

Applying Process Capability Analysis in Measuring Clinical Laboratory Quality - A Six Sigma Project

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Abstract

The clinical laboratory has received considerable recognition globally due to the rapid development of advanced technology, economic demands and its role in a patient's treatment cycle. This paper deploys Statistical Quality Control (SQC) to measure, analyze and monitor Turnaround Time (TAT) of CBC test in a clinical laboratory of Benghazi Medical Center (BMC). The objective of this study is to assist laboratory staff in releasing the CBC test results with high service quality performance within responsive time. It is also assumed that patients who delivered their test request in the laboratory have been come from out-patient departments (OPD). The use of Statistical Process Control (SPC) tools such as; Boxplots, probability plot, and the implementation of Shewhart, X bar, and R control charts as primary techniques, are presented to display the monitoring aspects of the process. In addition, Process Capability Analysis (PCA) a Six Sigma analysis phase method was performed to ensure that the process outcomes are capable of meeting certain requirements or specifications. The Process Capability Ratio (PCR) and sigma level for the process are also presented. This analysis is an essential part of an overall Six Sigma quality improvement project.

Keywords

Clinical laboratory, Process capability analysis, Shewhart control chart, Six Sigma, Turnaround time.

1. Introduction

Continuous improvement of healthcare systems requires the measuring and understanding of process variation. It is important to eliminate extraneous process variation wherever possible, while moving well-defined metrics toward their target values. In healthcare, most performance metrics are of the lower-the better or higher-the-better variety. Examples of important variables in healthcare involve lab turnaround times, days from positive mammogram to definitive biopsy, waiting times, patient satisfaction scores, medication errors, emergency service response times, infection rates, mortality rates, numbers of patient falls, post-operative lengths of stay, "door-to-needle" times, counts of adverse events, as well as many others (Woodall et al. 2011). Careful monitoring and study of such variables often can lead to significant improvements in quality. For example, monitoring infection rates, as discussed by Morton et al. (2008), can provide insights leading to improved standardized cleaning procedures or the early detection of new outbreaks.

Within this context, statistical process control (SPC) tools and techniques are very useful tools for studying important process variables and identifying quality improvements or quality deterioration. This method has been adopted since 1940s in the industrial area. The use of this method has a significant improvement towards the quality characteristic of manufactured products in industrialized countries, such as Japan and United States. The idea of this method is to thoroughly control production process of products/services such that fit the customer satisfaction. The manufactured products should have fitness values for use, such as well-performed, reliable, durable, easy to repair, good visual appearance, has outstanding function, good reputation, and satisfy the expected requirements.

The implementation of SPC has also been widely used in the medical area. This method can assist medical practitioners to improve the quality characteristic and healthcare process/service. Goldenberg, et al. (2002) described an early statistical detection of anthrax outbreaks by tracking Out-The-Counter (OTC) medication sales. They used a statistical framework for monitoring grocery data to detect a large-scale but localized bioterrorism attack and an early detection statistical system designed for bio surveillance to improve clinical preparedness for bioterrorism. Stevens (2007) has been studied that SPC with its core tool, the control chart, considerably potential to facilitate medical practitioners in managing the change of healthcare systems and improving patients' health. He also

explained that SPC helped patients with chronic conditions, such as asthma and diabetes, to manage their own health and therefore, improve therapeutic qualities.

Much effort has in the past and in some places still is directed at imposing quality rather than concentrating on optimizing the healthcare system. Six Sigma methodology is an optimization tool that focuses on developing and delivering near-perfect services. It is one of the most powerful performance improvement methodologies that are changing the face of modern healthcare delivery. Aiming for a Six Sigma level is essentially aiming for a process that eliminates nearly all defects. In terms of percentage accuracy, it means a process that is 99.9997% free of defects. In Six Sigma language, this is considered a “perfect” process. In practical terms it may be challenging to conceptualize a significant difference between processes that is operating at 99% defect free (approximately 3.8 Sigma level) versus a 99.9997% defect-free process (Six Sigma level). The following example (Chassin 2008) helps illustrate the magnitude of this difference by providing practical case that highlights the need for nearly error-free processes: the pharmacy operating at a 99% performance level, would fill prescriptions with the wrong drug 200,000 times a year versus just 68 if operating at a 99.9997% level. Because of the large volume of patients that come through the health care system, achieving a Six Sigma level is critical for high-quality patient care and medical system performance.

This study aims to evaluate the service quality of BMC clinical laboratory in monitoring turnaround time of CBC test. This quality of service can be investigated first using boxplots, probability plot, and the implementations of Shewhart, X bar and R control charts as a primary technique to summarize the performance of the process. In addition, this study will display the potential capability of the laboratory process as a part of Six Sigma improvement project. Capability Ratio (PCR) is used to show how capable the clinic laboratory is in meeting TAT specification. This study uses a data of 120 outpatient samples from January 26, 2013 to February 22, 2013.

