

# EXTERNAL QUALITY ASSESSMENT FOR BACTERIAL IDENTIFICATION: A 4-YEAR MULTICENTRE IMPLEMENTATION STUDY

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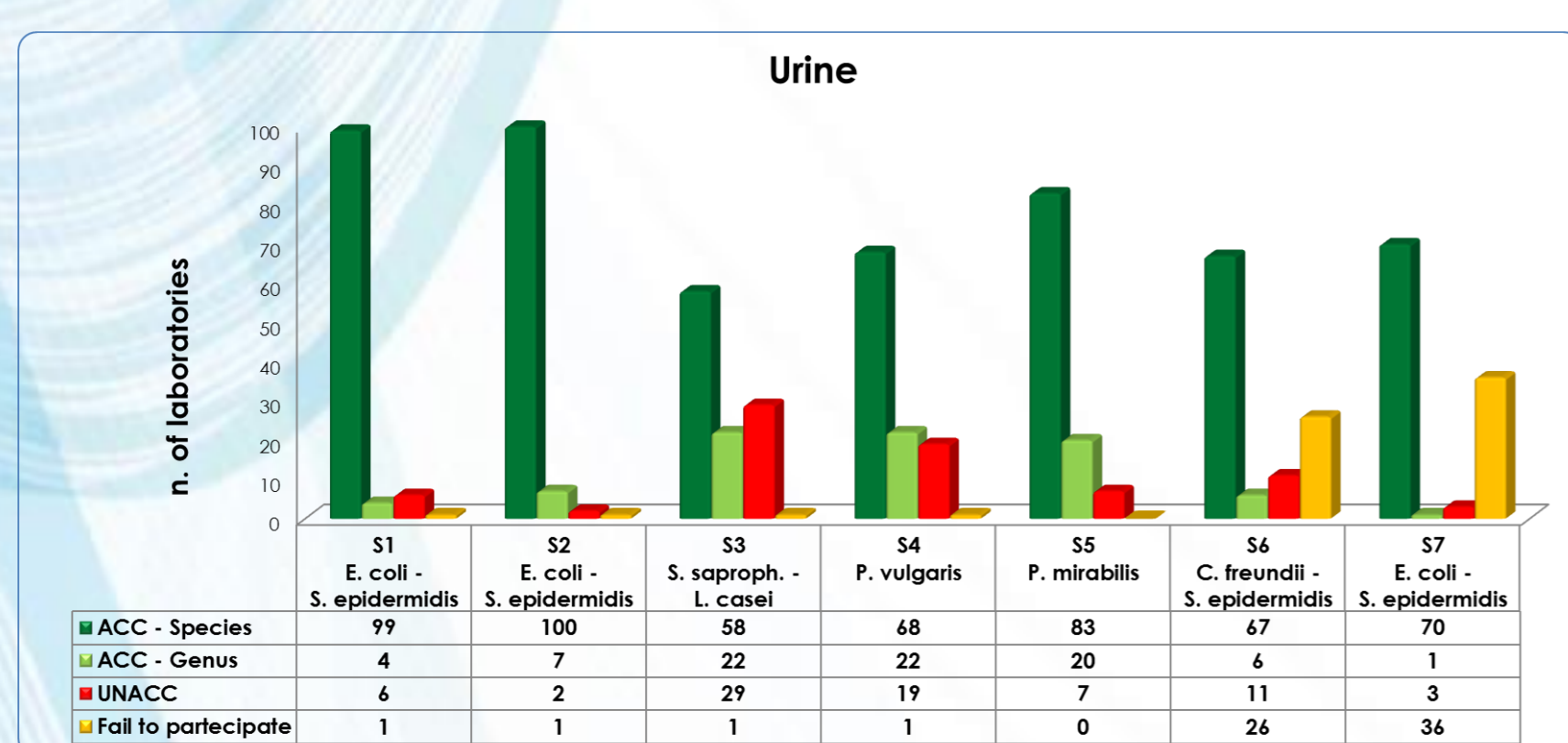
## AIM OF THE STUDY

The accurate identification of bacterial species isolated from different biological sources is of pivotal importance in the diagnosis and management of bacterial infections and, consequently, in preventing increased morbidity and healthcare costs. Regular participation to External Quality Assessment (EQA) schemes plays an essential role as constant monitoring of accurate bacterial identification is aimed at improving labs' performance. This study analyzed the results collected for a Bacterial Identification EQA program in a systematic manner in order to identify potential benefits from participating to an EQA scheme and common issues with bacterial testing.

