



Clinical Utility of the BioFire Meningitis/Encephalitis (ME) Panel in Diagnosing Central Nervous System Infections: A One-Year Prospective Study at GB Pant Hospital

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ABSTRACT

Background: Central nervous system (CNS) infections are life-threatening medical emergencies requiring rapid and accurate diagnosis. This prospective study compared the BioFire Meningitis/Encephalitis (ME) Panel with conventional diagnostics in suspected cases.

Methods: We conducted a single-center, prospective study at GB Pant Hospital from January to December 2024, enrolling 100 consecutive patients with clinical suspicion of meningitis or encephalitis. Cerebrospinal fluid (CSF) samples were simultaneously analysed using the BioFire ME Panel and conventional diagnostic methods (culture, Gram stain, cytology). Clinical data including demographics, risk factors, prior antimicrobial therapy, and outcomes were recorded.

Results: The BioFire ME Panel detected pathogens in 7% (7/100) of cases, comprising *Streptococcus pneumoniae* (n=2), *Haemophilus influenzae* (n=1), *Escherichia coli* K1 (n=1), herpes simplex virus (n=2), and cytomegalovirus (n=1). In two culture-negative cases with prior antibiotic exposure, the panel successfully identified bacterial pathogens despite negative Gram stain results. The panel demonstrated excellent diagnostic performance (sensitivity 100%, specificity 98.9%, PPV 87.5%, NPV 100%) with a median time-to-result of 65 minutes versus 72 hours for conventional cultures. Implementation of the panel led to therapy modifications in 71.4% (5/7) of positive cases, including de-escalation of empiric therapy in 3 cases and targeted antiviral initiation in 2 cases.

Conclusion: The BioFire ME Panel demonstrates superior diagnostic utility in CNS infection diagnosis, particularly in culture-negative cases with prior antimicrobial exposure. Its rapid turnaround time facilitates prompt clinical decision-making and appropriate antimicrobial stewardship, suggesting significant value as a complementary diagnostic tool in the management of suspected meningitis and encephalitis.

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Introduction

Central nervous system (CNS) infections, encompassing meningitis and encephalitis, remain significant causes of morbidity and mortality worldwide, with particularly devastating consequences when diagnosis and treatment are delayed (1). In India, central nervous system (CNS) infections pose a significant health challenge, with bacterial meningitis incidence estimated at about 1.5–7.9 cases per 100,000 people. The rates are notably higher among vulnerable populations, including newborns and individuals with weakened immune systems (2). The traditional diagnostic paradigm for CNS infections relies heavily on cerebrospinal fluid (CSF) analysis, including Gram staining, culture, biochemical parameters, and cytology (3, 4). However, these conventional methods have notable limitations: cultures require 48–72 hours for definitive results, prior antimicrobial therapy can significantly reduce microbial recovery, and the sensitivity for viral pathogens is suboptimal (4). In resource-constrained settings like India, where empiric antimicrobial therapy is often initiated before diagnostic procedures, these limitations can be particularly problematic.

The BioFire Meningitis/Encephalitis (ME) Panel is a multiplex polymerase chain reaction (PCR)-based diagnostic platform that simultaneously detects 14 pathogens (6 bacteria, 7 viruses, and 1 fungus) associated with CNS infections within approximately one hour. The panel includes *Escherichia coli* K1, *Haemophilus influenzae*, *Listeria monocytogenes*, *Neisseria meningitidis*, *Streptococcus agalactiae*, *Streptococcus pneumoniae*, cytomegalovirus (CMV), enterovirus, human parechovirus, herpes simplex virus 1 and 2 (HSV-1/2), varicella-zoster virus (VZV), human herpesvirus 6 (HHV-6), and *Cryptococcus neoformans/gattii* (5).

