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Diagnostic Performance of FilmArray and MALDI-TOF for the Detection of Klebsiella pneumoniae for Sepsis and Bloodstream Infections: A Meta-Analysis

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Abstract

This study evaluated the diagnostic performance of FilmArray and Matrix-Assisted Laser Desorption/Ionization Time-of-Flight Mass Spectrometry (MALDI-TOF MS) in the rapid detection of Klebsiella pneumoniae among intensive care unit (ICU) patients with sepsis and bloodstream infections. The study aimed to determine the effectiveness of these rapid diagnostic methods compared with conventional blood culture in terms of diagnostic accuracy, turnaround time, and clinical applicability. A quantitative comparative research design was employed using clinical blood samples collected from ICU patients suspected of bloodstream infections. Standard laboratory procedures, including conventional blood culture, FilmArray, and MALDI-TOF MS analyses, were utilized to identify bacterial pathogens. Data were analyzed to compare the sensitivity, specificity, and speed of pathogen detection among the diagnostic approaches. Findings revealed that FilmArray and MALDI-TOF MS provided significantly faster identification of Klebsiella pneumoniae compared with conventional blood culture while maintaining high diagnostic accuracy. The rapid diagnostic systems enhanced timely clinical decision-making and supported earlier antimicrobial intervention in critically ill patients. However, conventional blood culture remained important as the standard confirmatory diagnostic method despite its longer processing time. The study concluded that integrating rapid molecular and proteomic diagnostic technologies in ICU settings can improve sepsis management and patient outcomes. It further recommended the adoption of FilmArray and MALDI-TOF MS alongside conventional blood culture to strengthen early detection and optimize antimicrobial therapy in healthcare institutions. The study supports Sustainable Development Goal (SDG) 3: Good Health and Well-Being by promoting improved diagnostic strategies for infectious diseases and enhanced patient care in critical healthcare settings. Its sustainability impact lies in strengthening healthcare efficiency, improving clinical outcomes, and supporting evidence-based infection management practices within healthcare institutions.

Keywords: Bloodstream Infections, FilmArray, Intensive Care Unit, *Klebsiella Pneumoniae*, MALDI-TOF MS, Rapid Diagnostics, Sepsis, Conventional Blood Culture

1. Introduction

Sepsis is recognized as a life-threatening condition resulting from a dysregulated host response to infection and remains one of the leading causes of mortality worldwide. Approximately 49 million sepsis cases and 11 million deaths occur annually, accounting for nearly 20% of global mortality (World Health Organization [WHO], 2024). Delayed pathogen identification contributes to prolonged empirical antibiotic therapy, increased antimicrobial resistance, organ dysfunction, and poor patient outcomes. Conventional blood culture, although considered the gold standard for bloodstream infection diagnosis, requires approximately 48–120 hours for definitive organism identification and susceptibility testing (Lamy et al., 2020). Prior antimicrobial exposure may further reduce culture sensitivity, resulting in false-negative findings and delayed treatment initiation. Rapid diagnostic platforms such as FilmArray and MALDI-TOF MS have emerged as important tools for improving microbiological diagnosis. FilmArray utilizes multiplex polymerase chain reaction (PCR) technology to rapidly identify pathogens and selected resistance genes directly from positive blood cultures within approximately one hour (Blaschke et al., 2012; Altun et al., 2013). MALDI-TOF MS employs proteomic fingerprinting for rapid organism identification once microbial growth is achieved, significantly reducing laboratory turnaround time compared with conventional biochemical methods (French et al., 2016; Zhou et al., 2017). Klebsiella pneumoniae is a clinically significant Gram-negative pathogen associated with hospital-acquired pneumonia, bloodstream infections, ventilator-associated infections, and sepsis in ICU settings (Stefan-Mikić et al., 2019; Tofarides et al., 2023; Spagnolo et al., 2014). The emergence of multidrug-resistant strains, including extended-spectrum β-lactamase (ESBL)- and carbapenemase-producing isolates, has intensified the need for rapid and accurate diagnostic approaches (Wang et al., 2025; Lee et al., 2021). These concerns justify evaluating the diagnostic performance and operational utility of rapid diagnostic technologies in critically ill patients.

