# Implementation of the WASPLab™ and first year achievements within a university hospital

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**Keywords**: project management; change management; accuracy; turn-around time; efficiency; workflow; WASPLab™

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## Abstract

**Background**: In essence, automation can be driven by several of the following incentives: increased processing capacity of the laboratory, better costs control through processes standardization, optimized traceability, or improved workflows to reduce turn-around times (TAT).

**Purposes**: This project aims at presenting an overview of the project management and change management with a focus on the major challenges addressed by lab staff and laboratory leadership during the different phases of the implementation of the WASPLab™ in a routine clinical bacteriology laboratory.

**Content**: This paper reports our experience and reviews changes in the bacteriology laboratory at Geneva University Hospitals when shifting to the WASPLab™. Practically, the whole automation process was segmented into different packages (specimen type-based segmentation) allowing sequential validation, staff training and routine implementation. Such process allowed reaching 90% of the identified "automatable" samples within one year, including personal training, documentation for accreditation supported by publications, without interrupting routine operations. In addition, we implemented a validated automated solution for antimicrobial disk diffusion susceptibility testing.

**Conclusions**: Structured supervision and accurate monitoring of all the activities related to the automation project including key partners such as IT support, technical committee, and after-sales service guaranteed a swift and timely achievement of the project allowing the improvement of the workflow in routine bacteriology within one year.

## Introduction

The degree of efficiency of an automated system in modern clinical bacteriology laboratories depends largely on in its ability to accommodate the high diversity and complexity of the procedures governing the three phases of culture-based bacteriological testing (preanalytical, analytical, and postanalytical). Clinical bacteriology laboratories receive a broad number of different specimens which can be divided into two groups. The first group is constituted by specimens screened for a defined microorganisms carriage. For instance, vagino-rectal screening swabs for Group B *Streptococcus*, nasal and inguinal/perineal swabs for methicillin-resistant *Staphylococcus aureus*, and rectal swabs for extended spectrum beta-lactamases producing (ESBL-E) and carbapenemase-producing (CPE) Enterobacteriaceae. All such specimens are easily amenable to automation through the use of a small number of solid culture media that are often chromogenic. The other group consists of a large variety of specimens that require different and complex processing for the successful recovery of pathogens and for ensuring maximal safety precautions to prevent laboratory-acquired infections (e.g., biopsies, joint fluid, cerebrospinal fluid, bronchoalveolar lavage, …). Automating the latter group requires greater investment in the preanalytical phase by focusing first on the harmonization of sample collection devices. The second challenge is related to the antimicrobial susceptibility testing and the various processes required for addressing that topic. Despite considerable hurdles to automate clinical bacteriology laboratories, technological advances helped to overcome a large number of such barriers during the last few decades. An array of instruments are now commercially available for automating specific manual procedures (e.g, inoculation of culture media, blood culture systems, performing Gram stainings,...). However, only two manufacturers have successfully commercialized

laboratory automation systems fulfilling all the routine requirements for automated culture-based bacteriological testing within a single and integrated line: the Becton Dickinson's Kiestra™ TLA and the Copan's WASPLab™. By analogy with other fields in laboratory medicine, these manufacturers have early identified the potential operational benefits of the laboratory automation systems in clinical bacteriology. Not surprinsingly, the two instruments systems have turned out to be rather similar in terms of standardizing sample collection devices and by incorporating high-resolution imaging systems in the incubators. These two instrument systems have been thoroughly compared in previous reviews [1-5].

This project has several purposes: i) to share our experience and highlight key issues when shifting to the WASPLab™; ii) to illustrate practical project and change management without discontinuing routine diagnostic service; iii) to discuss the impact of the WASPLab™ on various metrics within the year following implementation, such as the time required to implement 90% of the specimens referred to the bacteriology laboratory at Geneva University Hospitals on the WASPLab™, training and adherence of our laboratory technologists, management quality of the operational processes, and efficiency; iv) to describe the implementation of the antimicrobial disk diffusion susceptibility testing on the WASPLab™; and v) to provide an outlook of the ongoing challenges following the implementation of the WASPLab™ in routine diagnosis.