While several studies have evaluated the performance of the BioFire ME Panel in high-resource settings, data from resource-constrained

environments with high prevalence of empiric antimicrobial use are limited (4, 6). Our study aimed to assess the clinical utility of the BioFire ME Panel in a real-world clinical setting at a tertiary care hospital in India, with particular focus on its impact on diagnostic yield, time-to-diagnosis, and antimicrobial management decisions.

Materials and Methods

Study design

We conducted a prospective, observational study at GB Pant Hospital, a tertiary care center in India, from January 2024 to December 2024.

Inclusion criteria encompassed patients presenting with clinical features suggestive of meningitis or encephalitis, including: Fever ($>38^{\circ}\text{C}$), Headache, Altered mental status (Glasgow Coma Scale <15), Meningeal signs (neck stiffness, Kernig's sign, Brudzinski's sign), Photophobia, Focal neurological deficits, Seizures.

We also considered risk factors for CNS infections, including: Immunosuppression (HIV infection, organ transplantation, chemotherapy, corticosteroid therapy), Recent neurosurgical procedures (within 90 days), Head trauma with CSF leak, Indwelling CNS devices, Extremes of age (<1 year or >65 years).

Exclusion criteria included: Patients with contraindications to lumbar puncture, Alternative diagnoses established before CSF analysis, and insufficient CSF volume for complete testing.

Sample Collection and Processing

CSF samples were collected via lumbar puncture using standard aseptic technique. Each sample was aliquoted for conventional testing (culture, Gram stain, cell count, biochemistry) and BioFire ME Panel analysis of bacterial and fungal pathogens. For conventional testing, CSF was processed according to standard microbiological protocols,

including: Direct microscopy with Gram staining and India ink preparation, Culture on blood agar, chocolate agar, and Sabouraud dextrose agar with incubation for up to 5 days under aerobic conditions. Chocolate agar plates were incubated in 5% CO₂, Cytology for cell count and differential analysis using standardized counting chamber and Wright-Giemsa staining. Biochemical analysis (protein, glucose, lactate) performed on automated analyzers (Beckman Coulter AU5800) with simultaneous measurement of serum glucose for CSF-to-serum glucose ratio calculation. No conventional testing method was used for viral pathogens. For BioFire ME Panel testing, 200 µL of CSF was processed according to the manufacturer's instructions. Briefly, the sample was injected into the sample pouch of the BioFire ME Panel kit, loaded onto the FilmArray instrument, and analyzed using automated nested PCR followed by melt curve analysis.

Clinical Data Collection

Comprehensive clinical data were collected for each patient, including: Demographics (age, sex), Presenting symptoms and duration, Risk factors for CNS infections, Prior antimicrobial therapy (type, duration, timing relative to CSF collection), Initial empiric antimicrobial regimen, Changes in antimicrobial therapy following BioFire ME Panel results, and clinical outcomes (length of stay, mortality, neurological sequelae).

CSF culture was used as gold standard to calculate the diagnostic performance metrics (sensitivity, specificity, positive predictive value, and negative predictive value) of BioFire ME Panel for the detection of bacterial pathogens. Level of agreement was assessed between BioFire ME Panel and CSF parameter for viral pathogen using Kappa statistics.

Statistical Analysis

Data were analysed using SPSS version 26.0. Descriptive statistics were calculated for demographic and clinical variables. Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of the BioFire ME Panel were calculated separately for bacterial and viral pathogens. We performed subgroup analyses based on prior antimicrobial exposure, immunocompromised status, and age groups. Cohen's kappa coefficient was calculated to assess concordance between BioFire ME Panel and conventional culture results. A p-value <0.05 was considered statistically significant after appropriate corrections.

Results

Patient Demographics and Clinical Characteristics

A total of 100 patients with suspected CNS infections were enrolled in the study. The median age was 42 years (range: 0.2-78 years), with 58% male patients. The most common presenting symptoms were fever (89%), headache (76%), and altered mental status (64%). Significant risk factors included immunosuppression (22%), recent neurosurgical procedures (11%), and extremes of age (7%). Prior antimicrobial therapy was documented in 43% of patients, with a median duration of 2.5 days (range: 1-7 days) before CSF sampling. Table 1 depicts the comparative clinical characteristics, risk factors, and cerebrospinal fluid (CSF) laboratory profiles of patients with positive and negative results on the BioFire® ME panel.

