

## Abstract

**Background:** Urine cultures can constitute up to 30-40% of the workflow in clinical microbiology laboratory and many cases submitted for culture are often reported as negative or of limited clinical significance. Staffing considerations represent contemporary challenges for microbiology labs and new tools are needed to address increasing demands and evolving diversification of microbiology workflow. The APAS Independence is a diagnostic test system for the automated assessment and enumeration of bacterial colonies on urine cultures from suspected cases of urinary tract infections. The present study aims to assess the accuracy of the APAS Independence for urine culture reporting in a routine clinical setting. **Methods:** A total of 6200 urine cultures, representing 50 unique bacterial organisms in varying amounts of quantitation, were tested with the APAS independence. Reporting rules/criteria incorporated in the APAS are shown in Figure 1. Application of the reporting rules allows an automated reporting structure into four categories associated with urine culture reporting which include: i) negative ii) denotation of high clinical significance involving  $>10^4$  CFU/ml, iii) doubtful reporting/low clinical significance and iv) requires review. Separation into each category was assessed as percent agreement with manual clinical technologist review. **Results:** APAS Independence has 100% agreement in reviewing, interpreting, and removing “no growth” urine cultures from clinical practice. The ability of APAS Independence to correctly enumerate  $>10^4$  CFU/ml among clinical urine cultures is 94%. Removing defects in media as a variable of reporting increased this percent agreement to 98%. Based on reporting rules 35.9% of urine cultures were correctly reported, auto verified and removed from the clinical workflow without the need for technologist review. **Conclusions:** Contemporary instrumentation incorporating active decision-making tools into clinical microbiology workflow is needed. Automation within clinical microbiology can help define workflow and optimize needed technology resources. The APAS Independence can help stratify urine culture work auto-verifying and clearing 35.9% of the urine cultures from clinical workflow. Automation provides the provision of highly accurate and quicker reporting. Ongoing work to evaluate the impact on workflow and relative value unit savings of this lab automation is occurring.

## Materials & Methods

The APAS Independence is a modular automated culture plate reading instrument that screens plates and sorts them into significant and non-significant growth using digital image capture and computer algorithms.

A total of 6200 clinical urine cultures, representing 50 unique bacterial organisms in varying amounts of quantitation, were tested with the APAS independence under routine clinical conditions. Reporting rules/criteria incorporated in the APAS are shown in figure 1. Application of the reporting rules allows an automated reporting structure into four categories associated with urine culture reporting which include: i) negative ii) denotation of high clinical significance involving  $>10^4$  CFU/ml, iii) doubtful reporting/low clinical significance and iv) requires review. Separation into each category was assessed as percent agreement with manual clinical technologist review