2. Literature Review

2.1 Statistical Process Control

Statistical Process Control (SPC) is one of techniques used to monitor processes and provide immediate feedback control. The feedback control is used to maintain and improve the capability of the process that result in product / service conformance to meet customer satisfaction. Some techniques associated with SPC include histograms, and control charts. A histogram is a visual display of frequency distribution to show shape, location, and spread of data. While, a control chart is a statistical tool used to monitor the variation and trends occurring in a process and ensure that the process is in a state of control. A control chart has its limits: Upper Control Limit (UCL), Central Limit (CL), and Lower Control Limit (LCL) measured from the dispersion happened in the process. Walter A. Shewhart gives a general model for a control chart. Let w be a sample statistic that measures some quality characteristic of interest, and suppose that the mean of w is μ_w and the standard deviation of w is σ_w . Then the center line, the upper control limit, and the lower control limit become where L is the “distance” of the control limits from the center line, expressed in standard deviation units (Montgomery 2009).

2.2 Process Capability Analysis (PCA)

A process capability index is a metric used to indicate the performance of the process relative to requirements, as indicated in the following equations:

$$C_p = \left[\frac{USL - LSL}{6\sigma} \right] \quad (1)$$

$$C_{pk} = \min \left[\frac{USL - \mu}{3\sigma}, \frac{\mu - LSL}{3\sigma} \right] = \frac{d - |\mu - m|}{3\sigma} \quad (2)$$

Where USL and LSL are the upper specification limit and lower specification limit, respectively, σ is standard deviation, μ is the mean of the process, m is the target, and d is the tolerance (i.e., $d = USL - m = m - LSL$).

Perhaps the biggest drawback of using process capability indexes is that they take the analysis a step away from the data. The danger is that the analyst will lose sight of the purpose of the capability analysis, which is to improve quality. To the extent that capability indexes help accomplish this goal, they are worthwhile. To the extent that they distract from the goal, they are harmful. The analyst should continually refer to this principle when interpreting capability indexes.

(C_p) This is one of the first capability indexes used. The “natural tolerance” of the process is computed as 6σ . The index simply makes a direct comparison of the process natural tolerance to the engineering requirements (USL – LSL). Assuming the process distribution is normal and the process average is exactly centered between the engineering requirements, a C_p index of 1 would give a “capable process.” However, to allow a bit of room for process drift, the generally accepted minimum value for C_p is 1.33. In general, the larger C_p is the better. For a Six Sigma process, that is, a process that produces 3.4 defects-per-million opportunities including a 1.5 sigma shift, the value of C_p would be 2.

The C_p index has two major shortcomings. First, it can’t be used unless there are both upper and lower specifications. Second, it does not account for process centering. If the process average is not exactly centered relative to the engineering requirements, the C_p index will give misleading results. In recent years, the C_p index has largely been replaced by C_{pk} . (C_{pk}) The value of C_{pk} is simply as shown in equation (2). Since the smallest value represents the nearest specification, the value of C_{pk} tells you if the process is truly capable of meeting requirements. A C_{pk} of at least +1 is required, and +1.33 is preferred. Note that C_{pk} is closely related to C_p , the difference between C_{pk} and C_p represents the potential gain to be had from centering the process. For a Six Sigma process C_{pk} would be 2.

Figure 1 shows the relationship of C_p and C_{pk} . The top two normal distributions both have $C_p = 2.0$, but the process in panel (b) of the figure clearly has lower capability than the process in panel (a) because it is not operating at the midpoint of the interval between specifications. This situation is more accurately by C_{pk} , which takes process centering into account. Generally, if $C_p = C_{pk}$, the process is centered at the midpoint of the specifications, and when $C_{pk} < C_p$ the process is off-center. Thus, we usually say that C_p measures potential capability in the process, whereas C_{pk} measure actual capability (Montgomery 2009).

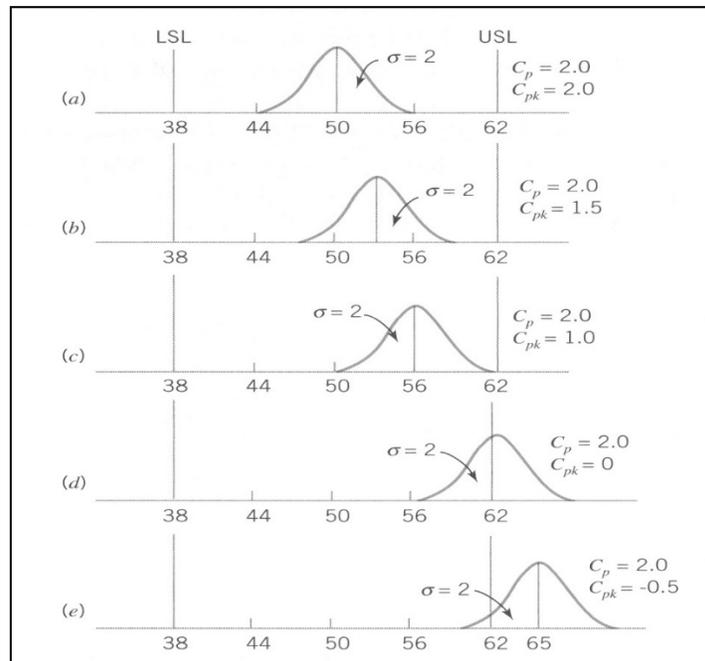


Figure 1: Relationship of C_p and C_{pk}

2.3 Measuring Model of Six Sigma

According to Linderman et al. (2003) mentioned Motorola set this goal so that process variability is $\pm 6\sigma$ from the mean. They further assumed that the process was subject to disturbances that could cause the process mean to shift by 1.5σ off the target. Hence, this section will research the corresponding value between numbers of Sigma and C_{pk} when the process mean shift 1.5σ (i.e., $|\mu - m| = 1.5\sigma$). When that the process quality level arrived $k\sigma$ (i.e., $d = k\sigma$) and the process mean shifts 1.5σ , C_{pk} can be showed as follows:

$$C_{pk} = \frac{d-|\mu-m|}{3\sigma} = \frac{k\sigma-1.5\sigma}{3\sigma} = \frac{k-1.5}{3} \quad (3)$$

