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ORIGINAL ARTICLE

The Effect of Total Laboratory Automation on Urine Culture Result Times in a Consolidated Laboratory

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SUMMARY

Background: **The Provincial Health Directorate of Istanbul province (Turkey) established a consolidated laboratory network consisting of four regional central laboratories to reduce general laboratory costs and increase laboratory efficiency and quality in all affiliated hospitals. As part of the consolidation project, the Total Laboratory Automation (TLA) system was installed in the microbiology department of the ISLAB-2 central laboratory. In this study, the turnaround time (TAT) of urine samples of a satellite laboratory where the system was not installed and the ISLAB-2 central laboratory were compared to evaluate the effect of consolidation and the TLA.**
Methods: **The TAT values of all urine samples processed between March 2021, when the TLA was installed, and October 2021, were retrospectively examined in the laboratory information system. While the TLA was used for the processing and evaluation of samples in the ISLAB-2 central laboratory, manual methods were employed in the satellite laboratory. Both laboratories used MALDI-TOF MS (bioMérieux, France) for bacterial identification and VITEK 2 Compact (bioMérieux, France) for antibiotic sensitivity testing. Kruskal-Wallis test was used to compare TAT between the two laboratories. $p < 0.05$ was taken as the level of statistical significance.**
Results: **A total of 78,592 urine cultures (71,906 in the central laboratory and 6,686 in the satellite laboratory) were included in the study. Negative samples were reported in 23.5 hours in the central laboratory and 37.1 hours in the satellite laboratory and positive samples in 55 hours and 61.7 hours in the same laboratories, respectively. The mean TAT of both positive and negative urine cultures were found statistically significantly lower in the central laboratory than in the satellite laboratory ($p < 0.0001$).**
While 82% of negative urine cultures were completed within the first 24 hours in the central laboratory, only 17% were processed in the satellite laboratory. While 61% of positive samples were processed within the first 48 hours in the central laboratory, 38% were completed in the satellite laboratory.
Conclusions: **We assume that TLA has a positive effect on the diagnosis and treatment of patients, thanks to its contribution to standardization, efficiency, increased quality, and earlier reporting.**
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total laboratory automation, turnaround time, urine culture, WASPLab

INTRODUCTION

Automation systems are widely utilized in clinical biochemistry and hematology laboratories; however, microbiology laboratories have been involved in this process for the past 15 - 20 years [1,2]. Some of the reasons

for the delay in the automation process in microbiology can be listed as follows: types and quantities of samples; diversity in sample containers; tests that require pretreatment in the cultivation process according to the characteristics of the sample type; differences in the medium, incubator, and degree and time of incubation; the existence of many variables in antimicrobial susceptibility testing and evaluation process. Due to the difficulty of creating an automated standard process with so many variables together, the medical device industry had been reluctant to work on this issue for many years. Fortunately, two companies, namely BD Kiestra Total Laboratory Automation (Becton-Dickinson, Sparks, MD, USA) and Copan WASPLab (Copan Diagnostics Inc., Murrieta, CA, USA), have overcome all these difficulties and managed to develop total laboratory automation (TLA) systems [3].

Turnaround time (TAT) has been one of the biggest problems of microbiology laboratories since their establishment. While the test volumes of laboratories have increased by 10 - 15% every year due to the aging population requiring more health care services, infection control that has become more difficult due to increasing antibiotic resistance, and new tests that have been added to the system, the problem of limited budget allocated to laboratories and shortage of competent personnel in our country, as in the rest of the world, is gradually increasing [4-7]. TLA has been utilized to meet the expectation of completing more work quickly while maintaining analytical quality with less budget and personnel [8,9]. Decreased TAT, early diagnosis and treatment, and shorter hospital stays are associated with a lower risk of nosocomial infections and a reduction in concomitant overall health expenditures [10].

ISLAB-2 is the second consolidated laboratory of Turkey established in Istanbul, Turkey, in December 2020. Quality and efficiency improvements were given priority in the microbiology laboratory, including the transition to TLA. The entire process of culture samples was automated by installing the WASPLab, matrix-assisted laser desorption/ionization time-of-flight mass spectrometry (MALDI-TOF-MS), and fully automated antibiogram systems in the microbiology department.

