

## DEVELOPING A LEAN CONSCIOUSNESS FOR THE CLINICAL LABORATORY

### RAZVIJANJE LEAN FILOZOFIJE U KLINIČKIM LABORATORIJAMA

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**Summary:** This is an overview of the principles of Lean and Six Sigma as a means of streamlining operations and improving productivity. Manufacturing sectors have employed these concepts with much success. The primary goal of a lean initiative is to deliver quality products and services the first time and every time. To accomplish this, all activities that do not add value (i.e., waste) must be eliminated or, if not feasible, reduced. The demands of today's healthcare environment warrant the integration of quality management systems such as these to meet increased workloads, staff shortages, and the demand for rapid turnaround for specimen results. This paper discusses Lean and Six Sigma strategies as well as their application for the clinical laboratory, specifically utilizing tools such as 5S, the Kaizen Blitz, process mapping, and value stream mapping. By implementing these tools to maximize process flow, eliminate waste, and recognize the variations that can hinder the delivery of high-quality services, healthcare professionals can reach their efficiency goals, reduce costs, and provide customer satisfaction.

**Keywords:** Lean, Six Sigma, Kaizen Blitz, Value Stream Mapping, 5S, Specimen Management System

### Introduction

Today's healthcare facilities are faced with the challenge of increasing workloads and the demand to produce more at a faster rate with limited errors. These demands dictate the need to employ quality management tools to redesign workflow, increase productivity, and reduce errors. The philosophies of suc-

**Kratak sadržaj:** Ovo je pregled principa *Lean* i *Six Sigma* kao sredstava protoka operacija i poboljšanja produktivnosti. Proizvođački sektori su iskoristili ove koncepte sa mnogo uspeha. Primarni cilj lean inicijative je da se daju kvalitetni proizvodi i usluge odmah i uvek. Da bi se ovo postiglo, sve aktivnosti koje ne doprinose vrednosti (npr. trošak) treba da se eliminišu ili, ako to nije izvodljivo, da se smanje. Zahtevi današnjeg sistema zdravstvene zaštite opravdavaju integraciju sistema upravljanja kvalitetom kao što su oni za prihvatanje povećanja radnog opterećenja, deficit osoblja, i zahtev za brz obrt rezultata uzorka. Ovaj članak diskutuje *Lean* i *Six Sigma* strategije kao i njihove aplikacije za kliničke laboratorije, specifično upotrebljavajući sredstva kao što su 5S, *Kaizen Blitz*, planiranje procesa i planiranje protoka vrednosti. Implementacija ovih sredstava maksimalno povećava protok proces, eliminiše troškove, i prepoznaje varijacije koje mogu sprečiti pružanje visoko-kvalitetnih usluga, zdravstvenim radnicima omogućava dostizanje ciljeva efikasnosti, smanjuje cenu, i obezbeđuje zadovoljstvo korisnika.

