

April 13, 2017 - Vancouver

A L E R T

New panel for Rapid and Comprehensive Central Nervous System (CNS) Pathogen Detection

WHAT'S NEW?

Effective April 24, 2017, PeaceHealth Laboratories in Vancouver will offer a multiplex PCR panel for the detection of 6 bacteria, 7 viruses, and 1 yeast from a single specimen providing results within 2-3 hours after specimen receipt in the laboratory.

The FilmArray Meningitis/Encephalitis Panel from BioFire Diagnostics is FDA-cleared and provides an overall sensitivity and specificity of 94.2% and 99.8%, respectively. Rapid and accurate diagnostic testing for suspected community-acquired CNS pathogens allows for better patient management by reducing the time patients wait for diagnosis.

This assay is capable of simultaneous detection and identification of multiple bacterial, viral, and yeast nucleic acids directly from cerebrospinal fluid (CSF) specimens obtained via lumbar puncture from individuals with signs and/or symptoms of meningitis and/or encephalitis. The panel is not intended for testing of specimens collected from indwelling CNS medical devices. The panel is indicated as an aid in the diagnosis of specific agents of meningitis and/or encephalitis and results are meant to be used in conjunction with other clinical, epidemiological, and laboratory data. There is a risk of false negative values due to the presence of sequence variants or rearrangements in the gene targets of the assay, inhibitors in specimens or infection

caused by an organism not detected by the meningitis/encephalitis panel. Test results may also be affected by concurrent antimicrobial therapy or levels of organism in the sample that are below the limit of detection.

The Meningitis/Encephalitis Panel testing is intended to be used in conjunction with standard of care culture for organism recovery, serotyping and antimicrobial susceptibility testing. CSF Culture and Gram Stain (LAB2046) and Fungal Culture, Not Skin, Hair or Nails (LAB240) should be ordered in addition to the Meningitis/Encephalitis Panel CSF by PCR (LAB6736).

QUESTIONS:

Denise Jones, MT, SM(ASCP)
Microbiology Manager
360-514-3838
djones@peacehealthlabs.org

Berle Stratton, M.D
Medical Director, PeaceHealth Laboratories
360-514-2237
bstratton2@peacehealthlabs.org

The Meningitis/Encephalitis Panel simultaneously tests for 14 Pathogens:

Bacteria	Viruses	Yeast
<i>Escherichia coli</i> K1 ²	Cytomegalovirus (CMV)	<i>Cryptococcus neoformans/gattii</i>
<i>Haemophilus influenzae</i>	Enterovirus ⁴	
<i>Listeria monocytogenes</i>	Herpes simplex virus 1 (HSV1)	
<i>Neisseria meningitidis</i> ³	Herpes simplex virus 2 (HSV-2)	
<i>Streptococcus agalactiae</i> (GBS)	Human herpesvirus 6 (HHV-6)	
<i>Streptococcus pneumoniae</i>	Human parechovirus	
	Varicella zoster virus (VZV)	

¹ Compared to CSF bacterial culture for bacterial assays and compared to two PCR assays with bi-directional sequencing for viral and fungal assays.

² Only *E. coli* stains possessing the K1 capsular antigen will be detected. All other *E. coli* strains/serotypes will not be detected.

³ Encapsulated *N. meningitidis* (serotypes W135, A, B, C, D, Y and strains with variant *ctrA* gene) will be detected. Unencapsulated *N. meningitidis* will not be detected.

⁴ All species (A-D) and several serotypes of human Enterovirus (68, 70, 71), Coxsackievirus (A6, A9, A10, A16, A17, A21, A24, B1-5) and Echovirus (6, 9, 18) will be detected.

Specimen Requirements

Test Name/Order Code	Meningitis/Encephalitis Panel CSF by PCR (LAB6736)
Container Type	Sterile plastic container
Specimen Type	CSF collected via lumbar puncture
Preferred Volume	Submit 3 mL for Meningitis/Encephalitis Panel, CSF Culture & Gram Stain (LAB2046) and Fungal Culture Not Skin, Hair or Nails (LAB240) Panels positive for <i>Escherichia coli</i> K1, <i>Haemophilus influenzae</i> , <i>Listeria monocytogenes</i> , <i>Neisseria meningitidis</i> , <i>Streptococcus agalactiae</i> or <i>Streptococcus pneumoniae</i> reflex to CSF Culture & Gram Stain (LAB2046). Add'l charges apply. Panels positive for <i>Cryptococcus neoformans/gattii</i> reflex to a Fungal Culture Not Skin, Hair or Nails (LAB240). Add'l charges apply.
Minimum Volume	0.25 mL for PCR testing only (additional fluid required for culture)
Collect	Sequentially collect CSF into sterile tubes. Tube number 2 should be submitted for PCR and bacterial culture.
Storage and Transport	Ambient or refrigerated Note: If bacterial culture is also ordered, submit an unrefrigerated aliquot for the culture.
Stability	Ambient: 24 hours Refrigerated: 7 days
Unacceptable Conditions	Frozen, specimen received in a nonsterile container, centrifuged specimen, specimen collected from a shunt
CPT Codes	87496, 87498, 87529 x 2, 87532, 87653, 87798 x 8
Testing Schedule	Daily
Turnaround Time	2-3 hours from specimen receipt in the lab
Method	Biofire FilmArray (NAAT; nucleic acid amplification testing)