The aim of this study is to evaluate the contribution of the WASPLab to our laboratory and the hospitals that we serve by comparing the TAT of urine cultures in two different laboratories that employ the same methods and devices for identification and antimicrobial susceptibility testing, except for the processing (culturing, incubition, and evaluation) of urine samples on the WASPLab.

MATERIALS AND METHODS

An overview of laboratory demographics and workflow

ISLAB-2 laboratory (Central laboratory)

The ISLAB-2 laboratory started operations in December 2020 within the scope of 4 ISLAB consolidated laboratories, whose planning was initiated in Istanbul in 2017. Samples come from 13 hospitals with a total of 6,382 beds and 450 family health centers (FHCs) to the ISLAB-2 laboratory. While specific biochemistry and immunoassay, specific autoantibody, infection serology, molecular microbiology, and microbiology tests belonging to hospitals are studied in the ISLAB-2 laboratory, which is the central laboratory, a limited number of samples for routine biochemistry tests, hemogram, complete urinalysis, urine culture, restricted infection serology, and hemoglobin electrophoresis come from FHCs. Samples are transported to the central laboratory by couriers twice a day from satellite hospitals and once a day from FHCs. Urgent samples are studied in satellite hospitals, and no testing is performed on the weekend.

In the central microbiology laboratory, urine cultures, which constitute the highest sample load of hospital laboratories, are sent to the central laboratory in the sample form, while all culture samples, except for urine culture, are cultured and incubated in satellite hospital laboratories and plates with growth are sent to the central laboratory for identification and antimicrobial susceptibility testing. All urine samples accepted as specimens are processed, incubated, and evaluated on the WASPLab system. The TLA solution consists of a single line connecting 2 WASPs and 3 smart incubators. Since couriers bring the samples in bulk from the satellite laboratories, the urine samples admitted to the laboratory are constantly loaded into 2 WASPs. In the central laboratory, identification studies are carried out with VITEK MS (bioMérieux, France), and antimicrobial susceptibility testing is performed with VITEK-2 Compact (bioMérieux, France) systems.

Satellite laboratory (Hospital laboratory)

The hospital included in the study is a 600-bed institution that provides specialist educated in clinical microbiology. It studies all culture samples, except for urine samples, by using conventional methods. Urine samples are sent to the central laboratory between 8 a.m. and 4 p.m., while samples that are collected between 4 p.m. and 8 a.m. and on the weekend and those of the emergency department and inpatients are sent to the satellite laboratory. Samples are not piled up; they are continuously cultured. While the processing and evaluation of the samples are done by manual methods, identification studies are carried out with VITEK MS (bioMérieux, France) and antimicrobial susceptibility testing is performed with VITEK-2 Compact (bioMérieux, France) systems.

Study design

Sample selection

The study included urine culture samples that were admitted between March 2021, when the WASPLab system started functioning actively, and October 2021 for processing on the WASPLab system in the consolidated central laboratory and manually in the satellite laboratory.

Processing of samples

All urine samples were cultured using CHROMID® CPS® Elite (BioMérieux, France) mediums in both laboratories, 10 µL disposable loops manually in the satellite laboratory, and 1 µl disposable loops on the WASPLab system in a zigzag pattern in the central laboratory. Incubation took place in the smart incubators of the system in the central laboratory at 37°C and in conventional laboratory incubators in the satellite laboratory.

Evaluation of samples

In the central laboratory, only the samples that completed the 16-hour incubation time during the day shift were evaluated at 8 a.m., and the samples that did not complete the incubation time were evaluated each time the TLA gave a warning. In the satellite laboratory, only the samples that completed the 18 - 20-hour incubation time during the day shift were evaluated at 8 a.m. and the samples that did not complete the incubation time were evaluated at 1 p.m.

In the central laboratory, negative urine cultures were evaluated by microbiology specialists during the first 2 months when the WASPLab was installed. The evaluation results were used by the application specialists of the manufacturer company, and a segregation algorithm was created. As of May 2021, negative urine cultures were separated using WASPLab Segregation Software. The urine cultures that could not be separated by segregation in the central laboratory and all urine cultures in the satellite laboratory were evaluated by microbiologists based on the internationally defined urine culture evaluation criteria for colony morphologies and colony numbers in plates [11].

Urine cultures classified to have reproduction by microbiologists in both laboratories were identified with the VITEK MS (bioMérieux, France), and antibiotic susceptibility tests of microorganisms defined as uropathogens were performed with the VITEK-2 Compact (bioMérieux, France) system.