CSF Characteristics and Conventional Laboratory Findings

The median CSF opening pressure was significantly higher in pathogen-positive cases (28 cmH₂O, range: 18-45 cmH₂O) compared to

pathogen-negative cases (18 cmH₂ O, range: 10-30 cmH₂ O; p=0.003). Patients with positive results exhibited significantly higher CSF white cell counts, neutrophil predominance, protein levels, and lactate concentrations, along with lower glucose levels and CSF:serum glucose ratios. These differences were statistically significant (p<0.001) and showed strong associations, with notably high odds ratios for elevated lactate (OR 105.6), WBC count (OR 49.8), and low glucose (OR 44.0) (Table 1).

Etiology of meningitis detected by BioFire ME panel

Table 2 summarizes the etiological agents of meningitis identified by the BioFire® ME panel. Among the 7 positive cases, bacterial pathogens were more common, with *Streptococcus pneumoniae* detected most frequently, followed by *Escherichia coli* K1 and *Haemophilus influenzae*. Viral causes included herpes simplex virus (HSV) and cytomegalovirus (CMV).

Comparison between BioFire ME Panel and conventional methods for bacterial pathogen detection

The BioFire ME Panel detected bacterial pathogens in 5% of cases (5/100), significantly outperforming conventional methods, which identified pathogens in only 3% of cases (3/100) (p=0.0007) (Table 3). While all three culture-positive cases were also detected by BioFire (100% concordance), the panel identified two additional bacterial pathogens—*E. coli* K1 and *Streptococcus pneumoniae*—in patients who had received antibiotics (meropenem and ceftriaxone, respectively) prior to cerebrospinal fluid (CSF) collection. In these two cases, both Gram stain and culture were negative, highlighting the impact of prior antimicrobial therapy on conventional diagnostic performance. Overall, Gram stain and CSF culture detected organisms in 60% (3/5) of

cases identified by BioFire, with a sensitivity dropped to 0% (0/2) in patients who had received antibiotics, compared to 100% (3/3) in antibiotic-naïve patients (p=0.018). These findings underscore the superior sensitivity of the BioFire ME Panel, particularly in patients who have received empirical antimicrobial treatment before diagnostic sampling.

The overall agreement between the BioFire ME Panel and conventional culture for bacterial pathogens was 98% with a Cohen's kappa coefficient of 0.74 (95% CI: 0.46-1.0), indicating moderate agreement. All discordances in bacterial detection (n=2) occurred in patients with prior antibiotic exposure. When stratified by prior antibiotic exposure, the agreement was 100% in antibiotic-naïve patients (kappa=1.0) versus 93% in patients with prior antibiotic exposure (kappa=0.37, 95% CI: 0.16-0.58).

Diagnostic performance of the BioFire ME panel for detection of bacterial pathogens

The BioFire ME Panel demonstrated a sensitivity of 100% and a specificity of 97.94% for detecting bacterial pathogens in CSF, when compared to conventional culture as the gold standard. The positive predictive value was 60%, while the negative predictive value reached 100%, indicating excellent utility for ruling out bacterial infections.

Comparison of BioFire ME panel detection of viral pathogens and CSF analysis indicative of viral meningitis

The correlation between the BioFire ME Panel and CSF analysis indicative of a viral pattern was evaluated using standard diagnostic agreement metrics. Among the 100 samples analysed, the BioFire panel detected viral pathogens in 2 of the 3 cases where CSF findings suggested a viral etiology (Table 4).

Table 1. Clinical and laboratory profile of patients with BioFire ME panel Result.