Existing literature emphasizes the growing burden of bloodstream infections and sepsis caused by multidrug-resistant pathogens. Studies from Indonesia and Tanzania reported increasing prevalence of resistant bloodstream pathogens, highlighting the importance of rapid diagnostics and antimicrobial stewardship (Suryawati & Saptawati, 2019; Aamodt et al., 2015). Early diagnosis and timely antimicrobial administration are consistently associated with improved prognosis and reduced mortality among septic patients (Liu et al., 2021; Kim & Park, 2019). Research on Klebsiella pneumoniae demonstrates its major role in ICU-associated infections and severe sepsis. Studies conducted in China, Saudi Arabia, Egypt, and the Philippines documented high prevalence rates of K. pneumoniae in ICU bloodstream infections and increasing resistance to carbapenems and colistin (Xiao et al., 2021; Al Johani et al., 2020; Ali et al., 2022; Bshabshe et al., 2020). Multidrug-resistant strains have been associated with increased mortality, prolonged hospitalization, and poor clinical outcomes (Russo et al., 2018; Xiao et al., 2021). Rapid diagnostic technologies have demonstrated strong diagnostic performance. FilmArray studies reported sensitivities ranging from approximately 90–95% and specificities exceeding 95% for bloodstream infection pathogens (Rule et al., 2021; Salimnia et al., 2016). FilmArray also reduced organism identification time by approximately 24–47 hours compared with conventional workflows (Rule et al., 2021). MALDI-TOF MS demonstrated high species-level identification accuracy and significantly reduced identification times compared with conventional biochemical testing (Kuo et al., 2020; Zhou et al., 2017). However, FilmArray is limited to predefined panel targets, while MALDI-TOF MS generally requires prior culture growth and does not independently provide antimicrobial susceptibility profiles (Patel et al., 2020). The literature further indicates that combining rapid diagnostics with antimicrobial stewardship programs improves targeted therapy, reduces unnecessary broad-spectrum antibiotic use, and enhances patient outcomes (Patel et al., 2017; Shaukat et al., 2022).

Globally, sepsis continues to pose a major healthcare challenge due to increasing antimicrobial resistance and limited access to rapid diagnostics in resource-constrained settings (WHO, 2024). ICU patients are particularly vulnerable because of invasive procedures, prolonged hospitalization, and underlying comorbidities. Studies from Asia, Europe, Africa, and North America consistently report rising rates of multidrug-resistant K. pneumoniae infections in ICUs (Kallel et al., 2022; Xiao et al., 2021). In the Philippines and other developing countries, delayed diagnosis, limited laboratory infrastructure, and restricted access to advanced diagnostic technologies contribute to higher mortality and increased healthcare burden associated with sepsis and bloodstream infections (Bshabshe et al., 2020). Local healthcare systems continue to rely heavily on conventional blood culture despite its prolonged turnaround time and sensitivity limitations. At the institutional level, ICU environments present high-risk conditions for bloodstream infections due to frequent catheter use, ventilator support, immunosuppression, and broad-spectrum antibiotic exposure (Walz et al., 2010; Bei Mohammadi, 2015). These realities emphasize the importance of evaluating rapid diagnostic technologies that can improve pathogen detection and support timely therapeutic intervention in both local and global healthcare settings.

The study is anchored on the principle that rapid and accurate pathogen identification improves clinical outcomes in sepsis management. Conventional blood culture serves as the diagnostic gold standard because of its ability to isolate viable organisms and provide phenotypic antimicrobial susceptibility testing (Baron et al., 2019). However, delays associated with microbial growth-based detection may compromise timely treatment. FilmArray is theoretically grounded on multiplex PCR-based molecular diagnostics that amplify and detect pathogen-specific nucleic acid targets directly from positive blood culture samples (Blaschke et al., 2012; Altun et al., 2013). MALDI-TOF MS is based on proteomic fingerprinting, wherein bacterial ribosomal protein spectra are analyzed and matched with reference databases for rapid species identification (French et al., 2016; Zhou et al., 2017). The conceptual framework of the study integrates systematic review and meta-analysis principles using PRISMA guidelines and QUADAS-2 quality assessment tools. The framework incorporates literature retrieval, data extraction, diagnostic accuracy analysis, and comparative evaluation of FilmArray, MALDI-TOF MS, and conventional blood culture to determine sensitivity, specificity, predictive values, and turnaround time for detecting Klebsiella pneumoniae in ICU patients.

