

(REVIEW ARTICLE)



Total lab automation in microbiology: An overview of BD Kiestra Inoqula and Copan WASP

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Abstract

Total Laboratory Automation (TLA) is the future of laboratory diagnostics due to its efficiency, reproducibility, better turnaround time (TATs), precision, sensitivity, and specificity. Microbiology is generally considered a human dependent field and still, most of the microbiology world is confused with TLA implementation. Two better-claimed technologies BD Kiestra Inoqula and Copan WASP have emerged as a well satisfactory solution of microbiology automation in the last decade. Here we design a practical approach and reviewed all studies of BD Kiestra Inoqula and Copan WASP, assessed microbiology samples in a healthcare setting.

Keywords: Microbiology Total Laboratory Automation (TLA); Total Laboratory Automation (TLA); BD Kiestra Inoqula; And Copan WASP

1. Introduction

Clinical laboratory investigations are a key tool in today's healthcare system for true diagnosis which leads to precise treatment [1]. Automation testing is not a new idea of other disciplines of Clinical laboratory-like Chemical Pathology, Hematology, and Molecular biology and highly recommended due to its efficiency, productivity, better turnaround time. The concept of microbiology automation was originated very late due to its complex nature. Japan was first to float this idea in the early 1990s and gain excessive regard from the diagnostic community [1, 2]. The microbiology reporting system from sample to the final decision is a complex one to replicate in the automation process. Although, some middleware systems have been introduced to increase productivity and minimize laborious processes like automated blood culture systems, identification systems, and antimicrobial susceptibility systems. These all systems automated in nature but disconnected and separated from each other. These systems were widely accepted and utilized by clinical microbiology laboratories. The main drawback of these systems that they all required particular manual tasks depending upon the automation type [3]. With the technology advancement, complete automated systems have been introduced in clinical laboratories which include a complete framework of the diagnostics process, including preanalytical, analytical, and post-analytical processes integrated with each other. An advanced interfaced system also connected for result interpretation, quality control, and quality assurance. This complete conceptual framework is called total laboratory automation (TLA) [2, 3].

There were various impediments for delay of microbiology TLA implementation, some particular ones were; Complex nature of Microbiology to design a TLA, human dependency, automation cost, and restrain area for automation [3].

The major components of TLA that contribute to the design of an efficient system are Inoculation unit, Track system, Incubation system, High-resolution imaging the system, and Workstations [4]. There are two microbiology TLA integrated systems, which are largely installed and accepted by laboratories, are "BD Kiestra TLA and Copan WASPLAB" due to better efficiency, productivity, turnaround time, and simple processing [Bailey AL]. Both systems

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have more or less the same features and productivity. Another TLA system of bioMérieux FMLA is under development and did not find any laboratory research on it [3].

Kiestra was one of the first installations of microbiology TLA in 2006. It is a modular system from sample processing, streaking modules, incubation systems both CO₂ and non-CO₂, microbial identification, and antimicrobial susceptibility testing. The application of artificial intelligence in automation and reporting can also make these systems more reliable and efficient [3, 5]. The WASP system was first installed in 2012, 6 years later after Kiestra. The WASP systems are connected to Inpeco, a centralized system of TLA to track and sort appropriate laboratory tests including chemical pathology, hematology, and microbiology [3]. Here we design a systemic review based on reported parameters of BD Kiestra TLA and COPAN WASPLAB”.

2. Methods

We conducted this systematic review of data search and screening in accordance with the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement [6].