## Vision of the total lab automation process

There can be quite different incentives and expected deliverables when planning to implement laboratory automation. Consolidation of several laboratories might require lab automation to simplify lead to a higher degree of standardization of pre-analytical processes and to harmonize analytical and post-analytical phases, associated with a

higher degree of traceability across these different phases. Depending on the local organization and implementation process, these gains may in turn favor a better reagent costs control, fulfilling higher quality control requirements such as enhanced and systematic traceability, as well as providing a faster sample throughput. Coupled with expert validation systems, such increase in sample throughput may also translate into reduced turn-around times (TAT), a necessity to prioritize medically-actionnable decisions and hopefully, to enable improved patient workflows and individual care. We selected the WASPLab$^{TM}$ option mostly to maximize our ability to absorb a constant workload increase (~3% per year) during the following 8 years at constant human ressources levels, and customized it in a way to optimize our TAT.

## WASPLab™ project management and change management

A key message in terms of change management that had to be understood by all the stakeholders involved in the implementation process is that automation is not meant to replace laboratory technologists, but to empower their specialized skills and expertise by i) dedicating more of their time to the analysis of complex specimens, ii) by achieving new tasks including system troubleshooting (both the instrument and its software), and iii) by establishing, validating and accreditating new protocols. Ensuring the good understanding of such concept by all the stakeholders was early identified as a communication challenge of strategic importance necessary to warrant a wide acceptance of the project by the laboratory technologists. To this aim, the vision of our project was rapidly shared with the lab staff by organizing regular and frequent lab meetings based on the participation method (one to two meetings per month, starting in 2016), with the purpose of improving the communication and preparing the staff for

such important changes. Thus, any point of disagreement or fear was quickly identified and discussed, so that a consensus guiding coalition could be reached to rally all laboratory technologists and microbiologists. The technologists were involved at an early stage in the reorganization of the laboratory activities during the sensitive transition phases. We also organized regular and frequent feedback sessions (i.e. every three months) to report the progress of the automation project and discuss difficulties encountered by the lab staff.

Besides providing a more accurate description of the system requirements, our experience confirmed the importance of visiting other automated microbiology laboratories (n=6, Belgium, France, Italy, Netherland and Switzerland) with a representative delegation of all the stakeholers involved in the project, including clinical microbiologists, technologists, biomedical engineers, and computer systems analysts. These visits were not only instrumental to better frame the perception of the pitfalls, needs and challenges by the different participants of our delegation, but also contributed to foster a team spirit aligned on the future and specific needs of our project, while taking advantage of the experience gathered by the visited laboratories. These visits allowed to quickly identify that IT-related issues, especially those concerning the laboratory information system (LIS) interface customization, were crucial. The early implication of our institutional IT team in this process and the visits allowed a timely estimation of the ressources required to adequately secure this critical part of the project. As we use an in-house developed laboratory information system (Unilab2, version 2.38.1), the foreseen major mobilization of our institutional IT team (e.g., LIS interface customization) enabled deadlines to be fulfilled and the continuity of developments to be ensured. Last but not least, the strong commitment of the technical committee led by our biomedical engineers was key to make the best

informed choice regarding the optimal automation system in our specific environement, as well as to define and guarantee adequate after-sales service for each potential case-scenario. Figure 1 depicts the specific steps executed during each of the project phases.

### LIS interface customization

In order to exchange data during all steps in the workflow, the communication between the LIS and the WASPLab™ has been customized by our institutional IT team. This included the transmission of the seeding protocols, the reception of the seeding status with detailed information on agar media plates, broth and slides, as well as the microbial growth information collected by imaging at the specified time points. An additional communication channel for creating sample isolates on request of the WASPLab™ was also set up. Finally, processes to synchronize data (e.g., patient demographic, and strain identification obtained by MALDI-TOF/MS) between the LIS and the WASPLab™ were also developed in the scope of this project.