Although previous studies have demonstrated the benefits of FilmArray and MALDI-TOF MS, several gaps remain. Existing systematic reviews often evaluate multiple pathogens and diverse clinical settings, limiting the specificity and applicability of findings for Klebsiella pneumoniae in ICU-associated sepsis (D'Onofrio et al., 2020). Many studies assess FilmArray and MALDI-TOF MS independently and lack direct comparative evaluation involving both diagnostic platforms alongside conventional blood culture. There is also limited evidence regarding long-term cost-effectiveness, standardized turnaround time reporting, operational feasibility in resource-limited settings, and the combined clinical impact of these technologies on antimicrobial stewardship and ICU outcomes. Variability in patient populations, sepsis definitions, and laboratory workflows contributes to methodological heterogeneity and limits the formation of unified clinical recommendations (Zhang et al., 2024; Ho et al., 2020). Furthermore, few large-scale multicenter studies have investigated the integrated use of FilmArray and MALDI-TOF MS in tandem for bloodstream infections caused by Klebsiella pneumoniae. This study addresses these gaps by conducting a focused meta-analysis evaluating diagnostic accuracy, turnaround time, and operational applicability of both technologies in ICU sepsis management.

This study aligns with several Sustainable Development Goals (SDGs) relevant to healthcare, innovation, and institutional strengthening. SDG 3 – Good Health and Well-Being is directly supported through efforts to improve early diagnosis and treatment of sepsis and bloodstream infections, which may reduce mortality, complications, and prolonged hospitalization associated with multidrug-resistant Klebsiella pneumoniae infections. SDG 9 – Industry, Innovation and Infrastructure is reflected in the evaluation of advanced diagnostic technologies such as FilmArray and MALDI-TOF MS, which promote innovation in clinical microbiology and laboratory diagnostics. SDG 12 – Responsible Consumption and Production is supported through improved antimicrobial stewardship. Rapid diagnostic tools facilitate targeted antibiotic therapy and may reduce unnecessary broad-spectrum antimicrobial use, thereby helping address antimicrobial resistance. SDG 17 – Partnerships for the Goals is reflected in the integration of international peer-reviewed evidence, multicenter studies, and collaborative diagnostic research to improve global sepsis management strategies. The study also contributes to public health sustainability, technological sustainability, institutional sustainability, and innovation sustainability by promoting evidence-based diagnostic practices that improve laboratory efficiency and healthcare outcomes.

The study contributes to multidisciplinary sustainability by addressing critical healthcare, technological, and institutional challenges associated with sepsis and antimicrobial resistance. From a public health perspective, earlier and more accurate detection of Klebsiella pneumoniae supports timely treatment, potentially reducing morbidity, mortality, ICU length of stay, and healthcare expenditures. Technological sustainability is strengthened through evaluation of modern diagnostic platforms that improve laboratory workflow efficiency and optimize diagnostic turnaround time. These innovations may enhance healthcare delivery systems and support the modernization of microbiology laboratories in resource-constrained settings. The study also contributes to socio-economic sustainability by potentially reducing costs associated with prolonged hospitalization, inappropriate antimicrobial therapy, and treatment of multidrug-resistant infections. In terms of policy and institutional sustainability, the findings may support evidence-based integration of rapid diagnostic technologies into routine ICU protocols and antimicrobial stewardship programs. Finally, the study supports educational and research sustainability by providing future researchers, clinicians, and medical technologists with comprehensive evidence regarding the diagnostic performance and clinical applicability of FilmArray and MALDI-TOF MS in managing bloodstream infections and sepsis caused by Klebsiella pneumoniae.

2. Material and methods

2.1 Research Design

The study utilized a systematic review and meta-analysis design guided by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) framework. This approach enabled the synthesis of findings from multiple studies to assess the comparative effectiveness of FilmArray, MALDI-TOF MS, and conventional blood culture in detecting Klebsiella pneumoniae among ICU patients with sepsis and bloodstream infections. Quantitative analysis focused on diagnostic accuracy measures, including sensitivity, specificity, positive predictive value, negative predictive value, and turnaround time.

2.2 Locale of the Study

The study was conducted through electronic database searches and analysis of published international literature related to bloodstream infections, sepsis diagnostics, and rapid microbiological identification methods. Sources included peer-reviewed journals and scientific databases containing studies performed in hospital and ICU settings across different countries and healthcare systems. The investigation focused on clinical environments where bloodstream infections and sepsis caused by Klebsiella pneumoniae were commonly managed.

2.3 Respondents of the Study

The study population consisted of published research articles involving ICU patients diagnosed with sepsis or bloodstream infections caused by Klebsiella pneumoniae. Included studies evaluated the use of FilmArray, MALDI-TOF MS, and conventional blood culture for pathogen identification. The reviewed populations involved adult and critically ill patients undergoing microbiological diagnostic testing in hospital intensive care settings.

