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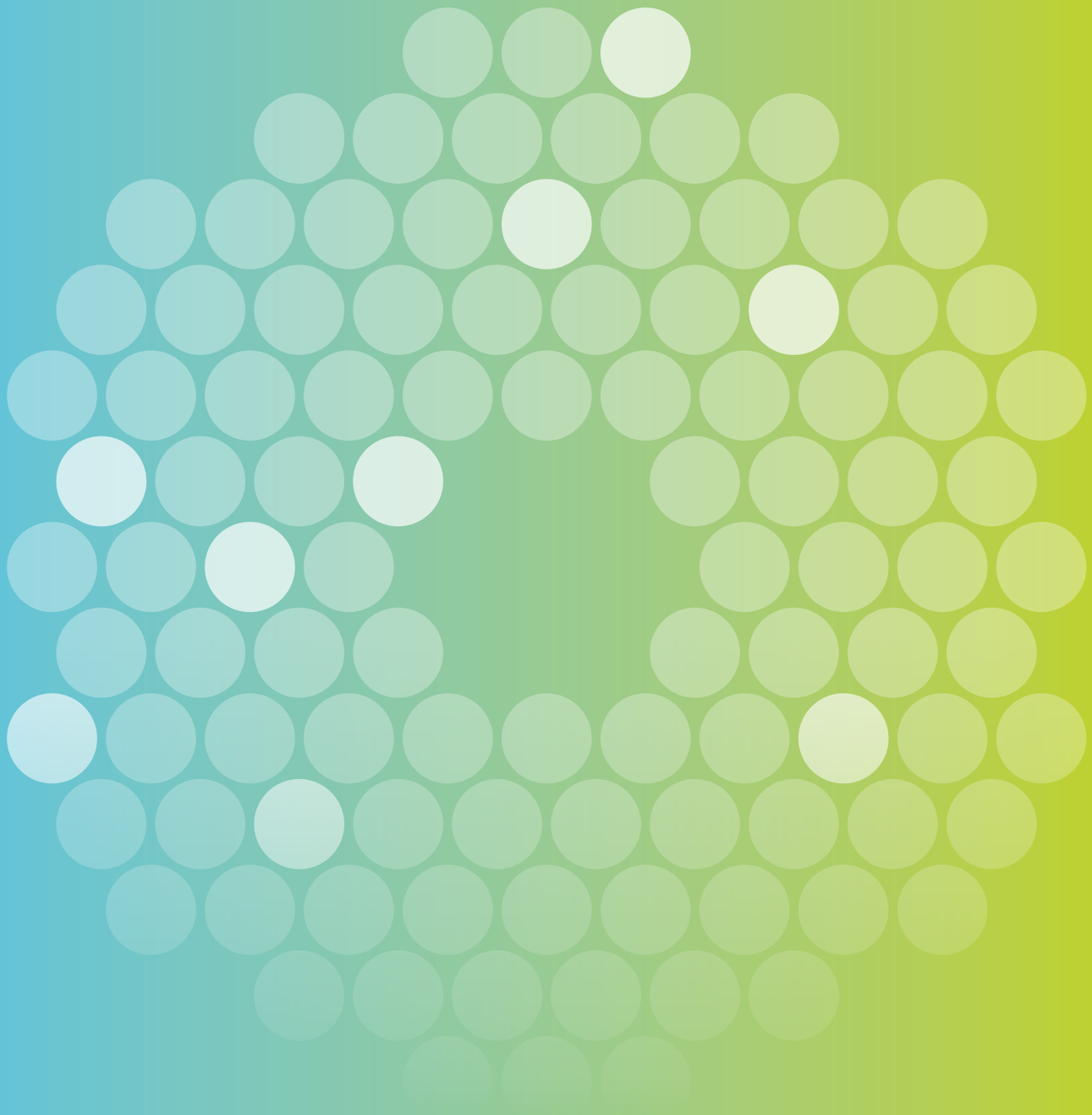

PIONEERING DIAGNOSTICS

BIOFIRE® INSTRUMENTS

BIOFIRE® FILMARRAY® TORCH
FDA cleared,
and CE marked

BIOFIRE® SPOTFIRE®
FDA cleared,
and CE marked

BIOFIRE® PANELS

- BIOFIRE® FILMARRAY® RESPIRATORY PANELS
- BIOFIRE® SPOTFIRE® RESPIRATORY/SORE THROAT PANELS
- BIOFIRE® FILMARRAY® PNEUMONIA PANELS
- BIOFIRE® BLOOD CULTURE IDENTIFICATION 2 PANEL
- BIOFIRE® FILMARRAY® GASTROINTESTINAL PANEL
- BIOFIRE® FILMARRAY® MENINGITIS/ENCEPHALITIS PANEL
- BIOFIRE® JOINT INFECTION PANEL
- BIOFIRE® FILMARRAY® TROPICAL FEVER PANEL
- BIOFIRE® FIREWORKS™

BIOFIRE® SYNDROMIC APPROACH

THE BIOFIRE® SYNDROMIC APPROACH EMPOWERS CLINICIANS AND LAB PERSONNEL TO CHOOSE THE RIGHT TEST, THE FIRST TIME.

The BIOFIRE® syndromic approach is a symptom-driven broad grouping of probable pathogens into one fast test. Using multiplex polymerase chain reaction (PCR) technology, a BIOFIRE syndromic test targets a comprehensive menu of microorganisms that may present with similar signs and symptoms. The syndromic approach **maximizes the chance of getting the right answer in a clinically relevant time frame.**

SYNDROMIC TESTING

Syndromic testing provides a streamlined workflow and fast, comprehensive results.

BIOFIRE® syndromic testing allows simultaneous detection of multiple pathogens with results in as little as ~15 minutes to ~1 hour. Results aid in making vital decisions regarding admission, isolation, cohorting, targeted antimicrobial therapy, and appropriate use of antivirals and antibiotics.

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ABBREVIATIONS & ACRONYMS

The following abbreviations and acronyms are used throughout the Selection of Publications.

AGE acute gastroenteritis
AMR antimicrobial resistance
aOR adjusted odds ratio
ARTI acute respiratory tract infection
ASP antimicrobial stewardship program
AST antimicrobial susceptibility testing
BAL bronchoalveolar lavage
BC blood culture
BCID2 blood culture identification 2
BSI bloodstream infection
CAP community-acquired pneumonia
CI confidence interval
CNS central nervous system
CoNS coagulase-negative *Staphylococcus*
CRKP carbapenem-resistant *Klebsiella pneumonia*
CRP c-reactive protein
CSF cerebrospinal fluid
CTX ceftriaxone
CTX-M cefotaximase-munich
DAPRI debridement, antibiotic pearls and retention of the implant procedure
DOT days of antimicrobial therapy
EAEC enteroaggregative *Escherichia coli*
ED emergency department
EPEC enteropathogenic *E. coli*
ESBL extended-spectrum beta-lactamase
ETEC enterotoxigenic *E. coli*
GF global fever
HAP hospital-associated pneumonia
ICU intensive care unit
IEAT inappropriate empirical antibiotic treatment
IQR interquartile range
JI joint infection
LOS length of stay
LP lumbar puncture
LRTI lower respiratory tract infection
ME meningitis/encephalitis
MREJ mec right extremity junction
MRSA methicillin-resistant *Staphylococcus aureus*
MSSA methicillin-susceptible *S. aureus*
NPA negative percent agreement
OR odds ratio
PCR polymerase chain reaction
PICU pediatric intensive care unit
PJI prosthetic joint infection
PN pneumonia
PN*plus* pneumonia *plus*
POCT point-of-care test
PPA positive percent agreement
PSM propensity score matching
R/ST respiratory/sore throat
RAT rapid antigen testing
RDT rapid diagnostic test
RP respiratory
SA septic arthritis
SFC synovial fluid culture
SOC standard of care
SOFA sequential organ failure assessment
TAT turnaround time
TF tropical fever
TOT time to optimal therapy
TRENDS a feature of BIOFIRE® FIREWORKS™
TW traditional stool work-up
US United States
VAP ventilator-associated pneumonia
VRE vancomycin-resistant *Enterococcus*

BIOFIRE® FILMARRAY® RESPIRATORY PANELS

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JOURNAL OF INFECTION AND CHEMOTHERAPY
AUG 2019;26(1):82-85 DOI: 10.1016/J.JIAC.2019.07.014

The Impact Analysis of a Multiplex PCR Respiratory Panel for Hospitalized Pediatric Respiratory Infections in Japan

Kitano T, Nishikawa H, Suzuki R, et *al*.

OBJECTIVE

To investigate the impact and the cost-effectiveness of a multiplex PCR (mPCR) respiratory Panel for pediatric respiratory infections in a Japanese community hospital.

STUDY DESIGN

- **Type of study:** Retrospective pre-post study at a community hospital in Japan
- **Date:**
  - **Control:** March 2012 to March 2018
  - **Intervention:** March 2018 to April 2019
- **Patient population:** 1,281 pediatric inpatients with symptoms of respiratory infection (1,132 in control arm and 149 in the intervention arm)
- **Intervention:** BIOFIRE® FILMARRAY® Respiratory (RP) Panel
- **Control:** Rapid antigen testing (RAT)
- **Outcomes:**
  - **Primary:** Days of antimicrobial therapy (DOT) and hospital length of stay (LOS)
  - **Secondary:** Net cost (including hospital cost, societal cost, and test cost), pathogen detection rate, and treatment failure rate

Patients were well matched for most demographic measures. However, patients in the BIOFIRE RP Panel group were younger, and more likely to have a clinical diagnosis of other than pneumonia, upper respiratory infection, asthma, or bronchitis/bronchiolitis.

RESULTS

In the BIOFIRE RP Panel group, 210 patients were initially tested. Of these patients, 38 were excluded for a diagnosis other than respiratory infection, and 2 patients were excluded for previous treatment with antimicrobials. A remaining 21 patients were excluded because the clinician chose to discharge them after receiving the test result.

Testing with the BIOFIRE RP Panel produced an **87.2% microbiological detection rate compared to 30.2% for the RAT group** ($p < 0.001$). The most common pathogens detected were rhinovirus/enterovirus, respiratory syncytial virus, and parainfluenza virus.

For DOT, there was a **mean decrease of about 4 DOT with the BIOFIRE RP Panel group compared to the RAT group (8.56 *vs.* 12.82,** $p < 0.001$), with statistically significant reductions seen for the following antibiotic classes: macrolides, 3 days ($p < 0.001$); cephalosporins, 1 day ($p < 0.001$); tetracyclines, 0.4 days ($p < 0.001$). For LOS, patients tested with the BIOFIRE RP Panel had a mean reduction of about 1.35 days compared to the control group (6.83 *vs.* 8.18, $p = 0.032$).

There was no significant difference in treatment failure rate between the groups (BIOFIRE RP Panel 2.0%; RAT 2.6%, $p = 0.661$).

Difference in net cost of admission was evaluated between the two groups with **an average overall cost savings of approximately $135 USD per case seen in the BIOFIRE RP Panel group**.

CONCLUSIONS

Implementation of the BIOFIRE RP Panel significantly increased pathogen detection rates and reduced both antimicrobial therapy duration and hospital LOS. Additionally, overall hospital costs decreased, supporting the Panel's clinical and economic value in managing pediatric respiratory infections.

KEY FINDINGS

- **There was a higher pathogen detection rate in the BIOFIRE RP Panel group compared to the RAT group (87.2% *vs.* 30.2%).**
- **Patients tested with the BIOFIRE RP Panel showed a reduction in average antimicrobial DOT (8.56 *vs.* 12.82) and average LOS (6.83 *vs.* 8.18) *vs.* control.**
- **After implementation of the BIOFIRE RP Panel, overall hospital costs were reduced by about $135 USD per patient case.**

CLICK TO ACCESS ARTICLE

ANTIBIOTICS
MAR 2021;10(283):1-10 DOI: 10.3390/ANTIBIOTICS10030283

Rapid Molecular Tests for Detecting Respiratory Pathogens Reduced the Use of Antibiotics in Children

Kim Y, Lee J, Kim S, et *al*.

OBJECTIVE

To assess the clinical efficacy of the BIOFIRE® Respiratory (RP) Panel in children who underwent testing for respiratory pathogens.

STUDY DESIGN

- **Type of study:** A retrospective pre/post observational study at a hospital in South Korea
- **Date:** November 2015 to July 2018
  - **Phase I:** 1st November 2015 to 30th June 2016
  - **Phase II:** 1st July 2016 to 30th June 2017
  - **Phase III:** 1st July 2017 to 31st July 2018
- **Patient population:** 915 children hospitalized who underwent testing for respiratory pathogens
  - **Phase I:** 321
  - **Phase II:** 264
  - **Phase III:** 330
- **Intervention:** Tested using the BIOFIRE RP Panel (Period II and III)
- **Control:** Tested with routine PCR (Period I)
- **Outcomes:**
  - Duration and frequency of antibiotic use
  - Waiting time, turnaround time and lead time

Periods II and III were split to check whether medical practices changed after the initial introduction period of the BIOFIRE RP Panel.

RESULTS

Positive detection rates between routine testing (71.3%) and the BIOFIRE RP Panel (83.3%) were significantly different ($p < 0.001$).

There was a **significant decrease in waiting time, turnaround time and lead time** between routine PCR and the BIOFIRE RP Panel. **Length of stay (LOS) was significantly shorter during Period III (3.0 days)** *vs.* Period I (3.2 days) ($p = 0.004$); however, there was no significant difference during Period I *vs.* Period II (3.5 days) and Period I *vs.* Period II-III (3.2 days).

Frequency of IV antibiotic use was reduced from Period I (51.7%) *vs.* Period III (39.4%) ($p = 0.002$), but there was no significant difference during Period I *vs.* Period II (52.7%) and Period I *vs.* Period II-III (45.3%).

Duration of IV antibiotic use was different in Period I (1.7 days) *vs.* Period III (1.2 days) ($p < 0.001$) **and Period I *vs.* Period II-III (1.4 days)** ($p = 0.015$), but there was no significant difference during Period I *vs.* Period II (1.7 days). **Duration of IV + oral antibiotic use was shorter in Period III (2.7 days) *vs.* Period I (3.4 days)** ($p = 0.019$), and there was no significant difference during Period I *vs.* Period II (3.8 days) and Period I *vs.* Period II-III (3.1 days).

CONCLUSIONS

The adoption of the BIOFIRE RP Panel significantly improved pathogen detection and reduced turnaround time to under 3 hours, but also waiting time and lead time, enabling timely clinical decisions. This led to a marked decrease in intravenous antibiotic use and hospital length of stay, supporting its role in enhancing antimicrobial stewardship in pediatric respiratory infections.

KEY FINDINGS

- **There was a significant decrease in waiting time, turnaround time and lead time between routine PCR and the BIOFIRE RP Panel.**
- **Antibiotic use and length of stay were significantly decreased in Period III compared to Period I, but not in Period II compared to Period I.**
- **There was a delay between when diagnostic tests are implemented and changes in clinical practice.**

CLICK TO ACCESS ARTICLE

REVISTA ARGENTINA DE MICROBIOLOGIA
OCT-DEC 2023;55(4):337-344 DOI: 10.1016/J.RAM.2023.03.001

Impact of the multiplex molecular FilmArray Respiratory Panel on antibiotic prescription and clinical management of immunocompromised adults with suspected acute respiratory tract infections: A retrospective before-after study

Bergese S, Fox B, García-Allende N, et *al*.

OBJECTIVE

To measure the real-life impact of BIOFIRE® Respiratory (RP) Panel implementation on immunocompromised patients.

STUDY DESIGN

- **Type of study:** A single-center pre/post-implementation retrospective study in Argentina
- **Date:**
  - **Control:** April 2017 to May 2018
  - **Post-implementation:** January 2019 and July 2019
- **Patient population:** 142 immunocompromised adult patients with suspected acute upper or lower respiratory infection
  - **Intervention/Observation:** Post-implementation group (n = 78, referred as post-RP)
  - **Control:** Pre-implementation group (n = 64, referred as pre-RP)
- **Outcomes:**
  - **Primary outcome:** Reduction in antimicrobial prescription
  - **Secondary outcome:** Reduction in days of antimicrobial treatment, changes in antimicrobial treatment within 72 h, hospital admission rate and length of stay (LOS), admission and LOS in intensive care unit (ICU), use of complementary resource for diagnosis purposes and 30 day-mortality

Patients were well matched for most demographic measures. However, patients in the BIOFIRE RP Panel group were younger, and more likely to have a clinical diagnosis of other than pneumonia, upper respiratory infection, asthma, or bronchitis/bronchiolitis.

RESULTS

Study population:

- The median age of patients was respectively **60** and **61** years old in the pre-RP and post-RP groups.
- The proportion of female patients was higher in the pre-RP group (**66%** *vs.* **49%**, $p = 0.04$), as well as the proportion of solid organ transplanted patients (**22%** *vs.* **8%**, $p < 0.01$). The other parameters were similar between both groups.
- The pre-RP group included patients tested with at least one of these techniques: direct immunofluorescence (targeting adenovirus, *influenza A*/B, respiratory syncytial virus (RSV), human metapneumovirus (hMPV) and parainfluenza 1/2/3), serology (targeting *Mycoplasma pneumoniae* and *Chlamydia pneumoniae*), real-time PCR (targeting *Influenza A*/H1N1, adenovirus, *M. pneumoniae* and *C. pneumoniae*).
- The post-RP group only included patients who were tested with the RP Panel.

BIOFIRE RP Panel performance:

- The BIOFIRE RP Panel was able to detect several viruses that were not detectable by the pre-RP methods: HRV, PIV 2/3, RSV, CoV (SARS-CoV2 not included).
- The identification rate was higher in the post-RP group (**63%** *vs.* **11%**, $p < 0.01$). This difference was mainly due to a higher rate of *Influenza A* detection in the post-RP group (**23%** *vs.* **8%**, $p < 0.01$) and human rhinovirus detection by the BIOFIRE RP Panel (**23%** *vs.* **not performed** in the pre-RP group).
- **5 cases** of viral co-infection were detected in the post-RP group, none in the pre-RP group.