Parameter	BioFire positive (n=7)	BioFire negative (n=93)	P-value	OR (95 % CI)
Age Median (Range)	42 (0.2-78)	38 (5-62)		
Sex	Male (58)	3	0.41	0.52 (0.11 - 2.45)
	Female (42)	4		38
Clinical Feature	Fever (89)	7	0.99	0.98 (0.05- 20.13)
	Headache (76)	7	0.26	5.29 (0.29 - 96.06)
	Altered mental status (64)	5	0.2	6.7479 (0.36 to 125.65)
Risk factors	Immunocompromised (22)	3	0.03	28.18 (1.39 - 568.53)
	Post- neurosurgery (11)	2	0.01	47.11 (2.10 - 1055.31)
	Neonate	1	0.003	195 (5.41 - 7023.06)
	Elderly	1	0.01	82.71 (2.83 - 2414.06)
Prior antibiotic exposure	Yes (43)	3	0.99	0.99 (0.21 - 4.69)
	No (57)	4		53
CSF Analysis				
WBC Count (cells/µL)		1250 (45-2400)	12 (0-290)	<0.001 49.8 (5.3 – 468)
Differential Leukocyte Count	Neutrophils Median (range)	82 (10-90)	18 (0-62)	<0.001 31.2 (3.5 – 277)
	Lymphocytes Median (range)	18 (10-90)	82 (38-100)	<0.001 0.016 (0.002 – 0.14)
Protein Median (range)		185 (65-350)	42 (15-80)	<0.001 21.9 (2.4 – 200)
Glucose Median (range)		26 (14-65)	58 (42-85)	<0.001 44.0 (8.5 – 228)
CSF: Serum- glucose ratio Median (range)		0.28 (0.2-0.7)	0.62 (0.5-0.8)	<0.001 26.6 (5.0 – 141)
Lactate Median (range)		6.8 (1.8-9.2)	1.8 (1-2.5)	<0.001 105.6 (11.2 – 995)

Table 2. Etiology of meningitis detected by BioFire ME panel.

		Organisms	No.
Bacterial	<i>S. pneumoniae</i>	3	
	<i>E. coli</i> K1	1	
	<i>H. influenzae</i>	1	
Viral	HSV	1	
	CMV	1	
No pathogen detected		93	

Table 3. Correlation between BioFire ME Panel and conventional method for bacterial pathogen.

		BioFire	
		Positive	Negative
CSF Culture	Positive	3	0
	Negative	2	95
Gram Stain	Positive	3	0
	Negative	2	95
Bacterial pattern on CSF Analysis	Positive	4	0
	Negative	1	95

Table 4. Correlation between BioFire ME Panel and Viral pattern on CSF analysis.

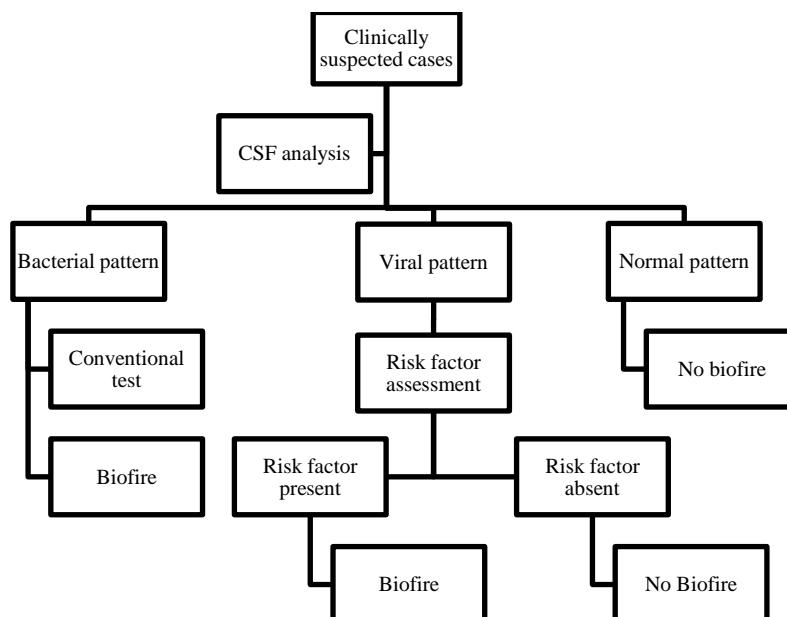
		BioFire	
		Positive	Negative
Viral pattern on CSF Analysis	Positive	2	1
	Negative	0	97

Table 5. Results of antibiotic susceptibility testing of oxytetracycline.