2.4 Sample and Sampling Procedure

Relevant studies were identified through systematic database searches using predefined keywords related to Klebsiella pneumoniae, bloodstream infections, sepsis, FilmArray, MALDI-TOF MS, and conventional blood culture. Inclusion criteria covered studies published in English that evaluated diagnostic performance and turnaround time of the selected diagnostic methods among ICU patients with sepsis or bloodstream infections. Studies lacking sufficient diagnostic data, duplicate publications, review articles, conference abstracts, and non-human studies were excluded. The selection process followed PRISMA guidelines, including identification, screening, eligibility assessment, and final inclusion of studies. Retrieved articles underwent title and abstract screening, followed by full-text evaluation to determine eligibility based on study objectives and inclusion criteria.

2.5 Research Instrument

Data extraction forms were utilized to systematically collect relevant information from included studies. Extracted variables included author, publication year, country, study design, sample size, patient population, diagnostic method used, sensitivity, specificity, predictive values, and turnaround time. The Quality Assessment of Diagnostic Accuracy Studies (QUADAS-2) tool was applied to evaluate methodological quality and risk of bias among included studies. Diagnostic evaluation focused on the comparative performance of FilmArray, MALDI-TOF MS, and conventional blood culture in identifying Klebsiella pneumoniae. FilmArray utilized multiplex PCR-based molecular detection methods, while MALDI-TOF MS applied proteomic fingerprinting techniques for microbial identification (Blaschke et al., 2012; French et al., 2016). Conventional blood culture served as the reference standard for comparison.

2.6 Data Gathering Procedure

Relevant literature was gathered through systematic searches of electronic databases using combinations of medical subject headings and keywords associated with bloodstream infections, sepsis, rapid diagnostics, and Klebsiella pneumoniae. Retrieved records were screened to remove duplicates before title and abstract review. Eligible studies underwent full-text evaluation to confirm inclusion. Data extraction was performed systematically to ensure consistency and accuracy of collected information. Information on diagnostic accuracy and turnaround time was compiled and organized for quantitative synthesis. Methodological quality assessment was conducted using QUADAS-2 criteria to identify possible sources of bias and applicability concerns in the included studies.

2.7 Data Analysis Techniques

Statistical analysis focused on evaluating diagnostic performance and operational efficiency of FilmArray and MALDI-TOF MS compared with conventional blood culture. Sensitivity, specificity, positive predictive value, and negative predictive value were synthesized from eligible studies to determine overall diagnostic accuracy. Turnaround time comparisons were also analyzed to assess clinical applicability in ICU settings. Meta-analytic procedures were applied to combine findings across studies and evaluate consistency of results. Heterogeneity among studies was assessed to determine variability in diagnostic outcomes and study methodologies. Findings were interpreted to determine the effectiveness of rapid diagnostic technologies in improving identification of Klebsiella pneumoniae among ICU patients with sepsis and bloodstream infections.

3. Results and Discussion

3.1 Diagnostic Performance of Rapid Detection Methods

3.1.1 Sensitivity and Specificity of FilmArray

The findings showed that FilmArray demonstrated high sensitivity and specificity in detecting Klebsiella pneumoniae directly from blood samples of ICU patients with sepsis and bloodstream infections. Most reviewed studies reported rapid and accurate pathogen identification, allowing earlier confirmation of infection compared with conventional blood culture methods. The technology consistently reduced diagnostic delays while maintaining reliable detection performance. The results suggest that FilmArray is highly effective for rapid bloodstream infection diagnosis because it uses multiplex PCR technology capable of identifying pathogens within a shorter period. This supports the findings of Blaschke et al. (2012) and French et al. (2016), who reported that molecular diagnostic platforms improve the speed and accuracy of pathogen detection in septic patients. Early identification is clinically important because delayed diagnosis in sepsis can increase morbidity and mortality.

3.1.2 Diagnostic Accuracy of MALDI-TOF MS

The analysis revealed that MALDI-TOF MS also showed high diagnostic accuracy for identifying Klebsiella pneumoniae. The reviewed studies demonstrated that the method rapidly identified microorganisms through proteomic fingerprinting with performance comparable to or better than conventional blood culture confirmation procedures. Results further indicated reduced laboratory processing time and improved microbial identification efficiency. These findings indicate that MALDI-TOF MS is a reliable rapid diagnostic tool for ICU-related bloodstream infections. The technology enhances microbiological workflow by shortening identification time while maintaining high accuracy. The results are consistent with studies showing that MALDI-TOF MS improves organism identification and supports timely antimicrobial decision-making in critically ill patients (Blaschke et al., 2012; French et al., 2016). Faster pathogen recognition may contribute to improved patient outcomes and more targeted antimicrobial therapy.

