Evaluation of the ePlex Blood Culture Identification Panels in an Academic Medical Center

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Introduction

Rapid diagnosis and treatment of pathogens causing bloodstream infections (BSI) remains a major challenge in the clinical setting. Increasing prevalence of drug resistance has hindered the efficacy of empirical treatments.1,2 Time to pathogen identification and detection of antibiotic resistance is therefore crucial for determining effective targeted therapies. Thus, there is great demand for diagnostic tools to expedite these critical results.

Several platforms utilizing multiplex PCR panels have been developed for such purposes. 3,4 The ePlex® (GenMark Diagnostics, Carlsbad, CA) Blood Culture Identification (BCID) is a FDA cleared system that provides organism identification and detection of select resistance genes within 1.5 hours after detection of a positive blood culture (BC). There are three BCID panels: Gram Positive (GP), Gram Negative (GN), and Fungal Pathogen (FP). Here we compared results for organism ID, detection of resistance genes, and turnaround time (TAT) from ePlex to our standard of care (SOC), consisting of MALDI-TOF, CHROMagar® and VITEK 2.

Study Design and Methods

• Prospective Observational Study
• Duration: November 2018 – April 2019
• Samples were tested in parallel by ePlex and SOC
• ePlex panels were Research Use Only (pre-FDA clearance)

The ePlex System

• Full-automated PCR-based system
• Includes identification and detection of select resistance genes
• All of positive BC broth
• ID results for 95% of isolates
• For rapid and fully automated pathogen identification and detection

Results

• Positive BC culture (BC)
• ePlex panels were Research Use Only (pre-FDA clearance)
• • 109 positive BC were compared, 113 BCID panels were run (GP: 51, GN: 54 and FP: 8)
• The overall inclusivity rate was 88%
• ePlex correctly identified 95% (100/105) of the organisms and 100% of resistance genes. Among the discrepant results 4/5 occurred in polymicrobial cultures
• On average, the difference between SOC and ePlex TAT for ID and antimicrobial susceptibility testing, respectively, was 26.3h and 51.3h
• The present study shows that the ePlex RUO BCID Panels are a rapid and fully automated method with high performance in identification and detection of resistance genes compared to SOC methods, especially for monomicrobial BCs
• Therefore, the ePlex BCID Panels present a comprehensive package that has the potential for rapid BSI pathogen and select resistance-marker detection

Discussion and Conclusion

References

Positive Blood Culture
Gram Stain

ePlex

- Panel (GP, GN, PP) chosen based on gram stain reaction
- Organism ID and detection of resistance markers
1.5 hours

SOC

- Media inoculated based on gram stain morphology
- Direct tests set up
- Organism ID by MALDI-TOF
- Susceptibility set up
- Susceptibility results reported
24 hours

*Times are approximated ideals