Impact of BIOFIRE RP Panel on clinical outcomes:

- The proportion of **patients treated with antimicrobials decreased after the implementation** of the BIOFIRE RP Panel (**94%** pre-RP *vs.* **68%** post-RP, $p < 0.01$), **especially for beta-lactams** (**89%** pre-RP *vs.* **61%** post-RP, $p < 0.01$) **and macrolides** (**44%** pre-RP *vs.* **13%** post-RP, $p < 0.01$).
- The reduction in macrolides prescription may be due to earlier availability of negative results for atypical bacteria.
- The reduction in beta-lactam prescriptions could be due to a reduction in empirical therapies with either a positive result for a viral agent or a negative Panel result.
- The **median duration of macrolides treatment was shorter in the post-RP group** (**2 days** *vs.* **5 days** in pre-RP group, $p < 0.01$).
- The **median duration of oseltamivir treatment was longer in the post-RP group** (**5 days** *vs.* **2.5 days** in pre-RP group, $p < 0.01$).
- The use of **chest X-ray for patients' diagnosis was lower** in the post-RP group (**79%** *vs.* **97%** in pre-RP group, $p < 0.01$).
- Other secondary outcomes were not statistically different between groups.

BIOFIRE® FILMARRAY® RESPIRATORY PANELS - Clinical Utility

CONCLUSIONS

Implementation of the BIOFIRE RP Panel significantly improved diagnostic yield and reduced unnecessary antimicrobial prescriptions, particularly beta-lactams and macrolides, in immunocompromised adults with suspected acute respiratory infections. However, no differences were observed in secondary outcomes: hospital length of stay, ICU admission, or mortality, highlighting its primary impact on antimicrobial stewardship.

KEY FINDINGS

- **The implementation of BIOFIRE RP Panel increased the proportion of identified causative agents (Δ = +52%), mainly by detecting of viruses that were not detected by diagnostic tests used in the pre-RP group.**
- **The use of BIOFIRE RP Panel resulted in a diminution of antimicrobial use (Δ = -26%), particularly for beta-lactams (Δ = -28%) and macrolides (Δ = -31%).**
- **The median days of treatment for macrolides treatment were shorter in the post-RP group (Δ = -3 days), but was longer for oseltamivir (Δ = +2.5 days).**

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ANTIBIOTICS
SEP 2022;11(9):1192 DOI: 10.3390/ANTIBIOTICS11091192

Point-of-Care and Rapid Tests for the Etiological Diagnosis of Respiratory Tract Infections in Children: A systematic Review and Meta-Analysis

Brigadoi G, Gastaldi A, Moi M, et *al*.

OBJECTIVE

To assess the effect of point-of-care tests (POCTs) and rapid tests, including the BIOFIRE® Respiratory (RP) Panel for respiratory tract infections on changing antibiotic prescription rate, length of stay (LOS), days of therapy (DOT), and healthcare costs.

STUDY DESIGN

- **Type of study:** Meta-analysis including 57 studies with randomized trials (14.0%), non-randomized observational studies (47.4%) and quasi-experimental studies (38.6%)
- **Date of publication:** Before 2021
- **Data base:** Embase, MEDLINE, and Cochrane Library
- **Patient population:** Pediatric populations (emergency department (ED), inpatient, and outpatient)
- **Inclusion criteria:** The implementation of rapid tests and POCTs for respiratory tract infections that included patients younger than 21 years, both in outpatient or in-hospital settings
- **Outcomes:**
  - **Primary:** Effect of POCTs and rapid tests on antibiotics prescriptions
  - **Secondary:** Impact of the tests on the rate of prescriptions, LOS, DOT, and reduction of cost

RESULTS

According to the NIH Quality Assessment Tool:

- 82.5% (47/57) of the studies were assessed as fair
- 3.5% (2/57) as poor
- 14% (8/57) as good

93% of the studies were performed in high income countries (43.9% NORAM, 33.3% Europe, 14.0% Asia) and 82.5% were published after 2007.

The most frequently studied tests in the articles were:

- The rapid influenza diagnostic tests (22/57, 38.6%)
- The BIOFIRE RP Panel (22/57, 38.5%)

Of the 49 studies that assessed **antibiotic prescription rates after implementation of rapid tests or POCTs, 65.3% found a statistically significant reduction. An overall reduction in antibiotic prescription was observed** when comparing the BIOFIRE RP Panel to standard testing, but not when compared to clinical diagnosis. Of studies that reported impact on oseltamivir prescription, 12 of 20 (60%) reported a significant increase with POCTs.

The **LOS significantly decreased with POCT in 16 of the 34** studies (47.1%) which included this outcome. 11 of the 18 studies (**61%**) **which measured DOT reported a significant reduction** after implementing rapid tests or POCTs.

Finally, the meta-analysis noted a **significant reduction in costs** for three of the eight studies (**37.5%**) which included cost as an outcome.

CONCLUSIONS

This meta-analysis confirms that implementing rapid tests and POCTs for pediatric respiratory infections significantly reduces unnecessary antibiotic prescriptions and improves appropriate antiviral use. While trends toward shorter therapy duration and hospital stay were observed, further high-quality studies are needed to validate these benefits and optimize integration with antimicrobial stewardship programs (ASP).

KEY FINDINGS

- **1st systematic review of rapid tests and POCTs in pediatric settings worldwide and their impact on antimicrobial prescription, healthcare costs, and patient outcomes.**
- **Implementation of rapid tests and POCTs could be a valuable tool for the improvement of antimicrobial prescription rates.**
- **More well-designed studies of implementation (well-structured antimicrobial stewardship programs) of rapid tests and POCTs are needed to improve patients' outcomes in high and low-middle income countries.**

BIOFIRE® SPOTFIRE®

RESPIRATORY/SORE THROAT PANELS

CLICK TO ACCESS ARTICLE

JOURNAL OF CLINICAL MICROBIOLOGY
DEC 2025; 1:E0131325 DOI: 10.1128/JCM.01313-25

Impact of multiplex PCR point-of-care platform implementation for respiratory pathogen detection in an emergency department with high daily patient volume

Bigaud B, Marjanovic N, Deroche L, et *al*.

OBJECTIVE

To evaluate the implementation of the BIOFIRE® SPOTFIRE® System in a real-life setting, to compare the patient management between patients with positive or negative tests, and to assess the added value of the BIOFIRE® SPOTFIRE® Respiratory/Sore Throat (R/ST) Panel instead of a quadriplex panel restricted to SARS-CoV-2, influenza A/B and RSV only.

STUDY DESIGN

- **Type of study:** Single-center, retrospective study at the emergency department (ED) of Poitiers University Hospital, France
- **Date:** 7th December 2023 to 15th March 2024
- **Patient population:** 1,310 adult patients (over 15 years and 3 months) with lower respiratory tract infection (LRTI) symptoms and nasopharyngeal swab (NPS) collected
- **Intervention:** Positive to the BIOFIRE SPOTFIRE test (n = 540)
- **Control:** Negative to the BIOFIRE SPOTFIRE test (n = 770)
- **Outcomes:**
  - **Primary:** Feasibility of implementing the BIOFIRE SPOTFIRE System in a real-life ED setting
  - **Secondary: Comparison between patients with positive or negative tests:** (i) need for respiratory support in ED; (ii) time from ED admission to medical decision; (iii) need for hospital admission; (iv) hospital length of stay; (v) 30-day mortality; (vi) prescription of additional lab/imaging investigations to explore impact of fast pathogen detection on patient management

RESULTS

The epidemiological results support the added diagnostic value of broad multiplex panels beyond the four usual viruses (the quadriplex panel SARS-CoV-2, *influenza* A/B, and RSV) targeted by existing point-of-care tests (POCTs). Notably, the 2023 – 2024 winter season coincided with an unusual worldwide resurgence of *Mycoplasma pneumoniae* infections.

- **Fast turnaround:** Median result time of ~37 minutes, enabling faster clinical decisions.
- **Broad syndromic coverage:** Detects 11 viruses + 4 bacteria, preventing missed diagnoses → **43% of pathogens would have been missed by quadriplex panels**.
- **Improved patient flow when positive detection:**
  - Medical decision time reduced (**380 *vs.* 431 min**).
  - Lower hospital admission rate (**65% *vs.* 78%**).
  - Shorter hospital stay (**10 *vs.* 12 days**).
- **Better outcomes:** Lower 30-day mortality (**7.8% *vs.* 14%**).
- **Antibiotic stewardship:**
  - Targeted therapy for 98% (42 of 43) of bacterial detections.
  - Reduced unnecessary macrolide/fluoroquinolone use.
- **Enhanced infection control:** 42% of patients needing isolation carried pathogens outside quadriplex targets.
- **High reliability:** 99.2% valid results; easy integration into ED workflow by trained nurses.

CONCLUSIONS

Implementation of the BIOFIRE SPOTFIRE system improved clinical decision-making, optimized treatment strategies, and strengthened isolation measures for positive patients compared to those without detected pathogens. It also supports the advantage of broader-spectrum detection over traditional quadriplex POCT use.

KEY FINDINGS

- **Fast turnaround with a median result time of ~37 minutes, which enables faster clinical decisions, added to a broad syndromic coverage (43% of pathogens would have been missed by quadriplex panels).**
- **Improved patient flow by a reduction of medical decision time, a lower hospital admission rate, a shorter hospital stay and enhanced infection control. Lower 30-day mortality is observed.**
- **Appropriate use of macrolide/fluoroquinolone at time of *M. pneumoniae* resurgence.**

BIOFIRE® SPOTFIRE® RESPIRATORY/SORE THROAT PANELS - Clinical Utility

CLICK TO ACCESS ARTICLE

ACADEMIC EMERGENCY MEDICINE
OCT 2025;0:1-6 DOI: 10.1111/ACEM.70190

Point-Of-Care Respiratory Diagnosis and Antibiotic Utilization in the Emergency Department: A Prospective Evaluation of Multiplex PCR

Meltzer A, Payette C, Heidish R, et *al*.

OBJECTIVE

To assess how the BIOFIRE® SPOTFIRE® Respiratory/Sore Throat (R/ST) Panel affects antibiotic monitoring, clinical, provider, and patient outcomes.

STUDY DESIGN

- **Type of study:** Prospective, single-center study performed at an urban academic emergency department (ED) in the US
- **Date:** March 2024 to January 2025
- **Patient population:** 200 adults presenting to the ED with suspected acute respiratory tract infection (ARTI)
- **Intervention:** Rapid multiplex polymerase chain reaction (PCR) testing using the BIOFIRE SPOTFIRE R/ST Panel
- **Control:** Prospective comparison of antibiotic prescription between patients with positive results to BIOFIRE SPOTFIRE R/ST and patients with no pathogens detected. Comparison of the antibiotic prescription rate and the ED length of stay (LOS) between patients tested with a retrospective cohort
- **Outcomes:**
  - **Primary:** Antibiotic prescribing among patients with a confirmed viral etiology
  - **Secondary:** Overall antibiotic prescribing, ED LOS, provider confidence, and patient satisfaction

RESULTS

The BIOFIRE SPOTFIRE R/ST Panel identified a viral pathogen in 92 patients (46%), most commonly influenza A (15%), rhinovirus/enterovirus (12%), and seasonal coronaviruses (8%). Bacterial pathogens were detected in 4 patients (2%), all appropriately treated with antibiotics. Patients who received antibiotics prior to the availability of the BIOFIRE SPOTFIRE R/ST Panel results were excluded from analyses of antibiotic prescribing.

Patients tested with BIOFIRE SPOTFIRE R/ST Panel – viral detections compared to no pathogen identified:

Patients with confirmed viral infections were significantly less likely to receive antibiotics than those with no detected pathogen (6.5% *vs.* 20.2%; OR 0.28; 95% CI [0.10 ; 0.68]; $p = 0.009$).

Patients tested with BIOFIRE SPOTFIRE R/ST Panel compared to patients of the retrospective cohort:

To enable comparison of antibiotic prescribing and ED LOS, a retrospective propensity-matched control cohort was constructed from a previous ARTI observational study performed at the same ED. After comparison, antibiotic prescribing rates were overall similar between experimental and control cohorts (14.9% *vs.* 12.0%; $p = 0.392$), but median predicted LOS was significantly shorter in the experimental group (4.3 *vs.* 6.5 h; OR 0.66; 95 CI [0.59 ; 0.74]; $p < 0.001$).

Patient satisfaction & provider confidence:

Among surveyed clinicians, 138 (138/182, 76%) reported feeling "confident" or "extremely confident" in their diagnostic decision-making after receiving PCR results.

Patient satisfaction was also measured and a total of 164 patients (164/178, 92%) reported high satisfaction with the timeliness of results and 115 (115/178, 65%) felt confident in their understanding of the diagnosis. Most patients indicated they would recommend both their provider (150/178, 84%) and facility (155/178, 87%).

CONCLUSIONS

Rapid point-of-care testing using the BIOFIRE SPOTFIRE R/ST Panel for ARTIs in the ED significantly reduced antibiotic prescribing among patients with confirmed viral infections, shortened ED LOS, and improved provider confidence and patient satisfaction.

KEY FINDINGS

- **Significantly less patients received antibiotics in the group with positive results with BIOFIRE SPOTFIRE R/ST Panel compared to those with no pathogen detected (6.5% *vs.* 20.2%).**
- **Median LOS was shorter for patients tested with BIOFIRE SPOTFIRE R/ST Panel compared to retrospective cohort.**
- **High provider confidence and patient satisfaction were observed with the BIOFIRE SPOTFIRE R/ST Panel.**

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MICROBIOLOGY SPECTRUM
NOV 2025; 28:E0219525 DOI: 10.1128/SPECTRUM.02195-25

Combining an antibiotic stewardship program with a 15-pathogen viral panel to reduce inappropriate antibiotic prescribing

Arnold C G, Furtado T, Bang H, et *al.*

OBJECTIVE

To evaluate the effect of the BIOFIRE® SPOTFIRE® Respiratory (R) Panel, a 15-pathogen panel, with integrated antimicrobial stewardship program (ASP) interventions on antibiotic prescribing in a community urgent care setting in the Southeast US.

STUDY DESIGN

- **Type of study:** Prospective cohort study in the Southeast US (Louisiana)
- **Date:** June to August 2024
- **Patient population:** 296 adults with acute respiratory tract infections (ARTI) who presented to an urgent care
- **Intervention:** Nasopharyngeal swab on BIOFIRE SPOTFIRE R Panel
- **Control:** A randomly selected, seasonally matched, historic usual care group of 600 patients seen for ARTI, using influenza and/or SARS-CoV-2 antigen tests
- **Outcomes:**
  - **Primary:** Number of participants receiving prescriptions for antibiotics and steroids after intervention as well as the number receiving an inappropriate antibiotic
  - **Secondary:** Number of respiratory pathogens identified by the BIOFIRE SPOTFIRE test, chest radiograph utilization, symptom resolution, and unscheduled medical visits within 7 days

RESULTS

The total number of patients with a positive BIOFIRE SPOTFIRE test result was 154 (52%), including 5 (3.2%) that tested positive for more than one pathogen.

Patients in the post-intervention cohort were **less likely to receive antibiotics** (adjusted odds ratio (aOR) 0.50; 95% CI [0.36 ; 0.68]; $p < 0.0001$). The rate of antibiotic prescribing was 38.2% prior to intervention and 24.3% post-intervention; a **difference of 13.9%** (95% CI [7.4% ; 20.3%]). **Inappropriate prescribing also decreased after intervention** (aOR 0.40; 95% CI [0.28 ; 0.57]; $p < 0.0001$). Patients were also **less likely to receive steroids post-intervention** (aOR 0.55; 95% CI [0.39 ; 0.78]; $p = 0.0008$). The rate of steroid prescribing was 29.0% pre-intervention *vs.* 17.9% post-intervention; **difference of 11.1%** (95% CI [5.2% ; 17.0%]).

Prior to intervention, 12 (2%) chest radiographs were ordered, and 2 (16.7%) were positive for pneumonia. Post-intervention, 15 (5.1%) chest radiographs were ordered, and seven (46.7%) of these were positive. Although the trends observed in post-intervention ordering behavior appear encouraging, no statistical difference was evaluated.

On a scale of 1 to 5 (1, less confident; 5, more confident), **89% of the clinicians (131/147) selected 4 or 5 points in case of not prescribing antibiotics after BIOFIRE SPOTFIRE R Panel results**.

CONCLUSIONS

Combining a BIOFIRE SPOTFIRE R Panel with an antibiotic stewardship program significantly reduced overall antibiotic prescribing (24.3% *vs.* 38.2%) and inappropriate antibiotic use (15.9% *vs.* 30.8%) in a community urgent care setting. These findings demonstrate that integrating rapid molecular diagnostics with stewardship interventions can effectively improve prescribing practices and support ASP in outpatient care.

KEY FINDINGS

- **Combining point-of-care (POC) multiplex testing with ASP interventions significantly reduces use of steroids and both overall and inappropriate antibiotic prescribing in urgent care.**
- **Supports broader adoption of molecular POC testing as part of outpatient antimicrobial stewardship strategies.**

BIOFIRE® SPOTFIRE® RESPIRATORY/SORE THROAT PANELS - Clinical Utility

Table 1. Difference between pre- and post-implementation cohort for antibiotics and steroid prescription
Adapted from Arnold CG, et *al*. *Microbiology Spectrum.* 2025;28:e0219525.

	PRE-IMPLEMENTATION	POST-IMPLEMENTATION	DIFFERENCE	95% CI
Antibiotic prescribing	38.2%	24.3%	13.9%	7.4% ; 20.3%
Steroid prescribing	29.0%	17.9%	11%	5.2% ; 17%

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ANAESTHESIA, CRITICAL & PAIN MEDICINE
DEC 2023;42(6):101300 DOI: 10.1016/J.ACCPM.2023.101300

Performance evaluation of a PCR panel (FilmArray® Pneumonia *Plus*) for detection of respiratory bacterial pathogens in respiratory specimens: A systematic review and meta-analysis

Moy AC, Kimmoun A, Merkling T, et *al*.

OBJECTIVE

To evaluate BIOFIRE® FILMARRAY® Pneumonia *plus* (PN*plus*) Panel performance for the detection of 15 bacteria from respiratory samples.

STUDY DESIGN

- **Type of study:** Systematic review and meta-analysis
- **Date of publication:** 1st January 2010 to 31th December 2022
- **Data base:** PubMed and EMBASE
- **Inclusion criteria:** BIOFIRE FILMARRAY PN*plus* Panel performance on respiratory samples compared to the reference standard, bacterial culture
- **Outcomes:** Overall diagnostic accuracy with sensitivity and specificity for the detection of typical respiratory bacteria

RESULTS

The electronic search identified 10,317 articles; among these, **30 studies** met the inclusion criteria. This study included **8,453 patients** from 17 countries, **8,968 respiratory samples** of which 3,904 were deep samples including bronchoalveolar lavage (BAL) and bronchial aspirates, 1,078 endotracheal aspirates, 455 sputa and 3,537 unspecified. Fourteen studies were performed in the intensive care unit (ICU), seven in a mixed unit (ICU and conventional service). Twenty-two studies evaluated this test based on a clinical suspicion of lower respiratory tract infection (LRTI).