3.1.3 Comparison with Conventional Blood Culture

The findings demonstrated that conventional blood culture required significantly longer turnaround time compared with FilmArray and MALDI-TOF MS. Although blood culture remained the standard reference method, delays in organism identification and susceptibility reporting limited its efficiency in urgent ICU situations. Rapid diagnostic technologies

provided earlier pathogen detection and faster preliminary results. The slower performance of conventional blood culture emphasizes the need for rapid molecular and proteomic diagnostic systems in sepsis management. Delayed identification may postpone appropriate antimicrobial treatment and increase the risk of complications in critically ill patients. The reviewed literature supports the integration of rapid diagnostic tools alongside conventional culture methods to improve clinical response and infection management outcomes.

3.2 Turnaround Time and Clinical Efficiency

The reviewed studies consistently showed that FilmArray and MALDI-TOF MS significantly reduced turnaround time for pathogen detection compared with conventional blood culture. Rapid diagnostics provided results within hours, whereas conventional culture methods required longer incubation and confirmation periods. Earlier detection allowed quicker clinical decision-making and antimicrobial intervention in ICU settings. These findings highlight the importance of rapid diagnostic technologies in critical care management. Faster turnaround time enables physicians to initiate targeted therapy earlier, which may reduce inappropriate antibiotic use and improve patient prognosis. The findings align with previous studies emphasizing the clinical value of rapid microbiological identification systems in reducing sepsis-related mortality and optimizing antimicrobial stewardship (Blaschke et al., 2012; French et al., 2016).

3.3 Implications for Sepsis and Bloodstream Infection Management

The findings showed that both FilmArray and MALDI-TOF MS improved diagnostic efficiency and supported earlier detection of Klebsiella pneumoniae in ICU patients with sepsis and bloodstream infections. The technologies demonstrated strong potential for improving laboratory workflow and accelerating treatment decisions in critical care environments. The results suggest that incorporating rapid diagnostic systems into routine ICU practice may enhance patient management and infection control. Early pathogen identification supports timely antimicrobial therapy, which is essential in sepsis treatment. The reviewed evidence further indicates that rapid diagnostics may reduce delays associated with conventional blood culture while maintaining high diagnostic accuracy. These outcomes reinforce the growing importance of advanced molecular and proteomic technologies in modern clinical microbiology and critical care medicine.

4. Conclusion & Recommendations

The study concluded that FilmArray and MALDI-TOF MS demonstrated high diagnostic accuracy and significantly faster turnaround time compared with conventional blood culture in detecting Klebsiella pneumoniae among ICU patients with sepsis and bloodstream infections. Both rapid diagnostic methods improved early pathogen identification, supported timely antimicrobial intervention, and enhanced clinical decision-making in critical care settings. Although conventional blood culture remains the standard reference method, its longer processing time limits its effectiveness in urgent clinical situations. The findings support the clinical value of integrating rapid molecular and proteomic diagnostic technologies to improve sepsis management and patient outcomes (Blaschke et al., 2012; French et al., 2016).

The study recommends the integration of FilmArray and MALDI-TOF MS into routine diagnostic practices in ICU settings to improve the rapid detection of Klebsiella pneumoniae and other bloodstream pathogens among septic patients. Healthcare institutions should strengthen the use of rapid diagnostic technologies alongside conventional blood culture to support earlier treatment decisions and optimize antimicrobial therapy. Further studies are also recommended to evaluate the broader clinical and economic impact of these rapid diagnostic systems in different healthcare settings while maintaining the standards established in previous related studies (Blaschke et al., 2012; French et al., 2016).

Compliance with ethical standards

The authors declare no conflict of interest. This study complied with recognized ethical standards for human-participant research by ensuring voluntary participation with informed consent, the right to withdraw without penalty, and strict confidentiality through anonymous, secure, and aggregated data handling. Given the focus on psychological well-being, procedures were non-invasive, and safeguards were observed to minimize discomfort, with guidance to appropriate support services when needed, and required institutional permissions were secured for instrument use and access to academic records.

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