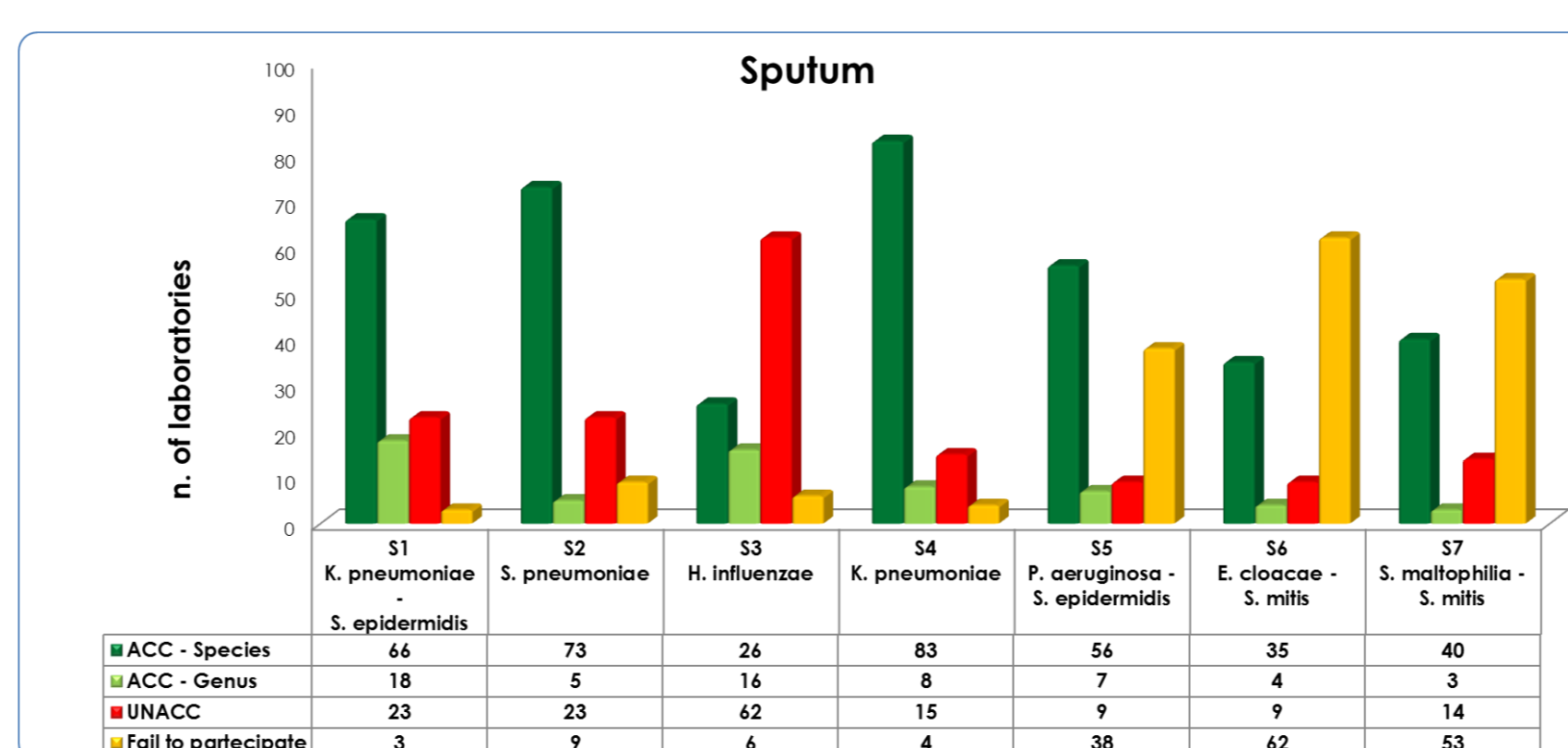
## METHODS

The EQA scheme for Bacterial Identification was designed and implemented by Oneworld Accuracy, renowned EQA Provider, to assess laboratories' testing proficiency. Design of the study:

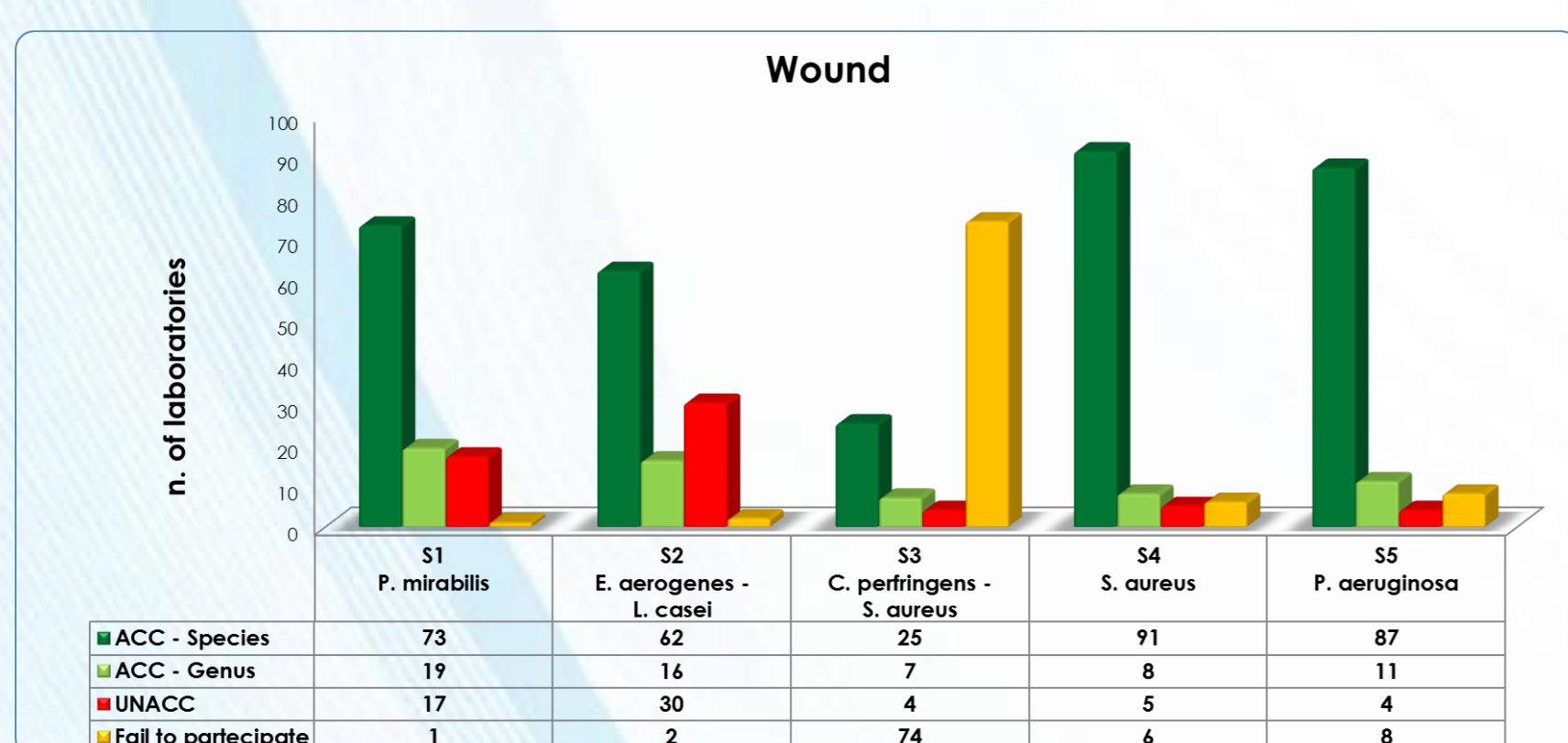
- ✓ 110 Italian laboratories
- ✓ 8 EQA test events (2014 – 2017)
- ✓ 5 samples (KWIK-STIK™), various matrixes (blood, urine, sputum, swab, wound) challenged in each EQA test event
- ✓ Methods used for testing: manual (16%) – semiautomated (39%) – automated (45%)
- ✓ Outliers: not evaluated samples (due to lack of consensus) were removed from the analysis
- ✓ 84% average participation rate across the study arc (participation rate varied based on sample matrixes).
- ✓ Established criterion: identification of bacteria at the species' level.