Primary outcome: Global diagnostic performance. The BIOFIRE FILMARRAY PN*plus* Panel showed **94% sensitivity** (50 - 100% range) and **98% specificity** (93 - 100% range across studies) for the 15 typical bacteria of the Panel.

For common bacteria: *Staphylococcus aureus* and *Pseudomonas aeruginosa* were the most frequently detected bacteria by both methods and their diagnostic performances were both high on the BIOFIRE FILMARRAY PN*plus* Panel. Poor performances were noted for *Klebsiella oxytoca* with a sensitivity of 74% and *Haemophilus influenzae* with a specificity of 91%.

For antimicrobial resistance (AMR) genes: 19 studies reported data. 463 resistance genes were detected by both the BIOFIRE FILMARRAY PN*plus* Panel and culture, of which, **55% concerned methicillin-resistant *Staphylococcus aureus* (MRSA)**. Moreover, the overall antimicrobial sensitivity and specificity on the BIOFIRE FILMARRAY PN*plus* Panel were 91% and 99% respectively.

For separate sample types: Deep respiratory samples (BAL and bronchial aspirates) showed a sensitivity and specificity respectively of 93% and 99%. For the endotracheal aspirate analysis, the sensitivity and specificity were respectively 95% and 96%. Finally, the sensitivity and specificity for the sputa group were respectively 86% and 95%.

Bacteria not included on the BIOFIRE FILMARRAY PN*plus* Panel: Bacteria not included on the BIOFIRE FILMARRAY PN*plus* Panel were detected at a rate of 9.3% in culture. The main identified pathogenic bacteria were *Stenotrophomas maltophilia* (23.5%), *Citrobacter koseri* (10%), and *Morganella morganii* (5.7%).

Turnaround time (TAT): Four studies compared the BIOFIRE FILMARRAY PN*plus* Panel and culture TAT. The **TAT was significantly different in favor of the BIOFIRE FILMARRAY PN*plus* Panel** - between 2.3 to 6.2h for the BIOFIRE FILMARRAY PN*plus* Panel compared to between 25.2 to 48h for culture.

Most studies included exhibited low bias risk and high applicability. Patient selection showed that 80% had a low risk of bias but high applicability issues, coming mainly from ICU patients with COVID-19 or suspected LRTI. Additionally, 33% of studies introduced bias risk in flow and timing due to frozen samples, leading to delayed interpretation. The study excluded analysis for viruses and atypical bacteria and had a limited number of studies for antimicrobial resistance genes, which might limit the generalizability of the findings.

CONCLUSIONS

The BIOFIRE FILMARRAY PN*plus* Panel demonstrated high diagnostic accuracy (94% sensitivity, 98% specificity) for detecting respiratory bacterial pathogens across diverse sample types and clinical settings. Its fast turnaround time and reliable performance may support its use as a valuable tool to guide antibiotic therapy in suspected LRTIs.

KEY FINDINGS

- **In this meta-analysis of 30 studies with 8,968 samples, the BIOFIRE FILMARRAY PN*plus* Panel showed robust diagnostic performance for typical bacteria (94% sensitivity, 98% specificity) compared to bacterial culture.**
- **The BIOFIRE FILMARRAY PN*plus* Panel is reliable and fast and may serve as a valuable adjunct for bacterial documentation of LRTIs for guiding antibiotic therapy.**

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BIOMEDICINES
FEB 2025;13(2):360 DOI: 10.3390/BIOMEDICINES13020360

Ten-Year Evaluation of Ventilator-Associated Pneumonia (VAP) According to Initial Empiric Treatment: A retrospective Analysis Using Real-World Data

Rodríguez A, Berrueta J, Huertas R, et *al*.

OBJECTIVE

To assess variations in crude intensive care unit (ICU) mortality among patients with ventilator-associated pneumonia (VAP) over a 10-year observation period and identify associated risk factors, examine potential variations in the etiology of VAP and assess the incidence of inappropriate empirical antibiotic treatment (IEAT), IEAT-associated microorganisms and their impact on mortality.

STUDY DESIGN

- **Type of study:** Retrospective observational single-center study in Spain
- **Date:** 3 periods between 2014 and 2024
  - **Pre-COVID period:** 2014 to 2018 (group 1, n = 47)
  - **COVID-19 period:** 2019 to 2021 (group 2, n = 96)
  - **Post-COVID/post-BIOFIRE® FILMARRAY® Pneumonia (PN) Panel implementation period:** 2022 to 2024 (group 3, n = 77)
- **Patient population:** 220 ICU adult patients with bacterial VAP
- **Control:** Pre-COVID and COVID-19 group
- **Outcomes:** All-cause mortality in the ICU

RESULTS

Study population:

- The median **Sequential Organ Failure Assessment (SOFA) score as well as C-reactive protein (CRP) levels were higher in the 1st group**. However, **the proportion of patients with hypertension and immunosuppression was lower in the 1st group**.
- The groups were similar regarding every other parameter.

Etiology of VAPs:

- There was **no significant difference** regarding the microorganisms identified. The **most frequently identified bacteria** were Gram-negative bacilli: ***Pseudomonas aeruginosa*** and ***Klebsiella* spp**. in the 3 groups.

Antibiotic treatment:

- The overall initial empiric treatment was meropenem (39.6%), piperacillin tazobactam (34.8%) or ertapenem (22.5%).
- 4.5% (10/220) of **patients received IEAT, with no statistical differences** between the groups (most common pathogens associated: *S. maltophilia* and *P. aeruginosa)*.
- 71.4% (150/210) of overall patients receiving appropriate empiric antibiotic treatment had treatment adjustments, 92% (138/150) of adjustments were de-escalation, 8% (12/150) were a reduction in the number of antibiotics.
- There was **no difference in treatment adjustments** between groups 1 and 2 ($p = 0.18$), but they significantly decreased ($p < 0.05$) in the 3rd group (77.8% *vs.* 66.7% *vs.* 56.9% respectively).

Primary outcome: ICU crude mortality rate

- The overall ICU mortality rate was 33.6% (74/220).
- **For patients receiving adequate treatment, the mortality rate decreased over the years:** 42.2% (19/45, group 1), 37.6% (35/93, group 2) and 22.2% (16/72, group 3).
- The impact of variables on mortality was assessed by a multivariate regression model. **The use of BIOFIRE FILMARRAY PN Panel was associated with a lower mortality rate** (OR: 0.23, 95% CI [0.07; 0.68]), such as mean arterial pressure (OR: 0.94, 95% CI [0.69; 0.99]). Age was associated with higher mortality rate (OR: 1.04, 95% CI [1.01; 1.08]), such as group 2, in correlation with the COVID-19 pandemic (OR: 2.8, 95% CI [1.1 ; 7.4]). Other variables had no significant impact on mortality.

CONCLUSIONS

Despite stable VAP etiology and empirical treatment practices, the implementation of the BIOFIRE FILMARRAY PN Panel was associated with a significant reduction in ICU mortality among VAP patients from 42.2% to 22.2% over the study period.

KEY FINDINGS

- **The mortality rate of VAP patients decreased over the years (42.2% in group 1, 37.6% in group 2, 22.2% in group 3).**
- **Etiology, IEAT and empirical antimicrobial treatment of VAPs did not significantly change between 2014 and 2024.**
- **The use of BIOFIRE FILMARRAY PN Panel was associated with lower ICU mortality rate in VAP patients.**

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JAMA NETWORK OPEN
MAR 2024;7(3):E240830 DOI: 10.1001/JAMANETWORKOPEN.024.0830

Diagnostic Stewardship in Community-Acquired Pneumonia With Syndromic Molecular Testing: A Randomized Clinical Trial

Markussen DL, Serigstad S, Ritz C, et *al*.

OBJECTIVE

To investigate the impact of a fast syndromic polymerase chain reaction (PCR) based panel on pathogen-directed treatment in adult emergency department (ED) patients with suspected community-acquired pneumonia (CAP).

STUDY DESIGN

- **Type of study:** Parallel-arm, single-blinded, single-center, randomized clinical superiority trial in Bergen (Norway)
- **Date:** 25th September 2020 to 21th June 2022
- **Patient population:** 374 patients with suspected CAP (excluding individuals with severe bronchiectasis, cystic fibrosis, recent hospitalization, or inability to provide a respiratory sample) randomized in a 1:1 ratio
- **Intervention:** Tested with the BIOFIRE® FILMARRAY® Pneumonia *plus* (PN*plus*) Panel in addition to standard of care (SOC) microbiological diagnostics
- **Control:** SOC alone
- **Outcomes:**
  - The assessment of the provision of pathogen-directed treatment based on microbiological test results
  - The time to provision of such treatment within 48 hours after randomization

RESULTS

Primary outcome: Intention-to-treat analysis

- Both arms showed similar distributions of patient characteristics.
- 48 hours after randomization, **more patients received pathogen-directed treatment** in the intervention arm compared to the SOC arm (**35.3%** (66/187) ***vs.* 13.4%** (25/187), $p < 0.001$).
- The **median time to provision of pathogen-directed treatment was notably shorter** in the intervention arm (**34.5h *vs.* 43.8h**), resulting in a **mean difference of -9.4 hours** (95% CI [12.7h ; -6.0h], $p < 0.001$).

Primary outcome: Subgroup CAP analysis

- Within the intervention arm, a subgroup analysis revealed that **more patients diagnosed with CAP received pathogen directed treatment within 48 hours** in the intervention arm (**47.4%** (46/97) ***vs.* 15.5%** (16/103), $p < 0.01$).
- **The median time to provision** of pathogen-directed treatment differed significantly between the intervention and SOC arms (respectively **29.9h *vs.* 42.3h**), resulting in a **mean difference of -12.3 hours** (95% CI [-17.3h ; -7.3h], $p < 0.001$).

Clinical outcomes:

- **Length of stay** was similar with a difference of 0.15 days ($p = 0.67$).
- **Readmission rates** and **mortality rates at 30 and 90 days** were not significant between the intervention and SOC arms.

CONCLUSIONS

The use of the BIOFIRE FILMARRAY PN*plus* Panel significantly increased the proportion of patients receiving pathogen-directed treatment (35.3% *vs.* 13.4%) and reduced the median time to targeted therapy by 9.4 hours compared to standard care. These findings demonstrate the Panel's potential to accelerate accurate microbiological diagnosis and improve antimicrobial stewardship in community-acquired pneumonia management.

KEY FINDINGS

- **The use of the BIOFIRE FILMARRAY PN*plus* Panel led to faster results by reduced time to pathogen-directed treatment in both intention-to-treat and subgroup analyses for hospitalized patients with suspected CAP in the ED.**
- **The use of the BIOFIRE FILMARRAY PN*plus* Panel led to more targeted microbial treatment by increasing the proportion of patients who received pathogen-directed treatment.**

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CRITICAL CARE
AUG 2025;29(1):379 DOI: 10.1186/S13054-025-05623-0

Impact of syndromic molecular diagnostics on antimicrobial adequacy and time to therapy in critically ill patients with pneumonia: a systematic review and meta-analysis of randomized trials

de Albuquerque Pessoa dos Santos Y, Tomazini BM, Claro dos Santos MH, et *al*.

OBJECTIVE

To assess how syndromic polymerase chain reaction (PCR) based diagnostics influence mortality outcomes and antibiotic use management.

STUDY DESIGN

- **Type of study:** A systematic review and meta-analysis of randomized controlled trials (RCTs)
- **Date:** From inception to 16th July 2025
- **Data base:** PubMed, Embase, and Cochrane CENTRAL (manual searches of reference lists were also conducted)
- **Patient population:** Predominantly adult intensive case unit (ICU) patients with severe community-acquired, hospital-acquired, or ventilator-associated pneumonia. Data were synthesized using random-effects models and included five randomized controlled trials comprising 2,466 patients
- **Intervention/observation:** PCR-based molecular diagnostics
- **Control:** Standard culture techniques
- **Outcomes:**
  - **Primary outcome:** In-hospital mortality
  - **Secondary outcomes:** Adequacy of initial antimicrobial therapy and time to effective antibiotic administration

RESULTS

After a screening of 1,030 publications, only **five studies** followed the eligibility and inclusion criteria. Four of these RCT used the BIOFIRE® FILMARRAY® Pneumonia Panel as the PCR test.

In the pooled analysis, in-hospital mortality did not differ significantly between patients managed with syndromic PCR and those receiving conventional microbiological testing (risk ratio 1.04; 95% CI [0.90 ; 1.21]; $p = 0.57$; $I^2 = 0\%$). By contrast, **adequacy of initial antimicrobial therapy was significantly higher in the syndromic PCR group** (risk ratio 1.82; 95% CI [1.10 ; 3.00]; $p = 0.02$; $I^2 = 97\%$). Additionally, **time to effective antibiotic administration was significantly reduced with syndromic testing**, with a pooled mean difference of −27.98h (95% CI [-46.07 ; -9.89]; $p = 0.002$; $I^2 = 94\%$).

CONCLUSIONS

Syndromic PCR-based diagnostics did not reduce in-hospital mortality among critically ill patients with pneumonia but significantly improved the adequacy of initial antimicrobial therapy and shortened time to effective treatment. These findings support their role as a complementary tool for antimicrobial stewardship rather than a standalone intervention for improving survival.

KEY FINDINGS

- **First meta-analysis to systematically evaluate clinical outcomes of syndromic PCR diagnostics.**
- **Syndromic PCR diagnostics were associated with improved adequacy of initial antimicrobial therapy and faster initiation of effective treatment but did not reduce in-hospital mortality in critically ill patients with pneumonia.**

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CRITICAL CARE
AUG 2025;29(1):352 DOI: 10.1186/S13054-025-05428-1

Cost-effectiveness of rapid, ICU-based, syndromic PCR in hospital-acquired pneumonia: analysis of the INHALE WP3 multi-centre RCT

Wagner AP, Enne VI, Gant V, et *al*.

OBJECTIVE

The aim of this economic analysis of the INHALE WP3 randomized controlled trial (RCT) was to estimate whether implementing a fast, syndromic PCR test for pneumonia patients directly in the intensive care unit (ICU) is cost-effective compared to standard care, within the context of the original National Health Service (NHS) controlled trial. The original INHALE WP3 RCT conducted PCR testing by trained healthcare professionals in the ICU rather than sending samples to a laboratory, an application outside of cleared indications for use. The co-primary outcomes of the original RCT were antibiotic stewardship at 24 hours (*i.e.*, appropriate antibiotic use early after diagnosis) and clinical cure at 14 days. In this economic analysis study, data on resource use and costs, including ICU stay and PCR testing, were collected.

STUDY DESIGN

- **Type of study:** Cost-effectiveness study
- **Date:** 2020 to 2021
- **Patient population:** Target sample size of 552 patients in ICU with hospital-associated pneumonia (HAP)/ventilator-associated pneumonia (VAP) and empiric antibiotic therapy
- **Intervention/Observation:** BIOFIRE® FILMARRAY® Pneumonia (PN) Panel
- **Control:** Standard of care (SOC)
- **Outcomes:** INHALE WP3 outcome measures were used to inform two separate cost-effectiveness studies that were carried out using regression models adjusting for site. Sensitivity analyses explored assumptions and sub-group analyses explored differential impacts

RESULTS

A total of 529 patients were included in the economic evaluation.

A lower total ICU cost (including PCR costs) was found in the intervention (PCR-guided therapy) group. Base case costs were £40,951 for SOC compared with **£33,149 for the intervention group, a difference of −£7,802** (95% CI [−£15,696 ; £92]).

For antibiotic stewardship, the **PCR-guided therapy was both less costly and more effective** than routine patient management.

For clinical cure, it was not found that PCR-guided therapy is cost-effective due to fewer cases being cured in the intervention group.

CONCLUSIONS

Fast ICU-based syndromic PCR testing for HAP and VAP reduced overall ICU costs and improved antibiotic stewardship compared to standard care. However, it did not demonstrate cost-effectiveness for clinical cure, indicating economic benefits are limited to stewardship outcomes rather than patient recovery.

KEY FINDINGS

- **Lower average ICU costs were found with the BIOFIRE FILMARRAY PN Panel.**
- **Overall, while the BIOFIRE FILMARRAY PN Panel was cost-effective for antibiotic stewardship (particularly improving appropriate antibiotic use at 24 hours), for clinical cure, the economic analysis showed that the intervention was generally less costly but also less effective, resulting in a low probability of cost-effectiveness.**
- **The most impactful item of resource use was the cost of ICU stays, and that differences in this item far exceeded the unit cost of the BIOFIRE FILMARRAY PN Panel, and to a lesser extent, antimicrobial therapy costs.**

BIOFIRE® FILMARRAY® PNEUMONIA PANELS – Clinical Utility

Table 1. Unadjusted differences in mean cost (intervention minus control) with 95% confidence intervals
Adapted from Wagner AP, et *al*. *Critical Care.* 2025;29(1):352.

MEAN COST (£)	CONTROL	INTERVENTION	DIFFERENCE (£)	95% CI	
PN Panel	0	198	198	196	200
Base case	40,951 (n = 261)	33,149 (n = 268)	-7,802	-15,696	92
Total cost	75,998 (n = 212)	64,459 (n = 216)	-11,539	25,295	2,217

Base case = PN Panel + ICU; Total cost = PN Panel + ICU + general admission
The results observed are independent of the mortality
CI: confidence interval ; PN Panel: BIOFIRE FILMARRAY PN Panel

Table 2. Economic evaluation of stewardship and cure with sensitivity analyses
Adapted from Wagner AP, et *al*. *Critical Care.* 2025;29(1):352.

ECONOMIC ANALYSIS		TREATMENT EFFECT (INTERVENTION *VS.* CONTROL)		95% CI		INTERPRETATION
Stewardship	Base case (Control N = 256; Intervention N = 263)	Cost (£) (diff in means)	-7,373	-14,905	307	Intervention preferred
		Steward OR	2.51	1.76	3.79	
		Steward (diff in prop)	0.20	0.12	0.28	
	Total cost = PN Panel + ICU + spell income (Control N = 208; Intervention N = 212)	Cost (£) (diff in means)	-10,901	-23,743	1,834	Intervention preferred
		Steward OR	3.18	2.18	5.12	
		Steward (diff in prop)	0.24	0.16	0.33	
Clinical cure	Base case (Control N = 256; Intervention N = 263)	Cost (£) (diff means)	-7,147	-15,198	27	Intervention less costly, but less effective
		Cure OR	0.689	0.461	0.985	
		Cure (diff in pop)	-0.08	-0.17	-0.00	
	Total cost = PN Panel + ICU + spell income (Control N = 210; Intervention = 212)	Cost (£) (diff means)	-10,995	-23,843	1,234	Intervention less costly, but less effective
		Cure OR	0.714	0.466	1.04	
		Cure (diff in pop)	-0.08	-0.16	0.01	

CI: confidence interval; Diff: difference; ICU: intensive care unit; OR: adjusted odds ratio comparing BIOFIRE FILARRAY PN Panel to control; spell income: total revenue received for an entire hospital stay

BIOFIRE®

BLOOD CULTURE IDENTIFICATION 2 PANEL

BIOFIRE® BLOOD CULTURE IDENTIFICATION 2 PANEL – Clinical Utility

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CLINICAL INFECTIOUS DISEASE
AUG 2024;79(2):502-515 DOI:10.1093/CID/CIAE234

Rapid Diagnostic Test and Antimicrobial Stewardship Programs for the Management of Bloodstream Infection: What is their Relative Contribution to Improving Clinical Outcomes? A Systematic Review and Network Meta-Analysis

Peri AM, Chatfield MD, Ling W, et *al*.

