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Diagnostic performance of a new multiplex PCR in patients with meningitis and/or encephalitis

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Backgroung: Infectious meningitis and encephalitis, can lead to significant long-term morbitidy, mortality and high health care costs. Rapid and accurate molecular diagnostic tests for the most common causes of these infections have the potential for high clinical impact. We present our experience using the FilmArray Meningitis/Encephalitis (ME) panel in comparison with standard diagnostic methods.

Material/methods: A total of 46 cerebrospinal fluid (CSF) specimens obtained from individuals suspected to have meningitis and/or encephalitis were tested with the FilmArray ME panel (FilmArray, bioMerieux) which is a qualitative multiplexed nucleic acid-based diagnostic test for simultaneous detection of 14 targets (6 bacteria, 7 viruses, and a yeast) capable of causing ME. Bacterial and fungal testing was also performed by Gram stain and culture on solid and broth media and isolates were identified using VITEK 2 and API (bioMerieux, France). Testing for Enteroviruses and Herpesviruses group were in parallel carried out using the Enterovirus and Herpes Consensus PCR methodology respectively (Argene, BioMerieux, France). Samples with discrepant viral PCR results were retested by a single house PCR.

Results: Pathogens were identified in 10 (21.7%) CSF samples by routine evaluation and in 11 (23.9%) by ME panel (Table 1). Among FilmArray ME results, viral pathogens were most commonly detected followed by bacterial and fungal. *Neisseria meningitidis* was detected in 2 CSF samples by FilmArray PCR but isolation was achieved only in one of them; the second one had gram negative encapsulated diplococci detected on Gram's stain although CSF bacterial culture was negative because of a previous one-dose antibiotic administration. Although the FilmArray assay provided

100% sensitivity and specificity compared to routine bacterial and fungal evaluation of CSF specimens, one discrepant viral result (2.2%) was observed: varicella-zoster virus detected by FilmArray and confirmed by the house PCR, was falsely-negative by Consensus methodology. Overall, routine evaluation identified no pathogens in 35 FilmArray ME negative results. The time from receipt of CSF to report the organism identification was estimated for the FilmArray ME panel at 2.5 hours while for the standard methods at 16.5 hours.

Table 1: Pathogens identified in the CSF with FilmArray ME panel and standard diagnostic methods

Pathogens detected	**Positive with standard diagnostic methods (Gram stain and/or culture, PCR)**	**Positive with FilmArray ME Panel**	**Positive with house PCR (discrepant results)**
Neisseria meningitidis	2 (1 only in Gram)	2	-
Enterovirus	2	2	-
Varicella zoster virus	5	6	1
Cryptococcus neoformans/gattii	1	1	-

Conclusions: The FilmArray multiplex PCR panel offers a promising platform for the rapid diagnosis of ME and would be very useful and help to overcome some of the challenges for conventional laboratory-based diagnosis of these infections. Further studies are needed to prospectively evaluate the clinical impact and cost-effectiveness of FilmArray ME panel.