

FilmArray: Correction of Previously False-Positive Results by Improved Software

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Bloodstream infections (BSIs) are a leading cause of death and have high health care-related costs worldwide (1). Hitherto-published studies showed that receiving timely and accurate information as to the nature of the causative agent(s) and its antimicrobial susceptibilities is of the utmost importance for clinical management as well as for implementation of the optimal targeted antimicrobial therapy (2, 3). Thus, there is a great need to establish rapid identification methods with high sensitivities and specificities for the microbiological diagnosis of BSIs. False-positive and -negative results are important challenges for establishing these methods in a clinical routine. False-positive results obtained by microbiological methods may lead to untreated illness, higher medical costs, or inappropriate antibiotic use (4). It is therefore important to decrease the number of false-positive results while maintaining high sensitivity. Recently, we published the first clinical evaluation of the FilmArray blood culture identification (FA BCID) panel in the identification of microorganisms directly from positive blood culture bottles (5). The method was very user-friendly, and the total time to identification of a microorganism(s) from one blood culture using the FA BCID panel was 65 min. Moreover, the FA BCID system had high sensitivity and could detect 91.6% and 71% of all microorganisms in blood culture bottles with monomicrobial and polymicrobial growth, respectively (5). Surprisingly, the FA BCID system detected *Enterococcus* species nucleic acid in five blood culture bottles for which the cultures were negative. In repeat experiments, similar results were observed. We interpreted the results as falsely positive and described it in the paper. After the publication of the paper, the FilmArray BCID system was optimized to improve sample specificity by the manufacturer. The optimization of the product was designed to mitigate the cross-reactivity of the *Enterococcus* assay with *Staphylococcus* organisms. This was achieved by a modification to the software analysis. The present version of the software, 1.4.1, incorporates the conditional *Enterococcus* analysis and is the currently available version for commercial use. The software version that was used in the original study was 1.3.0. When five previous samples with false-positive *Enterococcus* species results were reanalyzed with the new software, no *Enterococcus* was detected.

The results showed that the previous FA BCID results were actually falsely positive and were corrected with the optimization of the system. The correction of the false-positive results with the new software had a positive impact on the performance of the FilmArray system. In the original study, we reported that the sensitivity and the specificity of the FilmArray panel in detecting *Enterococcus* spp. were 88.9% and 97.3%, respectively. When we analyzed the same material with the new software version, the sensitivity and specificity of the FilmArray system for *Enterococcus* spp. were 88.9% and 100%, respectively. The present report underlines the importance of ongoing improvement of the analysis of PCR results to achieve optimal specificity.

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