And then yield percent is the probability which is between USL and LSL. USL is $m+k\sigma$ and LSL is $m-k\sigma$. The yield % when the process mean shifts 1.5σ right can be described as:

$$Yield \% = \Pr(LSL \leq X \leq USL) = \Pr(m - k\sigma \leq X \leq m + k\sigma) = \Pr\left[\frac{(-k-1.5)\sigma}{\sigma} \leq Z \leq \frac{(k-1.5)\sigma}{\sigma}\right] \quad (4)$$

$$Yield \% = \Phi(k - 1.5) - \Phi[-(k + 1.5)] = \Phi(k - 1.5) + \Phi(k + 1.5) - 1$$

2.4 Clinical Laboratory

One of the most important units of the healthcare sector, particularly in hospitals, is undoubtedly clinical laboratories. Obviously, without accurate test results, physicians cannot make diagnoses or provide effective treatment. This is true even for experienced physicians. Currently, clinical laboratories affect 60~70% of all critical decisions, such as the admission, discharge, and drug therapy of patients (Forsman 1996). Coskun et al. (2010) believe that this rate is even higher. Despite these vital functions, in the healthcare sector, laboratory costs are a very low proportion (5~10%) of the total cost of patient care (Forsman 1996). Testing process in clinical laboratory is a multistep process that begins and ends with the needs of the patient. The number of steps may vary according to test types and laboratory organization. The eight activity steps in laboratory medicine were described as follow: (1) Receiving test request, (2) Collecting the sample, (3) Identification, (4) Preparation of the sample, (5) Transport the sample to laboratory (6) Test performing (7) Result validation, and (8) Reporting test result. Through literature found that all analytical tests are divided into three stages: (a) Pre-analytical phase (step 1-5), (b) Analytical phase (step 6-7), and (c) Post-analytical phase (step 8). Laboratory performance is measured in terms of test turnaround time (TAT), which is the time interval between the receipt of test orders in the laboratory and the release of test results by the laboratory. Some laboratories also analyze intervals form test order to specimen collection, collection to laboratory specimen receipt time, and receipt time to reporting time, in order to determine the specific points at which delays occur. A few laboratories also are expanding the scope of measurement by evaluating "therapeutic turnaround time," the time from initiation of the test order to the implementation of clinical decisions (Kilgore et al. 1998).

3. Results and Discussion

This study has used 24 samples, each of size five, were taken from outpatient of BMC clinical laboratory between January 26, 2013 and February 22, 2013. That is mean for 24 day the five TAT data of outpatient were taken each day. The time form receiving test order at reception to test result releasing was recorded for each patient. According to stages of clinical laboratory process mentioned above, the recorded TAT for each patient was divided into two parts namely per-analytical time "the time from receiving test order at reception to transport the specimen tube to hematology lab" and analytical time "the time from starting test perform to test result release" (i.e. TAT = per-analytical time + analytical time); all time in minutes. Three steps needed to perform process capability analysis technique for six sigma project. First step constructs boxplots to assess and compare sample distributions and investigate the outliers. Outlier is an unusually large or small observation. Values beyond the whiskers are outliers. Figure 2 shows the boxplots for pre-analytical time, analytical time and TAT. Then use probability plots to determine whether the data fit to normal distribution in the second step. The normality plots for pre-analytical time, analytical time and TAT are shown in Figure 3. The process capability analysis can produce a valid and accurate report if the observed process is in-control, so the final step before applying capability analysis is implementing X bar and R chart to ensure in-control process (see Figure 4)

