FilmArray ME Panel Pathogens

BACTERIA

Escherichia coli K1
*Haemophilus influenzae**
*Listeria monocytogenes**
*Neisseria meningitidis**
Streptococcus agalactiae
Streptococcus pneumoniae

VIRUSES

Cytomegalovirus (CMV)
Enterovirus (EV)
Herpes simplex virus 1 (HSV-1)
Herpes simplex virus 2 (HSV-2)
Human herpesvirus 6 (HHV-6)
Human parechovirus (HPeV)
Varicella zoster virus (VZV)*

YEAST

Cryptococcus neoformans/gattii

*Nationally Notifiable Conditions.[12] Refer to your state health lab for requirements pertaining to state-reportable pathogens.

Overall Performance of the FilmArray ME Panel[13]

- 94.2% Sensitivity
- 99.8% Specificity

Sample Requirements:
0.2 mL of CSF (do not centrifuge)

References & Guidelines

REFERENCES

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GUIDELINES

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FLM1-MKT-0166-04

14 PATHOGENS
1 hr

Clinical Impact of the FilmArray® Meningitis/ Encephalitis (ME) Panel

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Time to Diagnosis is Critical[1]

Bacterial meningitis can be fatal in healthy people in 24 to 48 hours.

Challenges with Diagnosing Meningitis and Encephalitis Infections

Distinguishing viral from bacterial meningitis based on clinical presentation is challenging. Patients often present with similar, flu-like symptoms.[1,2,3]

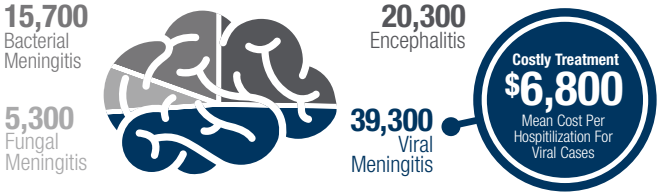
Culture is the standard method to test for bacterial meningitis. This method is:

- Time-consuming, taking 24 to 72 hours.[5]
- Technically complex, requiring specific expertise.
- Lacking in sensitivity, especially when specimen collection occurs after initiation of antimicrobial treatment.[4,5]
- Unable to detect non-bacterial pathogens, including the most common viral pathogens.

Viral testing requires a molecular amplification method that is time-consuming, often requiring several days for a definitive answer. Typically it is a send-out test and is expensive.

The current standard of care dictates that suspected meningitis and encephalitis cases are treated empirically.[A,B]

Annual Number of US Hospitalizations[6,7]



Who Should Get Tested?[2,11]

Meningitis and encephalitis can occur suddenly even in healthy people. Populations at higher risk include:

- Infants
- College students
- Travelers
- Military personnel
- Immunocompromised

Syndromic Testing

BioFire's syndromic testing allows clinicians to quickly identify infectious agents that produce similar symptoms in patients. BioFire's innovative PCR technology provides answers in a clinically actionable timeframe.

1 Test. 14 Pathogens. 1 Hour.

The FilmArray ME Panel tests for a comprehensive set of 14 of the most common bacterial, viral, and fungal pathogens associated with central nervous system (CNS) infections in 1 hour using only 0.2 mL of cerebral spinal fluid (CSF).[8]

The FilmArray ME Panel dramatically improves time to diagnostic results.[9]

Traditional testing
Receipt of sample in lab to report of organism identification

FilmArray ME Panel
Average time from collection to diagnosis

96%
Diagnostic yield for the FilmArray ME Panel compared to traditional testing

Rapid Diagnostic Evaluation Helps:

- Reduce mortality.[5]
- Modify empirical therapies sooner in favor of more specific treatments.[10]
- Reduce length of hospital stay by quickly identifying enteroviral meningitis.[10]
- Reduce patient and treatment costs.[10]
- Enact timely infection control measures.[10]
- Potentially increase patient satisfaction.

IDSA Guidelines[A,B]

Meningitis

- CSF cultures may take >48 hours for organism identification and are positive in 70-85% of patients with bacterial meningitis who have not received prior antimicrobial therapy; therefore rapid diagnostic tests should be considered to determine the bacterial etiology of meningitis.
- PCR may be useful for excluding the diagnosis of bacterial meningitis, with the potential for influencing decisions to initiate or discontinue antimicrobial therapy.
- Rapid PCR detection of enterovirus may lead to shorter hospital stays and decreased use of antimicrobial therapy.

Encephalitis

- >10% of patients with viral encephalitis can have normal CSF findings. Additional CSF tests, such as PCR, should be performed to establish the specific cause of encephalitis.
- Acyclovir should be initiated in all patients with suspected encephalitis.
- In patients who have negative herpes simplex 1 and 2 PCR results, do not modify treatment, repeat testing.

Please refer to the clinical guidelines for a complete list of recommendations.

Clinical Performance

A US 2016 published multicenter study demonstrated:[4]

- 99.8% overall agreement between the FilmArray ME Panel and comparator methods (CSF bacterial culture and PCR/sequencing assays for all other analytes).
- An overall positivity rate of 8.7%, consistent with the US prevalence of CNS infections.

"The FilmArray ME Panel represents a significant paradigm shift. It is the first test system allowing close-to-patient, rapid assessment of a broad range of infectious agents associated with central nervous system infections."[4]

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