### Comprehensive Testing of CSF Specimens Using The FilmArray® ME Panel Identifies Viral Infections Overlooked Using Current Clinical Practices

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**INTRODUCTION/BACKGROUND**

Infections of the central nervous system (CNS), such as meningitis and encephalitis, are potentially life-threatening. Caused by a myriad of pathogens (bacteria, viruses, fungi), CNS infections often present with similar clinical symptoms. Accurate diagnosis is limited because current methods for pathogen detection in cerebrospinal fluid (CSF), such as culture or single PCR reactions, have a long time-to-result and do not provide a complete answer. This may lead to additional patient health-risk and rising healthcare costs. Rapid, comprehensive testing for the most common causes of CNS infections has the potential to change the approach to patient therapy while leading to healthcare cost savings.

To address this current diagnostic need, BioFire Diagnostics, LLC developed the FilmArray® Meningitis/Encephalitis (ME) Panel for use on the FilmArray System. The FilmArray ME Panel simultaneously tests for six bacteria, eight viruses, and two fungi using approximately 200 µL CSF. Two minutes of user hands-on-time are required, and a comprehensive result is obtained in about one hour.

**The FilmArray System**

The FilmArray ME pouch has a fitment (B) containing freeze-dried reagents and plungers that plunges liquids into the film portion of the pouch. The pouch contains stations for cells type (C), magnetic bead based lysis and purification (D & E), first-stage multiplex PCR (F & G) and an array of 102 second-stage nested PCRs (H).

PCR primers are etched into the wells of the array and each primer set amplifies a unique product of the first-stage multiplex PCR. The second-stage PCR product is detected in a melting analysis using a fluorescent double-stranded DNA binding dye, LCGreen®.

**MATERIALS AND METHODS**

Following institutional review board (IRB) approval, for use of de-identified, discarded cerebral spinal fluid specimens, a pilot evaluation of the FilmArray ME panel was conducted on the FilmArray® ME Panel for use on the FilmArray System. The FilmArray ME Panel was concordant with all LUMC results. Secondary PCR assays were in agreement with the FilmArray ME Panel in 12 of 178 specimens; one EBV and one HIV-6 detection could not be confirmed.

**RESULTS**

LUMC laboratory methods collectively identified five pathogens in the 178 samples consisting of Enterovirus (6) and I2V (1). In contrast, the comprehensive FilmArray ME Panel detected 14 pathogens consisting of Enterovirus (6), HHV (4), EBV (1), Enterovirus + EBV (1) and I2V (1). The FilmArray ME Panel was concordant with all LUMC results. Secondary PCR assays were in agreement with the FilmArray ME Panel in 12 of 178 specimens; one EBV and one HIV-6 detection could not be confirmed.

**CONCLUSIONS**

These results suggest that the FilmArray ME Panel has the potential to identify additional pathogens compared to current clinical ordering practices. The significance of these detections in meningitis or encephalitis is unknown. However, providing a comprehensive result in these life-threatening infections may facilitate better patient care through improved antibiotic/antiviral stewardship or intensive care management.

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