## Implementation and deployment

The most significant challenges faced during the implementation and deployment phases consisted in the accurate planning of the routine laboratory activities before, during and after the installation of the WASPLab™. In our case, a dedicated area with temperature, noise and humidity control was built within the existing bacteriology lab, before the installation of the two automation systems. During such structural changes, our lab staff had to continue assuming routine diagnosis next to the construction site, implying enhanced space constraints and culture media contamination risks (Figure-1). The ongoing team management consisting in setting up special and privileged

occasions for exchanging impressions and difficulties revealed essential to maintain a friendly working atmosphere despite transient pressure increase in the working environnement. We were also personnaly supporting technologists who faced difficulties, and carried out several air control to detect any potential contamination. The WASPLab™, like other automation systems, typically involves a dedicated technologist for performing a defined set of tasks among the three defined ones (screening, reading or picking); this should permit improved efficiency and reduced time spent for switching between these tasks. However, we decided, at least for a certain period, to maintain the traditional workup on the WASPLab™ in which the same technologist performed all the analysis steps from screening to identification. This decision allowed us to consolidate the training and to control the anxiety related to a rapid change of the workflow. To optimize training, we have formed pairs (a young recruit with a very experienced technologist) to enhance the teamwork and avoid creating resistance among experienced technologists. Figure 2 depicts the number of laboratory technologists trained to perform analyses on the WASPLab™ from November 2018 (7/24, 29%) to September 2019 (24/24, 100%).

## Continuous implementation process and workflow improvement

The majority of the conventional diagnostic steps have important weaknesses that can adversely affect growth of a microorganism and therefore increase the turnaround time. Manual workup during which a technologist inoculates various clinical specimens before batch transfering culture plates to a conventional incubator; or the reading phase during which culture plates can lie up to five hours on a bench at room temperature, constitute some of such weaknesses. Automation systems enable microorganisms to grow rapidly after inoculation because culture media plates are

automatically transferred within a few minutes to incubators with optimal temperature and atmosphere control, and continuous monitoring by digital imaging. This represents optimal growth conditions by limiting exposure of microorganisms to room temperature, thereby shortening bacterial growth times and improving the recovery of fastidious organisms. Finally, the automated inoculation enables consistent streaking patterns which favor the detection of discrete colonies in polymicrobial samples, despite high inoculum.

To leverage the benefits offered by the WASPLab$^{TM}$, we performed sequential prospective validation studies where we compared the conventional diagnostic workup and WASPLab$^{TM}$ usage on a large number of clinical specimens [6-8]. Data gathered allowed us to significantly reduce the incubation times of the culture media plates and to perform earlier culture readings, while minimizing the number of images taken to prevent slowing down the incubators performances and interrupting the optimal incubation conditions. Table 1 depicts defined incubation protocols based on these studies. The implementation of the WASPLab$^{TM}$ was done sequentially, by specimens' type. We started with the easiest samples to handle such as urine and screening ESwabs to ensure better coordination with personel training, validation studies and routine implementations. Consequently, by respecting these requirements with careful change management, about 90% of the clinical samples defined as amenable to automation were successfully implemented on the WASPLab$^{TM}$ one year after system installation (Figure 3). We plan to reach 100% of such samples during the first quarter of 2020.

## Laboratory efficiency improvement

To face the challenges raised by the constant increasing demand for clinical bacteriology analyses consisting, basically, in the improvement of quality, productivity, TAT, and rationalization of laboratory technologist labor force, the implementation of an automation system constitutes an appealing option. In our laboratory, before automation, the time dedicated to manual inoculation, transferring of culture media between benches and incubators, as well as manual subculturing of the positive broth cultures onto solid culture media was estimated to represent 30 to 40% of a technologist's time. The WASPLab™ reduced indeed the hands-on time spent for these tasks by the technologists, thus improving daily efficiency. Before the implementation of the WASPLab™, the hours of operation of our clinical bacteriology laboratory of Geneva University Hospitals, a Swiss tertiary care centre with 1'920 beds, extended from 7.30 to 22.00 from Monday to Friday, 7.30 to 17.00 on Saturday and 7.30 to 13.00 on Sunday, with oncall service until 22.00 during the week-end. In addition, during the week between 17.00 and 22.00, only the urgent clinical specimens were analyzed (blood culture, joint fluid, and cerebrospinal fluid).

