Evaluation of APAS® Independence for routine urine culture reading within a private clinical setting.

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Overview

As culture reading can be highly subjective and time-demanding the use of artificial intelligence such as the APAS® Independence offers to introduce a higher level of consistency and reliability between results.

This evaluation was performed to determine if the APAS® Independence was able to be integrated into the routine workflow within a private clinical setting.

It was important that under routine conditions the APAS® Independence maintained its accuracy, consistency and throughput without negatively impacting staff efficiency.

APAS® Independence operation and interpretation

The APAS® Independence was run following manufacturers instructions. Using the instrument required little training and was intuitive and easy to use. The instrument is approximately 2m wide and 0.8m deep, requiring little dedicated floor space to fit into the laboratory without additional requirements.

The APAS® Independence separated growth into four distinct categories (termed Designations).

- No Growth – No growth on the agar plates
- Doubtful – a low likelihood that the growth is significant
- Review – swarming organism present, or the growth is of a complex nature requiring interpretation
- Probable – a growth of ≥10^8 cfu/L

Method

Urine samples were set up in duplicate based on current urine culturing protocols. Two Horse Blood Agar/Brilliance UTI plates (Thermo Fisher Scientific) were each inoculated with 1uL of urine.

Plate 1 was treated routinely and incubated at 35-37°C 'overnight' for anywhere between 8-16 hours. The plates were then run through the APAS® Independence. They were removed from the carriers and clinical growth significance was assessed by experienced microbiologists. Routine clinical work and reporting followed after this initial assessment.

Plate 2 was incubated at 35-37°C for a strict 18 hours. The plates were run through the APAS® Independence. Clinical growth significance was similarly assessed as with plate 1, no further work was required. Participants were blinded to the result of Plate 1.

Two separate assessments were made:

1. Plate 1 and Plate 2 microbiologist assessments were compared to APAS® Independence interpretation. In order to do this the microbiologist was asked to determine if the plate was likely to be significant or not for further investigations. An APAS® Independence designation of No Growth or Doubtful was grouped as 'not significant' (NSG) and an APAS® Independence Designation of Review or Probable was grouped as 'Significant' (SIG).
2. APAS-grouped designation of SIG and NSG was assessed against the routine result issued by the laboratory (using Plate 1).

Results & Discussion

Results showed a greater than 97% agreement between APAS® Independence and microbiologist for Plates 1 and 2. That is, the APAS® Independence interpreted bacterial growth correctly for both the 18 hour incubation and the routine incubation, with agreement as high as 99.5% for negative plates under routine conditions (See Table 1).

Table 1. Agreement rates for microbiologist assessment against APAS® Independence.

	Negative Agreement (%)	Positive Agreement (%)	Number of Samples
Plate 1 (Routine)	99.5	98.4	1731
Plate 2 (18 hours)	97.8	99.2	1628

1471 routine samples were included in statistical analyses to compare Plate 1 against routine reports, and the results are presented in Table 2. A sensitivity of 94.0% and specificity of 72.0% was achieved.

Table 2. confusion matrix of ACL routine reports V APAS® Independence interpretation after routine incubation (Plate 1).

		APAS® Independence	
		NSG	SIG
ACL	NSG	860	336
	SIG	17	264

The specificity estimate obtained is due to the laboratory reporting some growths ≥10^8 cfu/L as NSG whereas APAS® Independence would categorise these as SIG. These were typically heavy mixed growth of contaminating organisms or urogenital flora with no underlying suspicion of UTI. This usually requires skilled microbiologist interpretation to make this assessment and thus APAS® Independence was seen to augment the skill of the microbiologist by redirecting these plates for review. Table 2 shows that 17 discrepant results were found, where APAS® Independence categorised growth as NSG and the laboratory issued a positive report. These were investigated further and summarised below:

- *3 Candida sp.*
- *2 Aerococcus urinae*
- *2 Staphylococcal species*
- *10 E. coli ranging from 10^6-≥^{8} cfu/L*

The above discordant results were observed primarily because the overnight incubation yielded no growth *(e.g Candida sp.),* or a slight haze of growth that was more evident after extended and/or modified incubation was performed by the laboratory. The instrument was not interfaced for this evaluation. However, under routine conditions it is likely that the implementation of laboratory dependent flags (e.g. leucocyte count >100) would re-direct cases initially designated as No Growth or Doubtful to Review or Probable. The APAS® Independence flag function is a customisable feature of the system that requires LIS integration and would improve the sensitivity estimate to >98% for this study.

Conclusion

The APAS® Independence proved to be an instrument that was easy to operate, and was very user friendly.

- It showed a high level of agreement, reliability and consistency when evaluating plates that have been incubated and processed in a routine clinical setting, and with a strict incubation time of 18 hours.
- As the APAS® Independence has the ability to exclude non-significant urine cultures without an experienced microbiologist, it allows for more specific skills to be put toward more complex tasks.
- This coupled with a high throughput rate may provide benefits when integrated into an appropriate workflow.