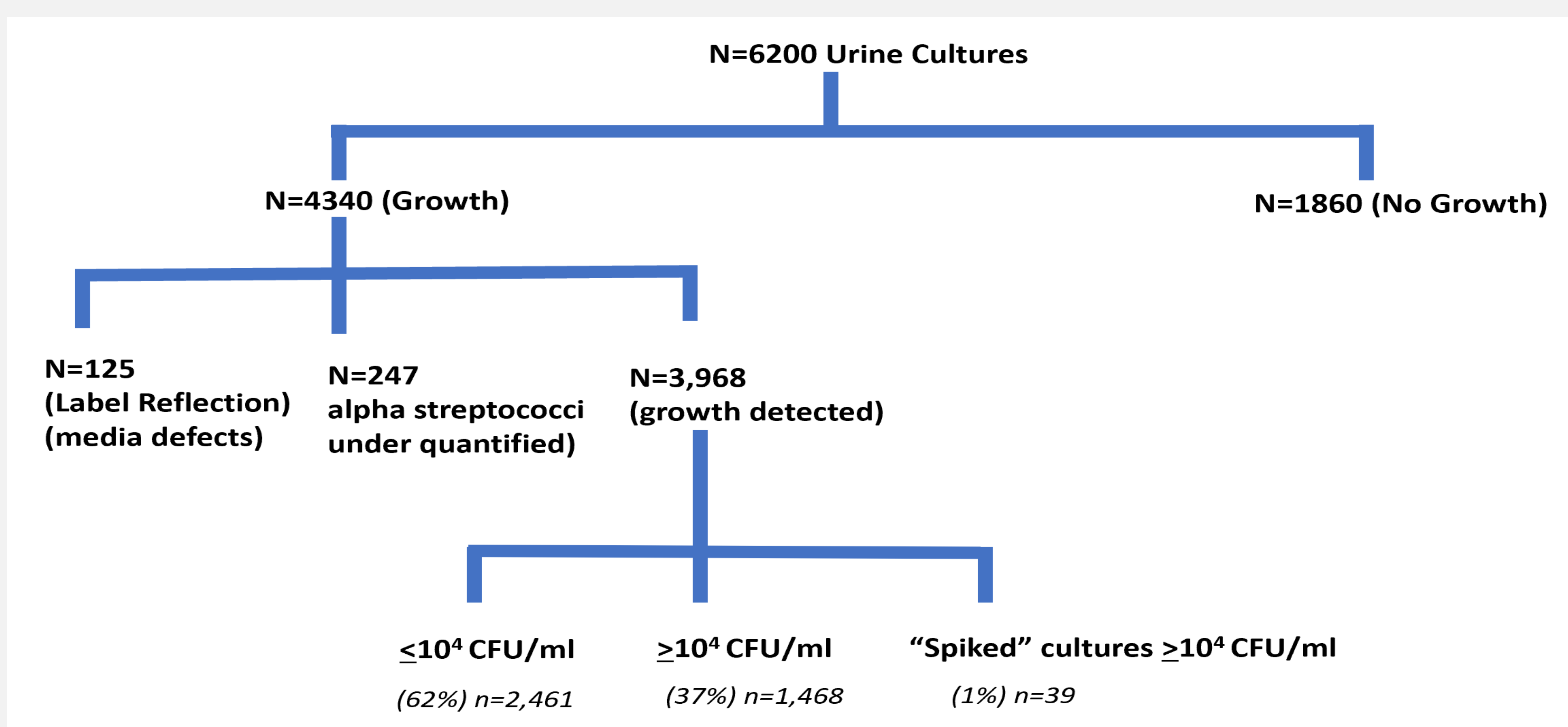


Figure 1. Study overview

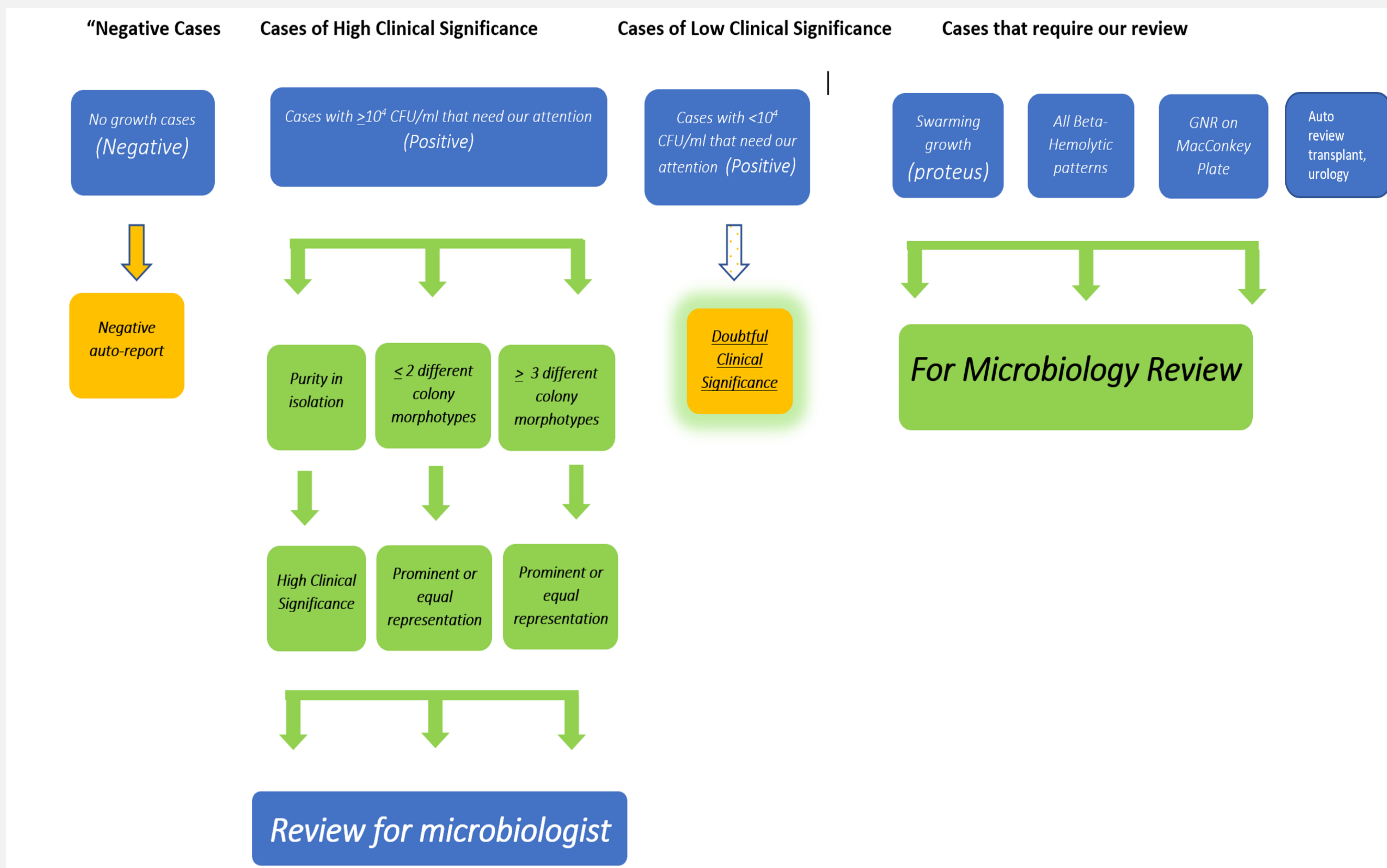


Figure 2. Reporting Structure Using the APAS Independence for UTI culture Assessment

## Objectives

To evaluate the clinical performance of the APAS independence in its abilities to:

- 1) correctly enumerate bacteria present on UTI cultures
- 2) identify the Impact of the APAS independence on removing cultures from the clinical workflow

## Results

Table 1. Clinical Evaluation of the APAS Independence for Urine Culture Assessment in Routine Clinical Practice

| Study Metric                             | Technologist review | APAS review | % agreement with technologist review | Accuracy of initial Technologist Review | Accuracy of the APAS        | Clinical Agreement of APAS decision with initial clinical reporting |
|--|---------------------|-------------|--------------------------------------|---|-----------------------------|---|
| No growth                                | 1858/1860           | 1860/18060  | 100%                                 | 100%                                    | 100%                        | 100%  |
| Swarming growth (proteus spp.) detected* | 70/70               | 70/70       | 100%                                 | 100%                                    | 100%                        | 100%  |
| Beta-hemolytic growth                    | 200/200             | 197/200     | 98.5% <sup>†</sup>                   | 100%                                    | 98.5% <sup>†</sup>          | 98.5% <sup>†</sup>  |
| GNR growth detected on MacConkey media   | 1626/1626           | 1626/1626   | 100%                                 | 100%                                    | 100%                        | 100%  |
| $\leq 10^4$ CFU/mL growth                | 1468/1468           | 1221/1468   | 83%                                  | 100%                                    | 83% (adjusted accuracy 94%) | 83% (adjusted accuracy 97%)   |
