the frequency of mishaps and tracking further improvement.<sup>15</sup>

The aim of this study was to evaluate TAT compared between our previous urinalysis workflow process and our new urinalysis workflow process that incorporates the use of fully automated instrumentation, the lean management approach, and autoverification.

## 2 | MATERIALS AND METHODS

This study was performed at the Central Laboratory of the Department of Clinical Pathology, Faculty of Medicine Siriraj Hospital, Mahidol University during June 2017 using data collected from the July 2012 and July 2014 study periods. The protocol for this study was approved by the Siriraj Institutional Review Board (SIRB) [No. 704/2557 (EC3)].

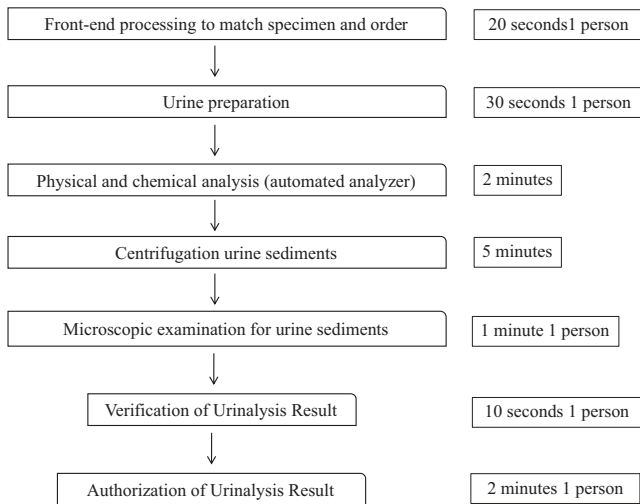
### 2.1 | Urinalysis workflow process with lean analysis

The urine analyzer that was used as part of the old urinalysis process could only analyze the physical and chemical properties of urine specimens. The value of urinalysis workflow process was the result with turnaround time less than 60 minutes. Due to the high workload, we received the complaint about the delay reporting of urine results around 1-2 times/day from the customer feedback. The waste and how to eliminate them are mentioned in the Table 1.

The value stream map (VSM) of old and new workflow processes are shown as workflow diagrams in Figures 1 and 2. The analyzer was replaced with a fully automated instrument that can examine all 3 of the evaluations that comprise urinalysis. To further improve the efficiency of the process, we set up autoverification criteria<sup>16</sup> that would trigger automatic direct reporting the physician if the urinalysis result was no flagging. For the urine specimen with flags was identified and rereviewed by manual microscopic method to report all abnormal cell. The improvement from this strategy could reduce process time from approximate 10 to 3 minutes as well as relocation 1 staff to another segment of the laboratory.

**TABLE 1** The waste and how to eliminate from the old urinalysis workflow process

Type of waste	Waste	How to Eliminate
Waiting	Waiting for centrifugation urine in manual microscopic method Waiting for staff release by manual Waiting for staff approve by manual	Fully automated instrument examine physical, chemical and sediment of urine combined with autoverification
Over Processing	Manual microscopic method in negative urine	Fully automated instrument examine physical, chemical and sediment of urine combined with autoverification
Defective Product	Result of urine sediment may be unreliable due to staff-related variability	Fully automated instrument examine physical, chemical and sediment of urine



**FIGURE 1** Value stream map of previous urine examination workflow

**2.2 | Data collection and analysis**

TAT data from our LIS were collected and analyzed. The mean and median TAT, standard deviation (SD), and proportion of acceptable tests (% of TAT within 60 minutes) were evaluated. The specimen volume and 90th percentile TAT data during July 2012 and during July 2014 were collected, analyzed, and plotted. The average test volumes and analytical TAT in 3-hour intervals during the 24-hour period were also plotted.