The results of the urine cultures without reproduction were automatically transferred to the Laboratory Information System (LIS) (Ventura Software, Turkey) through interface software from the WASPLab system in the central laboratory, while the results in the satellite laboratory were recorded on the LIS by a laboratory secretary. Antibiotic sensitivity results in both laboratories were automatically transferred to the LIS and approved after they were evaluated by microbiologists based on EUCAST rules [12].

Definitions

The TAT of urine cultures was obtained retrospectively from the LIS. TAT was accepted as the time between the acceptance of the sample to the laboratory and the reporting of the result with the approval of the specialist physician. Urine cultures without reproduction were labeled as negative, and those which underwent an identification process and antimicrobial susceptibility testing and had clinically significant reproduction were labeled as positive.

Statistical analysis

For the comparison of the TAT between the two laboratories, the Kruskal-Wallis test was used. Cases with a p-value of < 0.05 were considered statistically significant.

RESULTS

A total of 78,592 urine cultures, including 71,906 in the central laboratory and 6,686 in the satellite laboratory, were included in the study. No reproduction was observed in 84% of the samples, but reproduction was observed in 16%, for which identification and antimicrobial susceptibility testing were performed. During this period, the processing performance of the central laboratory for processing and reporting was 61,257 negative samples 23.5 hours and 10,649 positive samples 55 hours, while the processing performance of the satellite laboratory was 5,140 negative samples 37.1 hours and 1,546 positive samples 61.7 hours. The mean TAT of both positive and negative urine cultures was found to be statistically significantly lower in the central laboratory than in the satellite laboratory ($p < 0.0001$). The mean TAT values of both laboratories for negative and positive urine cultures are summarized in Table 1.

While 82% of urine cultures without reproduction were processed within the first 24 hours in the central laboratory, only 17% were processed in the satellite laboratory within this time. Also, 98% of the samples in the central laboratory and 87% in the satellite laboratory were reported in the first 36 - 48 hours. The turnaround time of negative urine cultures is summarized in Figure1.

While 61% of urine cultures with reproduction were processed within the first 48 hours in the central laboratory, only 38% were processed in the satellite laboratory within this time. Also, 95% of the samples in the central laboratory and 88% in the satellite laboratory were reported in the first 60 - 72 hours. The turnaround time of positive urine cultures is summarized in Figure 2.

After March-April, when the WASPLab system in the ISLAB-2 laboratory had been installed, the segregation process was applied for negative urine cultures. While the TAT value of negative samples was 24.1 hours in March–April, this duration decreased to 22.9 hours in other months ($p > 0.05$). Although there was no statistically significant decrease, while the turnaround time of 22% of negative samples was more than 24 hours be-

Table 1. Median TAT comparison of the central laboratory and the satellite laboratory.

	Time (hour) to*		
Culture Type	**Central Laboratory (TAT/n)**	**Satellite Laboratory (TAT/n)**	**Significant Level**
Negative	**23.5 (61.257)**	**37.1 (5.140)**	**p < 0.0001**
Positive	**55 (10.649)**	**61.7 (1.546)**	**p < 0.0001**

