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Integrating Lean and Automation for Enhanced Serology Diagnosis Efficiency in Tertiary Healthcare Microbiology Laboratories

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Abstract: Healthcare services and institutions are focused on providing the most appropriate medical service in terms of patient safety and satisfaction outcomes. According to Lean methodologies, effectiveness and efficiency can be improved by assuring value-added processes. This article presents a joint approach for the development and implementation of Lean techniques combined with Total Laboratory Automation (TLA) for serology diagnosis in a microbiology laboratory in a tertiary-level hospital. The results obtained show an improvement in the process efficiency and its key performance indicators. In particular, for the HIV and COVID tests, the process Turnaround Times (TAT) were decreased by up to 87.3% and 19.3%, having a direct effect in the diagnostic response time. The process added-value for HIV tests increased by 81%. This meant a cost reduction per test, a higher number of diagnostic tests and clinical samples processed and laboratory resource optimisation. The implementation of TLA also enabled the reallocation of skilled labour towards value-added tasks, increased the process quality and reduced sample waiting times. This work opens up new opportunities for their deployment in other laboratory areas and sample types, directly influencing the overall quality of patient diagnosis in the context of tertiary healthcare facilities.

Keywords: microbiology laboratory; automation; serology; Lean; Turnaround time

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1. Introduction

Lean management is a set of principles that constitute a mind-set oriented towards constant process improvement by identifying and eliminating waste or "muda", i.e., those process steps that do not create value [1,2]. This methodology has been traditionally used in automotive manufacturing, whose well-established approach assesses strategies in terms of resource optimisation and economic issues. Its application from production processes to services has gradually increased, in order to manage and improve other contexts such as Information technology (IT), Public Administration or medical services.

Lean Healthcare (LH) methodology applies Lean principles and techniques to healthcare services using scientific methods to plan, execute and apply continuous improvement in the work environment and its services, generating more value to the service offered to the patient [3,4]. This value optimisation of the process could affect healthcare services, reducing waiting times, improving the service's quality and the diagnosis offered, increasing the clinical efficiency and effectiveness and reducing costs with the ultimate target of improving patient satisfaction [5].

For the implementation of LH, the most important thing is to detect those activities that do not add value to the process but rather consume resources and generate waste. In healthcare, "muda" could increase process time, reduce clinician and sanitary personnel

productivity, increase patient dissatisfaction or generate unnecessary costs [6]. The importance of added-value culture and quality-related performance measures has been studied among medical organisations [7–9], also quantifying the readiness of healthcare institutions for implementing Lean [10]. Recent large-scale studies show the positive impact of Lean methodologies on both hospital performance [11] and ambulatory care [12], including emergency and clinic visits, imaging and other diagnostic services, clinical laboratory testing [13,14] and outpatient surgery.

Lean implementation in healthcare also involves the utilisation of various Key Performance Indicators (KPIs). While some KPIs are directly adapted from the industry to the medical sector, such as efficiency analysis, cost reduction, variation reduction and Turnaround Time, there are other KPIs that need to be tailored specifically to measure values that significantly influence healthcare performance. Common indicators often monitored are patient waiting time, revisit rate, diagnostic result times or length of hospitalisation required, which evaluate the process effectiveness [15]. The assessment of process efficiency includes other factors such as resources involved and costs derived [16]. Focusing on laboratory medicine, laboratories frequently measure their efficiency for diagnostic testing response using the Turnaround Time (TAT) indicator, which measures the time elapsed from the sample reception in the laboratory to the clinical validation of the result. Positive correlations have been assessed between TAT and throughput in critical services such as emergency, leading to reductions in the patient's hospitalisation length [17]. Other performance indicators in this area focus on error identification for measuring the process quality, timeliness of the result considering due dates, throughput taking into account samples processed and times invested, cost per test for assessing cost efficiency or indicators in relation to safety incidents, among others [18].

In the field of microbiology laboratories—and in combination with optimisation techniques and tools—the automation of processes also influences patient management by speeding up reporting and increasing the quality of results, as well as other equally important aspects [19,20]. This may involve a reduction in the number of changes associated with the process and an improvement in the indicators related to staff satisfaction [21]. In addition, the increase in diagnostic tests and clinical samples has led many laboratories to process more efficiently than when using traditional manual methods [22]. The reduction in human and financial resources, and a certain degree of centralisation, has led to Total Laboratory Automation (TLA) of merged microbiology laboratories [23,24], increasing their efficiency and diagnosis speed. Therefore, TLA is foreseen to become more widespread and consolidated in the future [25]. Furthermore, the use of artificial intelligence (AI) algorithms embedded in automated identification and testing systems can also make an important contribution to microbiology laboratory processes [26,27]. In fact, digitalisation can be implemented in every step of the microbiology diagnostic process, including pre-analytical, analytical and post-analytical phases [28]. The effectiveness of AI for image analysis and digital plate reading of bacterial cultures has already been proven and extended in tertiary-level hospitals [29].

It is important to point out that clinical laboratory diagnostics directly influence medical decisions [30], so any change in laboratory automation strategy must assure the quality of the process and test results' reliability. In this regard, the following facts need to be considered: (i) optimisation of the workflow to generate a continuous flow pull system, (ii) reduction in laboratory traffic and increased risk avoidance, including biological ones, (iii) harmonisation of procedures by eliminating manual activities, (iv) reduction in use of unsuitable containers, (v) improvement of sample traceability [31]. Lean methodologies could serve as a potent diagnostic and assessment tool for analysing the value chain of laboratory processes in microbiology, ensuring reliability, sustainability, efficiency and significant impact on patient outcomes, especially in process changes involving notable investment, such as TLA.

Concerning publications found in the literature, some commentaries, technical notes and systematic reviews have been focused on Lean Healthcare [9,32] and its implementa-

tion in medical [33], histology [34] and microbiology laboratories [16]. In this work, the state-of-art review is centred on clinical laboratories, where Lean methodologies have been applied. The literature review was carried out as follows. The databases used for the initial stage were SCOPUS (Elsevier) and Web of Science. The following keywords were used to perform the database search: Lean management, Lean Healthcare, Lean techniques, Lean implementation, Laboratory, Clinical Laboratory Sampling and Microbiology. English and Spanish search terms were applied to identify the most significant scientific contributions. Only the literature from 2010 or later was considered, in order to analyse the latest contributions with direct relation to Lean implementation in the healthcare context for improving laboratory processes. The database search was performed for articles until September 2023.

The core results of the literature review are shown in Table 1. For each considered reference, the presented actions and main findings have been highlighted. Furthermore, the different level of Lean application has been distinguished from 1 to 5 as following: (1) Empirical study; (2) Case study analysis (Kaizen ideas identification); (3) Implementation (pilot phase and control); (4) Final implementation (KPIs analysis and lessons learnt); (5) Cost analysis (economic impact quantification).

Table 1. Lean methodologies applied to clinical laboratories: literature review.