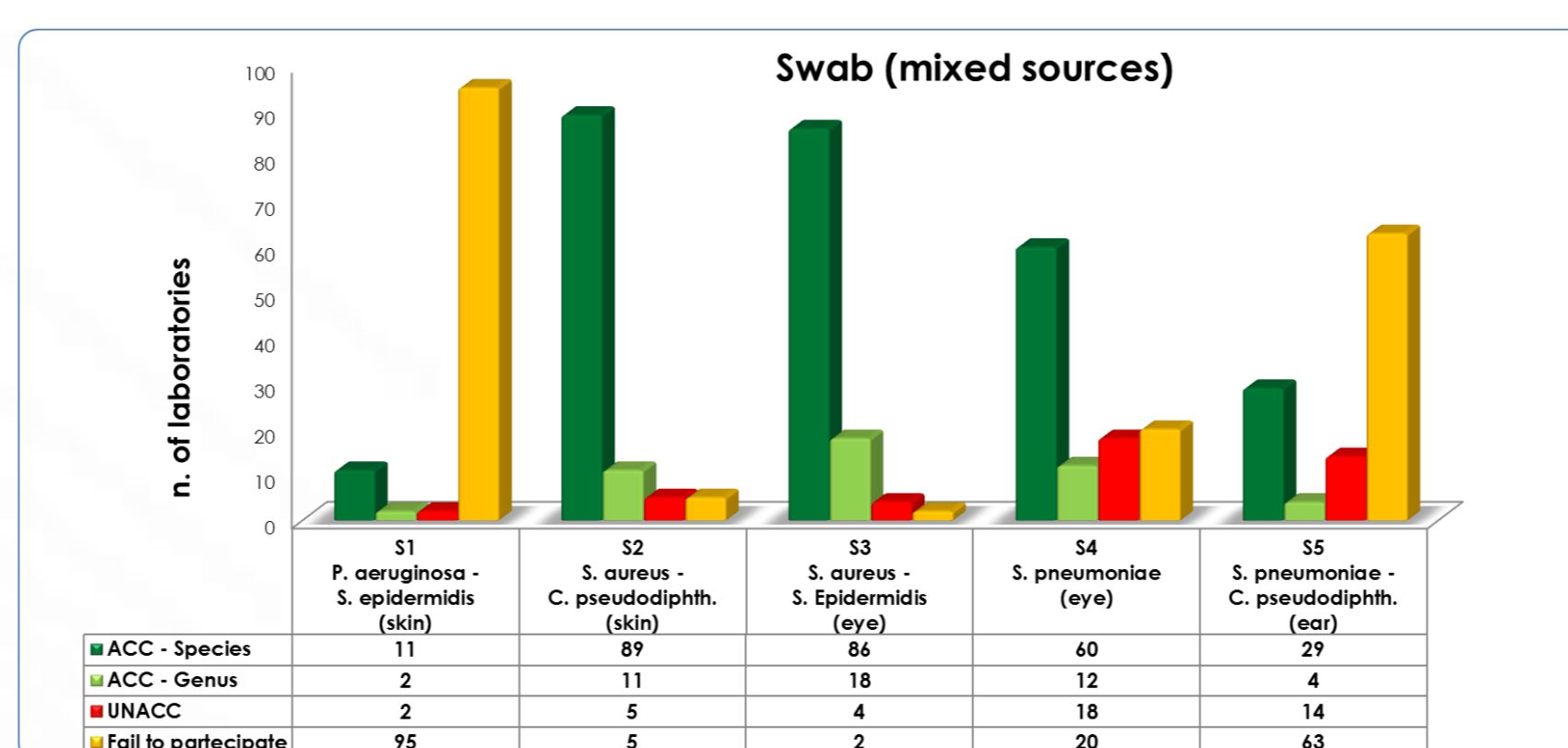
Graph.1 Bacterial identification in urine samples