OBJECTIVE

To compare the clinical impact of rapid diagnostic tests (RDTs) to conventional blood cultures (BC) with and without antimicrobial stewardship programs (ASP), with respect to mortality, length of stay (LOS), and time to optimal therapy (TOT) among patients with bloodstream infection (BSI).

STUDY DESIGN

- **Type of study:** Systematic literature review and meta-analysis
- **Patient population:** Patients with BSI (n = 25,682) from 88 studies
- **Inclusion criteria:** The review included randomized controlled trials (RCTs) and quasi-experimental studies that compared the clinical impact of RDTs and conventional BC, both with and without ASP
- **Outcomes:** Mortality, LOS and TOT

RESULTS

A total of 88 studies were included. The study confirmed that use of RDTs combined with ASPs leads to a significant reduction in mortality compared to conventional BCs alone. This benefit is also observed when comparing RDT + ASP to BC + ASP.

- **RDT + ASP *vs.* BC alone:** Significant reduction in mortality (odds ratio (OR), 0.72; 95% CI [0.59 ; 0.87]).
- **RDT + ASP *vs.* BC + ASP:** Significant reduction in mortality (OR, 0.78; 95% CI [0.63 ; 0.96]).

RDTs with ASPs significantly reduced TOT compared to BCs alone and BCs with ASPs. This reduction in TOT is crucial for improving patient outcomes and reducing the use of broad-spectrum antibiotics.

- **RDT + ASP *vs.* BC alone:** Reduced TOT by 29 hours (95% CI, [−35 ; −23]).
- **RDT + ASP *vs.* BC + ASP:** Reduced TOT by 18 hours (95% CI, [−27 ; −10]).
- **RDT + ASP *vs.* RDT alone:** Reduced TOT by 12 hours (95% CI, [−20 ; −3]).

The study found a limited impact of RDTs and ASPs on LOS. While RDT + ASP reduced LOS compared to BC alone, no significant differences were observed between other groups.

- **RDT + ASP *vs.* BC alone:** Reduction in LOS (OR, 0.91; 95% CI, [0.84 ; 0.98]).

CONCLUSIONS

The implementation of RDTs combined with ASP significantly improves survival outcomes in patients with BSI, even in settings already utilizing conventional BCs with ASP. The findings support the Infectious Diseases Society of America (IDSA) recommendation to use RDTs within ASPs for managing BSIs to optimize antimicrobial therapy and improve clinical outcomes. The study suggests that even institutions with effective ASPs in place can benefit from the introduction of RDTs.

KEY FINDINGS

- **A significant reduction in mortality by 28% and TOT by -29h associated with the use of RDTs + ASP versus BC alone.**
- **Survival benefits of RDT *vs.* BC when both are embedded within ASP, showing an incremental value of RDT.**
- **Even centers with efficient ASP in place may benefit from the introduction of RDTs.**

BIOFIRE® BLOOD CULTURE IDENTIFICATION 2 PANEL – Clinical Utility

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INTERNATIONAL JOURNAL OF ANTIMICROBIAL AGENTS
OCT 2024;64(4):107300 DOI: 10.1016/J.IJANTIMICAG.2024.107300

Reduced mortality with antimicrobial stewardship guided by BioFire FilmArray Blood Culture Identification 2 panel in critically ill patients with bloodstream infection: A retrospective propensity score-matched study

Tseng HY, Chen CL, Chen WC, et *al*.

OBJECTIVE

To investigate whether using the BIOFIRE® Blood Culture Identification 2 (BCID2) Panel leads to timely antimicrobial therapy and improves patient outcomes in critically ill patients with bloodstream infection (BSI).

STUDY DESIGN

- **Type of study:** A single-center retrospective observational study conducted in Taiwan
- **Date:** July 2021 to August 2023
- **Patient population:** Critically ill adult patients presenting with BSI and admitted to the intensive care unit with initially inappropriate antimicrobial therapy
- **Observation:** Receiving treatment adjustments using BIOFIRE BCID2 Panel
- **Control:** Receiving treatment adjustments using standard of care (SOC) testing
- **Analysis:** Two different models
  - **Model 1:** Propensity score matching (PSM) was used to eliminate sub-group differences related to pathogen group (Gram-negative, Gram-positive, polymicrobial) and Sequential Organ Failure Assessment (SOFA) score on day of BSI onset
  - **Model 2:** PSM was performed after excluding patients who died within two days of BSI onset to eliminate bias associated with delayed antimicrobial therapy (time-window bias)
- **Outcomes:**
  - **Primary:** Mortality at day 28 post-BSI onset
  - **Secondary:** Time from BSI onset to appropriate antimicrobial therapy

RESULTS

- A total of **181 patients receiving inappropriate therapy** were identified (**148** in the **SOC** group and **33** in the **BCID2** group). After PSM, **66** and **46** patients were respectively included in Model 1 and Model 2 analyses (**48** in the SOC group and **18** in the BIOFIRE BCID2 group for Model 1, **29** in the SOC group and **17** in the BCID2 group for Model 2).
- Pneumonia-related BSI was more prevalent in the SOC group in Model 1 (60.4% *vs.* 44.4%), and the disease severity according to Pittsburgh bacteremia score was higher in the BCDI2 group Model 2 (8 *vs.* 6).
- **Gram-negative bacteria accounted for approximately 80%** of the detected pathogens. Antimicrobial-resistant pathogens were responsible for **66.9%** of bloodstream infection. Drug resistant bacteria were the primary cause of **inappropriate antimicrobial treatment**, accounting for **48.6%** of such cases.
- In Model 1, **50%** of the BIOFIRE BCID2 group received treatment adjustment based on the detected bacterial strains, the remaining **50%** received adjustments based on antimicrobial resistance (AMR) gene detection.
- The **time to appropriate antimicrobial therapy was significantly shorter in the BCDI2 group** in both Model 1 (40.8h *vs.* 74.0h, $p = 0.008$, $\Delta = -33.2$h) and Model 2 (42.8h *vs.* 68.9h, $p = 0.027$, $\Delta = -26.1$h) analyses.
- The day-28 mortality rate was higher in patients receiving inappropriate antimicrobial therapy than in those receiving correct antimicrobial therapy. **The mortality rate at 28 days post-BSI onset was significantly lower in the BCID2 group** in both Model 1 (**27.8% *vs.* 77.1%**, $p < 0.001$) and Model 2 (**23.5% *vs.* 58.6%**, $p = 0.021$) analyses.

CONCLUSIONS

This is the first study to assess the real-world survival benefits of BIOFIRE BCID2 panel in critically ill BSI patients receiving inappropriate antimicrobial therapy.

For both models, BIOFIRE BCID2-guided antimicrobial stewardship (AMS) significantly reduced time to appropriate therapy and was associated with markedly lower 28-day mortality compared to SOC in critically ill patients with BDI. These findings highlight the clinical value of rapid molecular diagnostics for improving outcomes in high antimicrobial resistance settings.

KEY FINDINGS

- **BIOFIRE BCID2-guided AMS was associated with a notable reduction in time to pathogen identification and time to implement appropriate antimicrobial therapy.**
- **BIOFIRE BCID2-guided AMS was associated with a significant decrease in day-28 mortality compared to SOC.**

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JOURNAL OF MICROBIOLOGY, IMMUNOLOGY, AND INFECTION
AUG 2024;57(4):580-593 DOI: 10.1016/J.JMII.2024.06.004

The real-world impact of BioFire FilmArray Blood Culture Identification 2 panel on antimicrobial stewardship among patients with bloodstream infections in intensive care units with a high burden of drug-resistant pathogens

Chen HY, Tseng HY, Chen CL, et *al*.

OBJECTIVE

To compare the performance of BIOFIRE® Blood Culture Identification 2 (BCID2) Panel with culture regarding pathogen identification and antimicrobial resistance profiling and assess the impact of the BIOFIRE BCID2 Panel on antimicrobial treatment stewardship. Attending intensivists administered empiric antibiotic therapy for individuals presenting with bloodstream infection (BSI) and adjusted it based on the results obtained from BIOFIRE BCID2 and final conventional culture results.

STUDY DESIGN

- **Type of study:** Single-center retrospective observational study
- **Date:** July 2021 to August 2023
- **Patient population:** Critically ill adult intensive care unit (ICU) patients with BSI and positive blood culture
- **Observation:** Use of the BIOFIRE BCID2 Panel for fast identification of pathogens and antimicrobial resistance genes directly from positive blood cultures
- **Control:** Conventional blood culture methods including microbial identification via matrix-assisted laser desorption ionization–time-of-flight mass spectrometry and antimicrobial susceptibility testing (AST) using BD Phoenix™ M50 system
- **Outcomes:**
  - **Primary:** Concordance of BIOFIRE BCID2 results with conventional culture and AST; impact on antimicrobial stewardship
  - **Secondary:** Improvement of clinical outcome (time to diagnostic results, concordance in genotype-phenotype for resistance markers, adjustment or confirmation of antimicrobial therapy, length of stay (LOS))

RESULTS

Study population:

- Intra-abdominal infections (**33.6%**), pneumonia (**30.1%**), and urinary tract infections (**11.5%**) were the most common infection foci. The median LOS in the ICU was 13 [8 ; 22.5] days.

Pathogen identification performance:

- The BIOFIRE BCID2 Panel results were positive in **92.2%** (**119/129**) cases, with single-bacteria detection in 70.5% of cases.
- Top four identified bacteria: *Klebsiella pneumoniae* (**31%**, **40/129**), *Escherichia coli* (**16.3%**, **21/129**), *Acinetobacter calcoaceticus-baumanii complex* (**10%**, **3/129**) and *Pseudomonas aeruginosa* (**10%**, **13/129**).
- BIOFIRE BCID2 Panel specificity and negative predictive value were > 90% for all pathogen species; sensitivity was > 90% for *K. pneumoniae*, *E. coli* and *A. calcoaceticus-baumanii complex*, 78% for *P. aeruginosa*, 86% for *Enterococcus faecium* and 80% for *Staphylococcus aureus*.
- Time to results was significantly faster with BIOFIRE BCID2 Panel in comparison with traditional culture-based identification with complete AST: **46.2** (Q1:**30.4**, Q3:**56.7**) *vs.* **86.9** (Q1:**70.6**, Q3:**110.2**) hours, (Δ = 40.7 hours), $p < 0.001$.

Impact on antimicrobial treatment stewardship:

- **46.2%** (**66/143**) of culture-identified pathogens were drug-resistant: 57.1% carbapenem-resistant *K. pneumoniae* (CRKP), 100% *A. calcoaceticus-baumannii* complex, 70% methicillin-resistant *S. aureus* (MRSA), and 100% vancomycin-resistant *Enterococcus* (VRE).
- BIOFIRE BCID2 Panel demonstrated **100% concordance in genotype-to-phenotype** correlation in antimicrobial resistance (AMR) for CRKP, carbapenem-resistant *E. coli*, MRSA, and VRE. The concordance rates were lower for extended spectrum beta-lactamase (ESBL) strains: **71.4%** and **85%** for *K. pneumoniae* and *E. coli*.
- **40.5%** of patients were initially receiving inadequate antimicrobial therapy. BIOFIRE BCID2 Panel results led to treatment adjustment or confirmation in **55.4%** of cases, making this panel a valuable tool to allow treatment adjustments.
- Treatment de-escalation was observed in only 4 cases, while BIOFIRE BCID2 Panel results could have potentially led to more treatment de-escalations.

BIOFIRE® BLOOD CULTURE IDENTIFICATION 2 PANEL –
Clinical Utility

CONCLUSIONS

In the ICU, the BIOFIRE BCID2 Panel significantly accelerated pathogen identification and resistance gene detection in cases of critically ill patients with bloodstream infections, demonstrating strong concordance with conventional methods. Its integration into clinical workflows also supported antimicrobial stewardship in over half of the cases, reinforcing its value for timely and targeted therapeutic decisions.

KEY FINDINGS

- **BIOFIRE BCID2 Panel demonstrated 100% concordance in genotype-to-phenotype correlation in AMR for CRKP, carbapenem-resistant *E. coli*, MRSA, and VRE.**
- **Antimicrobial therapy was optimized and confirmed in 55.4% of patients after obtaining BIOFIRE BCID2 Panel result.**

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MICROBIOLOGY SPECTRUM
JAN 2024;12(1):E0313123 DOI: 10.1128/SPECTRUM.03131-23

Comparative analysis of a rapid diagnostic test and scoring tools for ESBL detection in *Enterobacterales* bloodstream infections for optimizing antimicrobial therapy

Andrews SR, Timbrook TT, Fisher MA, et *al*.

OBJECTIVE

To validate the usage of the BIOFIRE® Blood Culture Identification 2 (BCID2) Panel with the included CTX-M target in predicting ceftriaxone (CTX) susceptibility, and compare its performance against two extended-spectrum beta-lactamase (ESBL) diagnostic scoring tools (Augustine et *al*. and Lee et *al*. clinical risk tools to predict ESBL bloodstream infection (BSI)).

STUDY DESIGN

- **Type of study:** A retrospective observational study in the University of Utah Health system in the US
- **Date:** April 2021 to January 2023
- **Patient population:** 356 adult patients with BSI caused by selected *Enterobacterales* (*Escherichia coli*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, *Proteus* spp., or *Salmonella* spp.)
- **Intervention:** Switch empiric CTX to carbapenem 24h after blood culture (BC) draw if CTX-M was detected by the BIOFIRE BCID2 Panel, the ESBL prediction score by Augustine et *al*. was ≥ 3, or the ESBL prediction score by Lee et *al*. was ≥ 2
- **Control:** Patients who continued on empiric CTX treatment
- **Outcomes:**
  - Predicted CTX susceptibility by the determination of the sensitivity, specificity, positive and negative predictive value of each method
  - Evaluation of the theoretical number of patients who were unnecessarily escalated to a carbapenem or undertreated with CTX

RESULTS

- Among 356 patients, CTX resistance was observed in 41 (**11.5%**) isolates. The majority of blood cultures were drawn in the emergency department (ED) (219/356, 65.1%), followed by the floor (80/356, 22.4%) and the intensive care unit (ICU) (36/356, 10.1%).
- Detected organisms:
  - *Escherichia coli* (255/356, **71.6%**)
  - *Klebsiella pneumoniae* group (64/356, **18.0%**)
  - *Klebsiella oxytoca* (15/356, **4.2%**)
  - *Proteus mirabilis* (14/356, **3.9%**)
  - *Salmonella* spp. (8/356, **2.2%**)

CONCLUSIONS

BIOFIRE BCID2 Panel accurately predicted ceftriaxone susceptibility and significantly outperformed both ESBL scoring tools, which showed poor sensitivity and high rates of undertreatment. These results support using genotypic rapid diagnostic tests like BCID2 over clinical scoring tools and highlight the importance of local validation before implementation.

KEY FINDINGS

- **BIOFIRE BCID2 Panel was found to be a highly sensitive and specific diagnostic tool with a high positive predictive value and negative predictive value for predicting CTX susceptibility: area under curve under the receiver operating characteristic curves > 0.95 showed high diagnostic accuracy.**
- **BIOFIRE BCID2 Panel correctly predicted CTX susceptibility in 99.2% of patients, which was significantly higher compared with both ESBL prediction tools and was associated in CTX -resistant isolates in fewer cases of undertreatment (only 7.3%) compared to the same tools.**
- **These findings support the local validation and implementation of genotypic rapid diagnostics to optimize antimicrobial therapy and reduce inappropriate carbapenem use.**

BIOFIRE® BLOOD CULTURE IDENTIFICATION 2 PANEL – Clinical Utility

Table 1. Accuracy of diagnostic methods

N = 356	CUTOFF	APPROPRIATELY PREDICTED CTX SUSCEPTIBILITY	SENSITIVITY	SPECIFICITY	PPV	NPV
BCID2	CTX-M +	99.2%	92.7%	100%	100%	99.1%
Augustine	3	88.8%	31.7%	96.2%	52.0%	91.5%
Lee	2	84.3%	7.3%	94.3%	14.3%	88.7%

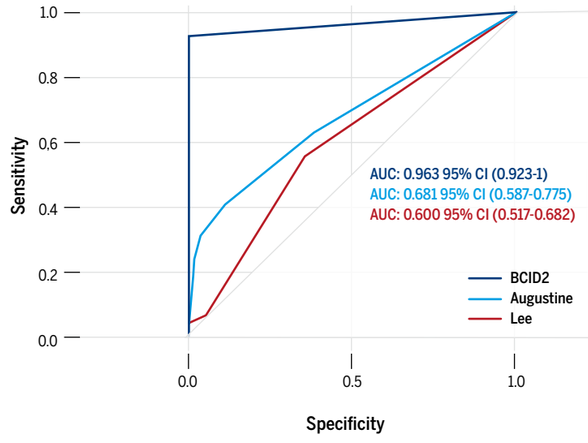
PPV: positive predictive value; NPV: negative predictive value

Table 2. Theoretical treatment outcomes

N = 356	OVERTREATMENT (N = 315)	UNDERTREATMENT (N = 41)
BCID2*	0 (0)	3 (7.3)
Augustine	12 (3.8)	28 (68.3)
Lee	18 (5.7)	38 (92.7)

Overtreatment = patient escalated to an empiric carbapenem at 24 hours (susceptibility = CTX susceptible);
Undertreatment = patient continued on ceftriaxone at 24 hours (susceptibility = CTX resistant).

Figure 1. Area under the receiver operating characteristic curves



AUC: area under the curve; CI: confidence interval

BIOFIRE® BLOOD CULTURE IDENTIFICATION 2 PANEL – Clinical Utility

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MICROBIOLOGY SPECTRUM
OCT 2024;12(12):E0062924 DOI: 10.1128/SPECTRUM.00629-24

Impact of rapid blood culture identification PCR panel on optimal antibiotic use in methicillin-susceptible *Staphylococcus aureus* bacteremia

Yetukuri J, Patel D, Bandali A, et *al*.