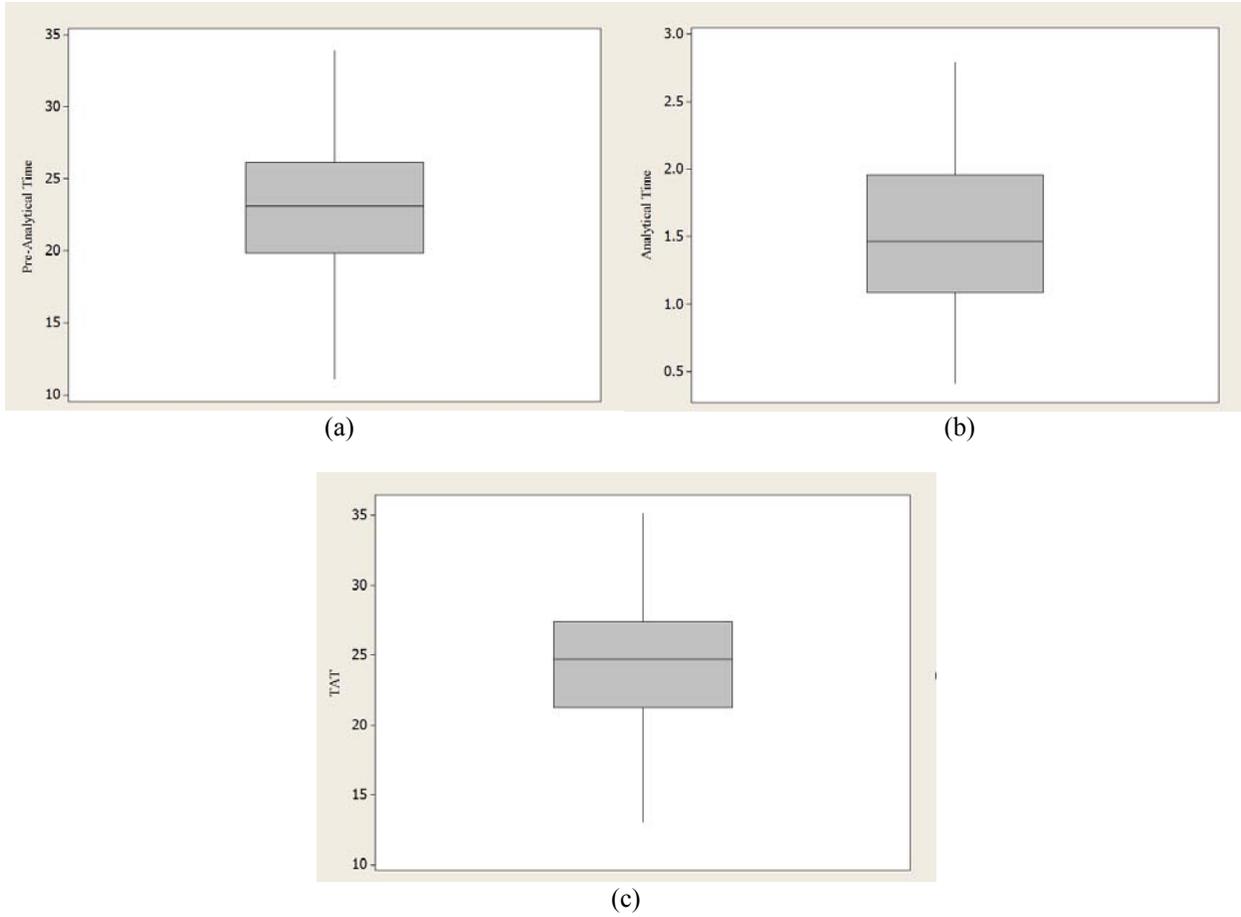
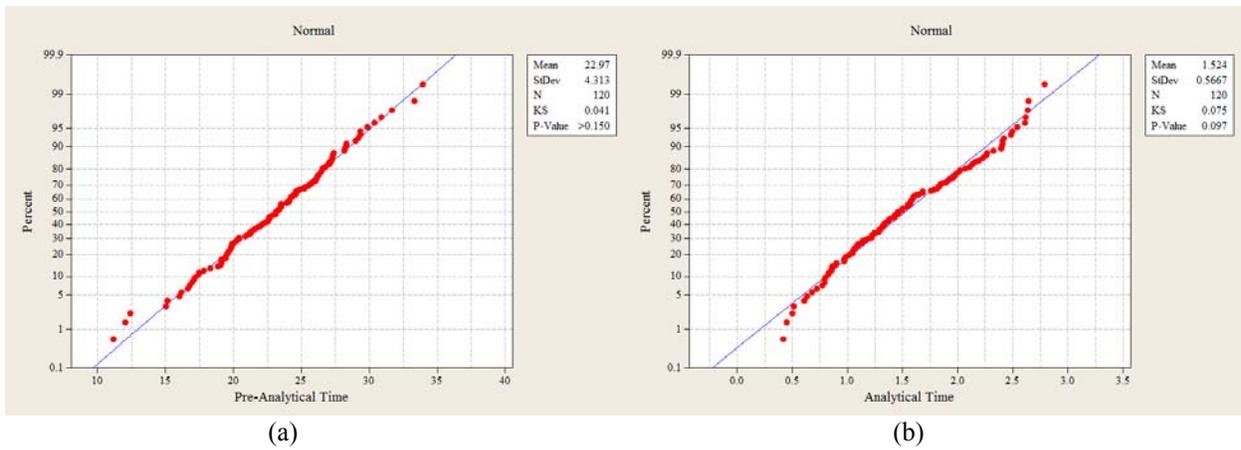
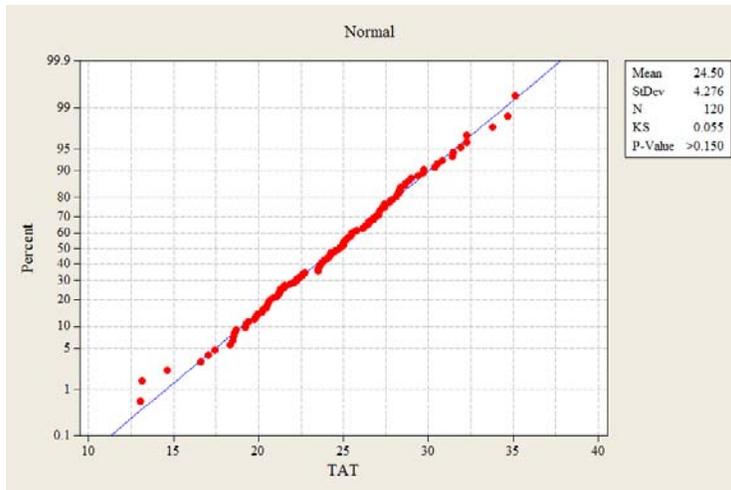