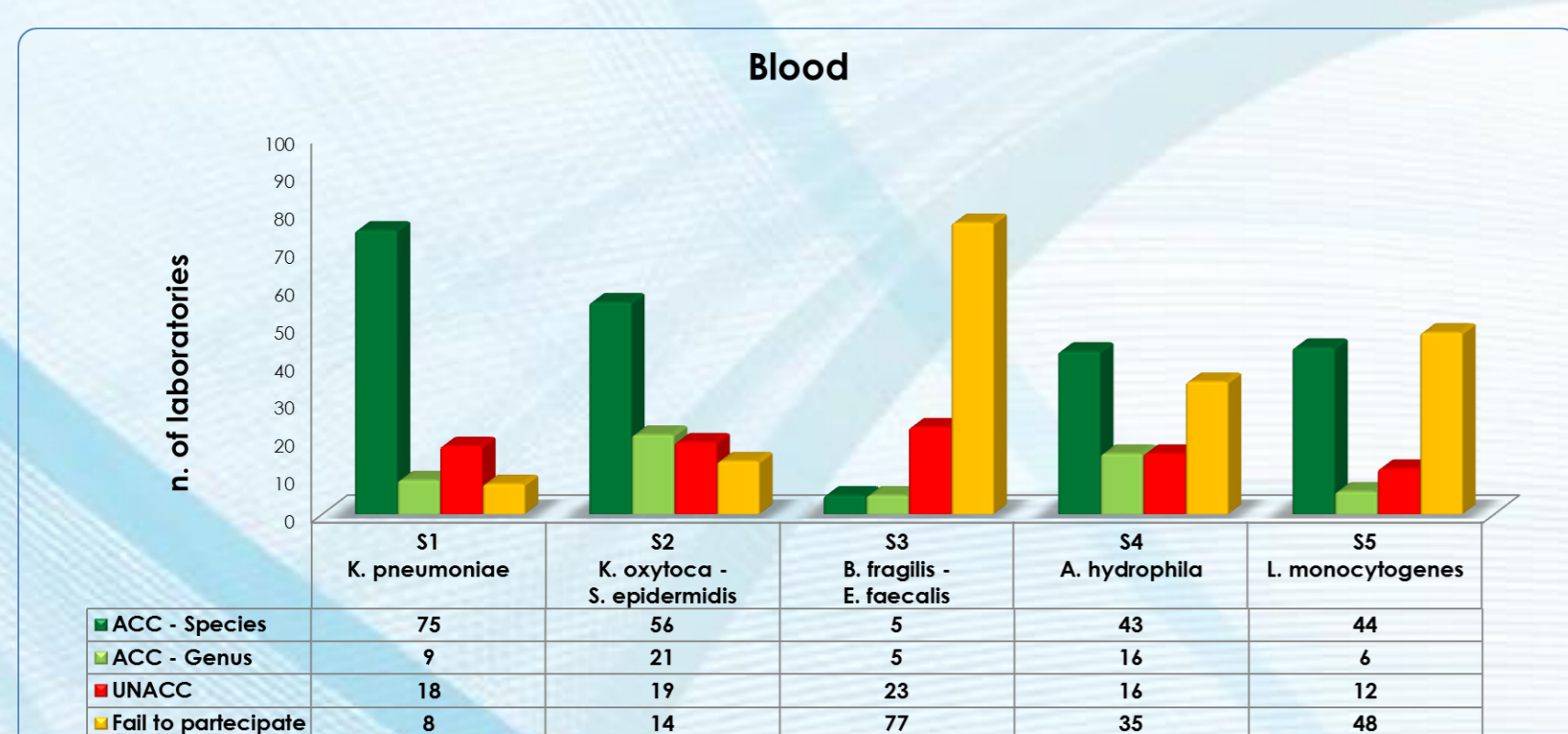
Graph.2 Bacterial identification in sputum samples