Country Area (Clinical Lab Test or Process)	Title	Actions	Level of Lean Application					KPIs and Findings	Reference
			1	2	3	4	5		
USA Clinical chemistry laboratory	Lean Six Sigma methodology for quality improvement in the clinical chemistry laboratory	- Quality control plan to reduce the chance of failures - Quality increasing to a 6σ level	☑					Impact of laboratory errors in patient health concerns Six Sigma level for superior patient care	[35]
Brazil Clinical pathology and pathological anatomy lab service (not hospital)	Lean Healthcare as a tool for improvement: A case study in a clinical laboratory	- Improvement identification (based on added-value): layout changes, standardisation and levelling of workforce, information data system modification	☑	☑				Total service time or expected TST minimisation (but not quantified) Waiting time at the reception detected the main problem	[36]
Turkey Pathology laboratory (gastric biopsy)	Lean methodology for pathology laboratories: A case study from a public hospital	- Long waiting periods identification - Improvements identification (based on added-value): appropriate transport containers and modification of management information of sample acceptance, macroscopy, reporting and archive sections	☑	☑				Total time by sample expected minimisation The most common causes of waste identified: problems with cleaning, equipment supply problems, lack of clinical information, equipment malfunction and errors.	[37]

Table 1. *Cont.*

Country Area (Clinical Lab Test or Process)	Title	Actions	Level of Lean Application					KPIs and Findings	Reference
			1	2	3	4	5		
Italy Pathology laboratory (histology: surgical specimens and biopsies)	Lean thinking in hospital: Case study at the pathology laboratory	- Improvement identification (based on added-value) - Simulation: new workflow, control points and actions to minimise waiting times	☑	☑				Total Cycle Time expected minimisation System unbalanced workload between work-cells and cycle time eliminated by software improvement Removed unnecessary change-of-floor	[38]
India Haematology and biochemistry labs (complete blood count analysis or CBCA)	Improvement of laboratory Turnaround Time using Lean methodology	- Improvement identification (based on added-value) - Adoption of 5S and visual management (alert indicators) - Process standardisation	☑	☑				Expected TAT reduction (considering ideal process defined) Required elimination of manual report delivery and data collection	[39]
USA Emergency Department or ER lab	Application of Lean Six Sigma techniques to optimise hospital laboratory Emergency Department Turnaround time across a multi-hospital system	- Consistent personnel responsibility definition - Dedicated roles to the ED area - Application of visual controls	☑	☑	☑	☑		Significant improvement of TAT process performance Improvements on improving phlebotomist and clerking processes	[40]
Austria Core Laboratory: clinical chemistry and immunology (natrium and Troponin I)	Concepts for Lean laboratory organisation	- Unnecessary methods and redundancies removed - Laboratory layout redesigned: clear floor plan and one working place - Process simplification and standardisation - Lab automation for sorting and auto-verification	☑	☑	☑	☑		Reduction in Turnaround Time and manual work performed by medical technicians given by automation	[41]
Australia Emergency department or ER pathology lab	Applying Lean flows in pathology laboratory remodelling	- Laboratory layout redesigned: one-way flow and multiple supplies repositories - Faster equipment installation	☑	☑				Evaluation of personnel and specimen distances avoided and time saved with the new layout Importance of sociotechnical impacts	[42]

Table 1. *Cont.*

Country Area (Clinical Lab Test or Process)	Title	Actions	Level of Lean Application					KPIs and Findings	Reference
			1	2	3	4	5		
Egypt Haematology (complete blood count or CBC)	Using Lean Six Sigma to improve timeliness of clinical laboratory test results in a university hospital in Egypt	- Unnecessary workload of microscopic examination reduced and scheduled - Training workshop conducted - Re-staining process and late urgent inpatient CBC request process standardised - Manual registration eliminated	☑	☑	☑	☑		Inpatient routine CBC test improvement (earlier verification) First-batch delivery time shortened Laboratory staff motivation and engagement for improvement ideas	[43]
Turkey Hospital Central Laboratory (clinical lab reception area)	Lean Six Sigma methodologies improve clinical laboratory efficiency and reduce Turnaround Times	- Retrained ward personnel - Purchase of high-quality barcodes - Eliminated written forms	☑	☑	☑	☑		TAT improvements. Wasted time, medical errors and potential biological risk reduced.	[44]
Malaysia Chemical pathology laboratory (renal profile or RP)	Improvement in urgent tests' laboratory Turnaround Time through laboratory Lean management	- Shortened workflow process - Kanban concept and visual control - Processes standardisation - Real time tracking of sample processing	☑	☑	☑	☑		Urgent RP TAT reduced Specimen triage (urgent request) with coloured barcodes Real-time TAT monitoring of urgent tests	[45]
Chile Medicine and Adult Emergency Services (glucose and haematocrit)	Workflow optimisation in a clinical laboratory using Lean management principles in the pre-analytical phase	- Reordered lab staff and reassigned their functions - Priority sample assignment in the reception area - Redesigned lab workflow	☑	☑	☑	☑		Turnaround time (TAT) significantly reduced in some tests. Intervention achieved with minimal financial investment.	[46]
Canada Core Laboratory (urea, potassium, thyroid stimulating hormone or TSH, complete blood count or CBC and prothrombin time or PT)	Multiple pre- and post-analytical Lean approaches to the improvement of the laboratory Turnaround Time in a large-core laboratory	- Total Laboratory Automation (TLA) - Electric-track vehicle (ETV) point-to-point delivery system - Auto-verification (AV) process	☑	☑	☑	☑		Overall improvement in phlebotomy to reporting (PR-TAT) Faster sample transport and delivery Personnel saving (2 FTEs) by auto-verification	[47]

Table 1. *Cont.*

Country Area (Clinical Lab Test or Process)	Title	Actions	Level of Lean Application					KPIs and Findings	Reference
			1	2	3	4	5		
USA Anatomic pathology lab (Rapid Papanicolaou or Pap test)	Value Stream Mapping of the Pap Test Processing Procedure: A Lean Approach to Improve Quality and Efficiency	- First-in first-out (FIFO) processes - Batch size minimisation - Redundant step elimination - Staff work reassignment: "in-cycle" vs. "out-of-cycle" (when possible)	☑	☑	☑	☑		Improved KPIs: Total PT; (processing time); Number of accessioning errors; Number of labelling errors Important influence of storage and waiting times Batching necessary for certain laboratory processes	[48]
USA Histopathology laboratory	Effect of Lean method implementation in the histopathology section of an anatomical pathology laboratory	- Ideal state by designing a one-by-one, continuous-flow work process - Quality tools considered: e.g., checklists, Kanban cards	☑	☑	☑	☑		Productivity ratio increased and specimen TAT decreased Single and continuous flow line	[49]
USA Core Laboratory (creatinine, CBC, differential, prothrombin time, urinalysis, ionised calcium)	Application of the Toyota Production System improves core laboratory operations	- Laboratory layout redesigned - Automated work cell building - Process standardisation - Extensive training period to the new standard work	☑	☑	☑	☑	☑	Improved Turnaround Time with increased testing volume, monetary savings in terms of fulltime equivalents (FTEs) and better space utilisation Lean concept limitations applied to lab LH	[50]
USA Anatomic pathology lab (specimen accessioning and gross-tissue examination areas)	The effect of a Lean quality improvement implementation program on surgical pathology specimen accessioning and gross preparation error frequency	- Work transformed into a single-piece-flow model with a pull system (when possible): staff to work on only a single patient specimen at a time. - Process standardisation	☑	☑	☑	☑		Dramatically decreasing the frequency of process-dependent near-miss events, though the frequency of operator-dependent near-miss events did not significantly improve	[51]