| $\geq 10^4$ CFU/mL growth                | 2462/2464           | 2464/2464   | 99.9%                                | 99%                                     | 100                         | 99%   |

\* 3 cases involved non-hemolytic *Streptococci agalactiae* ( $>10^4$  CFU/mL) which were not detected by the APAS

<sup>†</sup> 125 cases were unable to photo captured by the APAS because of defects in the media (e.g. scrapes, gouges). Analysis of those cases which were captured by the APAS resulted in adjusted accuracy of 94%

\* 247 cases were incorrectly enumerated by the APAS as  $<10^4$  CFU/mL which exclusively involved cases where small alpha streptococci spp which were not detected by the APAS but were also not reported in clinical reporting by the laboratory. Clinical accuracy was observed as 97%

Table 2. Hennepin County Medical Center APAS Urine Culture Reporting

|                                | Reporting Criteria  | Impact on Clinical Workflow          | Percentage of Clinical Cases |
|--------------------------------|---|--------------------------------------|------------------------------|
| Positive =                     | * $>10(4)$ cfu/ml &/or and GNR growth on the MacConkey plate<br>* Detection of Beta-hemolysis on Sheep Blood Agar Plate | High priority Cultures               | 27%                          |
| Negative =                     | no growth   | Auto Cleared from the workflow       | 16.2%                        |
| To Technologist Review         | = $>10(4)$ cfu/ml and/or swarming on the plate  | Review for technologist—low priority | 4%                           |
| HCMC “doubtful” classification | = $<10(3)$ cfu/ml, no beta-hemolysis, no GNR on the MAC   | Review for technologist—low priority | 19.7%                        |

Up to 35.9% (16.2% + 19.7%) of cases are auto-cleared by the APAS from the clinical workflow

## Conclusion

- ✓ The APAS Independence was highly accurate in enumerating colony counts in urine cultures grown in the lab.
- ✓ Adding a reporting structure for cases involving  $<10^4$  CFU/mL would successfully remove 35.9% from the workflow resulting in efficiency gains and reduced laboratory resources