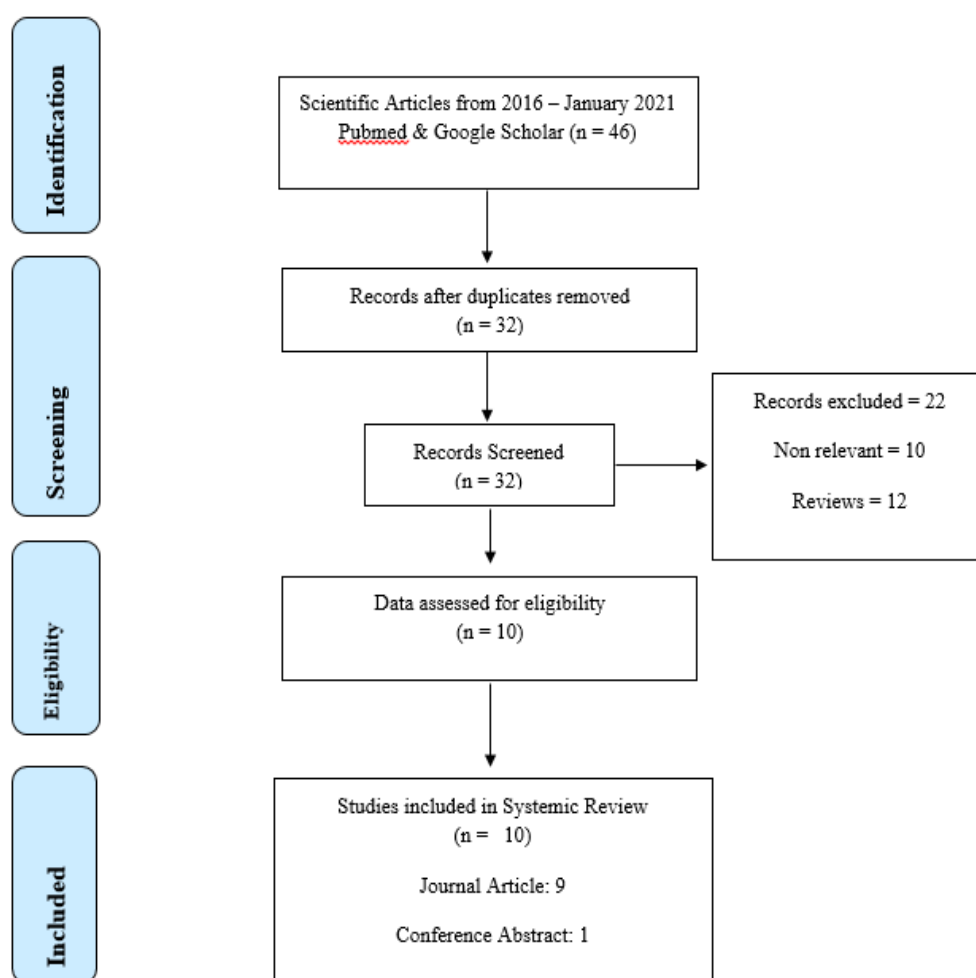


Figure 1 Summary of Study Selection Process

PRISMA flow diagram, Preferred Reporting Items for Systematic Review and Meta-Analysis

RCT: Randomized Control Trial

Data base: Cochrane Central Register of Controlled Trials (CENTRAL)

2.1. Inclusion Criteria

Scientific Journal articles and Abstracts based on microbiology testing evaluation either identification, or antimicrobial susceptibility testing by Total lab. Automation (TLA) including Kiestra or WASP, both or alone in comparison with manual or other testing methods.

2.2. Data extraction and management

Based on inclusion criteria, one author is responsible for data extraction from Pubmed and Google Scholar by using combination of key words to avoid data missing, from 2015 – January 2021 and screened by the PRISMA model.

2.3. Study Outcome

Evaluation of Total laboratory Automation of Microbiology and its implementation need in today's era.

3. Result and Discussion

TLA adaptation is still a fancy and puzzled requirement for most of the microbiology laboratories due to related concerns. Table 1 includes most relevant studies of microbiology TLA and explains the ambiguities in different manner. All the studies were reported from developed countries with overall a huge number of analyzed samples, see Figure 1.