Table 1. *Cont.*

Country Area (Clinical Lab Test or Process)	Title	Actions	Level of Lean Application					KPIs and Findings	Reference
			1	2	3	4	5		
USA Emergency Department or ER lab (troponin I, urinalysis and urine human chorionic gonadotropin)	Applying Lean methodologies reduces ED laboratory Turnaround Times	- Reorganisation of laboratory sample flow: screening and confirmatory testing platforms co-localised - Dedicated lab staff for some activities	☑	☑	☑	☑	☑	Lab times (TAT) of the Emergency Department (ED) decreased Cost analysis included only by reduced staffing cost per year calculation	[52]
USA Four clinical pathology labs (vitamin D testing in immunopathology, media preparation in microbiology, fluorescence in situ hybridisation staining in molecular pathology, and trace metals analysis in special chemistry)	A collaborative approach to Lean laboratory workstation design reduces wasted technologist travel	- Inventory management system improvement to reduce unnecessary touch points and technologist time - More efficient workstation layouts, reducing wasted travel	☑	☑				Aim of reducing the number of times employees must leave their workstations to complete their tasks. Lean applied to support the design of a new lab building construction	[53]
Turkey Endocrine laboratory (thyroid stimulating hormone or TSH)	An application of Lean thinking principles in a laboratory of a hospital	- Evaluation of causes of rejection of blood samples - Improvement identification (based on added-value): waiting times between stages	☑	☑				Aim of reducing the number of steps and distance of transportation per sample	[54]

As shown in Table 1 (in alphabetical order), research results are still limited but have been increasing quickly during last years. Regarding Lean philosophy, the main actions are focused on optimising or redesigning workflow and key processes to eliminate waste, reduce errors, balance workload, standardise and simplify activities. Other suggested guidelines for clinical laboratory Lean management are presented in [55]. Searching for joint application of Lean techniques and process automation in clinical laboratories, a study presented in [47] considers the combined Lean and Total Laboratory Automation (TLA) approach in the establishment of a consolidated laboratory to address different clinical tests. The common KPI analysed in the literature is the total delivery time of realising test results at a clinical lab, which considers three main phases: pre-analytical, analytical and post-analytical. Nevertheless, not only are accurate results obtained in a timely manner, but also other added-value advantages such as personnel safety (staff protection from laboratory hazards). Final implementation results are normally presented in case studies from university teaching hospitals. Demonstrated key success factors are training and

teamwork engagement aligned with Lean methodologies, culture of cooperation and continuous improvement. On the other hand, the cost analysis that evaluates the impact benefit of improvement actions is hardly ever justified, accounting for only 10 percent of the papers reviewed, although without a detailed or categorised budget.

To date, no empirical studies have been published on implementing Lean techniques in combination with Total Laboratory Automation (TLA) in microbiology laboratories of tertiary hospitals applied to serology diagnosis. Thus, this study presents the application of Lean methodologies and TLA within a microbiology laboratory at a tertiary-level hospital with a case study focused on serology diagnosis. The primary objectives are to analyse and enhance the efficiency of serology processes using Lean techniques and to evaluate the impact of the implemented changes derived from the optimisation and the TLA, not only in diagnostic time affecting the patient but also in cost terms.

The selection of the serology area for the case study was derived from the drastic increase in demand for serology tests during the COVID-19 pandemic. This situation forced the microbiology laboratory in study to adapt its resources and optimise the existing serology processes and equipment to cope with the growing demand and rapid response required. Due to its significance compared to the volume of tests processed annually in the laboratory, COVID-19 and HIV are the serology test type objects of study in this research. Key Performance Indicators (KPIs) of the serology process workflow are evaluated in pre- and post-full automation scenarios, showing an improvement in the diagnostic response time to the patient. This includes indicators such as the Turnaround Time (TAT), total equipment time (TET), total direct labour time (TDLT) and process waste reduction. The benefits derived from the process optimisation and automation directly affected the patient but also influenced the laboratory management. This allows the calculation of a total cost per serology test, fulltime equivalent (FTE) count required and productivity, together with an estimation of the savings derived from the optimisation and the TLA project.

2. Materials and Methods

2.1. Study Design and Data Collection

The microbiology laboratory in study is located in a tertiary hospital in the north of Spain.

Focus group interviews (FGIs) with the laboratory healthcare professionals were carried out to collect data in the study. FGIs were used to explore the serology clinicians' and technicians' views and opinions regarding the current serology processes, to gather relevant clinical information and to validate proposals along the different phases of the study. Two focus groups were defined: one with microbiology specialists and one with the serology technicians. As the minimum number of members required for a focus group is between three and five participants [56], the head of the microbiology section, two clinicians and four technicians were recruited. The focus group interviews, conducted throughout various stages of the study (pre-TLA and post-TLA), were limited to a maximum duration of one hour each.

The study was longitudinal, extending the period in study from January 2020 to May 2022, before and after the implementation of Lean methodologies and Total Laboratory Automation (TLA) in the facilities. Data were extracted from the laboratory information system (LIS), considering a period of eight months after deployment of the TLA in September 2021, to ensure the stability of the process and the information collected after the ramp-up period. From June 2020 to March 2021, the laboratory handled 233,266 serology tests, accounting for an increase of 85% versus the same observation period the previous year. This was due to the boost in COVID-19 serology test requests, which represented 58% of the total serology tests processed in the laboratory in that period. Among the non-COVID-19 serology tests, HIV accounted for 19%, being one of the most frequent tests, together with Hepatitis B surface antigen—HBsAg (18.4%), hepatitis C—HCV (15.6%) and syphilis (11.6%).

Concerning the laboratory output, the laboratory handled 210,315 serology tests in 2022. During the period of study, 77,216, 40,999 and 18,273 COVID-19 serology samples were processed in 2020, 2021 and 2022, respectively. For HIV tests, the volume of samples processed was 26,447, 27,997 and 29,216 for the mentioned years.

In COVID-19 serology tests, two SARS-CoV-2 antigens, the nucleocapsid (N) and spike (S) protein, are identified with antibody detection assays using different techniques such as chemiluminescence immunoassays (CLIA). Different antibodies are also measured in the tests, immunoglobulin G (IgG), immunoglobulin M (IgM), immunoglobulin A (IgA) or total immunoglobulin [57].

Based on the data extracted from the LIS and the clinicians' feedback in the focus group interview held at the beginning of the study for the selection of the key serology test types to analyse, two process workflows were defined: (i) HIV serological samples, (ii) total nucleocapsid (COVT) and spike IgG (COVIDIGG) SARS-CoV-2 antibody testing.

The peak period of samples arrival in the laboratory was between 09:30 AM and 11:30 AM, decreasing the load in the early evening. Process observation and data collection were performed during the complete working shift—from 8:00 AM to 3:00 PM.

2.2. Methodology: Lean Tools and KPIs

There is a great variety of tools used in the Lean approach, as well as for Lean Healthcare. They can have different characteristics and aims, making it necessary to select the one that best suits the defined objectives. Some of them, such as Value-Stream Analysis (VSA), are designed for the evaluation and optimisation of processes, minimising waste. This technique was implemented in the laboratory serology area to map the workflow followed by HIV and COVID-19 samples from the reception in the pre-analytical area, sample preparation, testing and technical review, until the final clinical review and validation. The whole value of the process chain was analysed and quantified in terms of process time, tasks, resources, materials, information and wastes. After the Value-Stream Mapping (VSM) analysis, a list of actions to improve the process was generated and Value-Stream Design (VSD) was performed, defining the optimised future process. Before the introduction of the TLA, the VSA played a crucial role as a reference point in the serology workflow, serving as a primary source for improvement ideas.

