**INTRODUCTION AND BACKGROUND**

Viral infections of the meninges (meningoencephalitis) or brain tissue (encephalitis) are potentially life-threatening conditions. No etiological diagnosis is made in the majority of aseptic meningitis and viral encephalitis cases. Patients presenting to intensive care units until a bacterial infection can be ruled out. Currently, laboratory gold standard PCR testing for meningitis and viral encephalitis is limited to technical “in-house” developed and validated assays or time-consuming reference laboratory testing. A rapid, accurate, comprehensive diagnostic system would facilitate better patient care through improved antibiotic stewardship and reduced hospital stays. BioFire Diagnostics is developing a Meningitis / Encephalitis (ME) panel for use in the FilmArray™ (FA) system. This comprehensive panel requires only 40 µL of cerebrospinal fluid (CSF) and 2 minutes of hands-on-time to test for 16 different bacteria, viruses, and fungi causing ME. Test results are returned in approximately 1 hour.

**MATERIALS AND METHODS**

Archived patient CSF samples were included in the study based on positive detection by in-house developed PCR assays from ARUP. Each sample was split into multiple aliquots for FA ME and qualitative real-time PCR (qPCR) testing. For the qPCR assays, nucleic acids were extracted using the QIAcube (QIAGEN, Germany) DNA Blood and Body Fluid extraction protocol. Extracted nucleic acids were tested using commercially purchased PCR assays from genesig ( PrimerDesign, UK) on a Bio-Rad CFX96 Touch™ real-time PCR system according to the manufacturer’s instructions. For qPCR testing, a research use only (RUO) version of the panel was used. CSF was diluted 1:4 with FA Sample Buffer and injected into a FA ME pouch. Each sample was tested in a single-use FA ME pouch in a FA instrument. Nucleic acid extraction, purification, amplification, and results analysis are automated within the FA system.

**RESULTS**

Detection results for the FA ME system were compared to the specific qPCR results (Table 1). No qPCR assay was available for Enterovirus; therefore, FA ME detection was compared to the in-house developed qPCR result from ARUP. The FA ME system exhibited similar sensitivity to the qPCR assays. Based on the qPCR results, DNA-sequences were present across a range of 10^−6-10^6 copies/ml. Further, the FA ME system detected multiple dual-infections that were not previously identified in the archived sample set. Each dual infection was confirmed using the qPCR assays. The FA ME system exhibits reliable results across a broad range of viral titers.

**CONCLUSION**

The FilmArray Meningitis / Encephalitis system was able to rapidly and accurately detect viruses across a broad range of concentrations, which could greatly improve medical management of cases of meningitis and viral encephalitis. The FA ME system has not been evaluated by the FDA for In Vitro Diagnostic use.