OBJECTIVE

To assess the impact of the BIOFIRE® FILMARRAY® Blood Culture Identification (BCID) PCR Panel on antibiotic use and clinical outcomes in patients with methicillin-susceptible *Staphylococcus aureus* (MSSA) bacteremia.

STUDY DESIGN

- **Type of study:** A multi-center retrospective study using patients' chart review conducted in two New Jersey centers (US)
- **Date:**
  - **Control:** June 2018 to December 2019
  - **Post-implementation:** June 2020 to December 2021
- **Patient population:** 200 adult patients (100 in each group) presenting with MSSA bacteremia
- **Observation:** Implementation of BIOFIRE FILMARRAY BCID Panel coupled with an antimicrobial stewardship during an 8-hour time period on weekdays
- **Control:** Traditional culture-based methods and Penicillin-binding protein 2a
- **Outcomes:**
  - **Primary:** Difference between the pre-BCID and post-BCID groups in time to optimal MSSA antibiotic therapy (oxacillin or cefazolin)
  - **Secondary:** Duration of anti-methicillin-resistant *Staphylococcus aureus* (MRSA) antibiotic use, in-hospital mortality, hospital and intensive care unit (ICU) length of stay (LOS), duration of bacteremia, and 30 days MSSA-related and all-cause readmissions

Patients who never achieved optimal antimicrobial therapy, had polymicrobial infection or had a positive blood culture (BC) in the previous 90 days, as well as patients from the post-BCID group who had not been tested with the BIOFIRE FILMARRAY BCID Panel or deceased within 24 hours of the Gram stain were excluded from this study.

"Complicated bacteremia" was defined as the presence of implanted prostheses, metastatic sites of infection, endocarditis, continued fever within 72 hours of initiating optimal therapy, or repeat positive blood cultures taken 2-4 days after the initial set.

Duration of bacteriemia was defined as the time between the collection of the first positive BC and the collection of the first negative BC.

RESULTS

Characteristics of patients and antimicrobial therapy:

- Both groups had similar patient characteristics except **complicated bacteremia incidence, which was lower in the post-BCID group (60%** *vs.* **73%**, $p = 0.049$).
- Vancomycin was the main empiric anti-MRSA antibiotic treatment in both groups.
- Cefazolin was the most commonly used optimal MSSA antimicrobial therapy in both groups.

Impact of BIOFIRE FILMARRAY BCID Panel implementation on study outcomes:

- The **time to optimal MSSA therapy was reduced by 19.9h** and the **duration of empiric anti-MRSA by 23.3h**.
- The **median duration of bacteremia was reduced by 21.3h in the post-BCID group**.
- **Empiric anti-MRSA therapy was withheld in more patients in the post-BCID group (16%** *vs.* **2%**, $p = 0.001$), resulting in less initiation of empiric anti-MRSA in this group (**84% post-BCID *vs.* 98% pre-BCID**, $p = 0.001$).
- No significant difference was observed between groups for other secondary outcomes.

CONCLUSIONS

Implementation of the BIOFIRE FILMARRAY BCID Panel in MSSA bacteremia significantly reduced time to optimal antibiotic therapy, shortened bacteremia duration, and decreased both the use and duration of empiric anti-MRSA treatment. These findings underscore the value of fast molecular diagnostics combined with antimicrobial stewardship in optimizing therapy for bloodstream infections.

BIOFIRE® BLOOD CULTURE IDENTIFICATION 2 PANEL – Clinical Utility

Table 1. Primary and secondary outcome results[a]

	PRE-PCR (N = 100)	POST-PCR (N = 100)	*P* VALUE
Time to optimal MSSA antibiotic therapy (hours)	49 (40.8, 67.5)	29.1 (22.3, 45)	< 0.001
Duration of empiric anti-MRSA antibiotic (hours)	44.2 (34.9, 60.4)	20.9 (7.1, 31.8)	< 0.001
Duration of bacteremia (hours)	68.6 (45.6, 110.1)	47.3 (35.5, 91.5)	0.015
Hospital LOS (days)	9.4 (6, 16)	11 (7, 15)	0.428
ICU LOS (days)	3 (2, 7.5)	4 (2, 8)	0.489
In-hospital mortality (%)	12	10	0.651
30-day all-cause readmission (%)	24	27	0.626
MSSA-related	7	4	0.537

[a]Data presented as median (IQR) unless otherwise specified. IQR: interquartile range

KEY FINDINGS

- **BIOFIRE FILMARRAY BCID Panel implementation was associated with a significant decrease in the time to optimal MSSA antibiotic therapy, reduced durations of bacteremia, and empiric anti-MRSA antibiotic therapy.**
- **Optimization of antimicrobial therapy was achieved without significant differences in hospital LOS, in-hospital mortality, or 30-day readmission rates.**
- **The study highlights the utility of routine stewardship review as a viable alternative to real-time notifications to translate fast diagnostic test results into timely optimization of antibiotic therapy and improved clinical outcomes.**

BIOFIRE® FILMARRAY®

GASTROINTESTINAL PANEL

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JOURNAL OF CLINICAL MICROBIOLOGY
FEB 2023;61(2):E0162822 DOI: 10.1128/JCM.01628-22

Relationship between Diagnostic Method and Pathogen Detection Healthcare Resource Use, and Cost in U.S. Adult Outpatients Treated for Acute Infectious Gastroenteritis

Moon RC, Bleak TC, Rosenthal NA, et *al*.

OBJECTIVE

To study the relationship between diagnostic testing and healthcare resource use and cost in adult patients receiving outpatient treatment for acute gastroenteritis (AGE).

STUDY DESIGN

- **Type of study:** A retrospective cohort study analyzing data from the Premier PINC AI Healthcare Database
- **Date of data:** 1st April 2016 to 30th June 2021
- **Patient population:** 248,896 adult outpatients with AGE
- **Intervention:** Multiplex PCR stool test with ≥ 12 targets (PCR ≥ 12) (*e.g.*, BIOFIRE® FILMARRAY® Gastrointestinal (GI) Panel)
- **Control:**
  - Patient with traditional stool work-up (TW)
  - Multiplex PCR stool test with < 12 targets (PCR < 12)
- **Outcomes:**
  - Health resource use and health care cost:
    - Discharge status (*i.e.*, discharged home versus requiring post-discharge services including home health, nursing or rehabilitation facility, and hospice)
    - AGE-related hospitalization and outpatient visits within 30 days of index discharge
    - Index visit, 30-day AGE-related follow-up, and total index visit plus 30-day AGE-related follow-up costs

RESULTS

Among the 36,787 patients who underwent outpatient stool testing (14.8%), 4,726 received a PCR <12, 11,098 a PCR ≥ 12, and 20,963 a TW. Regarding healthcare resource use, after adjustment for demographic and clinical characteristics, PCR ≥ 12 patients were **34% less** likely to be re-admitted within 30 days for AGE than TW patients.

Multiplex PCR ≥ 12 had a **shorter turnaround time (TAT) (6.3h)** compared to PCR < 12 (**12.4h**) and TW (**32.0h**) (both $p < 0.001$). These results are also associated with higher diagnostic yields on more than 10 types of pathogens compared to the TW described in detail in the publication (*e.g. Plesiomonas shigelloides*, Shiga toxin-producing *Escherichia coli* or norovirus).

After adjustment for patient, hospital and clinical characteristics, the mean cost of the index visit for PCR ≥ 12 patients was higher than for TW patients (+$97) but lower than for patients with PCR < 12 (-$98) ($p < 0.001$). However, the AGE-related 30-day follow-up cost per patient was similar between PCR ≥ 12 and PCR < 12 patients ($331 *vs*. $333), and lower compared with TW patients ($448), $p < 0.001$.

After adjustment there were fewer stool tests per patient, faster TAT **50% increased likelihood to be discharged home and lower likelihood of receiving antibiotics** for PCR ≥ 12 patients *vs.* TW patients.

CONCLUSIONS

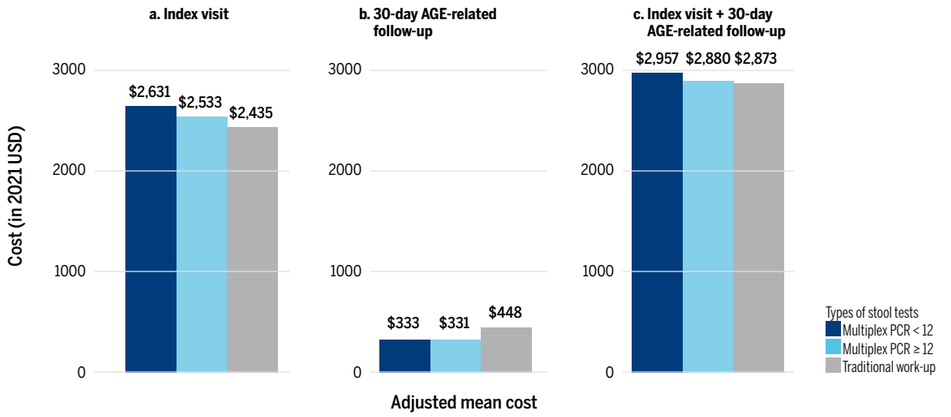
Multiplex PCR testing with ≥ 12 targets significantly improved healthcare resource utilization in adult outpatients with acute gastroenteritis by reducing the TAT, the number of stool tests, antibiotic use and the hospital readmissions, while providing a higher diagnostic yield for certain pathogens at a comparative mean cost to traditional stool workup.

KEY FINDINGS

- **Adult outpatients who received testing with multiplex PCR with ≥ 12 targets had fewer stool tests per patient, faster TAT, higher diagnostic yield, and reductions in in-hospital administration of antibiotics, as well as reduced 30-day risk of AGE-related hospitalization.**
- **These findings support the broader adoption of comprehensive molecular diagnostics to optimize resource use and enhance patient care.**

BIOFIRE® FILMARRAY® GASTROINTESTINAL PANEL – Clinical Utility

Figure 1. Adjusted mean healthcare cost index visit, 30-day AGE-related follow-up, and index visit + 30-day AGE-related follow-up stratified by the types of stool tests



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ANNALS OF CLINICAL MICROBIOLOGY AND ANTIMICROBIALS
JAN 2024;23(1):3 DOI: 10.1186/S12941-023-00662-3

The role of rapid syndromic diagnostic testing of gastrointestinal pathogens as a clinical decision support tool in a pediatric emergency department

Kang HM, Yoo IH, Jeong DC, et *al*.

OBJECTIVE

To evaluate the role of the BIOFIRE® FILMARRAY® Gastrointestinal (GI) Panel implementation in the decision to prescribe broad-spectrum antibiotics for acute diarrhea.

STUDY DESIGN

- **Type of study:** Retrospective study of academic center in South Korea
- **Date:** 1st April 2018 to 30th September 2019 (pre-implementation) and 1st April 2021 to 31st August 2022 (post-implementation)
- **Patient population:** 4,184 pediatric patients' data from the emergency department (ED)
- **Intervention:** Implementation of the BIOFIRE FILMARRAY GI Panel for fast syndromic diagnostic testing
- **Control:** Pre-implementation period using conventional diagnostic methods
- **Outcomes:**
  - **Primary:** Assessing clinical decision parameters (decision to prescribe antibiotics, knowing the etiologic pathogen of acute diarrhea, additional imaging modalities and change of prevention and control measures)
  - **Secondary:** Assessing change in duration of ED stay, number of ED revisits, hospitalization rate after discharge, change in disease progression rate

RESULTS

Regarding the decision to prescribe antibiotics, it was demonstrated that during the post-implementation period the rate of prescribing broad-spectrum antibiotics at discharge from the ED decreased compared to the pre-implementation period (15.8% *vs.* 9.9%, $p < 0.001$). Similarly, this rate also decreased upon admission after the implementation of the BIOFIRE FILMARRAY GI Panel (66.0% *vs.* 52.2%, $p < 0.001$).

A multivariate analysis showed the factors that were associated with the decision to prescribe broad spectrum antibiotics in the ED to children with acute diarrhea were (all $p < 0.001$):

- The need for admission, infectious disease consults.
- Pathogen identified.
- Patients with abdominal computed tomography with complication.

It was observed that the number of isolation ward consults to an infectious disease specialist during the post-implementation period were higher than the pre-implementation period (1.0% *vs.* 4.7%, $p < 0.001$). Simultaneously, in-hospital transmission decreased, and the time taken until appropriate isolation was significantly lower, showing a benefit overall of using the BIOFIRE FILMARRAY GI Panel.

It was also observed that ED stays were longer post-implementation (5.5h *vs.* 6.5h, $p < 0.0001$). This could have been explained by the time taken to review the BIOFIRE FILMARRAY GI Panel results. However, the proportion of patients that re-visited the ED during the same diarrheal episode decreased during the post-implementation of the BIOFIRE FILMARRAY GI Panel (5.2% *vs.* 2.6%, $p < 0.001$).

In addition, the admission rate from the outpatient after being discharged from the ED was lower post-implementation compared with the pre-implementation period (2.1% *vs.* 0.8%, $p = 0.001$), demonstrating that the overall quality of the ED was improved.

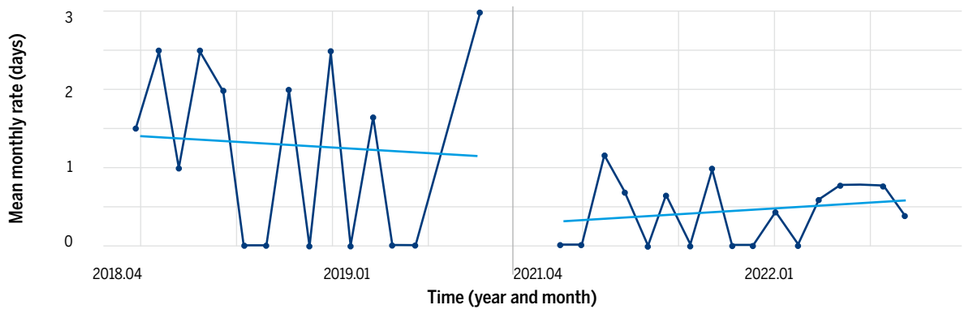
CONCLUSIONS

The implementation of BIOFIRE FILMARRAY GI Panel in a pediatric ED significantly reduced broad-spectrum antibiotic use and improved infection control measures. Despite a longer ED stay, the test contributed to better patient outcomes by lowering ED revisit and admission rates, supporting its role as an effective clinical decision support tool.

KEY FINDINGS

- **An advantage of using the BIOFIRE FILMARRAY GI Panel in the ED for a pediatric population is the reduction of broad-spectrum antibiotics prescriptions.**
- **The BIOFIRE FILMARRAY GI Panel was an aid in infection prevention measures.**
- **While ED discharge was delayed (possibly by the time taken to check results), there was a significant decrease in ED admission rate and ED revisits.**

Figure 1. Time taken for correct isolation precaution



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JOURNAL OF CLINICAL MICROBIOLOGY
MAR 2023;61(3):E0165222 DOI: 10.1128/JCM.01652-22

Impact of Rapid Molecular Multiplex Gastrointestinal Pathogen Testing in Management of Children during a *Shigella* Outbreak

Kanwar N, Jackson J, Bardsley T, et *al*.

OBJECTIVE

To evaluate the impact of BIOFIRE® FILMARRAY® Gastrointestinal (GI) Panel implementation on the detection of *Shigella* in a pediatric emergency department (ED) during an outbreak.

STUDY DESIGN

- **Type of study:** Prospective multicentric (5 centers) study in the US (Kansas City) during a community-wide *Shigella* outbreak
- **Date:** May 2015 to June 2016
- **Patient population:** 309 pediatric patients
- **Intervention:** Implementation to BIOFIRE FILMARRAY GI Panel and access to result in "real time"
- **Control:** Culture assay (standard of care (SOC)) and no access to BIOFIRE FILMARRAY GI results
- **Outcomes:** Clinical and epidemiologic characteristics of GI infections, IMPACT variables, treatment

RESULTS

Of the total number of patients enrolled, 244 subjects submitted stool samples and from those, 21% (51/244) were positive for *Shigella* spp. Of those, 41% (21/51) had co-infections, with the majority, 81% (17/21), indicating enteropathogenic *Escherichia coli* (EPEC) and/or enteroaggregative *E. coli* (EAEC) co-infections.

The BIOFIRE FILMARRAY GI Panel detected approximately 20% more *Shigella* spp. cases than culture during an outbreak.

- **Pre-implementation period:** 10/16 samples positive for *Shigella* spp. with the BIOFIRE FILMARRAY GI Panel (*vs.* only 8/10 samples positive with SOC).
- **Post-implementation period:** 6/20 samples positive for *Shigella* spp. with the BIOFIRE FILMARRAY GI Panel (*vs.* 6 positives as well with SOC). A reflex culture detected *Shigella* spp. in 17/27 samples, while the BIOFIRE FILMARRAY GI Panel detected *Shigella* spp. in 21/27 samples.

The authors determined the impact of patient management through the IMPACT analysis comparing different variables of both periods for *Shigella* spp. positive patients. No significant differences were present for the IMPACT variables, however fewer patients revisiting the health care providers and missing school days were observed.

It was also observed that more patients received targeted therapy in the post-implementation period (42.9% *vs.* 3.3%, $p < 0.001$), and the median time to targeted therapy was shorter in the post-implementation period (8.3h *vs.* 72.3h, no *p* value associated).

CONCLUSIONS

During a pediatric *Shigella* outbreak, implementation of the BIOFIRE FILMARRAY GI Panel enabled faster and more accurate pathogen detection compared to SOC. This approach substantially increased the proportion of patients receiving targeted therapy and shortened the time to initiation of appropriate treatment. Fast molecular diagnosis may also reduce repeat healthcare visits, demonstrating its value in optimizing patient management and outbreak response. However, no significant results were demonstrated.