In the study, process activities were classified as value-added (VA), non-value-added (NVA) and semi-value-added (SVA), and different types of wastes were identified such as waiting times, over-processing, unnecessary staff movements, samples' transports, and defects. Based on these, we also assessed Key Performance Indicators (KPIs) in the pre- and post-TLA scenarios to measure the process efficiency in terms of time and cost, which are the following:

- Turnaround Time (TAT): process lead-time or time elapsed from sample arrival in the laboratory to clinical validation—Equation (1);
- Total Equipment Time (TET): time the sample is processed in the laboratory equipment;
- Total Direct Labour Time (TDLT): time required by the laboratory staff for sample processing, checking or validation;
- Total Waiting Time (TWT): time the serology sample is waiting for the next workflow operation, classified according to its origin, personnel or equipment;
- Total Process Time (TPT): the Turnaround Time without considering waiting times, which represents the effective diagnosis time, as in Equation (1):

$$TAT = TPT + TWT = TET + TDLT + TWT \quad (1)$$

- Average cost per test (ACT): total cost per test, considering equipment, material and direct labour costs;
- Total Labour Cost per Day (LCD): total daily direct labour cost, considering the overall number of tests processed daily;

- Productivity: number of tests processed/number FTEs required on an average day to complete the work. In this case, fulltime equivalent (FTE) number is equivalent to the laboratory staff number, in view of their category of fulltime employees;
- Average improvement ratio: value calculated as the ratio between the pre-TLA and post-TLA scenarios to quantify the benefits of Lean implementation and automation.

2.3. Laboratory Workflow Overview and Equipment

Serology testing is one of the multiple test types performed in microbiology laboratories, and it searches for antibodies under certain circumstances, in addition to the detection of antigens, especially in the blood serum. In daily practice, serological diagnosis is performed by serological profiling, i.e., grouping of different test types to investigate several pathogens as possible aetiological agents being responsible for the patient's pathology. From a clinical point of view, this system of grouping is more efficient, as it allows progressive execution according to the results obtained at the previous level. The profiling method has been used for a long time, but the automation of processes has boosted its use. The advantages it provides are the excellent relationship among cost, efficiency and diagnostic response time. The most common test types are Toxoplasmosis, Rubella, Cytomegalovirus, Hepatitis B, Hepatitis C, Human Immunodeficiency Virus (HIV), syphilis and, recently, SARS-CoV-2 (COVID-19), among others.

To obtain the workflow diagram including processes, personnel and equipment, Gemba walk was performed. Gemba means the "go-and-see" principle, which refers to the "real place" where the work is happening, so that it is characterised by observation at the value-added location. In the pre-TLA serology workflow evaluation with VSM, neither was automation present nor were algorithms implemented and equipment was distributed into a non-optimised and separated layout. The laboratory operated a day-shift serology sample workup.

The testing cycle in the laboratory is divided into three main phases. The first one corresponds to the pre-analytic phase, covering the time since the serology test is ordered until the reception of the sample in the laboratory. Then, the analytic phase extends from the sample reception to the moment that the serology testing result is registered in the laboratory information system. The last one covers the activities from clinical result review and validation in the laboratory until receipt of the result by the applicant. The full list of test types, equipment and techniques in the pre and post-TLA are listed in Table 2.

The pre-analytical reception, centrifugation, sample identification, manual uncapping, separation and aliquoting processes were common to the COVID-19 and HIV serological sample workflows. After that, the samples followed different processes in various pieces of equipment using several techniques. Instrumental set-up for qualitative and quantitative SARS-CoV-2 antibody testing consisted of a multi-purpose Gyrozen 1696R (Gyrozen Ltd., Seoul, Republic of Korea) centrifuge, the pre-analytical system AQUA-7000 (Siemens Healthcare GmbH, Erlangen, Germany) for sample identification and aliquoting of secondary tubes, the COBAS e801 (F. Hoffmann-La Roche AG, Basel, Switzerland) analytical unit for immunoassay testing (qualitative SARS-CoV-2 antibody—COVT) and Liaison XL, (Diasorin S.p.A, Saluggia, Italy) for quantitative SARS-CoV-2 Spike antibody evaluation (COVIDIGG).

Unlike COVID-19 serology samples that were processed on the same day of arrival in the laboratory, HIV serology samples were analysed the day after arrival (if they were not urgent). Therefore, once the process was finished in the centrifuge and the AQUA-7000 (Siemens Healthcare GmbH, Erlangen, Germany) pre-analytic equipment, the tubes were transferred to racks for 24 h storage in the refrigerator. The next day, the samples were manually supplied to Versacell (Siemens Healthcare GmbH, Erlangen, Germany) robotic equipment for sample distribution to Inmulite 2000 XPI (Siemens Healthcare GmbH, Erlangen, Germany) or ADVIA Centaur XP (Siemens Healthcare GmbH, Erlangen, Germany) immunoassay system, where the HIV testing ends.

Table 2. Instrumental details of equipment: HIV and COVID-19.

Configuration	Test Type	Equipment	Description	Technique
Pre-TLA VSM analysis	HIV/COVT COVIDIGG	Gyrozen 1696R (Gyrozen Ltd., Seoul, Republic of Korea)	Samples centrifugation	
	HIV/COVT COVIDIGG	AQUA-7000 (Siemens Healthcare GmbH, Erlangen, Germany)	Pre-analytical system	
	COVT	COBAS e801 (F. Hoffmann-La Roche AG, Basel, Switzerland)	Immunoassay testing system	ElectroChemiLuminescence (ECL)
	HIV	Versacell/ADVIA Centaur XP (Siemens Healthcare GmbH, Erlangen, Germany)	Immunoassay testing system	Chemiluminescence
	COVIDIGG	Liaison XL (Diasorin S.p.A, Saluggia, Italy)	Immunoassay testing system	Flash chemiluminescence technology (CLIA) with paramagnetic microparticle solid phase
Post-TLA VSD analysis	HIV/COVT COVIDIGG	Gyrozen 1696R (Gyrozen Ltd., Seoul, Republic of Korea)	Centrifugation of samples	
	HIV/COVT COVIDIGG	COBAS p612 (F. Hoffmann-La Roche AG, Basel, Switzerland)	Pre-analytical system	
	COVIDIGG	Liaison XL (Diasorin S.p.A, Saluggia, Italy)	Immunoassay testing system	Flash chemiluminescence technology (CLIA) with paramagnetic microparticle solid phase
	HIV/COVT	COBAS e801 (F. Hoffmann-La Roche AG, Basel, Switzerland)	Immunoassay testing system	ElectroChemiLuminescence (ECL)

The TLA solution implemented in the laboratory consisted of a single line connecting a new pre-analytical COBAS p612 (F. Hoffmann-La Roche AG, Basel, Switzerland) system, one Liaison XL (Diasorin S.p.A, Saluggia, Italy) and two modules of a COBAS e801 (F. Hoffmann-La Roche AG, Basel, Switzerland) analytical unit, including an intelligent tracking system that auto-routes test orders and samples. The changes were implemented sequentially in six months from April to September 2021. Firstly, the pre-analytical equipment AQUA-7000 (Siemens Healthcare GmbH, Erlangen, Germany) was replaced with COBAS p612 (F. Hoffmann-La Roche AG, Basel, Switzerland), which integrates additional functions such as tube identification and registration, automated sample quality check, uncapping, aliquoting, archive tube generation and routing to specific immunoassay testing equipment. One of the main advantages of the new pre-analytical area is the avoidance of repetitive and manual workup existing in the pre-TLA solution for sample registration, identification, separation, re-racking and uncapping, reducing the risks of splashing and tendonitis. The elimination of manual transport and workup of specimens, biological materials or waste that are known or expected to contain biological agents between rooms in the laboratory, avoids biological hazards and reduce the risks of loss or damage of samples. Furthermore, the implementation of automation, eliminating repetitive tasks like uncapping, has led to a significant reduction in occupational health, especially tendonitis and physical fatigue, and safety risks for laboratory personnel.