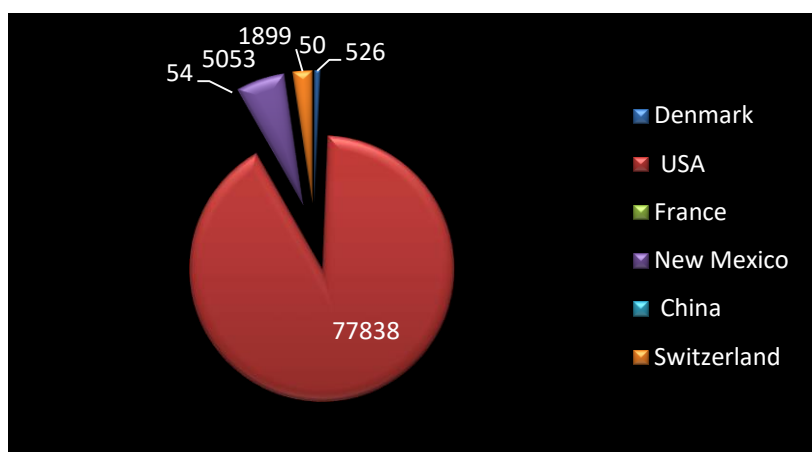


Figure 1 Number of evaluated sample among different countries

3.1. Urine Culture Evaluation by BD Kiestra Inoqula, Strauss S, et al. 2015 [13]

This sample study was one of the initial studies of microbiology automation. 8,125 urine samples were processed on BD Kiestra Inoqula 10ul inoculum volume. However, Kiestra also has the programming to set inoculums volume according to the laboratory protocol. The study reported very well satisfactory results of BD Kiestra, 95% CI multiple comparisons did for list of parameters including positive results, recovery of a single pathogen, reporting of 1 or 2 pathogens, negative results, no growth results, and multiple organism reporting. The transition of culture is another associated concern of urine culture reporting, to facilitate this BD Inoqula colonies were also compared to manually processed 1ul inoculated QC culture of known inoculums concentration were streaked with BD Inoqula. An additional advantage of this study was media turnaround time calculation which is another claimed advantage of automations. The significantly decreased TAT was reported for negative and no growth results. One additional advantage of Kiestra Inoqula was its consistent streaking and easy to read than manual streaking. One of the study's drawbacks was that it was not performed side by side. An additional component of this study was that the Pre-installation model of this study also used BD Phoenix for identification and susceptibility testing which is also an automation system.

Table 1 Overview of Selected Studies

References	Number of samples	Country	Parameters	Microbiology TLA	
				Copan WASP-10	BD Kiestra InoqulA
Iversen et al. 2016 [7]	526	Denmark	No growth	141	189
			Commensal flora	108	91
Snyder et al. (Article in press) [8]	7325	USA	Categorical agreement	–	97.50%
			Categorical agreement - repeat	–	99.80%
			Un resolved	–	0.20%
Croxatto A, et al. 2017 [9]	218	Switzerland	Sensitivity	–	97.10%
			Specificity	–	93.60%
Fihman V, et al. 2018 [10]	54	France	Quality of isolation score (type of sample and inoculation method)	67%	–
Timm K, et al. 2017 [11]	5053	New Mexico	No Growth	99.60%	–
			NGUF/ Contaminated	96.00%	–
			Culture Review for ID/AST	92%	–
Theparee T, et al. 2018 [12]	61,157	USA		Pre TLA n (%)	Post TLA n (%)
			Number of cultures	30,907 (100)	30,250 (100)
			organism reported	9,177 (29.7)	8,074 (26.7)
			Multiple organisms reported	713 (2.3)	718 (2.4)
			No pathogens reported	20,907 (67.6)	21,352 (70.6)
			Outliers	110 (0.4)	106 (0.4)
	42,259		Median turnaround time - Culture type - Negative (ID or preliminary negative result)	17.73 (14.97–22.25)	13.62 (12.60–16.80)
	17,251		Median turnaround time- Culture type - Positive (ID or preliminary negative result)	18.53 (15.00–31.62)	16.92 (14.95–25.87)