**Ključne reči:** *Lean*, *Six Sigma*, 5S, *Kaizen Blitz*, planiranje protoka vrednosti, 5S, sistem upravljanja uzorkom

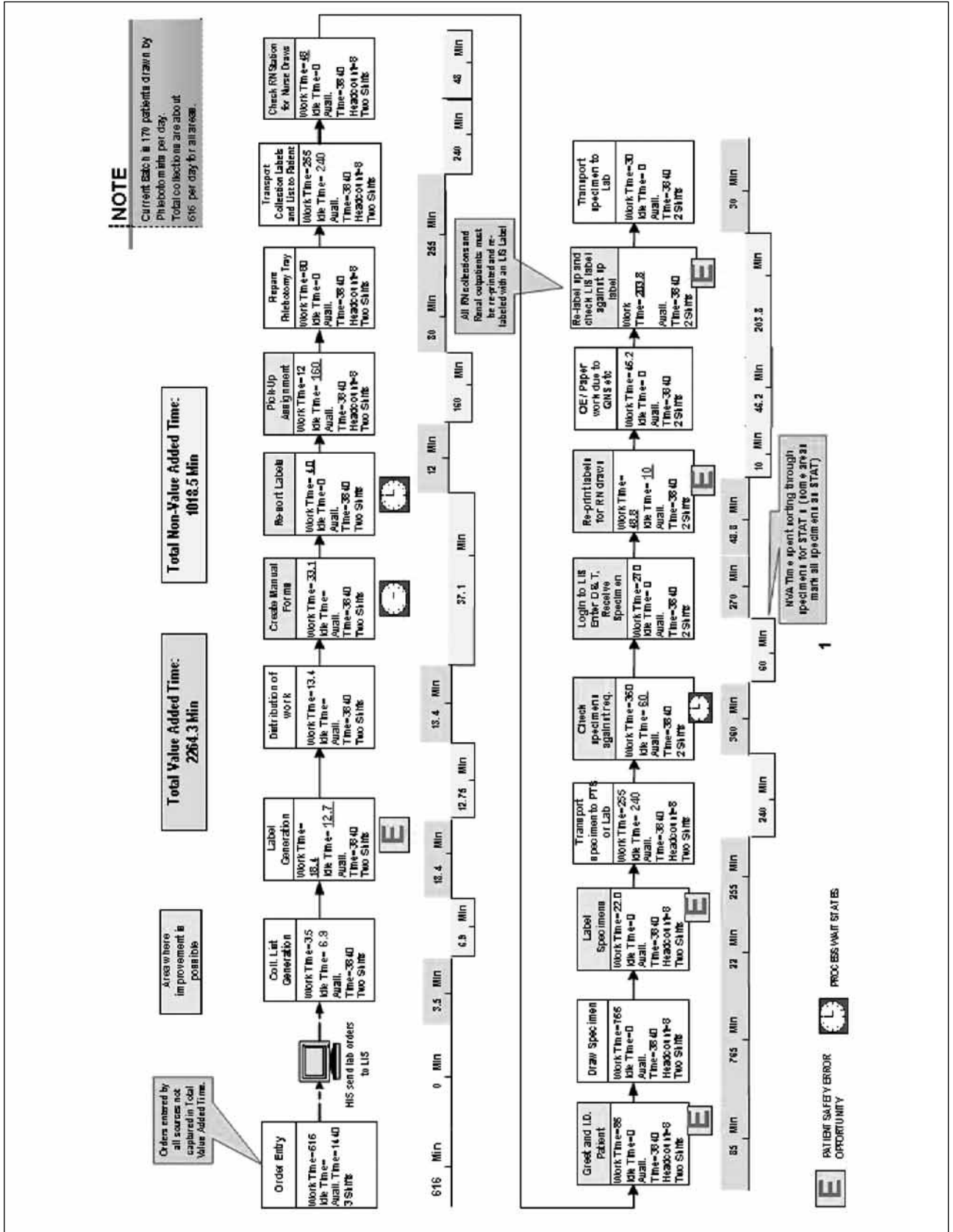
cessful manufacturing companies offer viable methods for the healthcare industry to address these challenges. Among these are the concepts of Lean and Six Sigma.

Although the origins of Lean may be traced as far back as the 1450s at the shipping Arsenal in Venice, Italy, Henry Ford of the automotive industry was the first individual to fully integrate an entire production process, described as flow production. This later became known as the moving assembly line (1). In the 1930s, this system was honed by Toyota founder, Sakichi Toyoda, his son, Kiichiro Toyoda, and engineer, Taiichi Ohno. The well-known Toyota Production System has been extensively studied and is steeped in