For serological test purposes, ADVIA Centaur XP (Siemens Healthcare GmbH, Erlangen, Germany) (HIV, HCV, HBsAg) and Inmulite 2000 XPI (Siemens Healthcare GmbH,

Erlangen, Germany) (syphilis) were replaced by the existing COBAS e801 (F. Hoffmann-La Roche AG, Basel, Switzerland). Secondly, a relocation study in the laboratory layout ended with the positioning of all equipment in the same area, which automated the sample distribution processes between equipment, minimised waste associated with sample transport and waiting times and generated one-sample flow. The implementation of VSM/VSD techniques assured the definition of Lean processes and efficient sample distribution, key factors for successful TLA deployment and results.

The workflow comparison in the two scenarios (pre-TLA and post-TLA) analysed with VSM/VSD Lean tools is schematised in Figure 1. Vertical swim-lanes represent the processes followed by the samples. Horizontal differentiation separates between pre-TLA and post-TLA configurations.

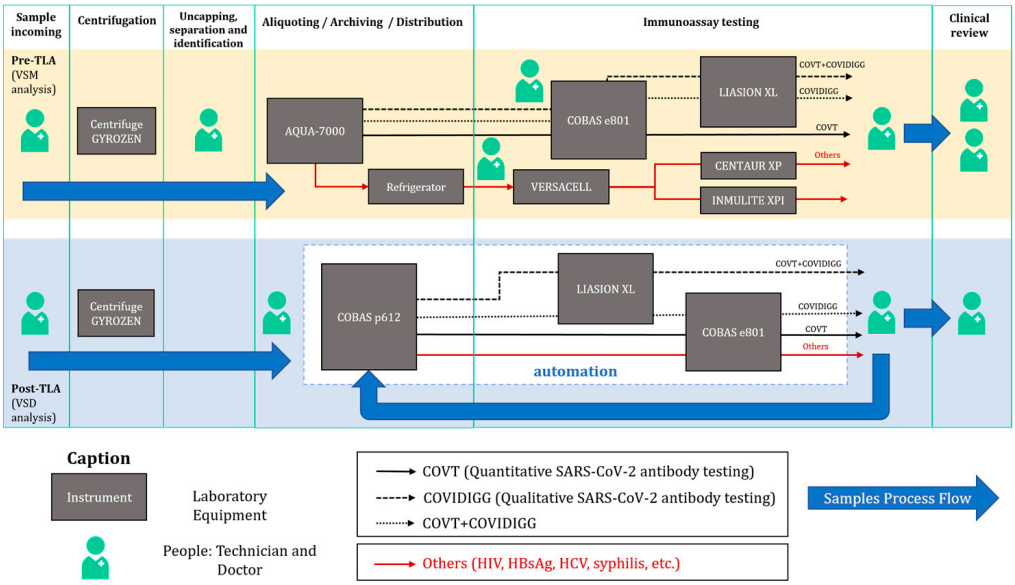

Figure 1. Workflow schematisation for laboratory analysis under study in this project: HIV and COVID-19.

3. Results

We analysed the serology workflow with Lean tools in pre- and post-TLA scenarios in terms of process added-value, sample Turnaround Time (TAT) and process costs, including cost per test. Only by this approach could improvements be evaluated in view of productivity, impact on the patient due to Turnaround Time decrease and use of resources when serological samples were evaluated.

3.1. Process Added-Value Analysis

Value stream analysis has been developed for pre-TLA (VSM) and post-TLA (VSD) serology workflow. This requires the identification of the true flow of material and information and the value-stream map of activities, which is directly related to the process lead-time (here defined as Turnaround Time, TAT).

Considering the process followed by an HIV serologic sample, the comparison between pre- and post-TLA results is shown in Figure 2. The total number of process activities was reduced by up to 31%, from 45 to 31, by minimising the numbers of non-value-added (NVA) activities (from 24 to 6) and semi-value-added (SVA) activities (from 11 to 2). Thus, the proportion of value-added steps in the process was increased. In view of technician tasks, these were reduced by up to 43% by automation and optimisation (elimination or modification) of manual activities. HIV total process time increased its added value by 81% versus the former pre-TLA situation, where the tasks with added-value accounted for only 14% of the total process time.

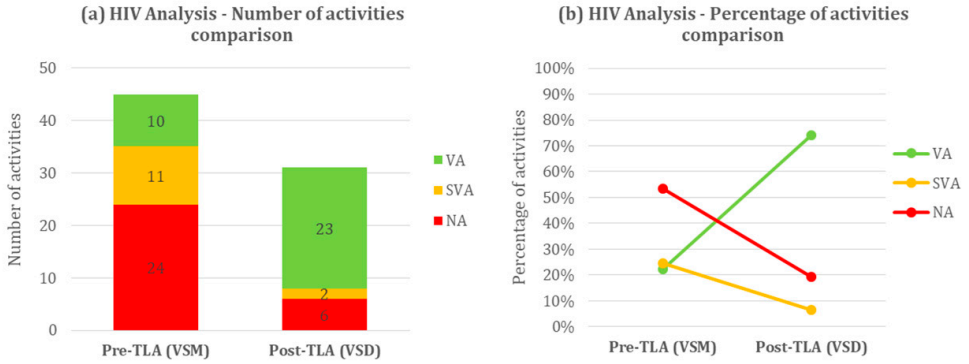

Figure 2. HIV serologic sampling: Results comparison between pre-TLA and post-TLA in terms of added-value. (**a**) Number of activities comparison; (**b**) Indicators of activities percentage.

The serology workflow's process time analysis is shown in Figure 3. For the HIV testing, the Total Process Time or TPT (TAT without waiting times) decreased from pre- to post-TLA from 28:04:28 h to 00:45:55 h, which represents a reduction in time up to 97.2%, due to the elimination of the 24 h storage in the refrigerator, the process workflow Lean optimisation and the automation implementation. The samples are now processed on the same day of arrival in the laboratory, which produced a clear improvement on the laboratory efficiency and a big impact on the patients due to sharp reduction in TAT.