*** Results are shown as median turnaround time in hours.**

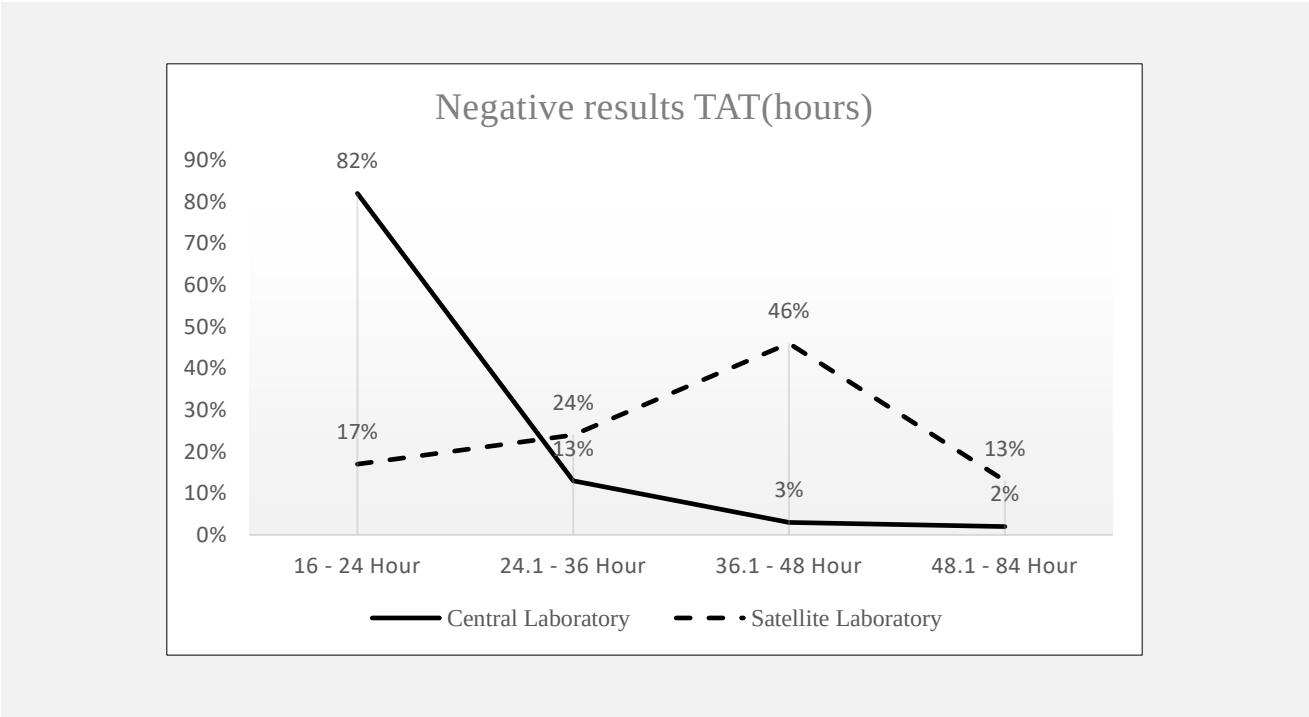

Figure 1. The TATs of negative urinary cultures, in the central and satellite laboratory.

fore the application of segregation, this rate decreased to 12% after the segregation application.

DISCUSSION

The main task of microbiology laboratories is to isolate and identify the causative agent using an appropriate, rapid, and accurate diagnostic method. Speed, which is one of the components in this definition, is the main problem. The speed of culture-based results depends on multifactorial factors, such as workflow in the laboratory, microbial growth kinetics, laboratory working hours, and daily human resource management. With TLA and improved workflow, microbiology laboratories have gained momentum and come with many advantages, such as increased efficiency, accountability, and reduced TAT, labor costs, operational errors, and environmental contamination [9,13-16].

The turnaround time difference between the two laboratories was 13.6 hours for negative urine samples and 6.7 hours for positive urine samples, which was found statistically significant. Considering that VITEK-MS was used for identification and the VITEK2 Compact system was used for antibiotic sensitivity in both laboratories, we think that the WASPLab system had an effect on the processing of antimicrobial susceptibility testing results in an average of 6.7 hours earlier in the central laboratory.

Research into the TLA, though there is none in our country, has drawn attention in the last 10 years. Similar to the results of our study, the TLA has decreased the TAT of both urine cultures with no reproduction and antimicrobial sensitivity tests [8,9,16-19].