Graph.3 Bacterial identification in wound samples



Graph.4 Bacterial identification in swab samples



Graph.5 Bacterial identification in blood samples

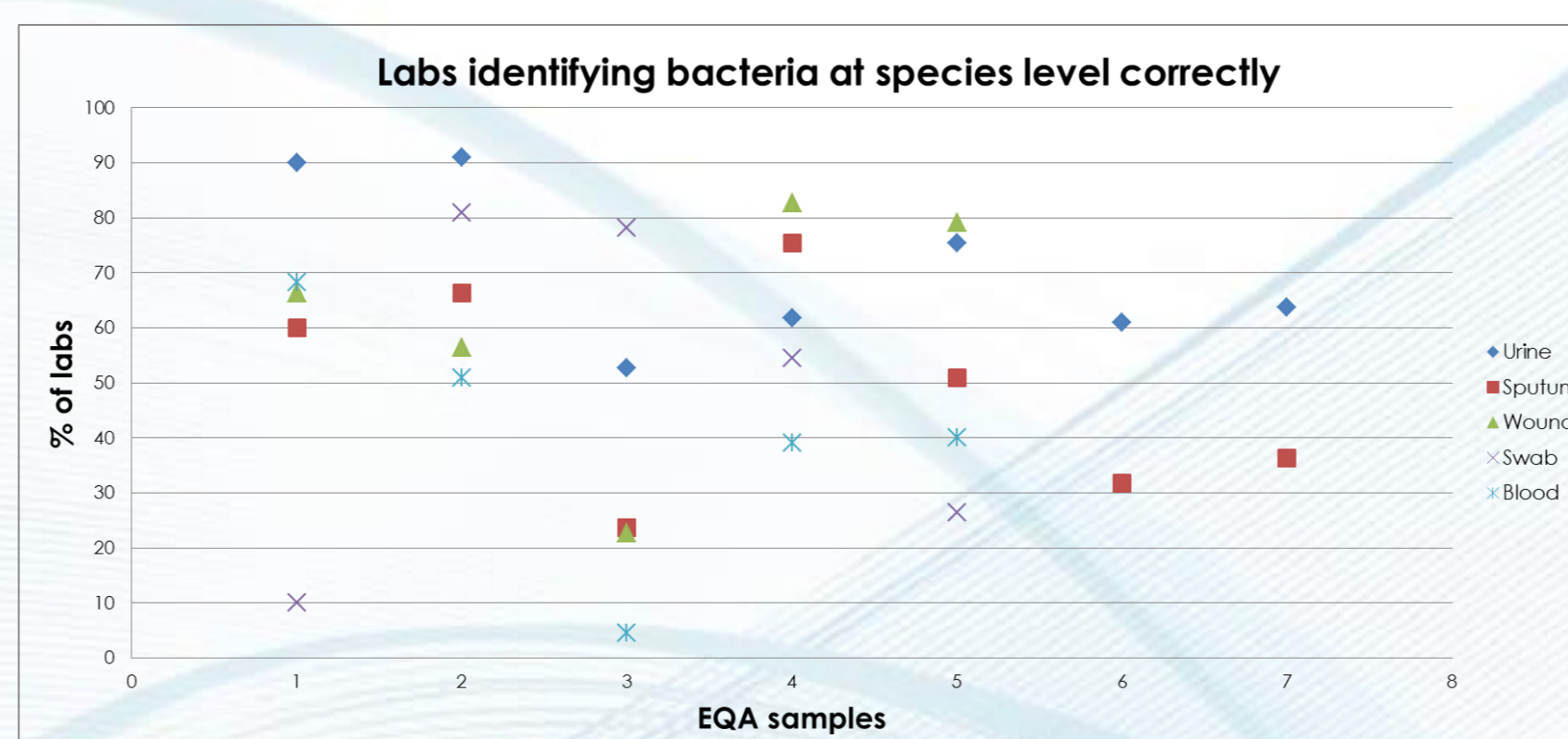


Figure 1. Trend of analytical performances meeting established criterion.

## RESULTS

Laboratories demonstrated good proficiency, proving their ability to identify bacteria at the species' level in urine, sputum, swab and wound with high accuracy. Lower accuracy was shown in bacterial identification from blood matrixes (see graph.5) and in cases where anaerobic cultures were required (e.g. sample 3 in graph.3 and graph.5). The study identified other issues encountered by participating laboratories, preventing them from meeting the study's criterion. These, most notably, included:

- 1) Wrong culture media employed and missed correlation between source material and clinical history (see sample 3 in graph.2. Appropriate enriched medium: Chocolate Blood Agar + CO<sub>2</sub>)
- 2) Misidentification (see sample 3 in graph.1: GRAM+ bacteria identified as GRAM-)

## CONCLUSIONS

Data collected show that continuous (over time) participation to EQA schemes can be instrumental in improving clinical laboratories' performances and in detecting common issues, provided that the scheme is designed to collect the widest range possible of pre-analytical, analytical and post-analytical information from participants.

The nature of an EQA scheme (continuous controlled challenges and timely results evaluations) makes it so that positive, as well as negative, trends may be identified to show the state-of-the-art and to allow for corrective actions to be identified and taken in a timely manner to restore high quality services. A properly designed EQA scheme, in fact, can take proficiency testing to the next level of CQI (Continuous Quality Improvement). For that to happen, active collaborations among laboratories, EQA providers, IVD manufacturers and Oversight Bodies will need to occur.