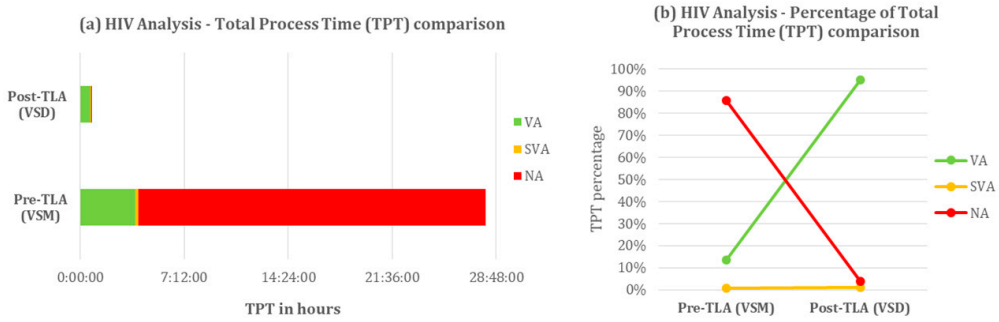

Figure 3. HIV serologic sampling: Results comparison between pre-TLA and post-TLA in terms of added-value. (**a**) Total Process Time (TPT) comparison; (**b**) Percentage in Total Process Time (TPT) comparison.

Analysing the process followed for total nucleocapsid (COVT) and spike IgG (COVIDIGG) SARS-CoV-2 antibody sample testing, the comparison between pre- and post-TLA results are shown in Figure 4. The total number of activities was reduced by up to 15%, from 39 to 33, by minimising the number of NVA activities (from 21 to 6) and SVA activities (from 9 to 2). Thus, the proportion of value-added steps in the process was increased. The technicians' tasks were reduced by 32% via automation of manual activities such as sample registration, identification, separation, re-racking and tube uncapping, which were eliminated with the new COBAS p612 (F. Hoffmann-La Roche AG, Basel, Switzerland) pre-analytical equipment. Manual sample transports and unnecessary staff movements were also reduced in the new TLA configuration, applying these actions to both process workflows. Total Process Time (TPT) added-value increased by 4% in the post-TLA scenario (see Figure 4). In this case, the Total Process Time (TPT) in Figure 5 decreased from 01:28:27 h to 01:24:38 h, which represents a reduction in time by up to 4.3%. Nevertheless, the main improvements were achieved in view of layout, personnel safety and ergonomic improvements in the workplace due to manual workup reduction.

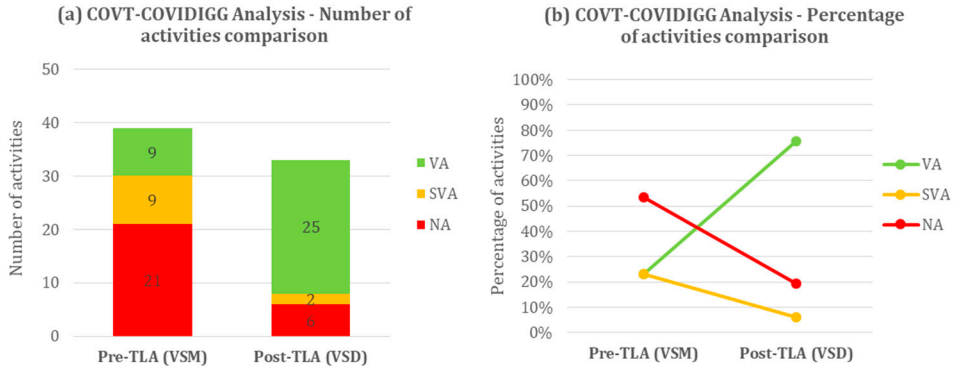

Figure 4. COVT–COVIDIGG serologic sampling: Results comparison between pre-TLA and post-TLA in terms of added-value. (**a**) Number of activities comparison; (**b**) Indicators of activities percentage.

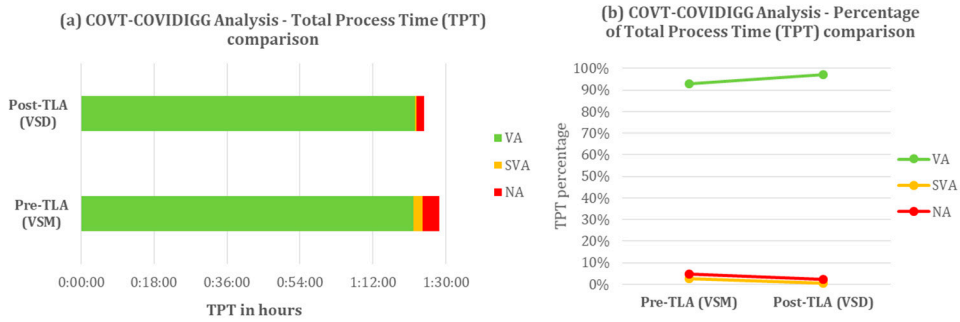

Figure 5. COVT–COVIDIGG serologic sampling: Results comparison between pre-TLA and post-TLA in terms of added-value. (**a**) Total Process Time (TPT) comparison; (**b**) Percentage in Total Process Time (TPT) comparison.

3.2. Process Turnaround Time (TAT) Analysis

The previous added-value approach has not considered waiting times of the process, which was the main type of waste identified in the VSM. The Turnaround Time (TAT) indicator not only includes the testing process time (equipment and direct labour time), but also identifies waiting times.

The obtained results when TAT is calculated for HIV and COVT–COVIDIGG testing, in the pre-TLA (VSM analysis) and post-TLA (VSD analysis) scenarios are shown in Figure 6. After Value-Stream Design, the TAT decreased from pre- to post-TLA by up to 87.3% and by up to 19.3% for HIV and COVT–COVIDIGG samples. This improvement is particularly significant for HIV samples, mainly due to the elimination of the 24 h storage in the refrigerator. Currently, the majority of tests can be completed within a single 7 h working shift.

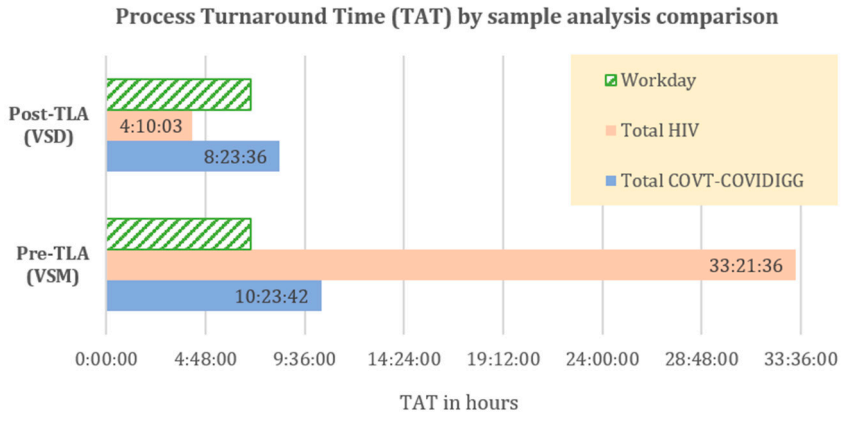

Figure 6. Total process Turnaround Time (TAT) for HIV and COVT–COVIDIGG testing in pre-TLA and post-TLA scenarios.

The time recordings obtained when results are analysed considering the TAT contributor, i.e., Total Equipment Time (TET), personnel time registered as Total Direct Labour Time (TDLT) and Waiting Time (WT) are included in Table 3. The reductions in percentage for HIV analysis are 97.6% in TET (Total Equipment Time), 13.6% in TDLT (Total Direct Labour Time) and 35.6% in TWT (Total Waiting Time). Considering COVT–COVIDIGG, the improvements achieved in time reduction were 3.7% in TET, 11.5% in TDLT and 21.7% in TWT.