KEY FINDINGS

- **The BIOFIRE FILMARRAY GI Panel detected approximately 20% more *Shigella* spp cases than culture during an outbreak.**
- **The implementation of the BIOFIRE FILMARRAY GI Panel reduced the time to targeted therapy and increased targeted treatment during this outbreak.**
- **A trend observed in this study was the reduction in re-visits with medical providers after the implementation of the BIOFIRE FILMARRAY GI Panel.**

BIOFIRE® FILMARRAY® GASTROINTESTINAL PANEL – Clinical Utility

Table 1. IMPACT variables in the pre-and post-intervention study phases

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IMPACT VARIABLE	PRE (N = 30)	POST (N = 19)*	*P* VALUE
No. of additional health care visits (%)	6 (20) (5 outpatient, 1 ED)	1 (5.3)	0.22
No. of parents who missed workdays (%)	13 (43.3)	10 (52.6)	0.57
Avg no. of days missed by parents (range)	1.8 (1-4)	2.4 (1-5)	0.42
No. of subjects who missed school/day care (%)	22 (73.3)	13 (68.4)	0.75
Avg no. of days missed by subjects (range)	2.8 (1-8)	2.8 (1-5)	0.94
Disease spread among family members, no. positive/ total no. (%)	8/133 (5.3)	4/86 (4.7)	1.0
*Follow-up interview was completed by 19 of the 21 *Shigella*-positive subjects.			

BIOFIRE® FILMARRAY® GASTROINTESTINAL PANEL – Clinical Utility

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CLINICAL INFECTIOUS DISEASES
DEC 2023;78(3):573-581 DOI: 10.1093/CID/CIAD710

Clinical Impact of Multiplex Molecular Diagnostic Testing in Children with Acute Gastroenteritis Presenting to an Emergency Department: a Multicenter Prospective Study

Pavia A, Cohen D, Leber A, et *al*.

OBJECTIVE

To determine the clinical impact of BIOFIRE® FILMARRAY® Gastrointestinal (GI) Panel implementation on children with acute gastroenteritis (AGE).

STUDY DESIGN

- **Type of study:** Prospective multicenter study
- **Date:** April 2015 to September 2016
- **Patient population:** 1,157 children (571 in the control and 586 in the intervention) with AGE
- **Intervention:** Implementation of BIOFIRE FILMARRAY GI Panel for molecular pathogen detection
- **Control:** Clinician-selected diagnostic testing in the emergency department (ED)
- **Outcomes:**
  - **Primary:** Return visits to healthcare provider within 10 days enrollment
  - **Secondary:** Number of return visits, subset of return visits to the ED or resulted in hospitalization, number of pathogens, potentially treatable and clinically relevant pathogens detected, proportion of children receiving appropriate treatment

RESULTS

Regarding the microbiology results, clinicians ordered testing on 80/571. It was found that clinician-ordered testing detected pathogens in 19/571 (3.3%) of the total of patients during the pre-intervention period, with **14 (2.5%) of them being treatable pathogens** and **16 (2.8%) clinically relevant pathogens**, defined as pathogens that are treatable and for which the reduction or avoidance of antibiotics is important (*e.g. Salmonella* and shigatoxin-producing *Escherichia coli*). During this period, the BIOFIRE FILMARRAY GI Panel was run in parallel in samples of 375/571 patients. For this group, **a potentially treatable pathogen was found in 65/375 (17.3%)** of the patients and a **clinically relevant pathogen was found in 84/375 (22.4%)**.

The BIOFIRE FILMARRAY GI Panel **detected a pathogen in 434/586 (74%)** of the patients during the intervention period.

The **difference between the clinician-ordered testing compared with the results** of clinically relevant pathogens detected by the BIOFIRE FILMARRAY GI Panel was **19.6%** (95% CI [15.2% ; 24.0%]; $p < 0.001$).

It was observed that the number of patients that had return visits to urgent care or the ED, or were hospitalized, decreased in the group that received the BIOFIRE FILMARRAY GI Panel in comparison with patients that received clinician-ordered testing: 9.2% *vs.* 9.3% (odds ratio (OR): 1.00; 95% CI [0.66 ; 1.53]). After a multivariate analysis it was observed that the intervention was associated with a **21% reduction in the odds of any return visit** (OR: 0.79 ; 95% CI [0.70 ; 0.90]; $p \leq 0.001$), and no significant difference between pre- and post-intervention periods in ED visits or hospitalizations.

Investigators observed no significant difference between the pre-intervention and intervention periods in the proportion of patients that received an antibiotic in the ED (3.5% *vs.* 4.1%) or after discharge (4.2% *vs.* 3.8%).

They also observed that more patients received the appropriate treatment for a potentially treatable pathogen during **the intervention period**, 12 of 61 (19.6%) *vs.* 7 of 62 (11.3%) ($p = 0.22$), and **appropriate treatment for *Shigella***, 11 of 24 (46%) *vs.* 7 of 33 (21%) ($p = 0.08$) (with an outbreak during the pre-intervention period).

CONCLUSIONS

The use of the BIOFIRE FILMARRAY GI Panel in pediatric emergency settings significantly increased the detection of clinically relevant pathogens and was associated with a 21% reduction in return visits.

KEY FINDINGS

- **Molecular testing increases sensitivity for pathogen detection. When compared with clinician-ordered testing, BIOFIRE FILMARRAY GI Panel identified more potentially treatable pathogens (17.3% *vs.*3.2%) and more clinically relevant pathogens (22% *vs.* 2.8%) in the pre-intervention period.**
- **For children who visited the ED with AGE, the use of the BIOFIRE FILMARRAY GI Panel was associated with a 21% reduction in the likelihood of a return visit compared with clinician-selected testing.**
- **These results support the clinical value of multiplex molecular diagnostics in improving care efficiency and may guide appropriate treatment decisions in children with AGE.**

BIOFIRE® FILMARRAY®

MENINGITIS/ENCEPHALITIS PANEL

BIOFIRE® FILMARRAY® MENINGITIS/ENCEPHALITIS PANEL – Clinical Utility

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EUROPEAN JOURNAL OF CLINICAL MICROBIOLOGY AND INFECTIOUS DISEASES
DEC 2023;39(12): 2379-2386 DOI: 10.1007/S10096-020-03986-6

Impact of cerebrospinal fluid syndromic testing in the management of children with suspected central nervous system infection

Posnakoglou L, Siahanidou T, Syriopoulou V, et *al*.

OBJECTIVE

To assess the impact of the BIOFIRE® FILMARRAY® Meningitis/Encephalitis (ME) Panel on antimicrobial therapy and economic outcomes in children with suspected central nervous system (CNS) infections.

STUDY DESIGN

- **Type of study:** Prospective randomized study
- **Date:** April 2018 to April 2019
- **Patient population:** 142 samples from patients ≤ 16 years with suspected CNS infection and cerebrospinal fluid (CSF) pleocytosis (> 15 cells/mm^3)
- **Intervention:** Tested with the BIOFIRE FILMARRAY ME Panel (n = 71)
- **Control:** Tested with the standard of care (SOC) methods (n = 71) (included bacterial culture and/or singleplex PCR testing)
- **Outcomes:** Length of hospital stay (LOS), duration of antimicrobials use, duration of acyclovir use, and total cost of hospitalization

RESULTS

The group tested with the BIOFIRE FILMARRAY ME Panel had **more positive detections than the control group overall (37 (52.1%) *vs.* 16 (22.5%)**, $p < 0.001$) and **more positive viral detections (27/61 (44.2%) *vs.* 11/66 (16.7%)**, $p < 0.001$). The BIOFIRE FILMARRAY ME Panel **detected 5 bacterial targets that were not detected by SOC**: 2 *Neisseria meningitidis, 2 Streptococcus pneumoniae*, and 1 *Escherichia coli* (all but the *E. coli* detection was confirmed by singleplex PCR). There were no negative detections on the BIOFIRE FILMARRAY ME Panel that were positive in bacterial culture.

Patients with a positive viral detection by the BIOFIRE FILMARRAY ME Panel had **fewer days of antimicrobial therapy (4 days *vs.* 7), fewer days of acyclovir (3 days *vs.* 5)**, and a **reduced LOS (5 days *vs.* 7)**. A sub-analysis of patients ≤ 3 months showed a greater **reduction in length of stay (5 days *vs.* 9)**. All previously mentioned findings were statistically significant with $p < 0.001$.

Median hospitalization costs were 31.5% lower overall in the BIOFIRE FILMARRAY ME Panel group (€1,042 *vs.* €1,522), and **36% lower for patients ≤ 3 months** (€1,042 *vs.* €1,632). Overall cost reduction for the duration of the 1-year study was €22,834.

CONCLUSIONS

The use of the BIOFIRE FILMARRAY ME Panel significantly improved pathogen detection and was associated with reductions in antimicrobial duration, LOS, and overall hospitalization costs among children with suspected CNS infections. These findings support its role in optimizing clinical management and resource utilization in pediatric care.

KEY FINDINGS

- **Pediatric patients who were tested with the BIOFIRE FILMARRAY ME Panel had reduced hospitalization costs, reduced antimicrobial therapy, and reduced LOS.**
- **The BIOFIRE FILMARRAY ME Panel detected more targets than SOC with no false negative results.**
- **Increased sensitivity to bacterial detection (especially after initiation of empiric antibiotics) was demonstrated with the BIOFIRE FILMARRAY ME Panel, which is critical for appropriate treatment of bacterial meningitis.**

BIOFIRE® FILMARRAY® MENINGITIS/ENCEPHALITIS PANEL – Clinical Utility

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ANTIBIOTICS
JUL 2022;11(8): 1028 DOI: 10.3390/ANTIBIOTICS11081028

Assessment of the Impact of a Meningitis/Encephalitis Panel on Hospital Length of Stay: A Systematic Review and Meta-Analysis

Hueth K, Thompson-Leduc P, Totev T, et *al*.

OBJECTIVE

To describe the impact of the BIOFIRE® FILMARRAY® Meningitis/Encephalitis (ME) Panel and the rapidity of pathogen identification on antibiotic stewardship programs and patient management.

STUDY DESIGN

- **Type of study:** Systematic review and meta-analysis of the current literature
- **Date of publication:** From 2015 to 2021
- **Data base:** MEDLINE and EMBASE
- **Inclusion criteria:**
  - Used the BIOFIRE FILMARRAY ME Panel to determine the etiology of suspected central nervous system (CNS) infections (irrespective of whether the patients were positive by the Panel or culture)
  - Study reported on patients' length of hospital stay (LOS) (*i.e.*, the primary outcome)
  - Study compared LOS of patients tested with the multiplex ME Panel to another cohort of patients (*i.e.*, comparative design)
- **Outcomes:** LOS, duration of acyclovir use, and duration of antimicrobial use

RESULTS

This systematic review analyzed 169 publications published from 2015 onwards in the EMBASE and MEDLINE databases. After a screening of the publications, 11 were retained for meta-analysis and 13 were retained for systematic review, which included a range of study designs: retrospective cohort (n = 4), case-control (n = 3), pre/post interventional (n = 3), cross-sectional (n = 1), combination designs (n = 1), and randomized control trial (n = 1). Five publications reported exclusively on pediatric patients, 1 study did not report ages, and the remaining 7 studies reported on either adults or combined pediatric and adult populations.

All 11 studies reported **a reduction in the mean duration of hospital LOS using the BIOFIRE FILMARRAY ME Panel** compared to SOC. There was a statistically significant reduction in mean duration of LOS by **1.2 days** (95% CI [-1.96 ; -0.44]). Both **LOS and acyclovir use demonstrated a statistically significant reduction** across all 11 studies.

7 studies reported information on the duration of acyclovir therapy. Meta-analysis of the 7 studies demonstrated a statistically **significant reduction in mean duration of acyclovir therapy in the BIOFIRE FILMARRAY ME Panel cohorts by 1.14 days** (95% CI [-1.78 ; -0.50]), with the strongest effect observed in studies that exclusively included pediatric patients.

Lastly, among the 6 studies which reported duration of antibiotic therapy, 3 studies (all of which exclusively evaluated pediatric patients) demonstrated a statistically **significant reduction in the mean duration of antibiotic therapy of 1.85 days** (95% CI [2.50 ; 1.21]). The overall reduction in mean duration of antibiotic therapy across the 6 studies was not statistically significant, but showed a reduction of 1.01 days (95% CI [2.39 ; 0.37]).

CONCLUSIONS

The BIOFIRE FILMARRAY ME Panel was associated with a significant reduction in hospital LOS (1.20 days) and acyclovir therapy duration (1.14 days), with a nonsignificant trend toward fewer antibiotic days. These findings highlight its potential to improve patient management and support antimicrobial stewardship through faster pathogen identification.

KEY FINDINGS

- **BIOFIRE FILMARRAY ME Panel was associated with faster turnaround time and increased viral yield.**
- **BIOFIRE FILMARRAY ME Panel may lead to reduced unnecessary antimicrobial administration and optimize antiviral therapies among patients with suspected CNS infection.**
- **BIOFIRE FILMARRAY ME Panel implementation may be cost-effective, particularly if there is a reduction in length of hospitalization.**

BIOFIRE® FILMARRAY® MENINGITIS/ENCEPHALITIS PANEL – Clinical Utility

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THE JOURNAL OF PEDIATRICS
FEB 2022 9; 244:161-168 DOI: 10.1016/J.JPEDS.2022.02.002

Clinical and Financial Impact of a Diagnostic Stewardship Program for Children with Suspected Central Nervous System Infection

Messacar K, Palmer C, Gregoire LA, et *al*.

OBJECTIVE

To assess the impact of the BIOFIRE® FILMARRAY® Meningitis/Encephalitis (ME) Panel implementation combined with a cerebrospinal fluid (CSF) diagnostic stewardship program in children with suspected central nervous system (CNS) infection.

STUDY DESIGN

- **Type of study:** A pre-post observational cohort study was conducted at Children's Hospital Colorado (US)
- **Date:**
  - **Control:** 2015-2016
  - **Intervention:** 2017-2018
- **Patient population:** Pediatric patients who underwent CSF sampling through lumbar puncture (LP) and met at least one inclusion criteria: age < 2 months; concern for encephalitis; immunocompromised; ≥ 5 white blood cells/µL in CSF
- **Intervention:** Post-implementation of BIOFIRE FILMARRAY ME Panel (n = 1,127)
- **Control:** Clinician-ordered conventional CSF testing (culture, targeted singleplex PCR assays) (n = 1,124)
- **Outcomes:** Time to positive CSF result, time to optimal treatment (TOT), probability to receive optimal treatment, duration of antimicrobial treatment, hospital costs, length of stay, mortality

RESULTS

Study population: The average age of patients in both groups was **3.5** years.

- There were fewer infants (< 2 months old) in the post-implementation group (**49% *vs.* 56%**, $p = 0.0019$), but more cases with suspected encephalitis (**53% *vs.* 46%**, $p = 0.0006$).
- **72%** of CSF samples were tested with the BIOFIRE FILMARRAY ME Panel in the post-implementation group in combination with a CSF diagnostic stewardship program.

ME Panel performance:

- **BIOFIRE FILMARRAY ME Panel detected bacterial meningitis in 5 culture-negative cases, 4/5** had positive Gram stains and received antibiotics prior to LP, **3/5** had positive blood culture with matching pathogen. For this reason, the BIOFIRE FILMARRAY ME Panel could potentially have a beneficial role for CNS infection diagnosis in case of pre-LP antibiotic exposure.
- In **2** cases, the BIOFIRE FILMARRAY ME Panel was negative while the CSF culture was positive, but the causative agent was off-Panel in both cases (*Staphylococcus aureus)*.

Outcomes comparison between groups:

- **Time to positive CSF results decreased** after implementation of the BIOFIRE FILMARRAY ME Panel (**4.6h *vs.* 8.6h**, $p < 0.0001$).
- **TOT decreased** after BIOFIRE FILMARRAY ME Panel implementation (**18h *vs.* 28h**).
- The **probability to receive the optimal antibiotic treatment was 1.13 times higher** in the post-implementation group.
- The **duration of antimicrobial treatment was reduced** in the post-implementation group (**36h *vs.* 24h**, $p = 0.0037$).
- Total cost was unchanged despite an increase associated with implementation of the BIOFIRE FILMARRAY ME Panel (**$193 *vs.* $95**)
- The proportion of patients receiving IV antimicrobial treatment, length of hospitalization and mortality were similar in both groups

CONCLUSIONS

Implementation of the BIOFIRE FILMARRAY ME Panel within a diagnostic stewardship program significantly reduced TOT in children with suspected CNS infections, without increasing overall hospital costs, highlighting the value of molecular testing combined with real-time stewardship support for improving care efficiency and antimicrobial use.

KEY FINDINGS

- **Implementation of the BIOFIRE FILMARRAY ME Panel decreased the average time to identification of the causative agent in CSF (4.6h before *vs.* 8.6h after).**
- **The time to optimal treatment was lower after BIOFIRE FILMARRAY ME Panel implementation (18h *vs.* 28h) and the probability to receive the optimal treatment was 1.13 times higher.**

BIOFIRE® FILMARRAY® MENINGITIS/ENCEPHALITIS PANEL – Clinical Utility

CLICK TO ACCESS ARTICLE

JOURNAL OF CLINICAL VIROLOGY
AUG 2025;180:105856 DOI: 10.1016/J.JCV.2025.105856

Impact on hospital length of stay and antimicrobial usage in children diagnosed with viral meningitis by rapid multiplexed PCR assay

Lu J, Florez-Vazques J, Lee J, et *al*.

OBJECTIVE

To determine the clinical utility of BIOFIRE® FILMARRAY® Meningitis/Encephalitis (ME) Panel in children diagnosed with human enterovirus (HEV)/human parechovirus (HPeV) meningitis.

STUDY DESIGN

- **Type of study:** Retrospective single-center pre/post analysis of pediatric patients testing positive for HEV or HPeV at a pediatric quaternary care center in United States
- **Date:**
  - **Control:** October 2011 to May 2016
  - **Intervention:** June 2016 to October 2023
- **Patient population:** Positive for HEV or HPeV, respectively 54 and 66 for the control and intervention group
- **Intervention:** Implementation of BIOFIRE FILMARRAY ME Panel in the clinical microbiology laboratory
- **Control:** Diagnosed by standalone polymerase chain reaction (PCR) (standard of care)
- **Outcomes:** Turnaround time (TAT), antibiotic therapy duration, time on antivirals discontinuation, and length of stay (LOS)

RESULTS

The TAT to HEV/HPeV detection was significantly reduced for BIOFIRE FILMARRAY ME Panel compared to standalone PCR (2.67h *vs.* 22.05h, $p < 0.0001$).

In the intervention group, 59.1% of patients (39/66) received empiric IV acyclovir. The absence of Herpes simplex virus (HSV-1/HSV-2) detection by the BIOFIRE FILMARRAY ME Panel enabled significantly earlier discontinuation compared to the control group (37%, 20/54), with a median time of 3.9h *vs*. 16.03h ($p = 0.03$).

Despite viral detection by BIOFIRE FILMARRAY ME Panel, no significant difference was observed in terms of empiric antibiotic discontinuation time between groups (42.3h *vs.* 35.7h, $p = 0.19$). Patients remained on antibiotics until cerebrospinal fluid (CSF) cultures were confirmed negative after 48 hours of incubation. This persistence of antibiotic therapy may be explained by the severe consequences of bacterial meningitis/encephalitis. Clinicians often adopt a conservative approach, requiring negative CSF culture confirmation before discontinuing empiric antibiotics.

