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Abstract

The target of this study was to investigate the application of the 5S improvement methodology in a Validation laboratory to determine the impact on test efficiency. Quantitative data was analyzed using statistical analysis tools for Bacterial Challenge test times per process step and laboratory technician before and after implementing the 5S. Qualitative data were gathered from the workforce through questionnaires before and after the tool's implementation. The study substantially improved laboratory test efficiency and employee engagement after applying 5S. Overall, test efficiency increased to 86.4% after the implementation of 5S. Future studies should utilize a larger sample size or expand to multiple areas to increase the reliability of the findings.

Introduction

The execution of laboratory assays is a key practice that relies on and is based on scientific evidence to identify areas for improvement in a specific product or service.[1] Currently, Laboratory ST is dedicated to validating cartridge filters. The primary services provided by this laboratory include viability testing (VT) and bacterial challenge testing (BCT). No lean processes are performed within this laboratory. Test turnover is high due to an unorganized laboratory, where technicians take approximately two hours searching for test materials throughout the laboratory.

Background

The main objective in this research is increase test efficiency in the Laboratory ST by implementing 5S technique in the area. Currently, the laboratory does not have 5S in place. Also, develop a standardized checklist that the technicians can use to evaluate the workplace organization to sustain the 5S program. Furthermore, assess if all the materials and equipment that are currently in the Laboratory are adequate for performing the VT and BCT.

Problem

No lean processes are performed within this laboratory. Test turnover is high due to an unorganized laboratory, where technicians take approximately two hours searching for test materials throughout the laboratory.

Methodology

The focus was to evaluate the current state of test efficiency in the laboratory before and after implementing the 5's and applying the tool. A single study method was executed to simplify observation and evaluation. The study was conducted in a filter validation laboratory of a medical device company.

Both qualitative and quantitative data were gathered using questionnaires. Overall, eight laboratory employees with a background in Science, Biology, and Microbiology participated in the study. The quantitative component of the study involved evaluating the turnaround time of the eight technicians during the execution of the BCT. The qualitative approach of the study consisted of interviewing technicians and gathering data on their perceptions and knowledge of the improvement tool before and after its implementation using the 5S method.

Based on the literature review, a standardized checklist was developed for laboratory ST for this project. The assessment of the materials will be performed mainly by following the first three 5s of the approach (sort, set in order, and shine). Lastly, an evaluation of the time technicians spend gathering materials for each test, both before implementing 5S and after the project is implemented. With these values, estimate the time saved by implementing the lean approach.

Table 1: BCT /VT Step Analysis Before the Implementation of the 5S Methodology

BEFORE	TECHNICIAN							
	A	B	C	D	E	F	G	H
1	10	9	11	10	8	10	7	7
2	45	40	39	48	38	41	39	39
3	8	9	10	9	8	7	7	9
4	5	5	5	5	5	5	5	5
5	8	6	6	6	6	6	6	6
6	18	19	15	14	18	11	15	14
7	6	7	4	7	6	8	5	6
8	22	19	20	21	17	21	19	22
9	5	5	5	5	5	5	5	5
TOTAL	127	119	115	125	111	114	108	113

Table 2: BCT /VT Step Analysis After the Implementation of 5S Methodology

AFTER	TECHNICIAN							
	A	B	C	D	E	F	G	H
1	5	4	5	3	5	5	4	4
2	15	12	5	11	11	11	12	11
3	5	5	5	5	5	5	3	5
4	5	5	5	5	5	5	5	5
5	6	6	6	6	6	6	6	6
6	5	7	3	6	5	4	6	6
7	2	2	2	2	2	3	3	3
8	15	18	14	15	17	18	17	16
9	5	5	5	5	5	5	5	5
TOTAL	63	64	50	58	61	62	61	61

Results and Discussion

Analysis of the current state showed that the test efficiency was 36.4% before the implementation of 5S. The nine steps to performed the BCT were analyzed per technician and time it took to execute the test. See Table 1 the results. After the 5S was deployed test execution times improved and show an efficiency 86.4%. See Table 2 for the results.

An analysis of variance was conducted to assess whether significant differences existed in technician execution before and after the implementation of the 5S in the laboratory. Using a one-way ANOVA, with a p-value of 1.0000 (> 0.05), indicates that there is no significant difference between the eight technicians, suggesting that they all work in a similar manner. See Figures 1 and 2.