The prime goal when implementing the WASPLab™ in our laboratory was to increase efficiency as well as to improve laboratory performances both in terms of TAT for critical analyses and for accommodating the steady increase in the workload (about 180'000 clinical specimens per year, with a 3-5% yearly increase). The implementation of the WASPLab™ enabled us - 11 months after initial deployment - to extend the hours of operation from 7:30 to 22.00 (7/7) with the same laboratory team (14 full-time equivalents). The implementation of the WASPLab™ further permitted to deeply restructure the laboratory activities by freeing up technologist resources, thus enabling to extend the opening hours of the laboratory and to process most of the specimens

referred to the laboratory between 17:00 and 22:00. In the present state, we cannot operate 24/7 but we have adjusted our workflow during opening hours to maximize operational benefits.

The laboratory workflow could further benefit from the integration of additional functions such as the automated picking and handling of AI-tagged colonies for MALDI-TOF/MS, or even rely on the AI-based identification of defined organisms directly from the images of the plates, based on chromogenic features or using more advanced AI-based determinations.

## Automated solution for antimicrobial disk diffusion testing

Success criteria for the automation should be rapidly visible and related to the guidelines objectives defined before the initiation of the project. In addition to the measurable indicators discussed in previous paragraphs (e.g., percentage of total clinical samples implemented on the WASPLab™ during the first year, reliability of the automation system, change management, increased quality, and increased efficiency), we considered also the implementation of the antimicrobial disk diffusion susceptibility testing on the WASPLab™ as one of the major indicators of success for the automation project. It was even more relevant in our case because we added a second automation line (Figure 1) with the purpose to specifically automate AST by disk diffusion. Firstly, we performed an important validation study in which we investigated the agreement at the categorical level between the WASPLab™ incorporating the BioRad expert system and the SIRscan 2000 automatic, which represents the routine AST method used in our laboratory. Three hundred and thirty eight non-duplicate clinical strains including *Pseudomonas aeruginosa, Staphylococcus aureus*, and Enterobacterales-isolates were analyzed in parallel on the two systems. Results showed that the overall

categorical agreement yielded to 99% [9]. We have therefore established that the WASPLab™ incorporating the BioRad expert system represented an optimal automated solution. Its implementation was unfortunately postponed to the second half of 2020 due to the need to troubleshoot the instrument and the expert system interface frequentely. These important issues were related to the dispensers and the variable quality of the springs contained in the antibiotic disk cartridges. To overcome these problems, the manufacturer developed a new module including a carousel that can hold fifty antibiotic cartridges. This module is also supposed to minimize the workflow bottlenecks on the AST line related to a specific streaking pattern. The installation of this new module is planned for the second trimester of 2020.

## Continuing challenges by using lab automation systems

Management of system errors constitutes one of the most important challenges faced by the technologists when using the automation system. This is especially true when the errors can stem from various unpredictable causes such as network issues, dirt particles, or wrong settings when updating the software. The origin of other errors are typically human-based, for example loading specific culture media plates in the wrong rack, which can affect the reliability of the analysis results (e.g., instead of chromogenic media plate for urine specimens, technologists load selective chromogenic media for ESBL screening). In several cases, errors prevent technologists from carrying out their tasks and mobilize others technologists to assist them in the troubleshooting process. Another evolving challenge, in face of which the technologists are typically disarmed, is the interface between the automation system and the laboratory information system (LIS) frequently due to upgrades of the automation system software that conflict with the LIS. Finally once implemented, continuously ensuring the operability of all critical

functions of the automation system remains an important challenge for laboratory workflow and its mission. Specifically, this implies keeping critical equipment fully functional as a backup strategy.

## Conclusion

The automation of culture-based bacteriology is developing in routine laboratories. Assessing optimal and specific approaches during the project management and the change management are crucial for successful implementation. The present paper illustrates a specific automation project and its change management with a focus on the most important challenges that had to be overcome by lab staff and laboratory leadership during the different phases of the project. Structured supervision and accurate monitoring of all activities related to the automation project, even those involving other partners (IT support, technical committee, after-sales service), guaranteed the achievement of the project with respect of the deadlines and the costs, ensuring optimal adherence, efficiency, and improvement of the workflows.

## Acknowledgments

The authors would like to thank all the individuals directly or indirectly involved in the total automation project of the Bacteriology Laboratory at Geneva University Hospitals. We would like to express our appreciation to Claire Poyart (France), Pierrette Melin (Belgium), Oliver Nolte (Switzerland), Nadia Liassine (Switzerland), Theo Liebregts (Netherland), and Simone Ambretti, Michela Paolucci (Italy) for their expert advices.

