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VALIDATION, IMPLEMENTATION AND ROUTINE WORK WITH TOTAL LAB-AUTOMATION BD-KIESTRA : A TWO-YEAR EXPERIENCE AT THE UNIVERSITY HOSPITAL OF LIÈGE, BELGIUM

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INTRODUCTION

Automation in Bacteriology is a major revolution in clinical microbiology laboratories. At the University Hospital of Liège (Belgium), a BD-Kiestra Total Laboratory Automation (BD-K-TLA) system has been installed in September 2015, and started in routine (“Go-live”) in November 2015. Here, we describe the validation process achieved for the implementation of the BD-K-TLA system, and some aspects of our two-year experience in the daily practice in the laboratory.

OBJECTIVES

1. A part of the process to qualify the BD-K TLA recently installed in our laboratory was to design a validation plan including scope, goals of the different steps, time-lines and acceptance criteria. Here, only a part of the validation plan is presented: i.e. all the parameters that had to be checked before BD-K TLA implementation, established by the Key User Group BD-Kiestra of the laboratory, University Hospital of Liège.
2. To evaluate the added-value of this full-automated system compared to manual bacteriology.

METHODS

Aiming to set up a Key-user group, inventory of competences and willing of the different staff members to be involved in the validation process and further management of the BD-K TLA has been established .

For the objective 2, we measured 3 parameters for 4 similar periods, before (February 2015) and after (February 2016, 2017, 2018) implementation of the BD-K TLA : (1) the number of lab technician resources (expressed in FTE) (2) the positivity rate (%), defined as the number of significant positive cultures among the total of samples analyzed and (3) the time to positive result (TTPR), defined as the time (in hours) between reception of a specimen in the Microbiology laboratory and the isolation of a significant pathogen in this sample. All specimens were included, except respiratory samples and blood cultures. During the different periods (pre- and post- BD-K TLA implementation), opening hours of the laboratory remained unchanged : from 8 am to 6 pm.

RESULTS

1. VALIDATION PLAN

During the implementation phase, a Key User Group (KUG) was created to carry on the validation process. It was composed of 5 lab technicians, 1 scientific PhD responsible for Quality Insurance in Microbiology and 2 clinical microbiologists. The validation plan as processed is schematized in Figure 1.

2. COMPARISON BETWEEN PRE- AND POST-IMPLEMENTATION OF THE BD-K TLA

Table 1. Compared parameters for 4 similar periods between Feb. 2015 and Feb.2018 in order to evaluate the added-value of the TLA BD-K compared to manual bacteriology

	February 2015 Before implementation of BD-K TLA	February 2016 3 months after « Go-live » with BD-K TLA	February 2017 15 months after « Go-live » with BD-K TLA	February 2018 27months after « Go-live » with - BD-K TLA
Number of specimens (except respiratory samples and blood cultures)	**5941**	**6202**	**6308**	**6774** *(+14.0%)*
Lab Technician resources	**13 FTE**	**13 FTE**	**14.5 FTE**	**14.5 FTE** *(+11.5%)*
Positivity rate	**19.7%** (1169/5941)	**18.2%** (1126/6202)	**21.5 %** (1358/6308)	**17.7%** (1200/6774)
Median TTPR (time to positive result)	**26.95 h**	**27.81 h**	**26.83 h**	**26.73 h**

Table 2. Number of samples per specimen- or procedure-type cultured in Feb. 2015, 2016, 2017 and 2018

	2015	2016	2017	2018	p-value (2018 *vs* 2015)
Urine	3099	3493	3491	3717	↑ **0.05**
Stool	638	504	451	484	↓ **< 0.001**
Swabs	420	454	453	430	0.1
MRSA screening	372	344	421	533	↑ **< 0.001**
BLSE screening	227	216	231	384	↑ **< 0.001**
Noble specimens	249	208	245	178	↓ **< 0.001**

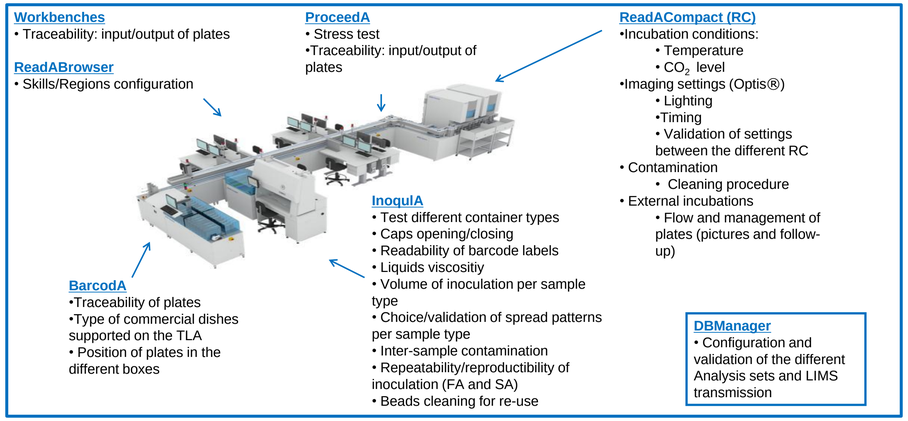
Table 3. Annual number of specimens (except respiratory samples and blood cultures) **processed manually in 2015 and on BD K TLA in 2016-2017**

	2015	2016	2017	2017 *vs* 2015
Total number of specimens	74957	79667	83943	+ 12.0%

Comparison of 3 periods of routine work processed with BD-K TLA (Feb. 2016, 2017 and 2018) and February 2015 when routine work was still processed with conventional manual bacteriology (Tables 1 & 2):

- Through the different periods, the number of processed specimens has increased: February 2018 compared with February 2015 showed an increase of 14,0% of the **number of samples** ; and globally, the number of processed specimens in 2017 was 12.0 % higher than in 2015 (see Table 3).
- In parallel, **lab technicians resources** has also increased: between Feb.2016 and Feb.2017, to process all the specimens, it was necessary to hire 1,5 additional FTE lab technician (+11,5%).
- The number of significant positive cultures has remained stable, with a mean **positivity rate** of 19,3%.
- The **median TTPR**, for the first identification of a pathogen, has also remained steady with 27,08 h on average.

Figure 1. Summarizing schema of the validation plan



DISCUSSION - CONCLUSION

- Between 2015 and 2018, the number of specimens for bacterial cultures processed each February, as well as the annual number of processed specimens, have increased (+14,0% and 12.0% respectively). Despite bacteriological full automation with the BD-K TLA, it was not possible to process the increasing amount of work with constant staff: the lab technician team was enlarged of 1.5 FTE (+11,5%).
- **To observe major time saving with BD-K TLA, in order to dedicate lab technician resources, as initially expected, to more added-value tasks, a well-considered configuration of the system, a major reorganization of the workflow and optimal technical performances (hardware and software) of the BD-K TLA are mandatory.**
- The optimization of the incubation times before reading, reading on screen at any time when pictures are ready, as well as improved isolation of colonies obtained with the “bead spreading” should theoretically decreased the TTPR. Our data have showed a stable positivity rate but have not impact the TTPR. To observe the expected theoretical improvement, working 24h/24 would possibly do better ; with a 8 am to 6 pm schedule, it is difficult to observe a significant shorter TTPR. **A 24/7 schedule, with continuous reading and follow-up, should be implemented in order to observe a major reduction of the general time to result** (for both positive and negative samples).
- **BD-K TLA provides traceability through the whole process, quality of inoculation, defined incubation times and better biological validation by clinical microbiologists, thanks to remote pictures review.**