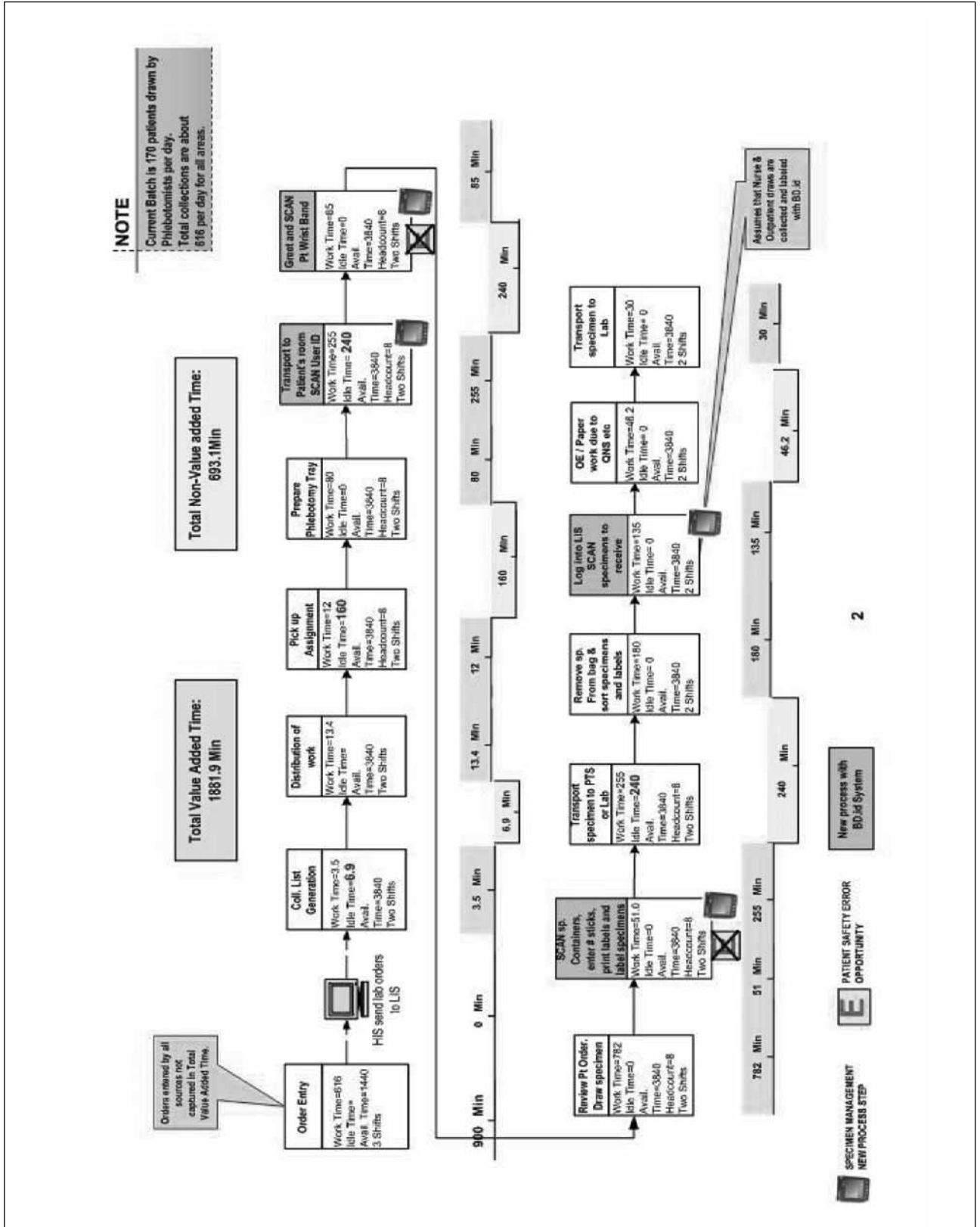
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*List of Abbreviations:* 5S (sort, set in order, shine, standardize, sustain), DPMO (defects per million opportunities), DMAIC (Define, Measure, Analyze, Improve, Control), CV (coefficient of variance)



**Figure 1** Specimen Collection Process »As Is« or »Current State«. Specimen collection process »As Is« or »Current State.« Twenty steps were identified, 5 of which were prone to specimen identification errors.



**Figure 2** Specimen Collection Process After Introduction of an Electronic Specimen Management System (i.e., the »To Be«, or »Future State«)  
 Specimen collection process after introduction of an electronic specimen management system (i.e., the »To Be«, or »Future State«). Six steps were eliminated, and two additional steps that had opportunities for specimen identification errors were made error-free.

the ideology that the complete elimination of waste will facilitate smooth delivery of the specified results (2).

### The Lean Way to Quality and Efficiency

The Lean concept builds on that of its predecessors; it can be best described as a quality philosophy that minimizes the consumption of resources that do not add value to the finished product. This is governed by a systemic set of principles that stress waste minimization by removing all activities that do not add value, while promoting continuous improvement, flexibility, and long-term relationships. Specifically, the key objective of Lean methodology is to reduce production time and effort by focusing on those steps which may be error prone, so they can be either eliminated or controlled. This is usually achieved with a low-tech, high-touch approach. It is not surprising that Lean methodology is finding its way nowadays into the clinical laboratory, which is the operational backbone of the health-care industry. In many aspects, its processes are similar to those of the manufacturing industry, and data have shown that introduction of Lean principles can greatly improve laboratory outputs.