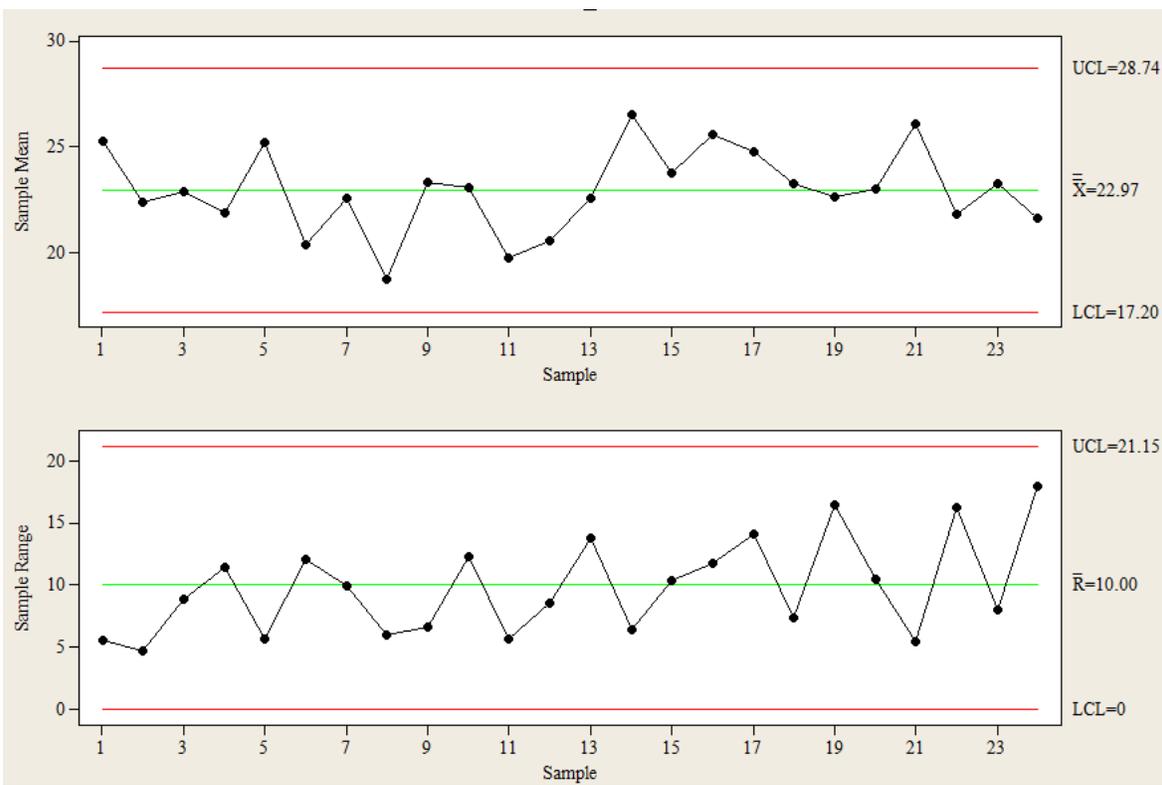
Figure 2: Boxplots of (a) Pre-Analytical Time (b) Analytical Time (c) TAT



