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**Central nervous system infection**

# Evaluation of the FilmArray™ ME-panel for the diagnostics of pathogens causing meningitis and encephalitis

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**Background:** The benefits of rapid diagnostics of central nervous system (CNS) infections have been shown previously. Molecular methods provide accurate detection of both bacteria and viruses in cerebrospinal fluid (CSF). In the present study the performance of the novel FilmArray™ Meningitis/Encephalitis (ME) panel, a multiplexed PCR for CSF analysis of 15 different pathogens relevant in CNS infection (6 bacteria, 7 viruses and 2 Cryptococcus spp) was evaluated by comparing it with current available in-house molecular methods.

**Material/methods:** Three sample types were analyzed in order to compare the different methods; contrived bacterial and viral samples: cultured bacteria or controls (Qnostic) with known concentrations of HSV-1, 2 and Varicella Zoster Virus (VZV) were diluted in pools of CSF (n=33), CSF from patients with infectious etiology of CNS disease (n=32) and external quality assessment (EQA) samples (n=10). The clinical samples had previously been analyzed with in-house PCR protocols and been stored frozen. All samples (200 µL) were analyzed using a RoU version of the FilmArray™ ME panel according to the manufacturer's instructions. Discrepant results were resolved using additional in-house PCRs specific for the target detected. All samples were run as single samples only.

**Results:** The FilmArray™ ME-panel showed a slightly lower sensitivity for the bacterial targets than a multiplexed inhouse PCR (Hedberg et al APMIS 2009), five times lower for *Streptococcus pneumoniae*, *Neisseria menigitidis* and *Streptococcus agalactiae* and ten times for *Listeria monocytogenes*. For Herpes Simplex virus-1, 2 and VZV the lowest detected concentrations of the Qnostics controls dilutions were 5000 c/mL, 100 c/mL and 50 c/mL respectively. The FilmArray™ ME-panel detected the expected pathogen in 28 out of 32 clinical samples giving a sensitivity of 87.5%. The false negative results were spread on four targets (*S. pneumoniae*, HSV-2, VZV and Enterovirus),in all cases in samples with low DNA concentrations. The FilmArray™ suggested four previously undetected co-infections. One of these could be verified with in-house PCR giving a specificity based on all possible targets of 99.3%. All EQA samples (both viral and bacterial) were correctly detected. The hands on time were 5 minutes per sample and the time to run each test was 75 min.

**Conclusions:** The FilmArray™ ME-panel showed a high specificity and showed in many cases equal

sensitivity as the comparison methods. The system was fast and easy to use. Importantly all clinical samples with HSV-1 were detected despite our results of the contrived samples indicating possible technical issues with this control. Our results are promising and suggest this panel to be a useful test for rule in diagnostics in patients with acute CNS-infections. Further studies are needed to further validate the performance in routinely obtained CSF samples.