One of the basics of the Lean system is recognizing the types of waste (those items that do not add value) in the work process. These include:

- Overproduction (i.e., unnecessary testing in the laboratory) slows results and ties up capital
- Retention of a large amount of inventory (i.e., supplies for laboratory testing) causing clutter
- Transporting specimens and other materials as well as unnecessary motion of laboratory personnel to locate supplies, process specimens, and run assays on instruments
- Waiting for specimens to arrive as part of the »batching« process
- Errors that result in rework and re-testing

One »fix« to decrease the waiting time of specimens in the laboratory and reduce turnaround time is the implementation of the one piece flow system. Rather than the traditional processing of specimens by batching, the one (i.e. single) piece flow system handles samples on a »first in, first out« basis, starting from specimen collection. Single piece flow allows specimens to be processed and tested in a continuous stream, thus preventing long waiting times that are characteristic of the batching process. This way, often there is no need for a distinction between stat (emergency) and routine requests; they are all processed equally as fast (3).

Lean tools also consist of the process map and value stream mapping. The process map records all steps in a current process and documents the existing state (the »As Is«). This enables laboratory managers to assess the activities taking place within and external to the laboratory that affect the total testing process. In this way, the management team is readily equipped to

identify troublesome areas and to obtain more productive outcomes.

Value stream mapping determines the amount of time required for completion of an entire process as well as for each step in the process and then categorizes these into value-added and nonvalue-added activities. The total time to perform both activities is quantified by flow charts. The reduction in nonvalue-added time can be measured as the potential savings of wages by personnel involved in these steps (4).

*Figure 1* illustrates the »As Is« process of specimen collection – from order entry to the transport of the specimen into the laboratory in a US hospital. One hundred seventy specimens were followed from order entry to transport to the laboratory, documenting the steps and time required to complete the process. The data were then extrapolated for all specimens that were collected in a day.

The laboratory management of this hospital wanted to improve the specimen collection process and decrease the number of specimen identification errors. This »Current State« consisted of 20 steps, five of which were at risk for specimen identification errors, and three of which were causing unnecessary delays in the specimen collection workflow. The value stream mapping showed that the total value-added time per day (based on 616 blood specimen collections/day) was 2264.3 minutes, while the nonvalue-added time was 1018.5 minutes.

By introducing an electronic specimen management system, the »Future State« process now consists of only 14 steps (*Figure 2*). All of the steps in which there was a potential for specimen identification error were either eliminated or changed, so that the new process was now error-free. Also, the new process allowed reduction in both value-added and nonvalue-added time.

### The Principles of 5S

The principles of 5S focus on visual order, organization, cleanliness, standardization, and maintenance. In short, the 5Ss can be defined as sort, set in order, shine, standardize, and sustain.

»Sorting« (organizing) – Items that are needed are distinguished from those which are unneeded; the latter is then removed. This process facilitates the discarding of all items which are not currently required during the work day.

»Set in Order« – A work area is organized for maximum possible efficiency. By setting in order, needed items are arranged to ensure availability for use and readily labeled for easy location and storage. When orderliness is implemented, wasted energy or excess inventory is eliminated.

»Shine« – All items in the work area are thoroughly cleaned (until they shine). This function ensures

that laboratory instruments are kept in top condition, thus requiring less maintenance.

Upon establishment of the first three »S«s, a »standardized« plan is implemented to maintain continual improvement activities. Standardized cleanup integrates sort, set in order, and shine into a unified whole; »sustain« (the fifth »S«) provides a plan for maintenance. The completion of designated tasks on a routine basis is the key to the 5S concept.

### The Kaizen Blitz

From the Japanese kai (change) and zen (good), kaizen simply means constant or continual improvement. The Kaizen business philosophy focuses on making constant improvements by taking something apart and putting it together in a more efficient way. This is based on the fundamental belief that there will always be room for improvement, regardless of how »perfect« a system or operation may seem (5). The term blitz refers to any sudden, overpowering attack. Hence, a Kaizen blitz may be defined as a sudden, overpowering effort for disassembly and reassembly in a more efficient manner (Table I).