	42,259		Median turnaround time - AST or final negative result	37.38 (34.35–42.17)	38.62 (36.85–42.53)		
	17,251		Median turnaround time - AST or final negative result	41.80 (38.08–55.78)	40.85 (38.53–8.68)		
Strauss S, et al. 2015 [13]	9,356	USA	Postinstallation/ preinstallation difference				
			Positive results	_ 0.85, 1.77			
			Single pathogen recovered	_ 2.20, 0.47			
			Two results reported with 1 or 2 pathogens	0.01, 2.62			
			Negative results	_1.76, 0.86			
			No growth	_4.83, _1.70			
			Multiple organisms	_0.85, _0.07			
			Single organism of <10 ⁴ /ml	0.40, 1.53			
			Median time to result (h)	Pre-BD Installation	InoqulA	Post-BD Installation	InoqulA
			Positive results	45.83		45.81	
			One pathogen reported	44.68		44.47	
			With BD Phoenix	44.65		44.47	
			Without BD Phoenix	45.61		44.6	
			Two results reported	47.25		47.97	
			No BD Phoenix result	43.75		43.55	
			One BD Phoenix result	46.41		47.5	
			Two BD Phoenix results	68.65		65.72	
			Negative results	40.6		39.38	
No growth	40.43		39.76				
Yue P, et al. 2020 [14]	50	China	Recovery of Pathogens and Isolated Colonies	Manual	Automated (BD Kiestra InoqulA)		

			Sputum - Blood Agar	104	113
			Sputum - V-Choc agar	70	69
			Sputum - CB agar	42	47
			Urine - CB Agar	25	25
			Sterile body fluids - Blood Agar	28	28
			Sterile body fluids - CB Agar	18	20
			Feces - XLD Agar	51	54
			Feces - CB Agar	59	56
Quiblier C, et al. 2016 [15]	379	Switzerland		Manual n(%)	Kiestra™ IdentifA
			Positive result	141 (37.2)	153 (40.4)
			Negative result	238 (62.8)	226 (59.6)
			Possible pathogens	159 (42)	172 (45.4)
			Contamination	10 (2.6)	10 (2.6)
Jacot D, et al. 2020 [16]	1302	Switzerland		Manual n(%)	Copan WASP n(%)
			Gram-negative bacteria	86.9% (334/384)	96.5% (369/382)
			Staphylococcus aureus and enterococci	93%	92.00%
			AST - overall agreement	-	98.82%
			category agreement	-	98.86%
			very major error	-	1.05%
			Major errors	-	0.16%
			Minor errors	-	0.91%

3.2. Urine Samples Study with BD Kiestra Inoqula and Copan WASP, Iversen et al. 2016 [7]

This laboratory evaluation testing was based on two WASP (WASP 1, and WASP 10) instruments with the BD Kiestra Inoqula. Two WASP units were simply used because of the lab. has two installed units. This study was also based on urine sample evaluation, which shares a huge burden of microbiology samples and quantitative reporting. In this study relative performances of all three instruments were compared by using 10ul sample plating by Kiestra Inoqula, and 1ul and 10 ul on WASP. The most important finding of this study was the reproducibility of results because manual methods are not reliable in terms of reproducibility and due to uncontrolled variables. Automated systems have the built-up process of loop calibration and depth of tube insertion. Another reported finding with limited comparison tools was Inoqula produce more accurate results than WASP. WASP produced more colonial count than Kiestra Inoqula specifically with 1ul calibration streak.

3.3. Copan WASP performance for Urine Microbiology, Quiblier C, et al. 2016 [15]

This study evaluated both inocula of 1 and 10 ul and streaking patterns by WASP (WASP SST6, WASP SST2) and Inoqula BT in comparison with the manual method. This study reported no difference between positivity rates and recovery of potential pathogens by using 1 or 10ul inocula. WASP SST6 was superior in pure culture streaking and recovered maximum single colonies than WASP SST2 and Inoqula.

3.4. Automated detection, identification, and semi-quantification of microbial growth of Urine Samples, Croxatto A, et al. 2017 [9]

The Automated system used in this study was BD Kiestra Inoqula. This study reported very well satisfactory results of BD Kiestra Inoqula with 93.6% specificity, 97.1% sensitivity, and 80.2% and 98.6% quantification accuracy. Different Culture media was also evaluated for microbial growth; chromogenic agar reported the highest accuracy for urine samples from 98.3% to 99.7%. Reduction of turnaround time is also a concluding feature of this study.

3.5. Expert Image Analysis of Urine Culture by Copan WASP, Timm K, et al. 2017 [11]

This study included a large volume of 5,053 consecutively collected urine samples. This study reported the 99.9% sensitivity of urine cultures by Blood Agar and MacConkey agar growth. All software results were compared with manual results with >90% agreement.