**2.3 | Statistical analysis**

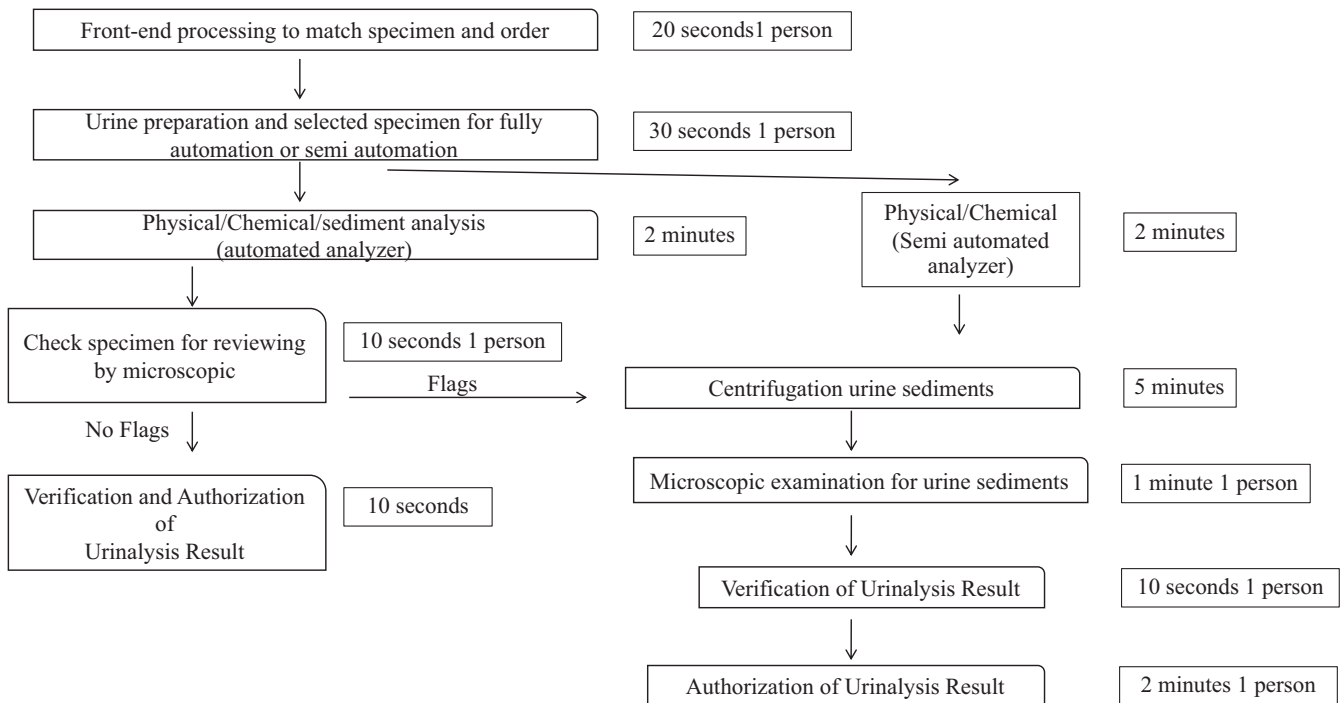
Microsoft Excel spreadsheet program (Microsoft Corporation) was used for data management and all statistical analyses. Two-tailed independent Student's *t* test was used to test the significance of differences between the old and the new urinalysis workflow processes. Data are reported as number, mean ± SD, and median. A *P*-value < .05 was regarded as being statistically significant.