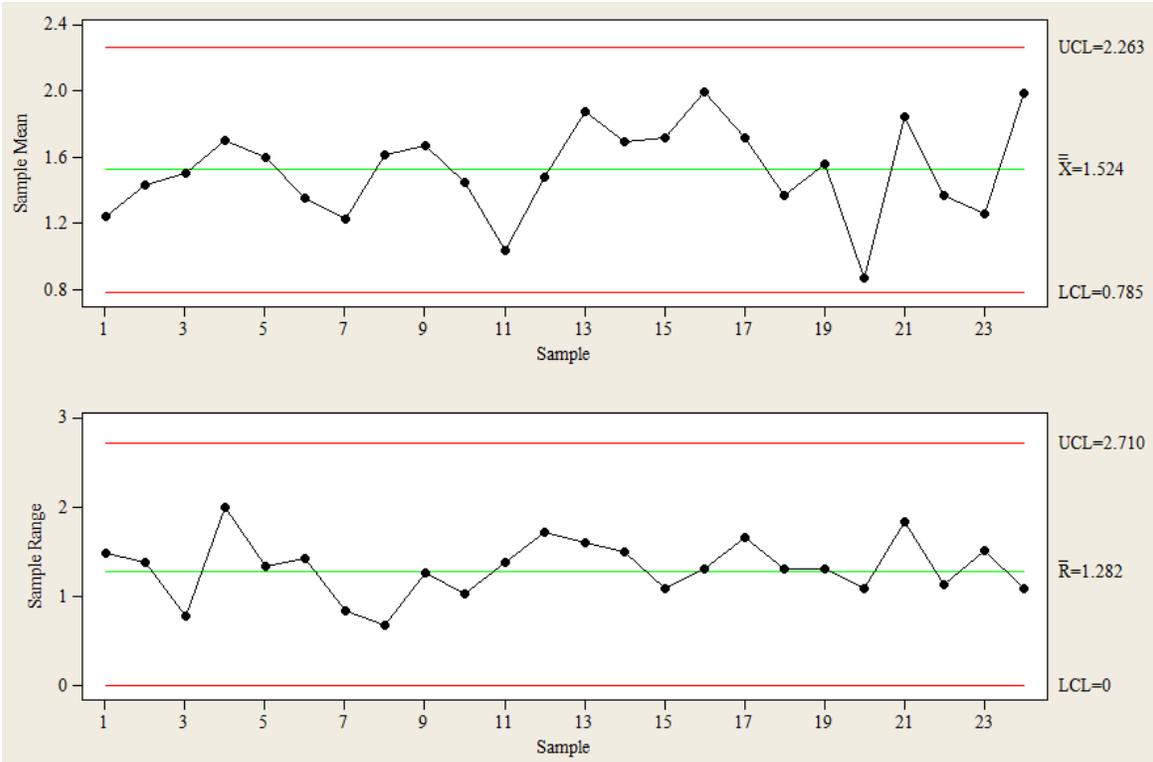


(c)

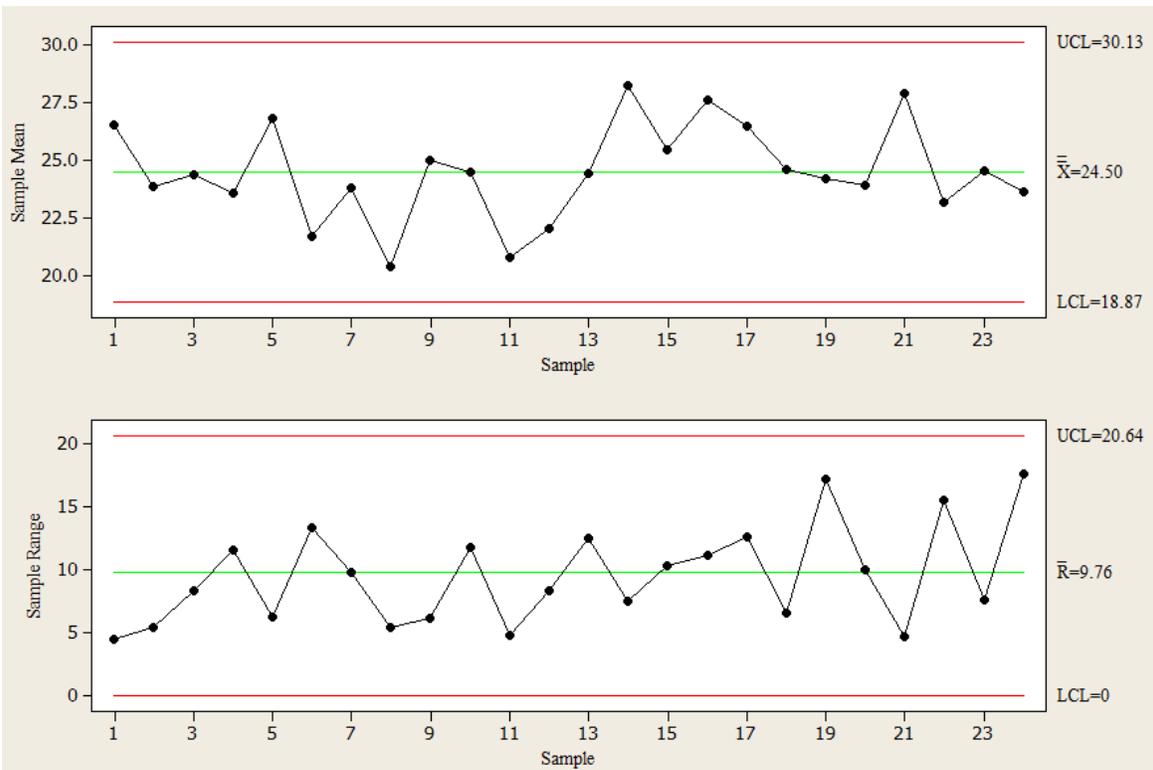
Figure 3: Probability Normal Plot of (a) Pre-Analytical Time (b) Analytical Time (c) TAT



(a)



(b)



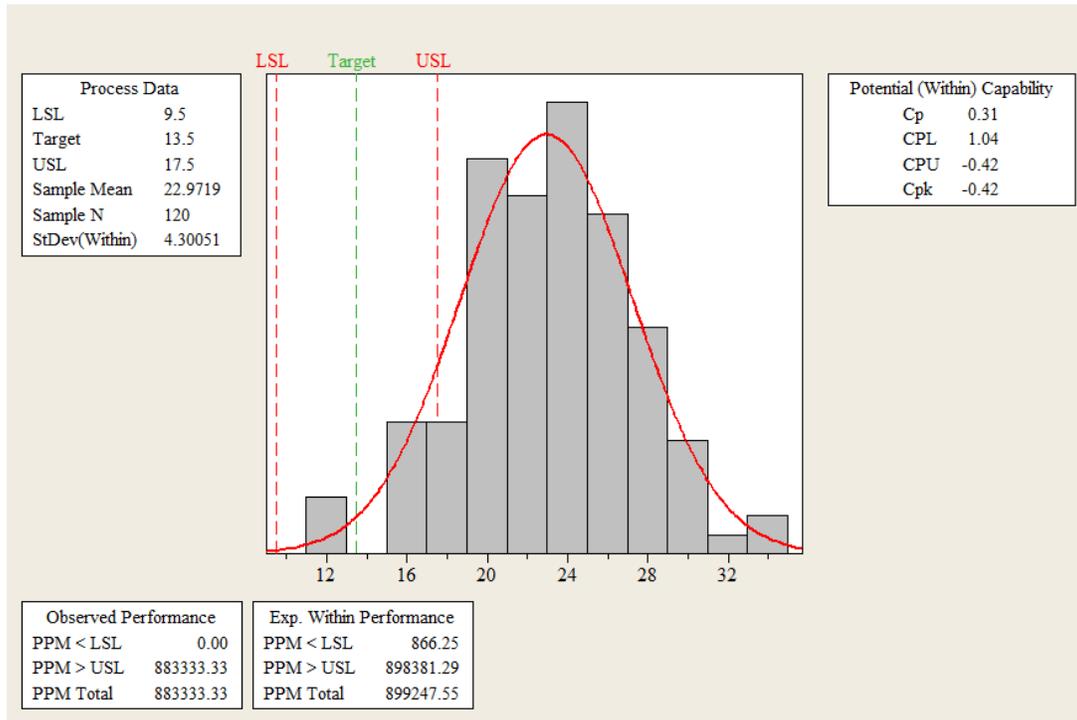
(c)

