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A multi-centre prospective evaluation of the new Filmarray meningitis/encephalitis panel for rapid PCR-based diagnostics

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Background: Rapid treatment of meningitis and encephalitis improves clinical outcomes. However, culture-based identification of pathogens is time-consuming. PCR-panel diagnostics may overcome such shortcomings. Hence, we aimed to assess the performance of a new PCR-panel assay.

Material/methods: We compared the performance of the Filmarray ME (Biofire, bioMérieux) to routine diagnostic approaches for cerebrospinal fluids (CSF) in four diagnostic laboratories. Filmarray ME covers six bacteria, seven viruses, and one yeast. We determined the detection limits by using serial dilutions of pathogen-spiked CSF, overall sensitivity and specificity, and compared turn-around times.

Results: Detection limits of the Filmarray system were 200, 3'700, 200, 10, 300, and 10 CFU/mL for *S. pneumoniae*, *S. agalactiae*, *L. monocytogenes*, *N. meningitidis*, *E. coli* K1, and *C. neoformans* respectively; and 63, 79, and 120 copies/mL for HSV-1, HSV-2, and VZV, respectively.

In total, 195 CSF samples from clinical routine were tested. 136 samples showed concordant negative results. 59 samples were tested positive by the Filmarray ME, of which 51 pathogens could be confirmed with routine diagnostics. The sensitivity and specificity was 100% and 94.4%, respectively (see **Table 1**). In 5/8 cases additional diagnostic testing (e.g. target-specific PCR) or patient's history confirmed the Filmarray ME result (e.g. bacteraemia with *H. influenzae*). 3/8 could not be confirmed by additional diagnostics including one case of HHV6, *H. influenzae* and *S. pneumoniae* each. Median time to bacterial identification was 3.1h (Filmarray ME) vs. 25.2h (culture-based, $p < 0.0001$).

Conclusions: The Filmarray ME panel provides sensitive and rapid detection of common pathogens associated with community acquired meningitis and encephalitis.

		Routine assay		
		Positive	Negative	
Filmarray ME	Positive	51	8*	59
	Negative	0	136	136
		51	144	195

Table 1. Comparison of detection rates of the Filmarray ME versus routine diagnostic assessment. *5/8 samples could be confirmed as true positive with further testing.