A mean hypothesis test was performed to assess if the implementation of the 5S in the ST Laboratory was statistically significant. The null hypothesis stated that the average before 5S application was greater than the average after the application of 5S ($\mu_a > \mu_b$). At the same time, the alternative hypothesis proposed that the average before the implementation of the 5S was not greater than the average after the implementation of the 5S ($\mu_a < \mu_b$). The results produced showed that μ_a (115 min) was greater than μ_b (60 min); therefore, the implemented improvements in the Laboratory yield a higher test efficiency and reduce waste in the form of waiting and movement.

Figure 1: Analysis of Variance (ANOVA) Output Evaluation per Technicians

One-way ANOVA: TIME versus TECH

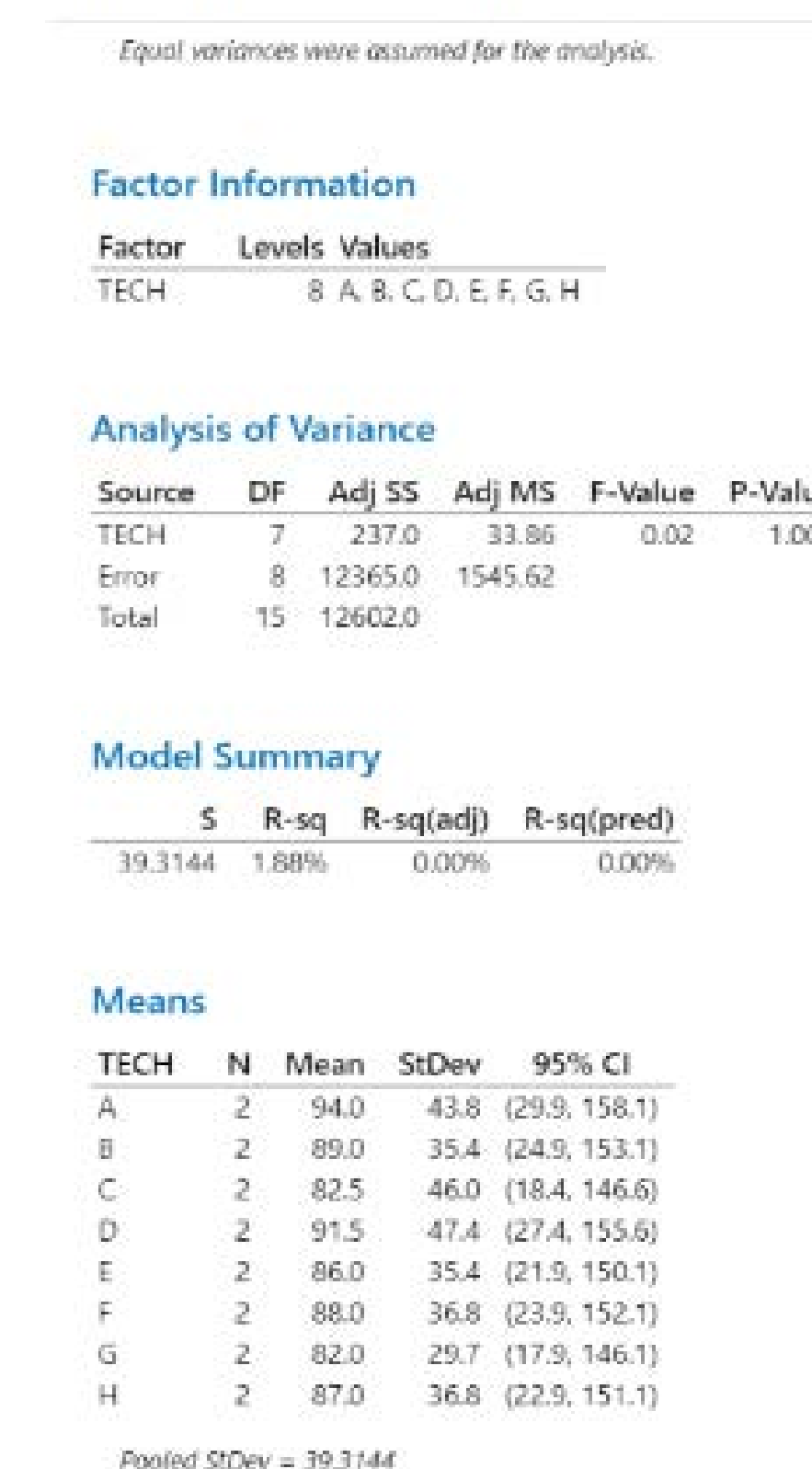
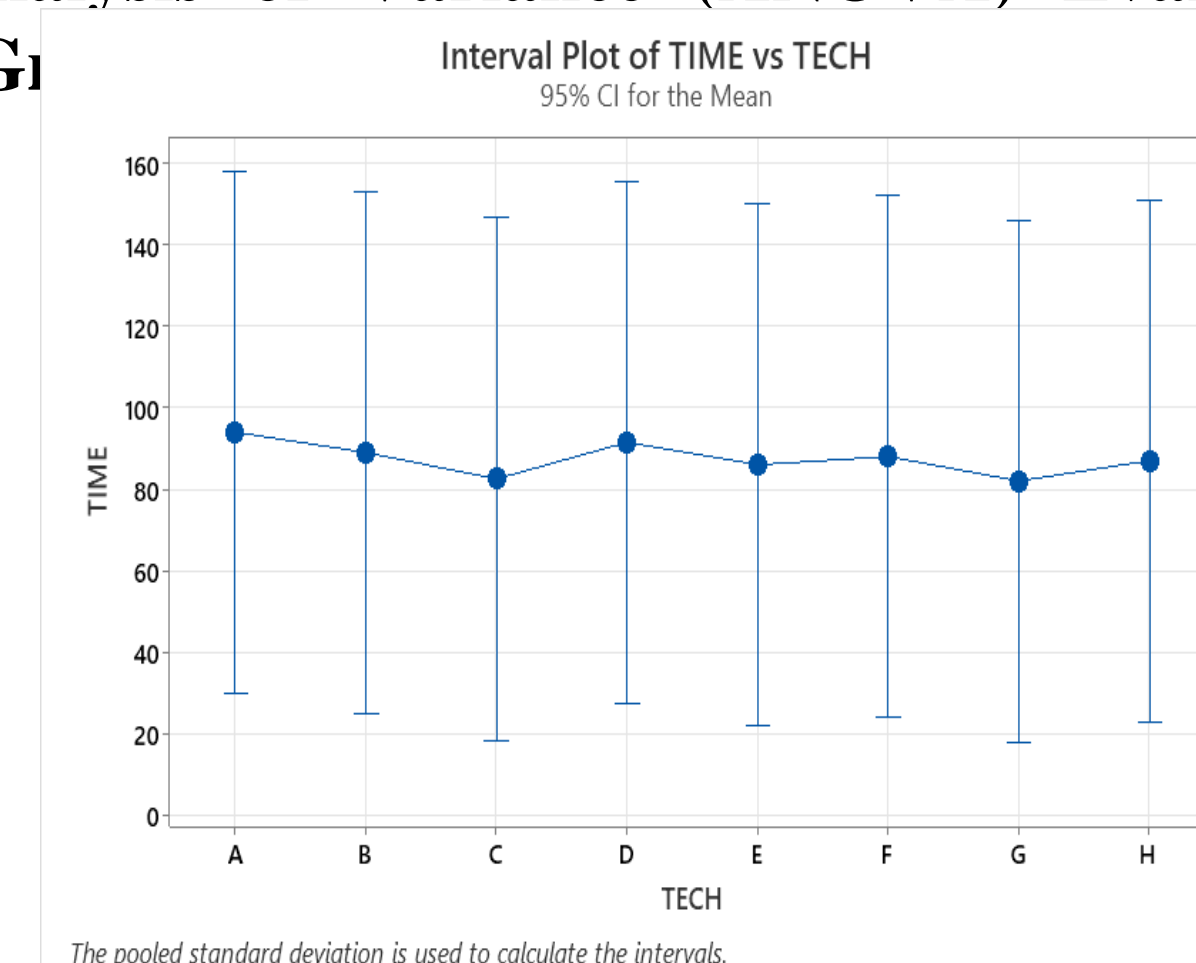


Figure 2: Analysis of Variance (ANOVA) Evaluation per Technicians G)



Conclusions

This study assessed the implementation of the improvement method 5S in a Validation Laboratory to evaluate the effect of the tool within the BCT process. The study also addressed the high test turnover at the Validation Laboratory. The test efficiency before the execution of this project was 36.4%, whereas after the project's implementation, the calculated test efficiency was 86.4%. The reduction in BCT time execution improved the laboratory's test efficiency and enhanced customer satisfaction. The methodology also yielded a positive increase in the work environment among the technicians. Furthermore, the implementation of the 5S method paved the way for the development of a checklist every laboratory technician could reference to guarantee this approach is followed through for other processes. Finally, continuous quality audits assured that this process was followed as established in the SOPs and ensured the constant sustainability of the approach.

Future Work

This project was limited only to the BCT and VT methodologies of the ST laboratory. Other test executed in the laboratory were not included as part of this project because BCT was considered as the test most of the ST laboratory clientele requested. This project can pave the way of the ST laboratory to include the 5S methodology for the rest of the methods executed in the laboratory. Additionally, the work can be further developed in the operational microbiology laboratory to increase test efficiency.

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References

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