Table 3. Turnaround Time (TAT) results comparison between pre-TLA and post-TLA and its contributors by analysis.

[Time in Hours]	KPI	HIV		COVT–COVIDIGG	
		Pre-TLA (VSM)	Post-TLA (VSD)	Pre-TLA (VSM)	Post-TLA (VSD)
Total Equipment Time	TET	27:57:14	0:39:39	1:21:20	1:18:20
Total Direct Labour Time	TDLT	0:07:14	0:06:16	0:07:08	0:06:18
Total Waiting Time	TWT	5:17:07	3:24:08	8:55:15	6:58:58
Equipment	WT_E	*	0:07:05	*	0:16:43
Technician	WT_T	0:46:48	1:28:49	0:32:21	1:31:15
Doctor	WT_D	4:30:19	1:48:14	8:22:54	5:11:00
Turnaround Time	**TAT**	**33:21:36**	**4:10:03**	**10:23:42**	**8:23:36**

* No data available. The total waiting time (TWT) is divided into waiting time for equipment, technicians and doctor. Turnaround Time (TAT) is marked in bold as process lead-time KPI.

However, in both cases, more than 80% of TAT is due to waiting times—the main waste identified in the laboratory workflow. These waiting times are related to equipment or personnel. Waiting times in equipment are a consequence of inefficient sample distribution to equipment, bottlenecks due to peak arrival of samples between 09:30 AM and 11:30 AM, etc. Personnel waiting times are mainly due to the following factors:

i. Lack of synchronisation in the flow between the sample incoming area and the pre-analytical COBAS p612 (F. Hoffmann-La Roche AG, Basel, Switzerland) equipment, which requires manual sample pick up and transport between the sections;
ii. Need for finished sample re-racking at COBAS e801 (F. Hoffmann-La Roche AG, Basel, Switzerland) exit before re-entering the COBAS p612 (F. Hoffmann-La Roche AG, Basel, Switzerland) equipment for sample archiving;
iii. Existing waiting time from the moment the result is registered in the laboratory information system until the final clinical review.

The waiting times were reduced in the post-TLA scenarios for both processes, HIV and COVT–COVIDIGG, decreasing by 35.0% and 21.7%, respectively, but they were not completely eliminated (see Table 3). Therefore, Kaizen ideas were proposed to optimise this issue. Waiting times are higher for COVID-19 testing, although, in both cases, the main contributor is the final clinical review by the microbiologist. We performed a root cause and longitudinal analysis for the years 2021 and 2022 in terms of waiting time, concluding that the sequencing, levelling and complexity of microbiologist work, depending on the patient, inevitably led to waiting times until the result was validated. However, areas for improvement have been identified related to the laboratory information system where the doctor validates the result, simplifying the existing filtering and manual process. Likewise, one possibility to drastically reduce waiting times until clinical validation and free up resources would be to analyse the possibility of self-validation of standard test results. The generation of AI algorithms that could assist in the self-verification of routine tests according to the patients' medical records have been recently established, and their impact need to be assessed.

3.3. Pre- and Post-TLA Cost Analysis

The cost per serology test type (HIV and COVT–COVIDIGG) was estimated in pre- and post-TLA scenarios, including the following cost items: reagents, instrumentation, equipment and direct labour costs. Indirect laboratory costs and other consumable costs were not considered in the calculation because no major changes were applied with the TLA. An average improvement ratio (pre- to post-TLA) was also calculated and the estimated savings per year after the TLA implementation were assessed.

The pre-TLA analysis was handled in 2020 (annual volume of 226,615 tests), and post-TLA analysis was performed in 2022 with the full laboratory automation implementation (annual volume of 210,315 tests). Partial automation and equipment replacement started in April 2021, and the change was completed in September 2021. The COVT and COVIDIGG serology testing started in March 2020. Because of the pandemic situation, the laboratory suffered a peak sample volume that stressed the laboratory personnel, routines and equipment, generating a bottleneck that was managed with additional working shifts to gain testing and diagnosis capacity. Neither laboratory automation nor specific algorithms existed at that moment.

Table 4 shows the cost comparison in the pre- and post-TLA workflows for HIV and COVT–COVIDIGG testing, showing an improvement ratio of 10.6% for HIV (EUR 0.43/test) and 1.4% for the second group of tests (EUR 0.14/test). The improvement of the process workflow minimised multiple sample transports and manual manipulations, influencing the direct labour costs per test. The equipment changes explained in Section 2.3 with the automation affected the equipment and reagent costs per test. In the case of COVT–COVIDIGG testing, the cost reduction does not consider the impact of equipment and reagents costs because no data were available for the pre-TLA scenario in 2020. The immunoassay testing systems used in the pre-TLA scenario did not change, but a reduction in the direct labour costs of 7.1% was assessed due to the improved workflow and task redefinition. The estimated annual cost savings are EUR 15,212.22, considering 29,216 HIV tests and 18,273 COVT–COVIDIGG tests performed in 2022.

Regarding main process KPIs in pre-TLA and post-TLA scenarios, the total labour cost per day was calculated by considering the direct labour time invested on each test by technicians and doctor. The percentage share of each test among the total, representing HIV (13.9%) and COVT–COVIDIGG (8.7%), has weighted fulltime equivalent (FTE). The reduction in the labour necessities (40%) supposes an improvement in terms of labour cost for HIV and COVT–COVIDIGG testing.

If results are evaluated for the whole-laboratory pre- and post-TLA scenarios, they show additional results concerning productivity considered as production rate of conforming serology tests per FTE, which is now equivalent to the laboratory staff number in view of their category of fulltime employees. Table 4 also shows productivity differentiation between processing and validation phases. The FTE number was reduced from five people in pre-TLA to three in post-TLA, removing one laboratory technician in the serology area that was assigned to other functions and one clinician. The average daily productivity of the laboratory increased from 171 to 284 tests/FTE, which meant an average improvement ratio of 65.9%. Personnel costs decreased with the removal of one clinician and one technician by EUR 70,841.24 per year, corresponding to the gross salaries per year in view of the category.

Table 4. Comparison of cost and process KPIs per serology test in pre-TLA and post-TLA scenarios.

		HIV			COVT–COVIDIGG (*)			All Serology Tests (***)	
		Pre-TLA	Post-TLA	Improvement Ratio	Pre-TLA	Post-TLA	Improvement Ratio	Pre-TLA	Post-TLA
Cost Item	Equipment per test (EUR/test)	2.10	0.65	10.5%	**	1.66	0.0%		
	Reagents per test (EUR/test)		1.23		**	6.36	0.0%		
	Direct labour cost per test (EUR/test)	2	1.78	10.9%	1.92	1.78	7.1%		
	Average cost per test (EUR/test)	4.1	3.67	10.6%	9.94	9.81	1.4%		
	Test volume 2022 (units)		29,216			18,273			
	Cost savings/year (EUR)		12,706.84			2505.39			
Main process KPI	Average test number/day (units)	109	118		311	74		855	851
	Full time equivalent (FTE)	0.70	0.42	40.0%	0.44	0.26	40.0%	5	3
	Processing (FTE)							3	2
	Validation (FTE)							2	1
	Productivity (tests/FTE)							171	284
	Processing (tests/FTE)							285	426
	Validation (tests/FTE)							428	851

* The cost considers one sample with two different determinations, one for each serology analysis: COVT and COVIDIGG. (**) No data available. (***) Serology tests: AVIH, HBS, VHC, LUES, HBCC, AHBS, COVT, TXG, RUBG, CMVG, HAVG, CMVM, HAVM, HTLV, TXM, CHAGAS, COVIDIGG, EBM, EBNAG, VZG, PARG, SARG, PARVOG, HSG, EBG, BORG, PARVOM, BORM.