Although not statistically significant, the median LOS of patients positive for HEV or HPeV by the ME panel was reduced by 0.51 days when compared to standalone PCR (1.95 *vs.* 2.46 days, $p = 0.66$). These observations are concordant with previous studies and the absence of significant results could be potentially explained by the underpowered sample size to detect small difference in LOS or the complex interaction between the different factors included in this study.

CONCLUSIONS

Implementation of a BIOFIRE FILMARRAY ME Panel significantly reduced diagnostic turnaround time and enabled earlier discontinuation of empiric acyclovir therapy in pediatric patients with viral meningitis. However, its impact on hospital LOS and antibiotic duration was minimal, underscoring the need for complementary antimicrobial stewardship interventions.

KEY FINDINGS

- **Implementation of BIOFIRE FILMARRAY ME Panel in a pediatric hospital improved overall time to diagnosis of viral ME.**
- **In case of the absence of HSV-1/HSV-2 detection, the discontinuation of empirical acyclovir treatment was significantly earlier.**
- **LOS and empiric antibiotic duration showed only minor, non-significant reductions despite quicker viral detection. Improvement of these outcomes is dependent on time to action by the care teams.**

BIOFIRE® FILMARRAY® MENINGITIS/ENCEPHALITIS PANEL – Clinical Utility

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JOURNAL OF CLINICAL VIROLOGY PLUS
JUN 2025; 5(3):100221DOI: 10.1016/J.JCVP.2025.100221

Decrease in SinglePlex Viral PCRs Use and acyclovir utilization following implementation of The BioFire Meningitis/ Encephalitis Panel at A Tertiary Care Cancer Center

McMillen T, Powell E, Krupa J, et *al*.

OBJECTIVE

To evaluate the immediate impact of implementing the BIOFIRE® FILMARRAY® Meningitis/Encephalitis (ME) Panel on targeted viral PCRs and antiviral utilization in a cancer patient population.

STUDY DESIGN

- **Type of study:** Single-center retrospective pre- and post-intervention study in New York City (US)
- **Date:**
  - **Pre-implementation:** July 2015 to July 2016
  - **Post-implementation:** July 2016 to July 2017
- **Patient population:** 476 adult and pediatric oncology patients (207 pre-intervention and 269 post-intervention)
- **Intervention:** Implementing the BIOFIRE FILMARRAY ME Panel
- **Control:** Viral PCRs requests (HSV-1/2 PCR, VZV PCR, CMV PCR, HHV-6 and Enterovirus PCR) were sent out to a reference laboratory (Viracor Eurofins lab)
- **Outcomes:** Number of singleplex viral PCRs ordered and acyclovir use including duration of treatment

RESULTS

In the post intervention period, the proportion of patients with viral detection more than doubled, rising from 2.9% (6/207) to 7.1% (19/269).

The number of targeted viral tests was significantly reduced by 64.9% (703 to 247 PCRs).

The total number of patients treated with acyclovir was significantly reduced by 29.1% (82 patients *vs.* 45; $p < 0.0001$). A reduction in the duration of therapy from 7.33 days to 4.47 days in the post-intervention period ($p = 0.0274$) was observed. Unnecessary acyclovir use also decreased by 14.3% from 98.7% (81/82 patients treated) to 84.4% (38/45 patients treated).

CONCLUSIONS

Implementation of the BIOFIRE FILMARRAY ME Panel significantly reduced the number of singleplex viral PCR tests while also decreasing both the use and duration of empiric acyclovir therapy in cancer patients. These findings highlight the Panel's potential to streamline diagnostic workflows and improve antimicrobial stewardship in oncology settings.

KEY FINDINGS

- **This study is the first to focus primarily on an oncology patient population.**
- **Implementation of the BIOFIRE FILMARRAY ME Panel contributed to a reduction in the number of singleplex PCR tests ordered and also reduced use of acyclovir therapy.**

BIOFIRE®

JOINT INFECTION PANEL

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JOURNAL OF CLINICAL MICROBIOLOGY
NOV 2023; 61(11):E00357-23 DOI: 10.1128/JCM.00357-23

Multicenter Evaluation of the BIOFIRE Joint Infection Panel for the detection of bacteria, yeast, and AMR genes in synovial fluid samples

Esteban J, Salar-Vidal L, Kensinger B, et *al*.

OBJECTIVE

To evaluate the performance of the BIOFIRE® Joint Infection (JI) Panel on synovial fluid samples.

STUDY DESIGN

- **Type of study:** Observational clinical trial performed in 13 sites in the US and Europe
- **Date:** May 2018 to March 2020
- **Patient population:** 1,544 samples of synovial fluid (SF) from patients with suspected JI
- **Observation:** Tested on BIOFIRE JI Panel and compared to the control. The trial used an Investigational Use Only version identical to the commercial (*i.e.*, FDA-cleared, CE marked) *in vitro* diagnostic version
- **Control:** Study sites standard of care (SOC) - culture, PCR assays, and sequencing for antimicrobial resistance (AMR) genes
- **Outcomes:** Specificity and sensitivity; positive percent agreement (PPA) and negative percent agreement (NPA)

RESULTS

A total of 1,544 samples were tested: 850 were from native joint infections (NJI), 442 from prosthetic joint infections (PJI), and 252 of unknown origin.

- **202 samples were positive by culture and negative by BIOFIRE JI Panel for at least one on-Panel organism:**
  - 20 samples were positive by culture and negative by BIOFIRE JI Panel.
  - **Following discrepant analysis:** 14/20 were confirmed to be false negatives, 2/20 to be true negatives, and 4/20 unresolved.
- **242 samples were positive by BIOFIRE JI Panel for at least one organism:**
  - 70 samples were positive by the BIOFIRE JI Panel and negative by culture.
- **79 additional organisms were detected by BIOFIRE JI Panel:**
  - Following the discrepant analysis, 76/79 were confirmed and 3 were unresolved.
- **75 off-Panel organisms detected in 70 culture positive samples were identified (not considered false negatives):**
  - The most prevalent were *Staphylococcus epidermidis* (n = 38) and *Cutibacterium acnes* (n = 8).
- **The performance of the BIOFIRE JI Panel for on-Panel organisms was:**
  - **Overall sensitivity was 90.5% and overall specificity was 99.6%.**
  - **For NJI: sensitivity was 88.2% and specificity was 99.6%.**
  - **For PJI: sensitivity was 92.0% and specificity 99.4%.**
- The **PPA for AMR genes** was estimated to be **100%** and the **NPA** was estimated to be **98.8%**.
  - There were 4 mecA/C and mec right extremity junction (MREJ) false positives detected that were finally confirmed to be true positives after discrepant analysis.

CONCLUSIONS

The BIOFIRE JI Panel demonstrated high sensitivity and specificity for detecting pathogens and AMR genes directly from synovial fluid, delivering results in about one hour. Its fast and accurate performance supports timely patient management compared to conventional culture methods.

KEY FINDINGS

- **Overall, 90.5% sensitivity and 99.6% specificity for on-Panel organisms.**
- **NJI: sensitivity: 88.2% and specificity: 99.6%. PJI: sensitivity: 92.0% and specificity: 99.4%.**
- **100% PPA and 98.8% NPA for AMR genes.**
- **70 samples with 75 off-Panel organisms → 50.6% of which were *Staphylococcus epidermidis*.**

CLICK TO ACCESS ARTICLE

ASM MICROBIOLOGY SPECTRUM
APR 2025; 13(4): E0223924 DOI: 10.1128/SPECTRUM.02239-24

Prospective evaluation of real-world performance and clinical impact of the Biofire FilmArray Joint Infection panel

Berinson B, Tanida K, Rohde H, et *al*.

OBJECTIVE

To assess the real-life laboratory performance such as the turnaround time (TAT) of the BIOFIRE® Joint Infection (JI) Panel and to evaluate its impact on patient management and related antibiotic treatment decisions.

STUDY DESIGN

- **Type of study:** Prospective evaluation performed at a German site
- **Date:** September 2022 to September 2023
- **Patient population:** 165 synovial fluids from 160 patients with suspected JI (57% had suspected native JI, and 43% had suspected prosthetic joint infection (PJI))
- **Observation:** Tested on the BIOFIRE JI Panel
- **Control:** Culture-based diagnostics
- **In case of discrepant:** Analyzed using species-specific PCRs or 16S-rDNA sequencing
- **Outcomes:** Specificity and sensitivity; TAT; pathogen recovery; antibiotic therapy

RESULTS

The final diagnosis was native JIs for 17.6% of the cases and PJIs for 14.5% of the cases. Overall, 67.3% of the cases were non-infectious.

There were 27 cases positive with the standard of care (SOC) and 38 cases were positive with the BIOFIRE JI Panel. 24/27 were concordant with the BIOFIRE JI Panel and 11 cases were positive with the BIOFIRE JI Panel only. 8/11 were confirmed by a 3rd method or by clinical data. No resistance marker was detected by any of the methods. The BIOFIRE JI Panel **sensitivity** was **96.3%** and the **specificity** was **97.8%**.

The BIOFIRE JI Panel **increased the pathogen recovery rate by 16.7%**. As a note, in this study none of the PJI were caused by *Cutibacterium acnes* or coagulase-negative *Staphylococcus* (CoNS).

The clinical impact on patient management was evaluated in terms of antibiotic therapies.

For **11/38 (28.9%) of cases, antibiotic therapy was optimized**.

- **6/11 occurred in SOC positive cases:**
  - 2/6 switched to optimized therapy for *Streptococcus pneumoniae* (Ceftriaxone) and *S. agalactiae* (Penicillin G) 1 to 2 days before SOC availability.
  - 4/6 patients received optimized therapies; for 3/4, Flucloxacillin for *S. aureus* was provided in 1.5 to 7 hours and Penicillin G for 1 *S. agalactiae* was provided in 20 hours.
- **5/11 cases occurred in SOC negative cases:**
  - Mainly *Streptococcus* and *Staphylococcus* species, for which the empiric therapy was optimized.

Mean TAT for culture positive samples was **14.11 hours for the BIOFIRE JI Panel and 35.17 hours for culture methods.**

CONCLUSIONS

The BIOFIRE JI Panel demonstrated high diagnostic accuracy (96.3% sensitivity, 97.8% specificity) and reduced TAT by approximately 21 hours compared to culture, enabling faster pathogen identification. Its use led to optimized antibiotic therapy in nearly 29% of cases, underscoring its potential to improve patient management when integrated with diagnostic stewardship measures.

KEY FINDINGS

- **BIOFIRE JI Panel sensitivity was 96.3% and specificity 97.8% compared with culture-based diagnostics.**
- **BIOFIRE JI Panel increased the pathogen recovery rate by 16.7% (with the limitation that none of the PJI in this study were caused by *C. acnes* or CoNS).**
- **Antibiotic therapy was optimized for 28.9% of the cases mainly due to the faster turnaround time and the increased diagnostic yield.**

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JOURNAL OF BONE AND JOINT INFECTION
FEB 2024; 9(1):87-97 DOI: 10.5194/JBJI-9-87-2024

Potential value of a rapid syndromic multiplex PCR for the diagnosis of native and prosthetic joint infections: a real-world evidence study

Pascual S, Noble B, Allantaz F, et *al*.

OBJECTIVE

To evaluate the performance of the BIOFIRE® Joint Infection (JI) Panel in comparison with synovial fluid culture (SFC) performed as per respective site standard of care. Subsequently, the sites were asked to comment on whether the BIOFIRE JI Panel results would have had an impact on patient management in order to evaluate the user experience and possible perspectives.

STUDY DESIGN

- **Type of study:** Multicentric study performed in 34 sites from 19 countries located in Europe and Middle East
- **Date:** February 2021 to June 2022
- **Patient population:** Synovial fluid obtained from patients with suspected joint infection, either septic arthritis (SA) or prosthetic joint infection (PJI)
- **Observation:** Tested by BIOFIRE JI Panel
- **Control:** Collected and tested by the site standard of care (SOC) method
- **Outcomes:** Diagnostic yield

All the samples were tested by SOC and BIOFIRE JI Panel. To capture the real-world data with the least amount of bias, the study allowed the SOC to vary across clinical sites.

RESULTS

There were 1,527 synovial fluid samples analyzed, including 57% (n = 873) samples with SA and 26% (n = 398) with PJI. More than half of the samples were collected from patients over 56 years of age and 70% of these samples were from knee or hip joints.

For SA, the overall agreement between SFC and BIOFIRE JI Panel results at sample level was 88.4%, when considering on-Panel organisms. There were 73 samples only positive by BIOFIRE JI Panel and 12 samples only positive by SFC. Among 12 mecA/C/MREJ *Staphylococcus aureus* resistance genes, 6 were only detected by BIOFIRE JI Panel and 2 only by SFC.

For PJI, the overall agreement between SFC and BIOFIRE JI Panel results at sample level was 85.7% when considering on-Panel organisms. There were 38 samples only positive by BIOFIRE JI Panel and 12 samples only positive by SFC. Among 9 mecA/C/MREJ *S. aureus* resistance genes, 4 were only detected by BIOFIRE JI Panel and none of them were missed.

In terms of **user experience, for SA, 64%** reported that the BIOFIRE JI Panel results would have modified the patient management when the Panel detected a positive outcome and for **PJI, 70%** reported that the BIOFIRE JI Panel results would have modified the patient management when the BIOFIRE JI Panel detected a positive outcome.

The most frequent microorganisms identified in both types of infections were *S. aureus*, *Streptococcus*, and *Enterococcus* species, including additional detection with BIOFIRE JI Panel.

Additionally, the panel detected more anaerobic organisms which can be generally difficult to detected with culture (30 only detected by BIOFIRE JI Panel). The panel enables simultaneous detection of multiple pathogens, most of them are individually less prevalent but collectively represent a significant proportion of all detections.

CONCLUSIONS

The BIOFIRE JI Panel demonstrated higher diagnostic yield than SFC, detecting additional pathogens and resistance genes with results available in about one hour. Its fast and accurate performance suggests significant potential to optimize antimicrobial therapy and improve patient management in both native and prosthetic joint infections.

KEY FINDINGS

- **BIOFIRE JI Panel has an overall agreement with conventional culture methods of 88.4% for SA and 85.7% for PJI.**
- **Overall, when compared with conventional culture methods, the BIOFIRE JI Panel detected more positive samples and microorganisms.**
- **The user experience was positive for both SA and PJI, specifically when the BIOFIRE JI Panel detected a positive outcome.**

BIOFIRE® JOINT INFECTION PANEL – Performance

CLICK TO ACCESS ARTICLE

JOURNAL OF CLINICAL MICROBIOLOGY
JUN 2025;2:E0027825 DOI: 10.1128/JCM.00278-25

Performance evaluation of a commercial multiplex pathogen panel for the diagnosis of pediatric joint infections

Copley L, Lee G, Villani M, et *al*.

OBJECTIVE

To assess the real-life performance of BIOFIRE® Joint Infection (JI) Panel and its potential impact on pediatric patient management in comparison with synovial fluid (SF) culture only, with 16S PCR followed by Sanger sequencing method (16S PCR/S) only or by both methods together (culture + 16S PCR/S), considered as standard of care (SOC).

STUDY DESIGN

- **Type of study:** Observational study in Texas (US)
- **Date:** August 2020 to October 2023
- **Patient population:** 65 SF samples from 63 pediatric patients under evaluation for JI who underwent arthrocentesis
- **Observation:** Analyzed by BIOFIRE JI Panel
- **Control:** Analyzed by culture, 16S PCR/S or SOC (culture + 16S PCR/S)
- **Outcomes:** BIOFIRE JI Panel performance and potential clinical impact

RESULTS

Study population:

- The average age of patients was **7.6** years (1 month – 19 years).
- In **63.1%** of cases, there was no antibiotic administration within 24 hours prior to specimen collection.
- **75.4%** of samples were collected from a knee joint infection.

Turnaround Time (TAT):

- The average TAT was **1.4 days** for culture and **8.9 days** for 16S PCR/S. The BIOFIRE JI Panel TAT was considered as **3 hours** for this study but can be reduced to 1 hour, depending on the lab workflow.

BIOFIRE JI Panel performance:

- Considering only on Panel organisms, positive percent agreement (PPA) between BIOFIRE JI Panel and SOC was **100%** and negative percent agreement (NPA) of the BIOFIRE JI Panel with SOC was **89%** (32/36), and **80% (20/25)** with 16S PCR/S.
- The BIOFIRE JI Panel detected all organisms that were detected by 16S PCR/S and all on-Panel organisms detected by culture but missed 6 off-panel organisms (5 coagulase-negative staphylococci and 1 *Bacillus*) detected by culture.
- 7 microorganisms were detected by 16S sequencing but not by culture and considered as clinically relevant (3 *Kingella kingae,* 2 *Streptococcus pyogenes*, 1 *S. pneumoniae* and 1 *S. agalactiae*), all were detected by BIOFIRE JI Panel.
- 4 cases of methicillin-resistant *Staphylococcus aureus* (MRSA) were detected by culture, 3/4 (75%) were also detected by the BIOFIRE JI Panel.

Potential clinical impact of the BIOFIRE JI Panel:

- **When positive:** in **27.7% (18/65)** of cases, results were considered as having a "potentially positive impact" (**1/18** high positive impact, **9/18** moderate positive impact, 8/18 low positive impact) mainly due to possible antibiotic optimizations.
- **When negative:** in **66.2% (43/65)** of cases, results had respectively "probably no impact" on patient care, in **4.6% (3/65)** of cases, the impact of results were judged as "unknown", and in **1.5%** of cases (**1/65**), impact of result was considered as "potentially negative" (MRSA case not detected by the BIOFIRE JI Panel).

CONCLUSIONS

The BIOFIRE JI Panel demonstrated high agreement with culture and 16S PCR/S for detecting common pediatric joint infection pathogens and identified all organisms detected by 16S PCR/S but missed by culture. Its fast TAT (approximately 3 hours) could enable earlier targeted antimicrobial therapy, with an estimated positive clinical impact in 27.7% of positive cases.