## Conflict of Interest Statement

JS received restricted research grants and participated to advisory boards from BioMérieux and Debiopharm. NV received restricted research grants from Roche. The remaining authors declare no conflict of interest.

## Functions and roles of the different persons implicated in the automation project

- Abdessalam CHERKAOUI: Clinical microbiologist Ph.D. (manager of the biological aspects)
- Gesuele RENZI: Expert medical laboratory technologist (co-manager of the biological aspects)
- Arnaud VIOLLET: Biomedical engineer (technical aspects)
- Mark FLEISCHMANN: Computer systems analyst (institutional LIS aspects)
- Ludovic METRAL-BOFFOD: Computer systems analyst (IT connexions)
- David DOMINGUEZ-AMADO: Expert medical laboratory technologist (pre-analytical aspects)
- Nicolas VUILLEUMIER: head of division
- Jacques SCHRENZEL: head of the bacteriology laboratory (medical and strategical aspects)

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Project initiation: defining needs

Project release: drafting tender

Phase release: Lab installation and IT

System delivery (September 2018)

Routine launch of the first system (November 2018)

**CURRENT 2016**

- Determination of the context and objectives
- Business plan
- Pre-study stage
- Project chart
- Project organization
- Validation of the dedicated budget

**CURRENT 2017**

- Visits of five automated microbiology labs in Europe
- Upstream assessment and definition of needs
- Writing of a comprehensive tender
- Call for tender
- Tenders presentations
- Selection of an automated system
- Lab workflow analyses
- Official system order

**1st SEMESTER 2018**

- Architectural and technical adaptation of the laboratory
- Defining detailed WASPLab specifications
- LIS interface development







**2nd SEMESTER 2018**

- WASPLab installation and activation
- System configuration
- Testing
- First validation projects
- Training of lab technologists







**2019**

- Sequential implementation of sample types
- Sequential validation projects
- Completion of the training
- Change management
- Continuous process and workflow improvement

**Figure 1** Automation of the clinical bacteriology laboratory at Geneva University Hospitals: Specific steps executed and time dedicated to perform each of the project phases.

**System-1** is composed of 2 WASP, 2 “CO2 (5%) atmosphere” and 1 “air atmosphere” incubators.
**System-2** for AST is composed of 1 WASP, and 1/2 “air atmosphere” incubator.

