

now offers the BioFire® FilmArray®  
Meningitis/Encephalitis (ME) Panel



## BioFire® FilmArray® Meningitis/Encephalitis Panel

1 Test. 14 Targets. ~1 Hour.

The BioFire 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 about one hour using only 0.2 mL of cerebrospinal fluid (CSF).

### Considerations for Use

- The BioFire ME Panel is indicated as an aid in the diagnosis of specific agents of meningitis and/or encephalitis and is intended to be used in conjunction with standard of care culture for organism recovery, serotyping, and antimicrobial susceptibility testing.
- Results from the BioFire ME Panel are not intended to be used as the sole basis for diagnosis, treatment, or other patient management decisions.
- Positive results do not rule out co-infection with organisms not included in the BioFire ME Panel and agents detected by the panel may not be the definite cause of the disease.
- Negative results by the panel does not rule out central nervous system infection as not all agents are tested for by the BioFire ME Panel.
- The performance of this test has not been established for monitoring treatment of infection with any of the panel organisms.
- Some organisms detected by the BioFire ME Panel, such as *Streptococcus pneumoniae* and *Haemophilus influenzae* can be shed from the respiratory tract of health individuals. HSV-1 may also be shed from individuals with active or recurrent cold sores. Caution should be exercised during specimen collection and testing to prevent contamination leading to false positive results.
- Refer to the panel Instruction for Use (IFU) for more information regarding panel performance and limitations.

### How to Order the BioFire ME Panel

### Laboratory Contact Information

#### BioFire ME Panel Menu

##### BACTERIA

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

##### YEAST

*Cryptococcus neoformans/gattii*

##### 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)

### Panel Specifications

- Approximately 2 minutes of hands-on time
- Run Time: ~1 hour
- Overall 94.2% Sensitivity and 99.8% Specificity<sup>1</sup>
- 0.2 mL of cerebrospinal fluid (CSF)  
Specimens should be processed and tested with the BioFire ME Panel as soon as possible, though they may be stored for up to one day at room temperature (approximately 23° C), or under refrigeration (approximately 4° C) for up to seven days.

### BioFire® ME Panel Instructions for Use

<https://www.online-ifu.com/ITI0035>

<sup>1</sup>The stated performance is the overall aggregate of the prospective data from the clinical trial.