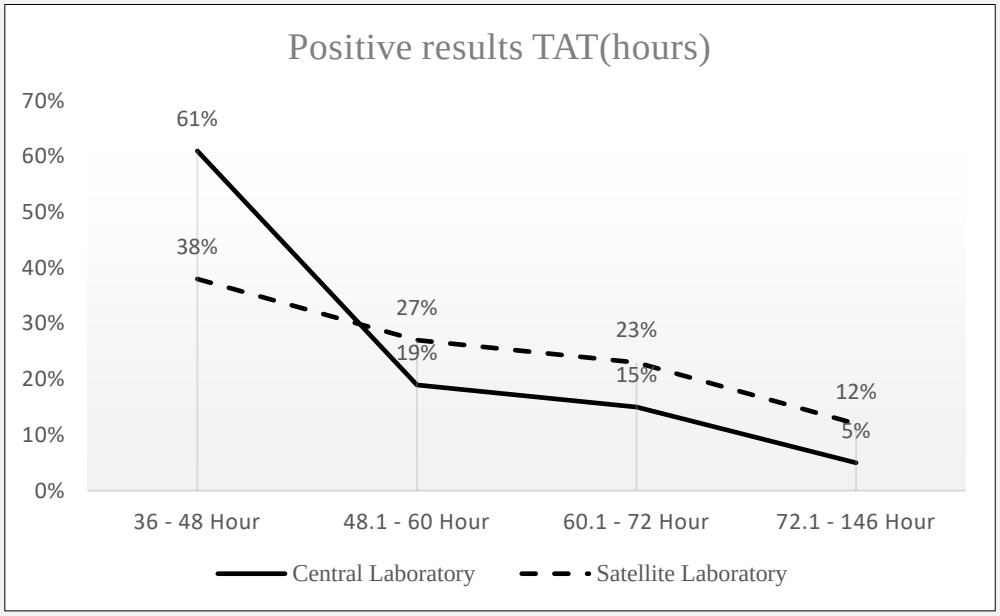

Figure 2. The TATs of positive urinary cultures, in the central and satellite laboratory.

As a result of the decrease in TAT, we think that central laboratories make an important contribution to the hospitals they serve. It is a well-known fact that decreased TAT leads to an earlier change of empirically inappropriate antibiotic therapy and a decrease in defined daily antibiotic doses used. In addition, the earlier effective antimicrobial therapy is initiated, the shorter the hospital stay is and the lower mortality rates and health expenditures are [8,20-22]. In antibiotic treatment, using effective antibiotics as soon as possible is as important as preventing unnecessary antibiotic treatment. Unnecessary antibiotic use causes increased antibiotic resistance and healthcare costs [23]. In our study, similar to the results of the study by Cherkaoui et al. [24], unnecessary antibiotic use was avoided by processing the results of 82% of urine cultures without reproduction within the first 24 hours, and we contributed to the appropriate and effective antibiotic treatment by reporting the antibiotic sensitivity results within 48 hours in 61% of the samples with reproduction.

In a review by Livermore and Wain [25], it was stated that due to the long turnaround time in the microbiology laboratory, only 3% of patients with community-acquired respiratory tract infections and approximately 50% of patients with urinary tract infections in the UK had laboratory tests requested and were treated according to the laboratory results. As inappropriate empirical treatment in patients with severe infections nearly doubles the mortality rate, if we can manage our microbiology laboratories by using 21st century technologies and technological workflows and reflect the time and quality in our reports, we can be the main determinant in the rational test requests of clinicians.

We think that multifactorial factors played a role in the shorter TAT in the central laboratory than in the satellite laboratory. Some studies have shown that while there are 45 manual steps applied from the entry of a culture sample to the completion of the process in laboratories working with conventional methods, the number of these manual steps is only 23 in laboratories where the TLA is used [8]. Yue et al. [26] found that the TLA helped perform culturing the same number of plates within a 45% shorter time than a competent laboratory worker. When we compare the workflow processes of our two laboratories, we see that the preanalytical stage is similar, but in the analytical stage, culturing, incubation, and evaluation are performed automatically in the central laboratory, while all these processes are carried out manually in the satellite laboratory. Although the same LIS software is used in both laboratories, negative results are automatically transferred to LIS via the interface module of the TLA and approved in the central laboratory, while they are entered into the system one by one by a medical secretary in the satellite laboratory and checked and approved by a microbiology specialist. Positive results are transferred directly to LIS via the VITEK 2 Compact interface in both laboratories and checked and approved by the microbiology specialist. While TLA solutions provide much more accountability than performing the same test manually, differ-

ences between personnel and human-induced errors are minimized as the processes are standard. Since the urine samples admitted to the laboratory are cultured quickly compared to conventional methods, placed in incubators without waiting, and incubation takes place under optimal conditions, a shorter incubation time may be enough compared to conventional methods, and the reproduction rate of bacteria that are difficult to reproduce has been found to be higher [27]. As a result of our examinations, the incubation time for urine cultures was determined as 16 hours in the central laboratory, while this period was 18 - 20 hours in the satellite laboratory. However, while cultures are evaluated in standard time in laboratories where the TLA has been installed, they are routinely evaluated during the activity as there is no measurability and accountability of this time, as in other laboratories that apply conventional methods [28].