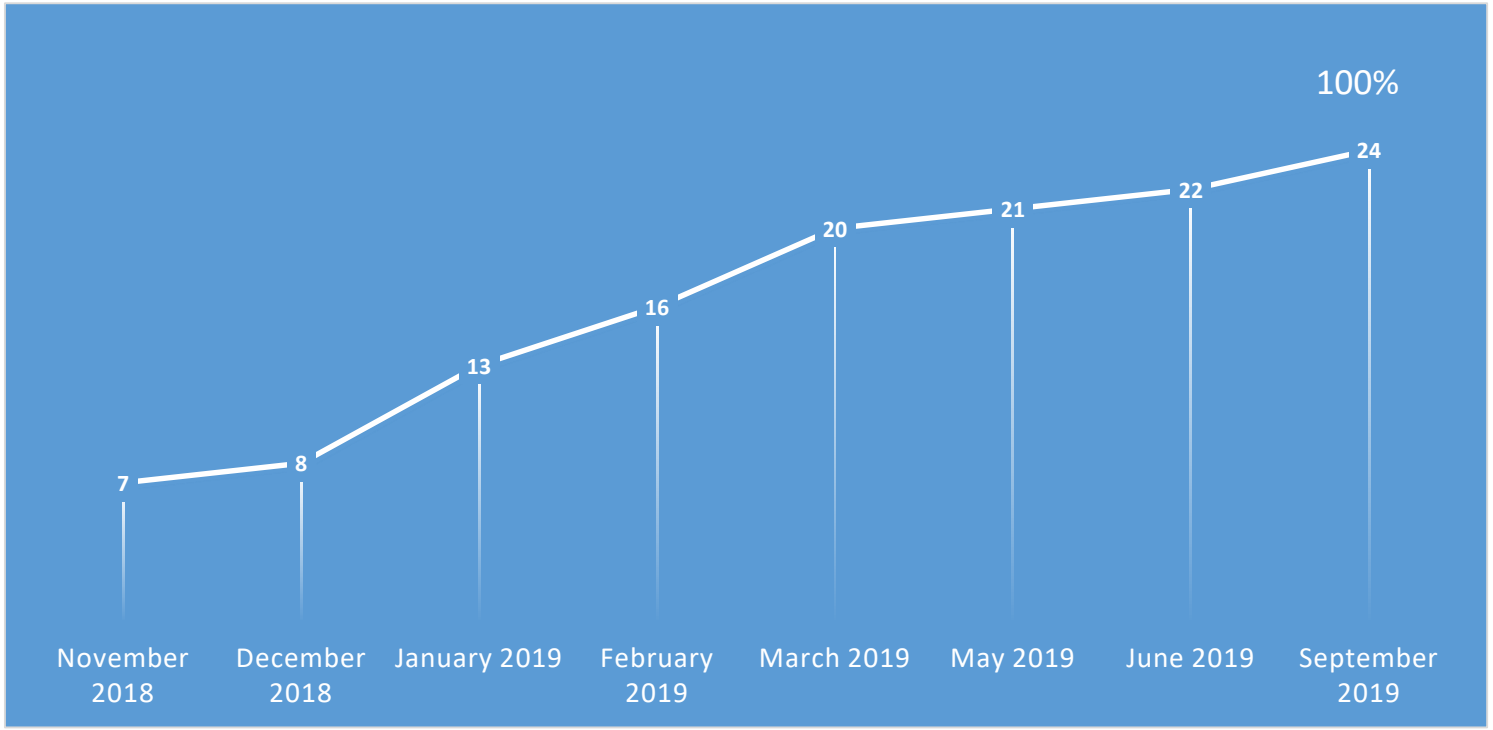



**Figure 2** Number of laboratory technologists trained to perform bacteriology analyses on the WASPLabTM

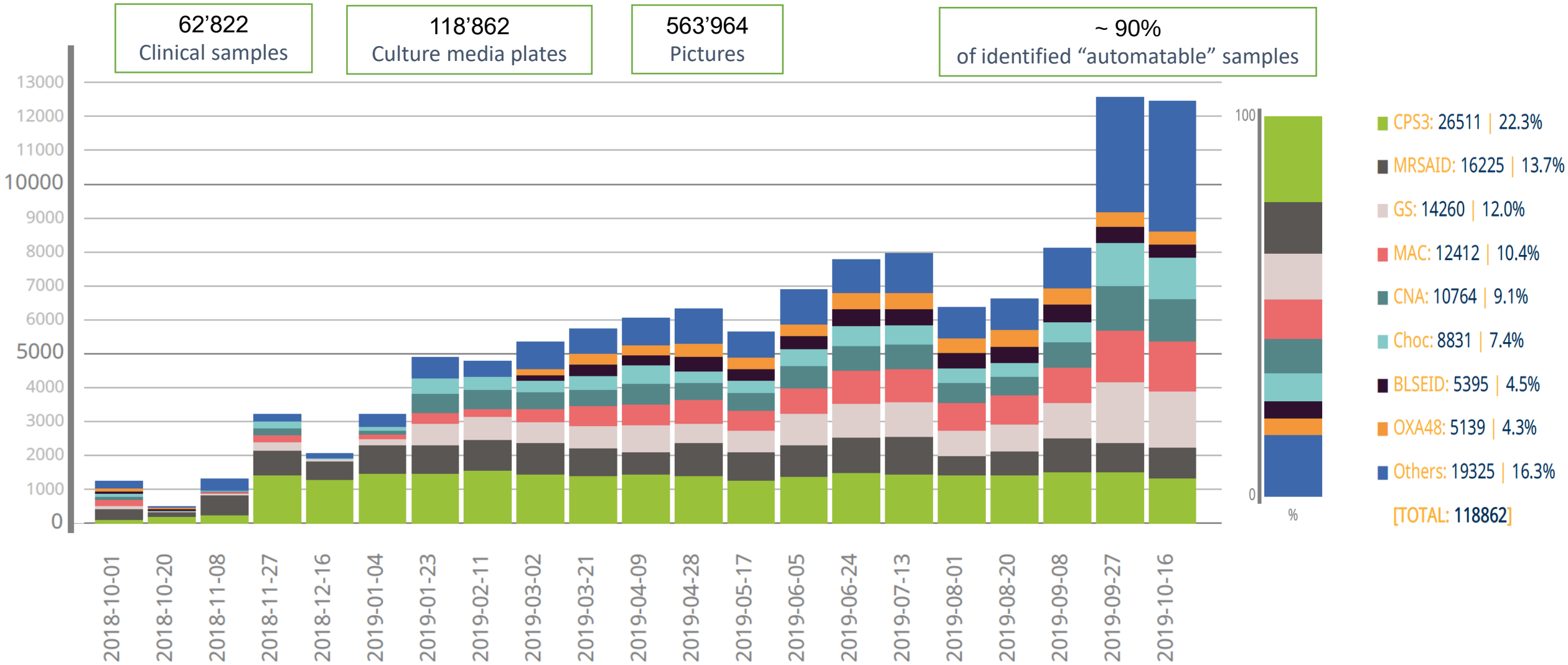



**Figure 3** Sequential implementation on the WASPLabTM of the various sample types referred to the bacteriology laboratory at Geneva University Hospitals between October 2018 and October 2019

CPS3, CHROMID® CPS® Elite; MRSAID, CHROMID® MRSA; GS, Blood agar; MAC, MacConkey agar; CNA, CNA agar; Choc, Chocolate agar; BLSEID, CHROMID® ESBL; OXA48, CHROMID® OXA-48

| Clinical sample type | Solid culture media type | Broth culture media type | Plating volume, µl | Incubation times | | | | Comments | Reference |
|---|---|---|---|---|---|---|---|---|---|
| | | | | Picture at T0 | First intermediate incubation time, hr | Second intermediate incubation time, hr | Final incubation time, hr | | |
| Urine specimens | CHROMID® CPS® Elite (BioMérieux) | | 10 | Yes | 18 | No | 24 | | [6] |
| Genital tract specimens | Blood agar, chocolate agar, CNA agar, and MacConkey agar | | 10 | Yes | 16 | No | 28 | | [6] |
| Non-sterile site specimens | | | 10 | Yes | 16 | No | 28 | | [6] |
| Nasal and inguinal/perineal screening-Eswab for MRSA and MSSA | CHROMID® MRSA (BioMérieux) and SaSelect Medium (BioRad) | | 30 | Yes | No | No | 18 | | [6] |
| Rectal screening-Eswab for ESBL-producer and CPE | CHROMID® ESBL (BioMérieux) coupled to CHROMID® OXA-48 (BioMérieux) | | 30 | Yes | No | No | 16 | | [6] |