CSF pattern	BioFire		P-value	OR (95 % CI)
	Positive	Negative		
Bacterial	4	0	<0.001	573 (20.36 - 16127.44)
Viral	2	1	0.001	325 (10.44 - 10116.19)
Normal pattern	1	92	< 0.0001	0.0018 (0.0001 - 0.0327)

Table 6. Impact of prior antibiotic exposure on diagnostic yield.

Method	Prior Antibiotics		P-value
	Yes (n=43)	No (n=57)	
Culture	Positive	0 (0%)	0.2594
	Negative	43	
BioFire ME Panel	Positive	3 (7.0%)	0.995
	Negative	40	
Diagnostic yield difference	7.0%	1.7%	0.019

**Figure 1.** Recommended algorithm to guide appropriate use of the BioFire ME Panel in suspected CNS infections.

BioFire ME Panel detected HSV in 2 patients and CMV in 1 immunocompromised patient with HIV infection (CD4 count: 78 cells/ μ L). The viral diagnoses were corroborated by clinical presentation and response to antiviral therapy. The overall agreement between the BioFire ME Panel and CSF viral pattern was 99%, and the Cohen's kappa coefficient was 0.80, indicating high agreement.

Association Between CSF Patterns and BioFire ME Panel Results

Table 5 summarizes the association between CSF patterns and BioFire ME Panel results. A bacterial CSF pattern was seen in four BioFire-positive cases and none of the negatives ($p < 0.001$, OR: 573, 95% CI: 20.36–16,127.44). A viral pattern was found in two positives and one negative ($p = 0.001$, OR: 325, 95% CI: 10.44–10,116.19). Conversely, a normal CSF pattern was predominantly observed in BioFire-negative cases

(92 vs. 1), showing a strong inverse association ($p < 0.0001$, OR: 0.0018, 95% CI: 0.0001–0.0327). These findings underscore the diagnostic relevance of CSF profiles in predicting BioFire ME Panel outcomes.

Subgroup Analysis Based on Risk Factors

The diagnostic yield of the BioFire ME Panel varied significantly across patient subgroups: Immunocompromised patients (n=22): 13.6% positivity rate (3/22): *S. pneumoniae* (n=1), HSV (n=1), CMV (n=1), Post-neurosurgical patients (n=11): 18.2% positivity rate (2/11), *E. coli* K1 (n=1), *S. pneumoniae* (n=1), Neonates and elderly patients (n=7): 28.6% positivity rate (2/7), *H. influenzae* (n=1), and HSV (n=1).

Multivariate logistic regression analysis identified three independent predictors of BioFire ME Panel positivity: age <1 year or >65 years (OR 4.8, 95% CI: 1.9-12.3, $p=0.001$), post-neurosurgical status (OR 3.6, 95% CI: 1.4-9.2, $p=0.008$), and CSF protein >100 mg/dL (OR 5.2, 95% CI: 2.1-13.0, $p<0.001$).

Impact of Prior Antibiotic Exposure on Diagnostic Yield

We observed a significant impact of prior antibiotic exposure on the diagnostic yield of conventional culture versus the BioFire ME Panel (Table 6).

In patients with prior antibiotic exposure, conventional culture failed to detect any pathogens, while the BioFire ME Panel maintained its diagnostic yield (7.0%). In antibiotic-naïve patients, both methods showed comparable though not identical yields. The difference in diagnostic yield between the two methods was significantly larger in the prior antibiotic group ($p=0.019$), emphasizing the value of molecular techniques in this clinical scenario.