**Table I** 5S Kaizen Blitz for Laboratory Order.

1. Separate unnecessary, unsafe, and unneeded equipment, tools, furniture, and any other items from the workspace, aisles, stairways, and corners.
2. Designate a location for each item according to frequency of usage and ensure the visibility of each.
3. Sweep work areas and equipment; visual sweeping must identify housekeeping issues (i.e., tools, manuals, inventory in incorrect places).
4. Standardize the above 3S into work instructions which should specify what is needed and not needed, indicate disposable procedures, dangerous areas, protective clothing, as well as when, what, and how to clean the work areas and equipment.
5. Continuously maintain and improve sorting, setting, and sweeping using self-discipline.

### Reducing Variability with Six Sigma

Originally developed by the Motorola Company, (6) the practices of Six Sigma attack process variability as a means of eliminating defects; a defect is considered as any nonconformity of specifications of a product or service. Reducing variability (i.e., counting and decreasing the number of defects in a process) is a key component of Six Sigma; the objective is to reduce process variation to no more than 3.4 defects per million opportunities (DPMO). As the process sigma value increases, the variation decreases, resulting in improved outcomes.

**Table II** Established Six Sigma Levels and Corresponding Laboratory Error Rates.

Sigma Level	% Accuracy	Error Rate	Number of laboratory errors in the US/year*
6	99.9997%	3.4	23.8–34 thousand
5	99.98%	233	1.6–2.33 million
4	99.4%	6.210	43–62 million
3	93.3%	66.807	467–668 million
2	69.1%	308.537	2.2–3.1 billion

\* The total number of laboratory tests performed in the US is estimated to be between 7–10 billion tests/year.

**Table III** Six Sigma DMAIC Methodology Components.

*Define* – Identify, prioritize and select the appropriate project(s); assess expectations

*Measure* – Identify key product characteristics and process parameters, understand processes, validate measurement systems, and measure performance

*Analyze* – Verify the causative process variables

*Improve* – Establish a prediction model and optimize performance

*Control* – Ensure that any variances are corrected before defects can result

Defects (errors) in the laboratory are not a rare occurrence. One laboratory error is identified every 164–8300 laboratory results (7) which translates to about 6098–120 DPMOs or, if applied to the laboratory setting, errors/million tests. When compared to the established Six Sigma levels (Table II), the quality of laboratory testing would fall between 4 and 5 Sigma. If one takes into account that in the US, for instance, the total number of laboratory tests performed is 7–10 billion tests/year, this would indicate that there are between 2 and 62 million laboratory errors annually (8).

The primary goal of Six Sigma is to reduce variability. Translated into the laboratory setting, this could mean, for example, a decrease in the coefficient of variance (CV) for certain laboratory tests or a decrease in turnaround time outliers. In order to reduce variability, Six Sigma improvement projects are conducted by employing a structured methodology—the DMAIC (Define, Measure, Analyze, Improve, Control) model (Table III). These elements enable the team to monitor projects, allocate resources, and ensure that each step of the process has been completed in an efficient manner.

### **The Power of Two: Combining Lean and Six Sigma in the Laboratory**

The pioneering laboratories in the United States that have employed Lean and Six Sigma to redesign workflow in their high-volume core chemistry and hematology departments found that in a 12- to 16-week project, these quality management systems could lead to a 50% reduction in average test turnaround time for a hospital lab and a 40% to 50% improvement in labor productivity (9). Following incorporation of both Lean and Six Sigma, these labs were able to recognize waste (streamline), reduce variation for consistent results, and error-proof operations—all of these translated into enhanced quality and efficiency (turnaround time).

### **Conclusion**

Demands for improved efficiency and higher quality in the clinical laboratory are driving the need for Lean and Six Sigma implementation. These methodologies stress an evolutionary process of change and adaptation. It behooves the healthcare industry, particularly the clinical laboratory, to integrate the quality system strategies of the manufacturing sector to more aptly manage resources, streamline operations, and reduce errors.

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