4. Discussion

With regard to the literature review presented in this paper, this work contributes to the research field of developing new Lean Healthcare approaches that are focused on the patient to improve processes in a clinical laboratory context. As shown in Section 1, Lean improvement methods included in this case study are in line with previous publications that centre on process added-value activities: reducing waiting times, redesigning laboratory layout and shortening the workflow process. The most-extended KPI identified in the literature for measuring the process lead-time in healthcare laboratories is the Turnaround Time or TAT, which we also evaluated. Alternatively, the main key points of differentiation compared to previously published articles are related to the following facts: (1) the unique application context, demonstrating Lean analysis in serology diagnosis processes for COVID-19 and HIV in a microbiology laboratory—a previously unexplored area, (2) the integration of Lean methodologies with Total Laboratory Automation (TLA) in both application and execution and (3) a comprehensive cost evaluation study, comparing scenarios before and after TLA implementation. Economic impact studies post-implementation, like the one presented, are relatively rare. Consequently, this research distinguishes itself through its extensive scope and practical application within a serology lab setting.

As previously mentioned, the results obtained proved the satisfactory implementation of Lean methodologies for process diagnosis, assessment and optimisation in a microbiology laboratory's serology workflow. Despite this fact, we acknowledge that the study could have some limitations. The primary concern is that it was conducted exclusively at a single institution, which may restrict the applicability of our findings to clinical laboratories

with substantially different workflow processes. However, our findings and the adoption of Lean principles can still offer valuable insights to other laboratories, albeit with some contextual adaptation. Quality in terms of patient satisfaction could have been another research variable resulting from our process improvement initiatives. Therefore, it is reasonable to infer that reduced waiting times and improved Turnaround Times (TATs) would likely lead to increased patient satisfaction.

The advantages were expanded to encompass other sections of the laboratory, including the pre-analytical area, where certain specimens still undergo manual processing but with a noticeably reduced workload. Notably, the automation has led to a remarkable reduction in laboratory waste. Nevertheless, there are still potential improvements under analysis that will enhance the current situation in the near future. They are related to the sample input and output processes of the serology-automated line, such as creating a pull flow between the sample incoming area and the pre-analytical equipment or eliminating the finished sample re-racking for sample archiving. In addition, pre-analytical equipment idle times could be also reduced improving the line schedule and levelling. Optimisations in the laboratory information system's filtering protocols for validating clinical results, along with algorithms for self-verification of routine tests based on the patient's medical history, have the potential to reduce wait times in the clinical results validation process.

5. Conclusions

This article presents an optimisation project, implementing Lean methodologies and Total Laboratory Automation (TLA) in the serology area of a microbiology laboratory. The Value-Stream Analysis (VSA) Lean technique was selected to map and analyse the serology workflow in the laboratory. Two process workflows were defined for analysis, the process followed by a HIV serological sample and the process for total nucleocapsid (COVT) and spike IgG (COVIDIGG) SARS-CoV-2 antibody testing. Pre- and post-TLA scenarios were considered for VSA, measuring the main process KPIs affecting the diagnostic response time and laboratory costs. The process optimisation ideas identified in the pre-TLA Lean analysis were implemented and assessed in the post-TLA analysis.

The results of HIV serologic samples in pre-TLA and post-TLA phases showed that HIV total process time increased its added value by 81% versus the former pre-TLA situation, where the tasks with added value accounted for only 14% of the total process time. The total process time or TPT decreased from pre- to post-TLA from 28:04:28 h to 00:45:55 h, processing the samples within a single 7 h working shift. For COVT–COVIDIGG serology testing, the total process time decreased from 01:28:27 h to 01:24:30 h, which represented a reduction in time of 4.3%. Process layout, safety in the workplace and ergonomic conditions improved with the new workflow. Total process time added value increased by 4% in the post-TLA scenario for COVT–COVIDIGG.

Manual sample transports and unnecessary staff movements were minimised in the new automated serology line. In addition, manual technician tasks decreased by 32% with the TLA by automation of manual activities such as sample registration, identification, separation, re-racking and tube uncapping that were eliminated with the new pre-analytical equipment. This avoided biological, health and safety risks for laboratory personnel.

TLA and Lean optimisation directly affected the serology process Turnaround Time (TAT), calculated as the time elapsed from the sample reception in the laboratory to the test results' validation. We could conclude that it decreased for all sample testing in the post-TLA scenario. The percentage of improvement from pre- to post-TLA was up to 87.3% and 19.3% for HIV and COVT–COVIDIGG samples, respectively. The laboratory could perform and inform sample diagnosis within a working shift, improving their diagnostic response time to the patient. It was assessed that, in both HIV and COVID-19 process workflows, process-waiting times contributed more than 80% to TAT, mainly due to existing direct labour waiting times in the pre-analytical area and in the clinical results validation process. The waiting times reduced by 35.0% and 21.7%, respectively, in the post-TLA

scenario with the implementation of the full automation and specific improvement actions, but they were not completely removed due to internal laboratory routines.

The Lean optimisation and full laboratory automation also had a direct effect on the process and laboratory costs. The fulltime equivalent (FTE) count decreased by one microbiologist and one laboratory technician in the serology area, as they were relocated to other laboratory sections. This move bolstered the laboratory's capacity to undertake additional activities, such as sequencing. We anticipate a possible decrease in the number of laboratory technicians, which will evidently influence direct productivity. The implemented measures generated an estimated annual cost savings of EUR 15,212.22 for the two serology tests in the analysis, considering improvements in the main cost items (reagents, instrumentation, equipment and direct labour costs). Further savings could be assessed with the extended calculation for all routine serology testing integrated in the automation.

Based on the former research, it could be concluded that the successful combination of Lean with Total Laboratory Automation (TLA) opens up new opportunities for its deployment in other areas of the microbiology laboratory or extension to other types of sample testing, directly influencing the overall quality of patient diagnosis in the context of tertiary healthcare facilities. The implementation of TLA enabled the reallocation of skilled labour towards value-added tasks, such as overseeing sample processing and quality indicators, as well as addressing quality concerns and minor automation failures. This enhanced the process quality, optimised the direct labour resources and reduced samples' waiting times in the area.

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Institutional Review Board Statement: This study was conducted according to the principles set forth by the Declaration of Helsinki and good clinical practice and follows the requirements of Spanish Policy for Biomedical Research 14/2007, of 3 July.

Informed Consent Statement: Not applicable.

Data Availability Statement: Restrictions apply to the availability of these data. Data was obtained from the hospital and could be available from the corresponding author (R.A.) with the permission of the hospital's Board of Management.

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Conflicts of Interest: The authors declare no conflicts of interest.

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