**3 | RESULTS**

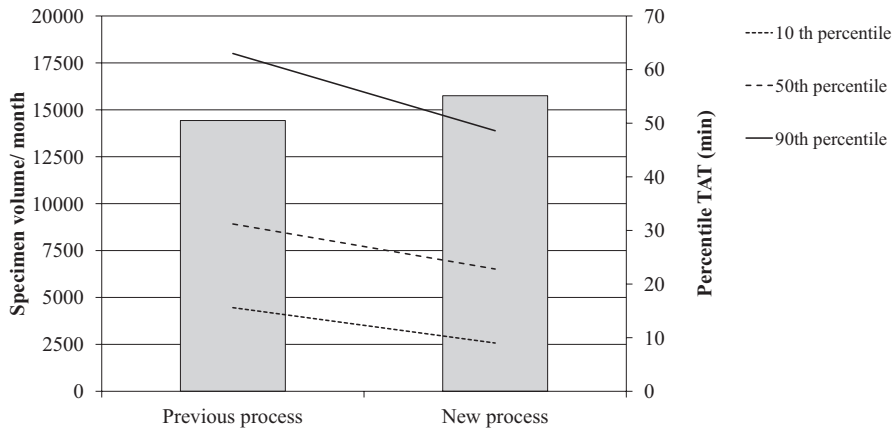
Specimen volume and the 90th percentile analytical turnaround times (TATs) in 3-hour intervals during the 24-hour period of a day are shown in Figure 3. A significant decrease in TAT while increasing sample volume was observed. The 90th percentile TAT was dramatically decreased from approximately 60 minutes in 2012 to <50 minutes in 2014.

The specimen volume and TATs in 3-hour intervals are shown in Figure 4. The two highest TATs were during 9:00 AM to 12:00 PM and 6:00 AM to 9:00 AM. Specimens were severely overdue during the 9:00 AM to 12:00 PM time period in 2012, but the 90th percentile TAT duration during that time period greatly decreased after implementation of the new process in 2014 (72 to 54.6 minutes, respectively).

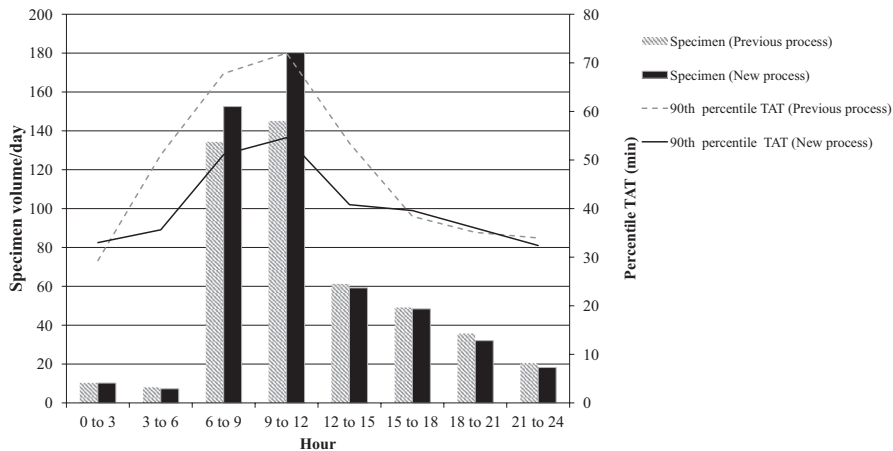
Mean ± SD and median with range of TATs compared between the previous process and the new process are shown in Table 2. The worst time of the old procedure was around 4 hours at the interval of 9:00 AM to 12:00 PM and the interval of 0:00 AM to 15:00 PM; the worst time was more than 150 minutes while the worst time of the new workflow was about 3 hours and the interval of 6:00 AM to



**FIGURE 2** Value stream map of new urine examination workflow



**FIGURE 3** Specimen volume and the 90th, 50th and 10th percentile turnaround times (TATs)



**FIGURE 4** Specimen volume and 90th percentile turnaround time (TAT) in 3-hour intervals during the 24-hour period of a day

**TABLE 2** Mean and median analytical turnaround time (TAT)  $\pm$  SD and range of specimens compared between the previous process and the new process

