

Diagnostic Performance of two novel PCR Assays Versus Conventional Culture in Identifying *Staphylococcus aureus* and detection of methicillin resistance

Ann-Sophie Jacob, Michelle Aerts, Wim Laffut, Ellen Van Even
Laboratory of Microbiology, Heilig Hart Ziekenhuis Lier, Belgium



OBJECTIVE

Staphylococcus aureus (SA) is a human pathogen responsible for a spectrum of infections, from skin lesions to invasive disease. Although routine screening is not universally recommended for high-risk procedures such as orthopedic surgery, targeted screening is supported by organizations including the European Society of Clinical Microbiology and Infectious Diseases due to its potential to reduce postoperative infections. Molecular techniques enable the direct detection of SA in primary clinical specimens, facilitating rapid diagnosis. Early identification, including resistance profiling, is essential for decontamination procedures and timely antimicrobial therapy, reducing morbidity and mortality. The aim of this study was to compare the diagnostic performance of the FlashDetect Flash 10 and the STANDARD M10 with conventional culture for the detection of *S. aureus* and methicillin resistance.

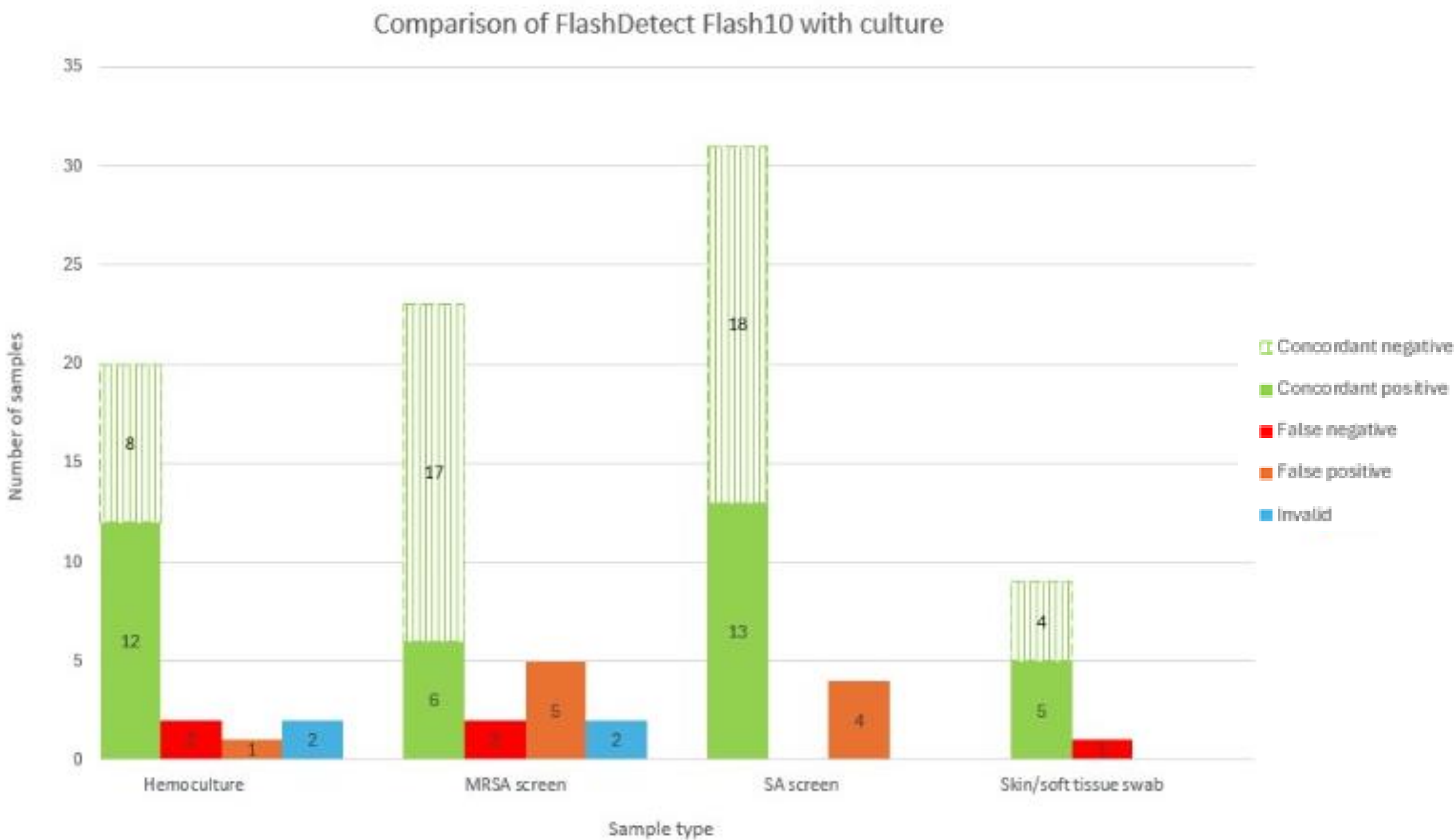
METHODS

The preoperative screening cohort comprised prospectively collected samples for SA and methicillin-resistant *S. aureus* (MRSA) screening. The other cohort addressing bacterial (wound) infections included blood cultures and skin and soft tissue swabs, obtained following culture-confirmed SA infection. To investigate false positivity, negative samples from each sample type were used. Specimens were analyzed using FlashDetect Flash10 (Coyote Bioscience) and results were compared against culture as gold standard. A subset of samples was additionally tested with the STANDARD M10 (SD Biosensor) to enable comparison of both PCR platforms and culture. The STANDARD M10 is validated only for nasal swab specimens, whereas the FlashDetect Flash 10 is approved for all included sample types.

RESULTS

To compare the FlashDetect Flash 10 with culture, 102 samples were tested. False positive results were mainly observed in MRSA and SA screenings, accounting for 15.6% and 11.4% of samples, respectively (Figure 1). When considering all samples, five false negative results and four invalids were observed. Most erroneous results occurred in blood cultures and MRSA screenings. Overall, the assay demonstrated a sensitivity of 94% and a specificity of 89% when compared to conventional culture. The performance of both PCR assays was largely comparable for the 45 samples:

Figure 1: Comparison of FlashDetect Flash10 results with culture



SA: *S. aureus*, MRSA: methicillin-resistant *S. aureus*

FlashDetect Flash 10 yielded five false positives and two false negatives, while the STANDARD M10 produced four false positives and one false negative. Interestingly, the STANDARD M10 showed more false positives in skin and soft tissue swabs, which was not seen in other specimen types.

CONCLUSION

In conclusion, the FlashDetect Flash 10 represents a reliable tool for ruling out SA infection/carriage, although positive results should ideally be confirmed by culture. The STANDARD M10 demonstrated comparable performance. Both assays may be particularly useful in settings with a high likelihood of SA colonization and infection, especially where rapid decision-making is essential. In such situations, these methods may play a role in strategies aimed at reducing postoperative wound infections following major surgical procedures, including orthopedic operations.