Streamlining Urine Processing with modular automation using DxM Autoplak and APAS Independence: A French Experience with CPSE media

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BIO MED 21 ANALYSES MEDICALES

Background

BioMed21 is a group of 13 medical analytical laboratories. The laboratory is accredited according to the NF EN ISO 15189 v.2012 standard, human health section. Bacteriology laboratory manages diverse samples (urines, skin, vaginal, urethral, blood cultures...) out of which just over 85% are urine samples. Before this evaluation, all bacteriology samples were inoculated manually by a laboratory technician, which represents almost a full-time position. During that work we evaluated the WorkStation Automation Solution including the automated plate streaker DxM Autoplak (Beckman Coulter) and the automated plates reader APAS® Independence (Clever Culture System). We evaluated robustness, accuracy and ease-of-use of those products in our routine. This evaluation used 2 chromogenic media CHROM ID® CPS® Elite (418284 - bioMérieux) and UriSelect™4 (63726 - BIO-RAD).

DxM Autoplak

Fully automated front-end and compact plate streaking, broth inoculation and slide preparation. 4 reusable loops are installed on a single module to streak sample and optimize throughput.

APAS® Independence + Urine CPSE Analysis Module

Intelligent imaging and machine learning technology to read and interpret the presence of significant bacteria in culture plates.

Method

Initial DxM Autoplak streaking verification was performed according to ISO 15189 standard and included: 1.Absence of cross contamination 2.Bacterial viability preservation 3.Reproducibility and repeatability 4.Quality and accuracy. Similar studies were performed comparing the performance of UriSelect™4 media and CHROM ID® CPS® Elite media. Once performance of the DxM Autoplak was verified, a comparison of DxM Autoplak + APAS® Independence with CPSE Analysis Module and UriSelect4 + DxM Autoplak streaking as the reference method (accredited process), was performed using 1520 routine urine samples.

This evaluation included: 1. Comparison of colonies enumeration 2. Accuracy of *E. coli* identification 3. Impact of the automatic reading in the lab workflow.

All tests and analyses were performed with a sample volume of 10µL and following French recommendations all urine samples received have been streaked, plates incubated (18 hours and 37° C) and read by qualify lab technicians.

Initial DxM Autoplak verification

1. Absence of cross contamination: No visible growth of bacteria observed on chromogenic media plates that has been inoculated by the sterile suspension. All plates inoculated by high positive bacterial suspension (0.5McF) only present with the organism they were initially inoculated with. No mixed culture observed (Figure 1).

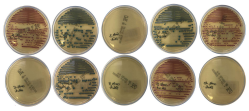

Figure 1. Absence of cross contamination results

2. Bacterial viability preservation: All plates inoculated by low positive bacterial suspension shown positive growth and a number of colonies comparable to manual streaking.

3. Reproducibility and repeatability: After inoculation and incubation all plates of approximately 1.10^4 & 1.10^5 CFU/mL (dilutions used for these tests) were comparable for both dilutions and both chromogenic media. DxM Autoplak demonstrated an excellent reproducibility and repeatability (see Figure 2).

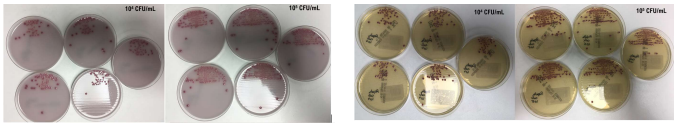

Figure 2. Reproducibility and repeatability results

4. Quality and accuracy of DxM Autoplak: Comparison of the 60 patient samples inoculated with DxM Autoplak shown 100% of concordance vs manual method for both bacteria enumeration and identification. Number and size of isolated colonies were significatively higher with DxM Autoplak streaking.

No cross contamination observed, and bacterial viability was preserved therefore both HEPA filter and loops decontamination system proved their efficiency in protection of samples and plates during all inoculation process.