Although the majority of the literature has shown that the TLA reduces TAT, there are also studies showing contrary results. In a study on the effect of the TLA on the TAT of urine cultures, although TAT decreased by approximately 24 hours in urine samples without reproduction, this decrease was limited to 2 hours in urine samples with reproduction. It was determined that the reason for the lack of improvement in antimicrobial susceptibility testing results was that the identification and antimicrobial susceptibility testing processes were performed only during the daytime and weekday shifts [24]. As seen in this study, the presence of the TLA system does not guarantee improvements in laboratory performance. Maximizing the potential benefits of the TLA is based on the correct organization of the workflows within the laboratory [17,22]. What matters is not having the system installed, but having the ability to constantly follow the workflow with continuous improvement activities and update it.

Segregation studies, which are created by considering the rules of laboratories for evaluating urine cultures, can increase efficiency and shorten TAT [29]. With the use of the WASPLab Segregation software, although the change in TAT was not statistically significant, 22% of negative samples were completed within more than 24 hours before segregation, while this rate decreased to 12% after segregation. This data showed us that the segregation software contributed to shortening TAT. Thanks to the TLA, microbiology specialists evaluate only positive samples in the central laboratory, while all negative and positive samples are evaluated by microbiologists in the satellite laboratory. Eighty-five percent of the urine samples studied in the central laboratory were negative samples, and the remaining positive samples, which accounted for 15% of the total, were evaluated by a clinical microbiologist. This allowed the identification and antimicrobial susceptibility testing studies to be started earlier and a limited number of clinical microbiology specialists to focus on positive samples that require more technical skills. It also allowed our clinical microbiology specialists to devote their time to the analysis of complex samples, apart from urine cultures, and the organization of new tests that would increase the diagnostic power of the laboratory.

In recent years, it has been mentioned that there is a shortage of microbiology specialists and laboratory technical personnel in many countries [30]. As a result, the number of laboratories that cannot help the solution process in complex clinical cases with delayed test times is increasing. As a solution to this increasing problem, TLA systems have made it possible to rationalize the workforce without sacrificing quality and increasing the workload of the staff more than they can fulfill. When we look at the demographic characteristics of the laboratories whose TAT values we compared, we see that they have different characteristics and workflows. Since the technical personnel working in both laboratories had different work organizations, working hours, and schedules, personnel productivity could not be compared exactly. However, it cannot be ignored that one medical secretary for the preanalytical stage and one medical technician for the analytical stage is enough for the workflow during the processing of approximately 600 urine samples a day on the WASPLab.

Changing patient demographics and demands, lack of educated personnel, the attitude of governments and insurance companies toward reimbursement, the costs of tests, and the rapid changes in technology have caused problems in the provision of health services in our country as well as in the rest of the world. To solve these problems, consolidated laboratories, where resources and services are centralized and which have different capacities and features and serve a large population, have been established, and there are ongoing projects for the establishment of new ones [31]. Although our study does not provide data on staff productivity, it is obvious that TLA allows us to do a lot with a small number of staff [32]. Although there is considerable international literature on the TAT results of TLA and its positive effects, we think that our results will be a source of local and national data for the already planned and existing consolidated laboratories in our country, since this is the first study on TLA in our country.

While there is a 0.5 - 2% need for subculture in the samples cultured with the WASPLab, this rate can vary between 8 and 20% with manual methods depending on the skills of the personnel [10,28]. Although the decrease in the need for subculture shortens the TAT, the number of subcultures in both laboratories and its effect on TAT could not be evaluated as this is a retrospective study. We recommend that this issue should be addressed in future studies.

The main benefit of the TLA for patients was found as the ability to start effective antibiotic therapy as soon as possible, with a clinically significant reduced reporting time. However, this is not something that can be achieved with the installation of automation systems only. It will also be achieved with the constant review of workflow processes and local conditions by the hospital management, laboratory management, and technical staff.

The total laboratory automation process is a major financial investment and requires a complete reorganization of the physical conditions of the laboratory and laboratory management processes. We assume that the TLA will provide microbiologists with new perspectives to rethink and evaluate microbiology and, as a result, to arrange some unnecessary, long, and established steps in a controlled and evidence-based manner.

Declaration of Interest:

The authors declare that they have no conflict of interest.

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