| Rectal screening-Eswab for VRE | CHROMID® VRE (BioMérieux) | | 30 | Yes | 18 | 24 | 30 | | [7] |
| Blood culture bottles | Blood agar, chocolate agar, CNA agar, and MacConkey agar, and CDC anaerobe agar | | 10 | Yes | 2 | 4, 12, 25 | 48 | In the absence of growth at 48 hours, the media plates are taken out of the WASPLab and incubated for five additional days in conventional incubators to check for a potential fastidious microrganism. | [8] |
| Sterile site specimens | Blood agar, chocolate agar, CNA agar, MacConkey agar, and CDC anaerobe agar | Mueller Hinton broth | 10 | Yes | 23 | 35 | 72 | In the absence of growth at 72 hours, the media plates are taken out of the incubators and the Mueller Hinton broth is subcultured using WASPLab onto solid media which are incubated for 72h. | Unpublished data |
| Respiratory tract specimens | Blood agar, chocolate agar, CNA agar, and MacConkey agar | | 10 | Yes | 20 | No | 30 | *Legionella, Actinomyces, Nocardia* and Fungi analyses are processed manually (i.e. out of the WASPLab) | Unpublished data |
| Vagino-rectal screening-Eswabs for GBS | CHROMID® Strepto B (bioMérieux) | LIM broth | 30 | Yes | No | No | 24 | LIM broth is subcultured after 12 - 18h of incubation onto a chromogenic plate | Unpublished data |

**Table 1** Analysis parameters on the WASPLabTM based on previous studies.