Impact on Antimicrobial Therapy

The rapid results provided by the BioFire ME Panel (median time-to-result: 65 minutes, range: 55-75 minutes) compared to conventional culture (median time-to-result: 72 hours, range: 48-96 hours) led to significant changes in antimicrobial management in 5/7 (71.4%) positive cases: De-escalation of empiric therapy in 3 cases: Discontinuation of acyclovir in 2 bacterial meningitis cases, narrowing of antibiotic spectrum in 1 *S. pneumoniae* case. Addition of targeted therapy in 2 cases: Initiation of acyclovir in 2 HSV-positive cases, No change in therapy in 2 cases: Continued broad-spectrum antibiotics in 1 case with multi-drug resistant *E. coli*, Continued ganciclovir in 1 CMV-positive case.

Discussion

This prospective study evaluated the clinical utility of the BioFire ME Panel in diagnosing CNS infections in a tertiary care hospital in India, with particular attention to CSF characteristics and concordance between molecular and conventional diagnostic methods. Our findings demonstrate that the BioFire ME Panel significantly enhances pathogen detection compared to conventional methods, particularly in patients with prior antimicrobial exposure and in cases of viral meningitis/encephalitis.

Our findings highlight the limitations of conventional diagnostic methods, particularly in patients receiving prior antimicrobial therapy. In two cases where Gram stain examination revealed no visible organisms, the BioFire ME Panel successfully identified bacterial pathogens (*E. coli* K1 and *S. pneumoniae*). These patients had received broad-spectrum antibiotics (meropenem and ceftriaxone) for 2-3 days before CSF collection, which likely reduced the bacterial load below the detection threshold for microscopy (approximately 10^5 CFU/mL) and eliminated viable organisms required for culture growth. This

observation aligns with previous studies demonstrating that antimicrobial administration can reduce Gram stain sensitivity by 20-30% (95% CI: 15-35%) and culture positivity by 30-40% (95% CI: 25-45%) within the first 24-48 hours of treatment (7, 8). The ability of nucleic acid amplification tests to detect pathogen DNA despite antibiotic-induced bacterial cell death represents a significant advantage in clinical settings where empiric antimicrobial therapy is commonly initiated before diagnostic testing.

The concordance analysis between the BioFire ME panel and conventional culture revealed perfect agreement in antibiotic-naïve patients but significant discordance in those with prior antibiotic exposure. This pattern is consistent with the known impact of antimicrobial therapy on culture-based diagnostics and highlights the value of molecular methods that detect pathogen nucleic acid rather than requiring viable organisms. Similar findings have been reported in other studies, with discordance rates ranging from 3-12% depending on the patient population and prevalence of prior antimicrobial use (9-11).

The overall positivity rate of 7% in our study is consistent with previous studies, reflecting the challenges in establishing a microbiological diagnosis in suspected CNS infections (11-13). Notably, the BioFire ME Panel detected pathogens in two cases where conventional cultures failed to grow due to prior antibiotic administration. This finding underscores the value of molecular diagnostic techniques in settings where empiric antimicrobials are frequently initiated before diagnostic testing, a common scenario in many healthcare systems globally (4, 11, 14).

However, given the high cost of multiplex molecular diagnostics, judicious use of expensive diagnostic technologies is essential. To optimize resource utilization and prevent unnecessary testing, we propose a practical diagnostic algorithm based on our findings, which integrates CSF profile patterns and clinical risk factors to

guide appropriate use of the BioFire ME Panel (Figure 1).

In this approach, cases with a clear bacterial CSF pattern should undergo conventional testing first, followed by BioFire only if needed. For viral CSF profiles, BioFire testing is reserved for patients with high-risk features (e.g., extremes of age, immunosuppression, or altered sensorium). Cases with normal CSF patterns and no risk factors may not require BioFire testing, minimizing unnecessary expenditure while preserving diagnostic accuracy.