DxM Autoplak successfully fulfilled the criteria required for ISO 15189 and demonstrated an excellent repeatability/reproducibility and standardization of the streaking.

APAS® Independence reading evaluation

1. **Comparison of colonies enumeration:** The APAS® Independence detects, differentiates and counts colonies on agar plate and the total reported as CFU/mL (Table 1). The Analysis Module incorporates commonly used and published guidelines for interpretation to assign each culture into one of four categories (Table 2).

Colonies counted	Enumeration category (10µL)
0	No growth detected
1 - 9	10^2 CFU/mL
10 – 99	10^3 CFU/mL
100-999	10^4 CFU/mL
≥1000	≥10^5 CFU/mL

Table 1. Categorization of colony counts

Designation	Definition	Icons
Probable	Likely significant cases that will require follow-up work such as sensitivity testing and/or identification.	
Review	Cases where APAS cannot determine whether there is clearly significant growth or not	
Doubtful	APAS Independence has detected some growth but is likely to be below the enumeration threshold	
No Growth	APAS® Independence has not detected any colonies/growth	

Table 2. Designations and explanation

All plates reported visually as negative were categorized as "No Growth" with APAS® Independence. All plates categorized "No Growth" with APAS® Independence were also reported negative by lab technicians. 1435 of the 1520 plates automatically enumerated were comparable to visual bacteria counting (+/- one dilution) as shown in Table 3. Regarding the 85 plates with differences observed, all shown a less counting for APAS® Independence but that differences didn't have clinical impact.

APAS® Independence automatic reading demonstrated over 94% of concordance with visual reading and a negative predictive value (NPV) of 100%.

	APAS® Independence Vs visual estimation
Colonies counting equal (+/- dilutions)	1435
Colonies counting difference >1 dilution	85

Table 3. Colonies counting results

2. **Accuracy of *E. coli* identification**: 299 of *E. coli* identified by automated reading were also reported *E. coli* with the visual reading and 15 reported by lab technician "Mixed colonies" or "Nonsignificant". Nevertheless, colonies of *E. coli* were visually confirmed on these 15 plates. Only one *S.saprophyticus* was misidentified.

APAS® Independence demonstrated 94.6% of correct *E. coli* identification and 99.7% of correct screening of *E. coli.*

3. **Impact of the automatic reading in lab workflow.** The 1520 plates were automatically classified by APAS® Independence to Table 2, results and percentage summarized in Table 4.

No Growth	Doubtful	Review	Probable	*E. coli*	Total
213	351	223	434	299	1520
14%	23%	15%	29%	20%	

Table 4. APAS® Independence classification

100% of "No Growth" and "Doubtful" classified by APAS® Independence have been reported Negative after visual reading and reported as it to clinician. By using APAS® Independence 37% ("No Growth" and "Doubtful") of urine plates can be automatically removed from our reading process without a review by a lab technician. 20% of our urine plates were classified *E. coli* suspected and can also be removed from reading process without further action as described in Figure 3.

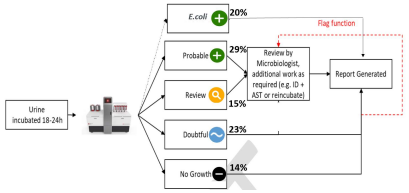

Figure 3. Classification by APAS® Independence of the 1520 urines from routine

Conclusion

The Full WorkStation Automation solution of the DxM Autoplak and APAS® Independence was installed and operational in 7 days which included training, instrument setup, and verification activities. DxM Autoplak was an easy-to-use and suitable alternative to manual streaking and since the installation in September 2021 DxM Autoplak is perfectly integrated in the routine of our lab and demonstrates an excellent reliability and robustness.

The use of the APAS® Independence delivered a high level of agreement with the current routine method and demonstrated the ability to segregate *E. coli* classification with a high degree of accuracy. This technology is easy to implement and help to drive and optimize lab workflow.