KEY FINDINGS

- **BIOFIRE JI Panel had a 100% PPA and 89% NPA compared with SOC when considering on Panel organisms.**
- **The combination of BIOFIRE JI Panel and 16S PCR/S detected 7 additional organisms missed by culture while the BIOFIRE JI Panel in comparison with culture missed 6 off-Panel organisms.**
- **The BIOFIRE JI Panel was considered as having a potential positive impact in 27.7% of positive cases, notably due to a shorter time-to-results, showing its complementarity with culture and 16S PCR/Sanger sequencing.**

CLICK TO ACCESS ARTICLE

JOURNAL OF EXPERIMENTAL ORTHOPAEDICS
JUL 2024;11(3): E12097 DOI : 10.1002/JEO2.12097

Multiplex PCR in septic arthritis and periprosthetic joint infections microorganism identification: Results from the application of a new molecular testing diagnostic algorithm

Ghirardelli S, Scaggiante F, Troi C, et *al*.

OBJECTIVE

To evaluate a new score-based diagnostic algorithm (adapted from international recommendations) as a routine testing technology in scenarios of suspected septic arthritis (SA) or periprosthetic joint infection (PJI). The algorithm was applied if the increase in microorganism identification rate could allow for a more targeted antibiotic treatment in the case of SA, and could increase the number of single-stage or 1.5-stage procedures instead of the traditional 2-stage procedure, in a PJI scenario.

STUDY DESIGN

- **Type of study:** Multicentric retrospective study performed in 4 different institutions in the US and in Europe
- **Patient population:** 117 patients with suspected SA/PJI
- **Observation:** Evaluation by the score-based diagnostic algorithm
- **Control:** Microorganism identification in synovial fluid by BIOFIRE® Joint Infection (JI) Panel only if the score was 6 or more
- **Outcomes:** Application of a new score-based SA and PJI diagnostic algorithm

RESULTS

The first step of the algorithm is based on serological markers: the threshold for erythrocyte sedimentation rate (ESR) was set at 30 mm/h and for C-reactive protein (CRP) was set at 1 mg/dL. Patients with a score ≥ 2 were considered at risk for SA/PJI and underwent synovial fluid analysis as the second step for which thresholds were set up for white blood cells at 3000 cells/µL, polymorphonuclear leukocytes (PMN) at 80% and synovial fluid CRP at 6.9 mg/L. Patients with a score ≥ 6 were considered to have a SA/PJI.

117 patients reached the second step, among them 43/117 reached the third step and 74/117 patients were diagnosed with non-infectious inflammatory joint diseases. Finally, 26/43 were PJI patients (4 acute and 18 chronic) and 17/43 were SA patients. **These 43 patients were tested using culture for 14 days and mPCR, BIOFIRE JI Panel**, as part of the third step.

The average turnaround time **(TAT) was 3.13h for BIOFIRE JI Panel, 4.5 days for culture and 3.2 days for next-generation sequencing (NGS)**.

When the **BIOFIRE JI Panel was the determinant test for diagnosis, average TAT for culture was 4 days while when mNGS was the determinant test for diagnosis, average TAT for culture was 5 days. BIOFIRE JI Panel was considered the determinant diagnostic test in 63% of affected joints. For irrigation and debridement in native joint, BIOFIRE JI Panel was the determinant in 88.2%** while culture was the determinant in 11.8% of the cases. **For PJI, BIOFIRE JI Panel was determinant in 65.3% of the cases**:

- 4 cases required a DAPRI (debridement, antibiotic pearls and retention of the implant procedure).
- 8 cases required single-stage surgery, and 2 cases required a 1.5-stage surgery → 5/10 were detected negative by BIOFIRE JI Panel and avoided the 2-stage [2-stage is the standard of care when an infecting microorganism is not identified] → therefore **19.2% underwent single-stage or 1.5 stage instead of 2-stage surgery**.
- 12 cases required 2-stage surgery.

CONCLUSIONS

The implementation of a stepwise diagnostic algorithm incorporating multiplex PCR significantly improved pathogen identification in SA and PJI, allowing detection in infected cases. Fast TAT (≈ 3 hours) and identification of pathogens and resistance genes enabled tailored therapy and support the reduction of two-stage surgical strategies in selected patients.

KEY FINDINGS

- **A four-step diagnostic algorithm for periprosthetic joint infections allowed the identification of 43/117 patients at risk for SA or PJI who underwent synovial fluid culture and mPCR testing.**
- **TAT was 3.13 hours for mPCR, 4.5 days for culture and 3.2 days for mNGS.**
- **BIOFIRE JI Panel was the determinant diagnostic in 63% of affected joints.**
- **For native JI: BIOFIRE JI Panel was determinant in 88.2% and culture in 11.8%.**
- **For PJI: BIOFIRE JI was determinant in 65.3% → 19.2% of patients underwent single-stage or 1.5-stage instead of 2-stage surgery.**

BIOFIRE® JOINT INFECTION PANEL – Performance

Figure 1. Diagnostic algorithm for periprosthetic joint infection
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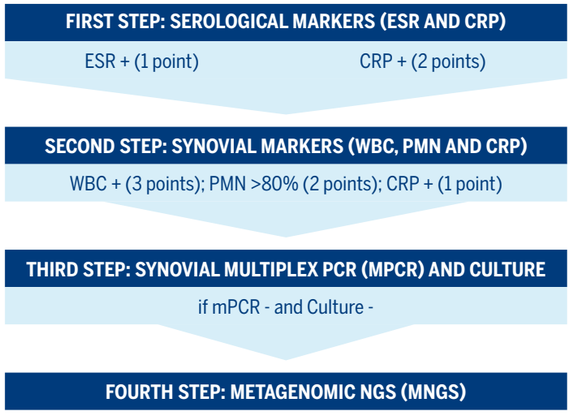

CRP: C-reactive protein; ESR: erythrocyte sedimentation rate; mNGS: metagenomic next generation sequencing; mPCR: multiplex PCR; PCR: polymerase chain reaction; PMN: polymorphonuclear leukocytes percentage; WBC: white blood cells count

BIOFIRE® FILMARRAY®

TROPICAL FEVER PANEL

BIOFIRE® FILMARRAY® TROPICAL FEVER PANEL - Performance

CLICK TO ACCESS ARTICLE

THE LANCET INFECTIOUS DISEASES
SEP 2022;22(9):1356-1364 DOI: 10.1016/S1473-3099(22)00290-0

Clinical evaluation of the BioFire Global Fever Panel for the identification of malaria, leptospirosis, chikungunya, and dengue from whole blood: a prospective, multicentre, cross-sectional diagnostic accuracy study

Manabe Y, Betz J, Jackson O, et *al*.

OBJECTIVE

To evaluate the accuracy of the BIOFIRE® Global Fever (GF) Panel[1] and compare to PCR assays for each of the 6 analytes using different primers.

[1]bioMérieux provides a product identical to BIOFIRE® Defense's BIOFIRE GF Panel called the BIOFIRE® FILMARRAY® Tropical Fever (TF) Panel. All product names and trademarks are property of their respective owners.

STUDY DESIGN

- **Type of study:** A prospective, multicenter, cross-sectional diagnostic accuracy study from 10 different sites ranging from rural to urban in tropical and sub-tropical settings in the following countries: United States (2 sites), Ghana, Kenya, Tanzania, Uganda, Cambodia, Thailand, Honduras and Peru
- **Date:** March 2018 to September 2019
- **Patient population:** Whole blood samples collected in EDTA tubes from 1,875 patients (adult and pediatric) included in the final analysis (1,965 initially enrolled patients)
- **Observation:** Analyzed by BIOFIRE GF Panel
- **Control:** Analyzed by PCR assays for each of the 6 analytes using different primers
- **Outcomes:** Performance of BIOFIRE GF Panel

RESULTS

At least one analyte was detected in 35.0% (657/1,875) of specimens:

- Dengue (1 - 4 serotypes) was detected in 266/1,875 (14.2%) by BIOFIRE GF Panel *vs.* 283/1,875 (15.1%) by comparator assay.
- Chikungunya was detected in 27/1,875 (1.4%) by BIOFIRE GF Panel, of which 25/27 (92.6%) were confirmed by comparator assay.
- *Leptospira* was detected in 19/1,875 (1.9%) by BIOFIRE GF Panel, of which 15/19 (78.9%) were confirmed by comparator assay.
- *Plasmodium* spp. (*P. falciparum*; *P. vivax/ovale*) was detected in 351/1,875 (18.7%) by BIOFIRE GF Panel and 339/351 (96.6%) were confirmed by comparator assay.

Overall, **multiple analytes were detected in 28 (1.5%) of 1,875 specimens**, including 28 of 657 (4.3%) positive specimens.

The positive percent agreement (PPA) for the six analytes was evaluated as follows in fresh samples:

- Chikungunya virus **100%** (95% CI [86.3 ; 100])
- Dengue virus **94.0%** (95% CI [90.6 ; 96.5])
- *Leptospira spp*. **93.8%** (95% CI [69.8 ; 99.8])
- *Plasmodium* spp. **98.3%** (95% CI [96.3 ; 99.4])
- *Plasmodium falciparum* **92.7%** (95% CI [88.8 ; 95.6]), and *P. vivax* or *P. ovale* 92.7% (95% CI [86.7 ; 96.6])

The negative percent agreement (NPA) was equal to **99.2%** for all analytes.

CONCLUSIONS

The BIOFIRE GF Panel demonstrated excellent diagnostic accuracy for six key analytes — dengue, chikungunya, *Leptospira* spp., and *Plasmodium* species (including *P. falciparum* and *P. vivax/ovale*) — with sensitivity ≥ 92.7% and specificity ≥ 99.2% across diverse global sites. This fast, one-hour, sample-to-answer platform offers significant potential for improving targeted management of acute febrile illness and enhancing public health surveillance in tropical and subtropical regions.

KEY FINDINGS

- **Patients with acute febrile infection present with general symptoms, making the presumptive diagnosis difficult.**
- **In this 10-site study, ranging from rural to urban in tropical and sub-tropical settings, there was at least one organism detected by the BIOFIRE GF Panel in 35.0% of samples.**
- **BIOFIRE GF Panel showed sensitive (PPA ≥ 92.7%) and specific (NPA ≥ 99.2%) detections for the 6 analytes.**

BIOFIRE® FIREWORKS™

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OPEN FORUM INFECTIOUS DISEASES
JUN 2022;9(7):OFAC296 DOI: 10.1093/OFID/OFAC296

Epidemiology of Antimicrobial Resistance Among Blood and Respiratory Specimens in the United States Using Genotypic Analysis from a Cloud-Based Population

Timbrook T, Olin K, Spaulding U, et *al*.

OBJECTIVE

To evaluate the epidemiology of antimicrobial resistance (AMR) determinants from respiratory and blood specimens, using genotypic analysis of data collected by FIREWORKS™ Trends, a feature of BIOFIRE® FIREWORKS™, from the BIOFIRE® FILMARRAY® Pneumonia (PN) Panel and the BIOFIRE® Blood Culture Identification 2 (BCID2) Panel, respectively, and to demonstrate proof-of-concept of the AMR capabilities of the surveillance network.

STUDY DESIGN

- **Type of study:** Retrospective observational study on data from FIREWORKS Trends (a cloud-based population surveillance network)
- **Date:**
  - **PN Panel:** February 2019 to October 2021
  - **BCID2 Panel:** July 2020 to October 2021
- **Data:** Collected using the BIOFIRE FILMARRAY PN and BIOFIRE BCID2 Panel, for both Gram-positive and negative organisms along with their AMR gene targets, as well as the detection of *Candida auris*
- **Observation:** Multiplex polymerase chain reaction by BIOFIRE
- **Outcomes:**
  - Proportion of detections evaluated by region and Panel
  - Co-detections of AMR and proportion of detections per organism analyzed for Gram-negative organisms

RESULTS

In total, **26,912 BIOFIRE Panels results were analyzed**. The proportions of AMR detection were greatest in the South and among respiratory specimens. Resistance proportions for Gram-negative were **7.0% CTX-M** and **2.9% carbapenemases** while Gram-positive AMR reflected **34.9% for methicillin-resistant *Staphylococcus aureus*** (MRSA) and **15.9% for vancomycin-resistant *enterococci*** (VRE). Emerging AMR detections occurred with **10 *mcr*-1** and **4 *C. auris*** positives, as well as 3 codetections of *mcr*-1 and *bla*^{NDM} in *Enterobacteriaceae*.

CONCLUSIONS

Near real-time genotypic surveillance using BIOFIRE Panels revealed significant AMR patterns in US blood and respiratory specimens, including high MRSA (34.9%) and VRE (15.9%) rates and emerging threats such as mcr-1 and *C. auris*. These findings underscore the value of cloud-based molecular surveillance networks for guiding antimicrobial stewardship and informing public health strategies.

KEY FINDINGS

- **Near real-time characterization of these resistance types is important for local guideline development and outbreak detection, regional benchmarking, and informing national public health initiatives.**
- **Nearly pandrug resistant detections (*e.g., mcr-1* and *bla*^{NDM} codetections) occurred, highlighting the importance of AMR surveillance.**

BIOFIRE® FIREWORKS™ - Epidemiology

Figure 1. Detection rates of genotypic AMR detections per region overall and stratified by syndromic testing type
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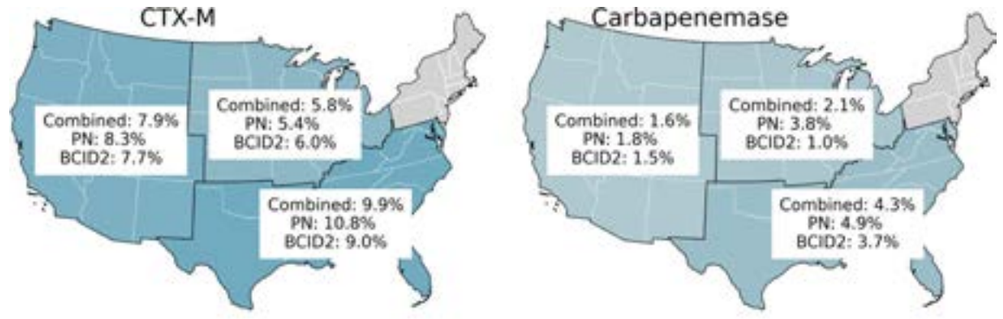

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PLOS ONE
APR 2021;16(4):E0250767 DOI: 10.1371/JOURNAL.PONE.0250767

Real-Time Gastrointestinal Infection Surveillance Through a Cloud-Based Network of Clinical Laboratories

Ruzante J, Olin K, Munoz B, et *al*.

OBJECTIVE

To describe the pathogen detection rates of the BIOFIRE® FILMARRAY® Gastrointestinal (GI) Panel.

STUDY DESIGN

- **Type of study:** A retrospective observational study in the US
- **Date:** 1st January 2016 to 31st October 2018
- **Patient population:** De-identified results from BIOFIRE FILMARRAY GI Panel through FIREWORKS™ Trends, a feature of BIOFIRE® FIREWORKS™
- **Observation:** Observed rate of pathogen detection from FIREWORKS Trends
- **Control:** Rankings of eight pathogens monitored by FoodNet (a Centers for Disease Control surveillance system)
- **Outcomes:** Detection rate

RESULTS

During the study period, **50,192 pathogens were detected. 71% were bacteria, 25% were viruses**, and 4% were parasites. The most common detections were *Clostridioides difficile* (30%), enteropathogenic *Escherichia coli* (EPEC) (16%), and norovirus (11%). No seasonal trends were seen for sapovirus, adenovirus, ***C. difficile, Vibrio,* and *Yersinia enterocolitica***. The winter season showed an increase in detection rates for astrovirus and norovirus, while the months of April and May showed an increase in rotavirus detections. *Campylobacter*, *Salmonella*, *Plesiomonas shigelloides*, EPEC, and *Cryptosporidium* had higher positive detection rates in the summer months.

The **co-detection rate was 10.2%. Most (80%) co-detections had two pathogens** detected; the remaining **20% had three detections**. Notably, co-detections were more likely to be seen in *P. shigelloides*, *Entamoeba histolytica*, enterotoxigenic *E. coli* (ETEC) and enteroaggregative *E. coli* (EAEC) cases. Positive correlations were seen between detections of *Shigella*/Enteroinvasive *E. coli* and *E. histolytica* as well as ETEC and EAEC, however the correlation was weak. Conversely, negative correlations were observed between *C. difficile* and other pathogens.

The proportion of detections of foodborne pathogens were similar between the BIOFIRE FILMARRAY GI Panel and FoodNet. Regarding the pathogen monitoring by FoodNet, **in both cases, *Campylobacter* and *Salmonella* had the highest rates of detection and *Vibrio* and *Cyclospora cayetanensis* had the lowest**. However, the **BIOFIRE FILMARRAY GI Panel detected higher proportions of all pathogens except *Campylobacter* and *Salmonella***.

CONCLUSIONS

BIOFIRE Trends provides near real-time surveillance of gastrointestinal pathogens, offering valuable insights into disease burden, seasonality, and co-detection patterns. Its adoption highlights a significant opportunity for public health to improve monitoring and potentially detect outbreaks through comprehensive molecular diagnostics.

KEY FINDINGS

- **The most commonly detected pathogens were *C. difficile*, EPEC, and norovirus.**
- **The co-detection rate was 10.2%.**
- **There was a weak positive correlation between co-detections of *Shigella*/Enteroinvasive *E. coli* and *E. histolytica* as well as ETEC and EAEC.**

Other evidence-based Selection of Publications available

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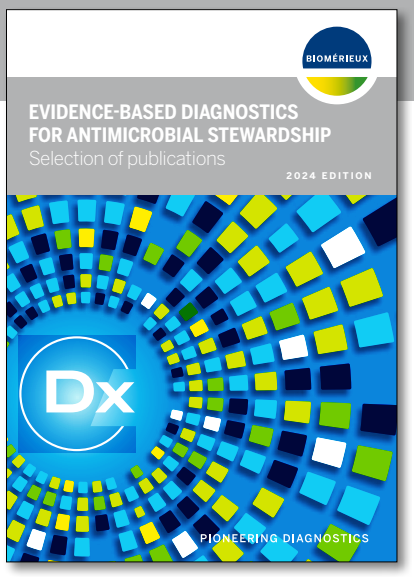

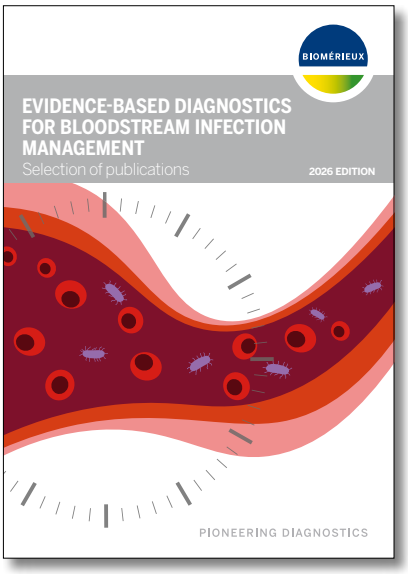

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