TAT range <sup>a</sup> (hours)	July 2012 (previous process)			July 2014 (new process)			p
	n	Mean $\pm$ SD (minutes)	Median (Range) (minutes)	n	Mean $\pm$ SD (minutes)	Median (Range) (minutes)	
Overall	14,430	35.9 $\pm$ 20.6	31.2 (10.8-238.2)	15,750	26.4 $\pm$ 17.4	22.8 (3-185.4)	.01
0-3	331	19.0 $\pm$ 12.3	16.8 (10.8-153.6)	317	16.7 $\pm$ 11.2	14.4 (3-60)	<.005
3-6	258	28.8 $\pm$ 17.8	25.8 (10.8-157.2)	225	21.7 $\pm$ 12.6	20.4 (3-87)	<.005
6-9	4,164	42.2 $\pm$ 19.7	38.4 (10.8-162)	4,727	28.2 $\pm$ 18.0	24.0 (3-185.4)	<.005
9-12	4,499	42.0 $\pm$ 22.8	37.2 (10.8-238.2)	5,588	30.1 $\pm$ 18.8	27.0 (3-175.8)	<.005
12-15	1,898	33.5 $\pm$ 19.4	30.0 (10.8-192.6)	1,835	23.1 $\pm$ 15.4	21.0 (3-130.8)	<.005
15-18	1,523	25.2 $\pm$ 10.4	24.0 (10.8-103.2)	1,500	21.2 $\pm$ 12.9	18.0 (3-91.8)	<.005
18-21	1,114	21.7 $\pm$ 9.7	20.4 (10.8-72)	993	19.3 $\pm$ 12.1	17.4 (3-78.6)	<.005
21-24	643	20.8 $\pm$ 8.9	18.6 (10.8-36)	565	18.7 $\pm$ 10.8	17.4 (3-33.6)	<.005

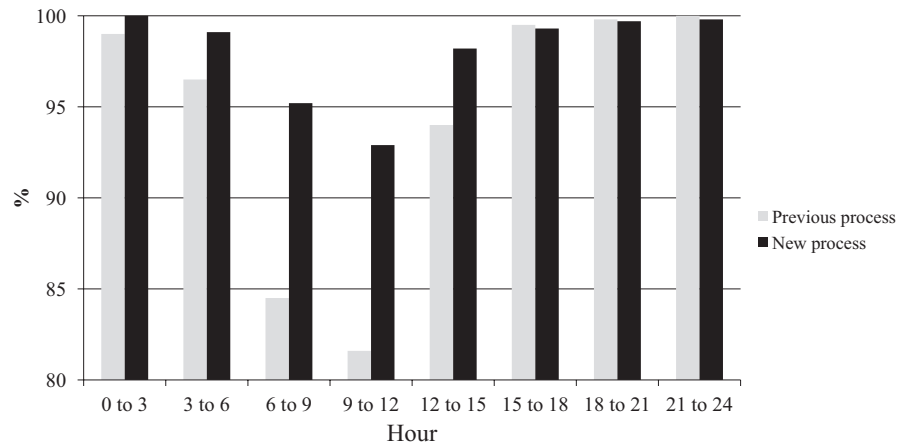
Note: A *p*-value <.05 indicates statistical significance.

<sup>a</sup>Total specimen volume, and 3-hour intervals during the 24-hour period of a day.

12:00 PM; the worst time was more than 150 minutes. The proportion of specimens that were reported within 60 minutes in 3-hour intervals during the 24-hour period of a day is shown in Figure 5. The significance level for the overall data was 0.01, but that increased to <0.005 when each interval was individually evaluated. The mean

TAT during both 6:00 AM to 9:00 AM and 9:00 AM to 12:00 PM was approximately 42 minutes in 2012; however, that duration was reduced to approximately 30 minutes for both of those time periods in 2014. Moreover, specimens that report within 60 minutes in both intervals increase from approximately 80% to more than 95%.

**FIGURE 5** Specimen that report with in 60 minutes in 3-hour intervals during the 24-hour period of a day



## 4 | DISCUSSION

Autoverification and the integration of lean management principles are essentially important factors for increasing efficiency within laboratories.<sup>5-13</sup> In this study, we present and describe our experience with a new urinalysis workflow process that includes fully automated instrumentation, autoverification, and the lean management approach in a university-based medical laboratory.