3.6. Bacterial Culture quantification, comparative performance of WASP, and ISO 15189 accreditation, Fihman V, et al. 2018 [10]

This study evaluated cross-contamination and result precision of WASP, which is one of the main concerns of every microbiology laboratory. The 72 evaluated samples were urine samples, swabs, bronchopulmonary specimens, and catheter tips. Result comparison was also performed among WASP, PREVI Isola, and manual inoculation. The results reported zero cross-contamination by WASP. The agreement of PREVI Isola and WASP was 100%. WASP also reported a better yield of colonial isolation than manual methods, due to precise inoculation strategy.

3.7. BD Kiestra and MALDI-TOF MS, Urine Culture evaluation, Theparee T, et al. 2018 [12]

This study was based on a large sample size of 61,157 urine cultures and evaluates turnaround times (TATs). 5,402 were positive cultures, evaluated till antimicrobial sensitivity testing. This study reported a significant improvement of TATs after TLA implementation. Another interesting finding was, preliminary reporting of approximately 70% of potential microbes after 12 hours of initial incubation. The remaining proportion required longer incubation due to slow-growing nature such as Candida, Aerococcus, and Actinotignum species.

3.8. Evaluation of Inoqula-Kiestra, Yue P, et al. 2020 [14]

This was the first sample evaluation study of Inoqula-Kiestra reported from China. A total of 200 in-patient samples of 50 sample groups, including sputum, urine, sterile body fluids, and feces were included. This study also reported the BD Kiestra Inoqula system superior to manual inoculation methods for better recovery of isolated colonies, specifically for the semi-quantitative plate streaking method.

3.9. Assessment of Kiestra IdentifA/ SusceptA, Jacot D, et al. 2020 [16]

This study exhibit high microbial identification and susceptibility performance as compare to conventional microbiology manual methods. Specifically, high performance was seen in species identification of Gram-negative bacteria. MacConkey agar showed significantly high efficiency of Kiestrs identification of 95.2% than manual method

75.2%. The additional feature of this study was AST evaluation, the overall agreement was 98.82%, 98.86% category agreement, with 0.05% very major errors, 0.16% major errors, and 0.91% minor errors.

3.10. Evaluation of microbial; identification and susceptibility testing, Kiestra IdentifA/SusceptA system, Snyder et al. (Article in press) [8]

This comprehensive study declared the high ID efficiency of 97.1% by Kiestra IdentifA, and the AST categorical agreement was 99.8% categorical agreement. The study conducted by a variety of microbiology specimens including Blood, Urine, Body fluids, and respiratory samples. Almost all the potential pathogens were tested for AST including *Staphylococcus pettenkoferi*, *Enterococcus faecalis*, *Klebsiella pneumonia*, *Staphylococcus aureus*, *Staphylococcus hominis*, *Escherichia coli*, *Pseudomonas aeruginosa*, *Enterococcus faecium*, *Serratia marcescens*, and *Proteus mirabilis*.

4. Conclusion

Automation is a great need of every diagnostic laboratory including a Microbiology section. Quality management, quality assurance, results reproducibility, precision, TATs, results traceability, record management, sensitivity, and specificity are of great concern for every diagnostics area due to better treatment management. Microbiology is one of the diagnostic fields which directly connect to treatment management. Total Lab. Automation is a one-answer solution; all the included studies did a detailed assessment of TLA from different aspects and give a very well satisfactory outcome. Cost is an associated concern, but the reduction of human resource may also contribute to resolve this concern. Although, an extensive cost study of Microbiology TLA is significantly required [17].

Limitations of the Study

All studies have different assessment parameters and patterns. Cost assessment and Laboratory area is one of the major concerns for most of the laboratories. No study reported the cost and required area assessment of pre and post TLA analysis.

Future Concerns

All studies were reported from developed countries, which clearly showed TLA as a fantasy for developing countries and due to lack of cost and area assessment this might take a long way to implement in developing countries.

Compliance with ethical standards

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Disclosure of conflict of interest

Author declared no conflict of interest.

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