Figure 4: X bar and R chart of (a) Pre-Analytical Time (b) Analytical Time (c) TAT

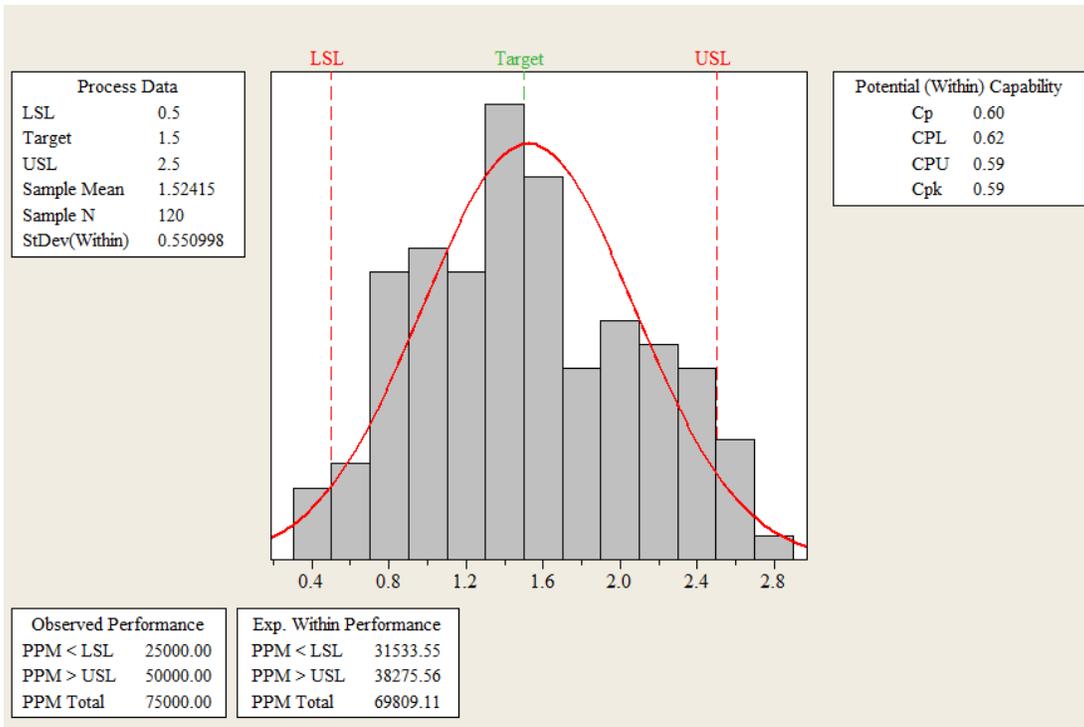
Figures 2a, 2b and 2c show that there are no outliers in the recorded data. And from normality plot shown in Figures 3a, 3b and 3c it can be noticed the data are normality distributed and the minimum P-value is 0.097. As mentioned earlier one can assess the capability of the process only when process is in-control. Figures 4a, 4b and 4c show the process is in-control. Using statistical package Minitab the results of the capability analysis have been provided in Figures 5a, 5b and 5c. It can be seen from Figure 5a that the $C_p = 0.31$ and $C_{pk} = -0.42$. The value of $C_p = 0.31$ indicates that the capability of the time from receiving test order at reception to transport the specimen tube to hematology lab to meet specification is very bad. While, the value of $C_{pk} = -0.42$ describes that the process skewed to the right, that is indicate that approximately 0.88 of pre-analytical time exceed 17.5 min and that will lead to sigma level is 0.53. So that is mean the two-way improvement method is needed to attraction the process average into the target and to reduce process variability. Figure 5b shows that the $C_p = 0.60$ and $C_{pk} = 0.59$. However, the fact of very close values of C_p and C_{pk} means that the process is centered but the analytical time is not meeting to specifications. The sigma level of analytical phase process is 2.94. So the improvement solutions are needed to reduce process variability. The process capability analysis of overall TAT shown in Figure 5c illustrates the same discussion of Figure 5a. That is mean the pre-analytical phase is more effective than analytical phase to improve the overall TAT. Table 1 shows the specification limits, target value and Sigma level for all times.

