



FilmArray[®] Meningitis/Encephalitis Panel - PCR

Qualitative detection of 14 CNS pathogens including viruses, bacteria and fungi directly from CSF specimens

Clinical Background and Methodology

The FilmArray Meningitis/Encephalitis (ME) Panel is a qualitative multiplexed nucleic acid-based in vitro diagnostic test using nested PCR. The FilmArray ME Panel is capable of simultaneous detection and identification of multiple bacterial, viral, and yeast nucleic acids directly from cerebrospinal fluid (CSF) specimens obtained via lumbar puncture **from individuals with signs and/or symptoms of meningitis and/or encephalitis**. Detection of 14 potential CNS pathogens from CSF includes: bacteria: *Escherichia coli* K1, *Haemophilus influenza*, *Listeria monocytogenes*, *Neisseria meningitidis* (encapsulated), *Streptococcus agalactiae* and *Streptococcus pneumoniae*; Viruses: CMV, Enterovirus, HSV-1, HSV-2, Human herpesvirus 6, Human parechovirus (HPeV) and VZV; Yeast: *Cryptococcus neoformans/gattii*.

Test Limitations

- False negative results may occur when the concentration of organism(s) in the specimen is below the device limit of detection.
- Concomitant culture is necessary for organism recovery if a sensitivity is necessary.
- This test is not intended for use with CSF collected from indwelling medical devices (e.g., CSF shunts).
- HHV-6 or CMV can exist in latent form that is reactivated during infection due to other pathogens, including agents not detected by the FilmArray ME panel that may cause meningitis/encephalitis (e.g., *Mycobacterium tuberculosis* or HIV).
- Viral shedding into the CSF often occurs in cases of zoster (shingles; caused by reactivation of VZV). VZV may not be the cause of CNS disease in these cases.
- This is a very sensitive PCR test. Therefore, **caution should be exercised during specimen collection and testing** to prevent contamination with rhinovirus associated with respiratory infections, which may crossreact with enterovirus. Caution is also indicated with respiratory tract pathogens shed from healthy individuals (e.g. *S. pneumoniae* and *H. influenza*). HSV-1 may also be shed from individuals with active or recurrent cold sores.
- This test does not detect other ME agents, such as *M. tuberculosis*, HIV-1/2, arboviruses, *Leptospira spp.*, *B. burgdorferi*, *Angiostrongylus*, *S. aureus*, and others.
- CSF specimens should not be centrifuged before testing.
- If two or more organisms are detected in a specimen, retesting is recommended to confirm the polymicrobial result.

Test Performance

Microorganism	SENSITIVITY (95% CI)	SPECIFICITY (95% CI)
E. coli K1*	86.3-98.9	98.5-100
H. influenza*	92.9-100	97.7-99.9
L. monocytogenes*	92.9-100	98.5-100
N. meningitidis*	95.1-100	98.3-100
S. agalactiae*	86.5-98.9	98.5-100
S. pneumoniae	51.0-100	98.7-99.6
CMV*	86.3-98.9	98.5-100
Enterovirus	85.5-98.8	99.0-99.8
HSV-1	34.2-100	99.5-100
HSV-2	72.2-100	99.5-100
HHV-6*	92.9-100	97.7-99.9
HPeV*	92.9-100	98.5-100
VZV	51.0-100	99.4-99.9
C. neoformans/gattii**	83.2-100	97.8-100

*Contrived specimens. **Archived specimens.

Test Ordering Information

Test Name	Test Code
CSF ME Pathogen Panel - PCR	4185

Specimen Collection and Transport

Specimen Type: CSF specimen, uncentrifuged
Optimum Specimen: 200 µL minimum required for testing
Other Specimen Types: None

Specimen Stability

Ambient Stability: Room temperature (Approximately 23°C) for up to one day.
Refrigerated (2-8°C): Refrigeration (Approximately 4°C) for up to 7 days.
Frozen Stability (-20°C or lower): Unknown
Local Transport: Room temperature (Approx. 23°C)
Long Distance: Room temperature (Approx. 23°C) or under refrigeration (Approx. 4°C) for up to 7 days.

CPT Code

Contact the Billing Department	CPT Code
	CSF ME Pathogen Panel - PCR

References

- Leber AL, Everhart K, Balada-Llasat J-M, Cullison J, Daly J, Holt S, Lephart P, Salimnia H, Schreckenberger PC, DesJarlais S, Reed SL, Chapin KC, LeBlanc L, Johnson JK, Soliven NL, Carroll K, Miller J-A, Dien Bard J, Mestas J, Bankowski M, Enomoto T, Hemmert AC, Bourzak K. 2016. Multicenter Evaluation of the BioFire FilmArray Meningitis Encephalitis Panel for the Detection of Bacteria, Viruses and Yeast in Cerebrospinal Fluid Specimens. *Journal of Clinical Microbiology* doi:10.1128/jcm.00730-16.
- Kimberly E. Hanson. 2016. The first fully automated molecular diagnostic panel for meningitis and encephalitis: how well does it perform and when should it be used? *J. Clin. Microbiol.* doi:10.1128/JCM.01255-16