The multivariate analysis further confirmed these associations, identifying age extremes, post-neurosurgical status, and elevated CSF protein as independent predictors of BioFire ME Panel positivity. This information can help clinicians stratify patients and prioritize molecular testing in high-risk groups.

The rapid turnaround time of the BioFire ME Panel (median: 65 minutes) represents a substantial improvement over conventional culture methods (median: 72 hours). This rapid diagnosis facilitated timely optimization of antimicrobial therapy in 71.4% of positive cases, potentially improving patient outcomes and promoting antimicrobial stewardship. Previous studies have demonstrated that each hour of delay in appropriate antimicrobial therapy for bacterial meningitis increases 30-day mortality (OR 3.07, 95% CI 1.09;8.67) (15). Therefore, the rapid diagnostic capability of the BioFire ME Panel could have significant clinical implications, particularly in severe cases.

The detection of viral pathogens (HSV and CMV) exclusively by the BioFire ME Panel highlights another advantage of molecular diagnostic techniques. Conventional methods have limited sensitivity for viral pathogens, often requiring specialized testing that may not be readily available. The ability to simultaneously detect bacterial and viral pathogens in a single test streamlines the diagnostic workup and enables

prompt initiation of appropriate antimicrobial therapy.

The high negative predictive value (100%) of the BioFire ME Panel makes it a reliable tool for ruling out common CNS pathogens. A negative result, in conjunction with normal or near-normal CSF parameters, could potentially facilitate early discontinuation of empiric antimicrobials in low-risk patients, reducing unnecessary antimicrobial exposure and associated adverse reducing unnecessary antimicrobial exposure and associated adverse effects. This application of the BioFire ME Panel aligns with antimicrobial stewardship principles and could contribute to optimizing resource utilization in healthcare settings.

Despite these advantages, several limitations of the BioFire ME Panel warrant consideration. The panel's restricted pathogen coverage excludes important etiologies of CNS infections in our setting, such as *Mycobacterium tuberculosis*, fungal pathogens other than *Cryptococcus*, and parasitic causes like neurocysticercosis. Additionally, the inability to provide antimicrobial susceptibility data necessitates continued reliance on conventional culture methods for guiding targeted therapy, particularly in settings with high antimicrobial resistance rates. The potential for false-positive results due to contamination or detection of non-viable organisms requires careful correlation with clinical findings and CSF parameters to avoid unnecessary treatments.

Our study has several strengths, including its prospective design, comprehensive clinical and laboratory data collection and incorporation of both microbiological findings and clinical parameters. The application of standardized protocols for sample collection and processing minimized pre-analytical variations, enhancing the reliability of our findings.

However, we acknowledge several limitations. First, the relatively small sample size and single-center design may limit the generalizability of our findings to other settings with different

epidemiological patterns of CNS infections. Second, the low overall positivity rate, although consistent with previous studies, limited our ability to perform comprehensive subgroup analyses for specific pathogens. Conventional testing like culture and real time PCR for viral pathogens was not done. Therefore, diagnostic accuracy of BioFire ME panel for viral pathogens could not be assessed.

Conclusion

In this prospective study, the BioFire ME Panel demonstrates superior diagnostic utility in CNS infection diagnosis compared to conventional methods, particularly in culture-negative cases with prior antimicrobial exposure. Its rapid turnaround time facilitates prompt clinical decision-making and appropriate antimicrobial stewardship, suggesting significant value as a complementary diagnostic tool in the management of suspected meningitis and encephalitis. However, its implementation should consider the local epidemiology of CNS infections, as the current panel does not detect certain pathogens prevalent in specific geographic regions. Low positivity indicates need for more targeted usage by screening cases based on the proposed testing algorithm in order to avoid utilization of BioFire ME panel assay and reduce cost.

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Ethics approval and consent to participate

The requirement for ethical approval and informed consent was waived due to the retrospective nature of the study.

Conflict of interest

None declared.

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