Table 1: Target value and Specification limits

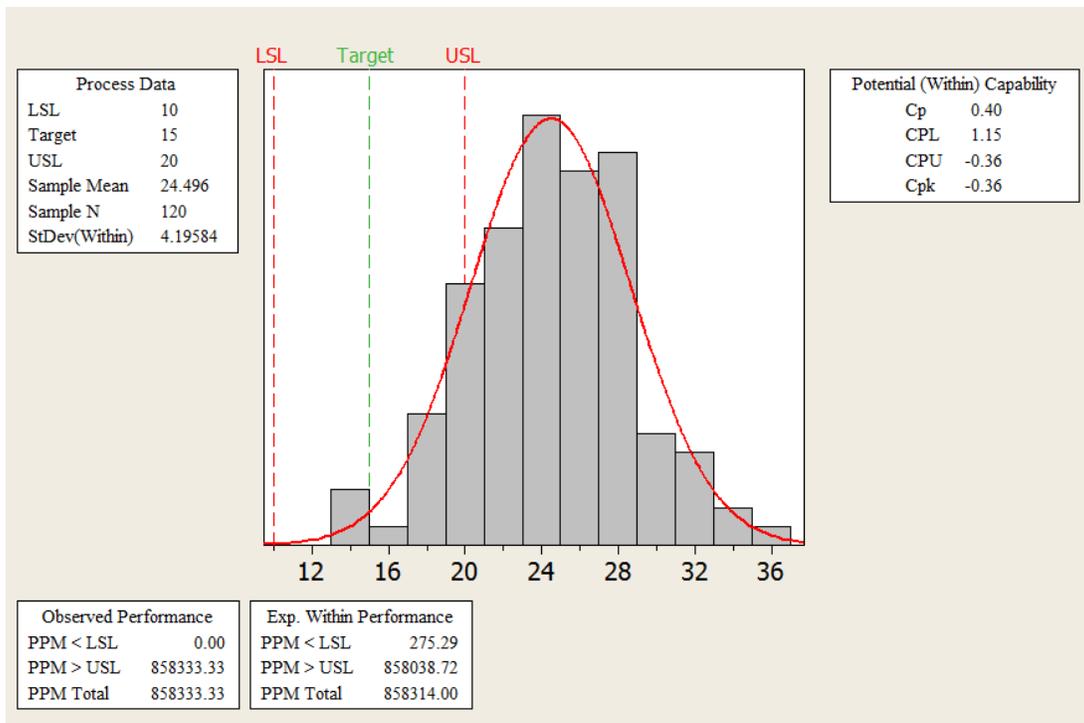
Time	LSL	Target	USL	DPMO	Sigma Level
Pre-Analytical Time	9.5	13.5	17.5	883333	0.53
Analytical Time	0.5	1.5	2.5	75000	2.94
TAT	10	15	20	858333	0.43



(a)



(b)



(c)

Figure 5: Process Capability Analysis of (a) Pre-Analytical Time (b) Analytical Time (c) TAT

4. Conclusion

In this study it has been shown that statistical process control and process capability analysis as a part of six sigma project can be applied effectively in healthcare service. Using real data based on the turnaround time of CBC test in BMC clinical laboratory, it has been first monitored the TAT using control charts, then followed by capability analysis to estimate the proportion of out-of-specification TAT and that will lead to calculate the DPMO and sigma level. However, the conclusion is that the service of an observed clinical laboratory of BMC is ineffective process that cannot reduce the time from the receipt of test orders at reception of laboratory to the release of test results. In other words, the BMC clinical laboratory produce quality characteristic (i.e. TAT) that cannot meet the specifications. So the two-way improvement solutions are required first to improve the process average and then reduce process spread.

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Biography

Khaled N. El-Hashmi is a postgraduate student at Industrial and Manufacturing Systems Engineering Department, University of Benghazi, Benghazi, Libya. He received a B.Sc. degree in Industrial Engineering from Industrial and Manufacturing Systems Engineering Department, University of Benghazi, Benghazi, Libya in 2007. After that he has decided to enroll Master of Science degree in industrial engineering program at same university, same faculty and also same department. His major is in Healthcare Engineering, the application of Industrial engineering methods and problem solving skills to solve important problems and develop solutions in healthcare sector. Mr. El-Hashmi is working as quality assurance engineer at Al-Nahr Company. It is one of the biggest companies in Libya were concentrated in the pipes manufacturing, and construction of infrastructure and buildings.

Omar K. Gnieber is a quality and operations management consultant for 14 years, Worked for numerous clients and provide a several consultancies for companies in manufacturing and service sectors. He has training experience extends for 20 years in improving organizations and their human asset. Currently works as professor of operations and quality management. Former dean of the faculty of engineering, and currently is head of Engineering Management Department in the Academy of graduate studies. Formerly joined the industrial field and worked with Japanese and British company. He has taught thousands of students and trainees at under and postgraduate levels. He is highly enjoyed training and consultancy in management and human soft skills field. Prof. Gnieber supervises research studies and publishing his work nationally and internationally. He is a board member of The Arabic Institute of Operations and Maintenance (Lebanon), representative of the society of the Arabic management (Egypt), member of British Institute of operations Management (UK), and a member of the International Association of Management of Technology (USA).