The basic principles of the lean management approach include: (a) define value according to customer's view and identify the source of wasted resources; (b) identify of value stream map by observation and analysis of processes; (c) create the flow that eliminated of waste and standardization of work to minimize variation; (d) response only the pull of customer demand; (e) continuous and systematic improvement.<sup>17</sup>

In 2014, our laboratory analyzed the workflow of urine process and found waste which was using man power in many steps (microscopic examination for urine sediments, verification and approve of urinalysis results), unnecessary microscopic examination in negative urine, and variations from sediment analysis. So we improved the procedure by using a fully urine automated analyzer and set the criteria for autoverification for standardization of urine results and reduce the need of human by decrease the rate of review by microscopic as well as using computer release and approval results instead of laboratory staff.<sup>16</sup>

Many studies showed the benefit of urine analyzers which are convenience, time-saving, accurate, and standardization.<sup>18-23</sup> To our knowledge, there is limited literature published on effectiveness analysis of automated urine analyzers as well as autoverification of urinalysis over the course of years.

This study revealed the benefit of fully automated urine analyzer combined with management of workflow and autoverification. After implementation of the new process in our laboratory, the review rate of microscopic examination was around 50%.<sup>16</sup> This rate was more than median rate from Sysmex participant of CAP Q-Probes study which only 32%.<sup>24</sup> In this study, there were 13 from 88 laboratories that used an automated microscopic analyzer (Iris = 7 laboratories and Sysmex = 6 laboratories). Most of them used flags from

automated microscopic analyzer. There are two reasons that our laboratory performed more manual microscopic method. First, our hospital is the tertiary care and academic hospital so we have many complex patients. Second, we set our criteria which united between chemistry part and microscopic part of the analyzer which different from that study.

Through the analysis of sample volume, we found that an increase in urine sample volume was observed during 2012 to 2014, the TATs were significantly reduced. In order to assess the performance of the urinalysis examination during a day, we analyzed the volume of specimen and 90th percentile TAT in 3-hour intervals. There were two peaks of TAT. The first one turned up at 9:00-12:00 AM when the outpatient units sent specimens to the laboratory. The second-longest TAT was during 6:00 AM to 9:00 AM when the inpatient units sent the specimen, and there were only 4 staff performing the test. The most severely delayed results during these two periods might postpone clinical decision-making in the practice of patient care. An improvement strategy was undertaken to shorten the TAT of both periods. The 90th percentile TAT of the previous flow was very wide range from around 30 to 70 minutes whereas the new one was only 30-55 minutes. In addition, mean and median of TAT of the old method were around 16-42 minutes while the improve flow was around 15-30 minutes.

However, the data demonstrated that if the specimen volume less than 40 specimens/3-hour intervals (around 300 samples/day) the 90th percentile TAT and percentage of specimen that report within 60 minutes were similar in both workflows.

The fully automated analyzer can increased effectiveness by high-throughput, savings on disposable products, and relocating operators<sup>3</sup> as the same as our laboratory that one staff reposition to another area of the laboratory.

This study has some limitations. First, even though this study used retrospective data, which is regarded in most cases as being a weakness or vulnerability, all data were complete and accurate. Second, even though this is a single-center study, our laboratory is the largest in Thailand, and the mean daily volume of specimens that requires evaluation is approximately 500. Third, an authentic limitation of this study is that we used only TAT as a parameter to

measure productivity. Cost-effectiveness, error rate, and patient/physician/laboratory staff satisfaction are other parameters that can and should be studied in the future.

In conclusion, the results of this study revealed our new urinalysis workflow process that incorporates fully automated instrumentation, the lean management approach, and autoverification to be effective for significantly increasing productivity as measured by analytical TAT.


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## CONFLICT OF INTEREST

The authors hereby declare no personal or professional conflicts of interest regarding any aspect of this study.

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