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| BioFire FilmArray Meningitis Encephalitis (ME) Panel | | | | | | | | |
| **Purpose** | This procedure provides instructions for testing cerebrospinal fluid (CSF) using the FilmArray Meningitis/Encephalitis Panel (ME) Kit. | | | | | | | |
| **Principal and Clinical Significance** | The FilmArray Meningitis/Encephalitis (ME) Panel is a qualitative multiplexed nucleic acid-based in vitro diagnostic test intended for use with FilmArray systems. The FilmArray ME Panel is capable of simultaneous detection and identification of multiple bacterial, viral, and yeast nucleic acids directly from CSF specimens obtained via lumbar puncture from individuals with signs and/or symptoms of meningitis and/or encephalitis. The following organisms are identified using the FilmArray ME Panel:   |  |  | | --- | --- | | Bacteria | | | Escherichia coli K1 | Neisseria meningitidis (encapsulated) | | Haemophilus influenzae | Streptococcus agalactiae | | Listeria monocytogenes | Streptococcus pneumoniae | | Viruses | | | Cytomegalovirus | Human herpesvirus 6 | | Enterovirus | Human parechovirus | | Herpes simplex virus 1 | Varicella zoster virus | | Herpes simplex virus 2 |  | | Yeast | | | Cryptococcus neoformans/gattii | |   The FilmArray ME pouch is a closed system disposable that houses all the chemistry required to isolate, amplify and detect nucleic acid from multiple meningitis and encephalitis pathogens within a single CSF specimen obtained from a lumbar puncture. The rigid plastic component (fitment) of the FilmArray ME pouch contains reagents in freeze-dried form. The flexible plastic portion of the pouch is divided into discrete segments (blisters) where the required chemical processes are carried out. The user of the FilmArray ME Panel loads the sample into the FilmArray ME pouch, places the pouch into the FilmArray instrument, and starts the run. All other operations are automated.  The following is an overview of the operations and processes that occur during a FilmArray run:   1. Nucleic Acid Purification - Nucleic acid purification occurs in the first three blisters of the pouch. The sample is lysed by agitation (bead beating) and the liberated nucleic acid is captured, washed and eluted using magnetic bead technology. These steps require about ten minutes and the bead-beater apparatus can be heard as a high pitched whine during the first minute of operation. 2. Reverse Transcription and 1st Stage Multiplex PCR - Some pathogens identified by the FilmArray ME pouch are RNA viruses, and a reverse transcription (RT) step is performed to convert the viral RNA into cDNA prior to amplification. The purified nucleic acid solution is combined with a preheated master mix to initiate the RT step and subsequent thermocycling for multiplex PCR. The effect of 1st stage PCR is to enrich for the target nucleic acids present in the sample. 3. 2nd Stage PCR - The products of 1st stage PCR are diluted and mixed with fresh PCR reagents containing an intercalating fluorescent DNA dye (LCGreen® Plus, BioFire Defense, LLC). This solution is distributed over the 2nd stage PCR array. The individual wells of the array contain primers for different assays (each present in triplicate) that target specific nucleic acid sequences from each of the pathogens detected, as well as control template material. These primers are ‘nested’ or internal to the specific products of the 1st stage multiplex reaction, which enhances both the sensitivity and specificity of the reactions. 4. DNA Melting Analysis – After 2nd stage PCR, the temperature is slowly increased and fluorescence in each well of the array is monitored and analyzed to generate a melt curve. The temperature at which a specific PCR product melts (melting temperature or Tm) is consistent and predictable and the FilmArray software automatically evaluates the data from replicate wells for each assay to report results. For a description of data interpretation and reporting see the Interpretation of Results section of this booklet. | | | | | | | |
| **Policy Statements** | This procedure applies to Microbiologists who perform culture set-up and plate reading. | | | | | | | |
| **Test Code** | MEPNL | | | | | | | |
| **Materials** |  | |  | | | |  |  | |
|  | **Reagents** | | **Supplies** | | | | **Equipment** | |
|  | Each kit contains sufficient reagents to test 30 specimens:   * Individually packaged FilmArray ME pouches * Single-use (1.0 mL) Sample Buffer ampoules * Single-use pre-filled (1.5 mL) Hydration Injection Vials (blue) * Single-use Sample Injection Vials (red) | | * Individually packaged Transfer Pipettes * External positive and negative controls: Maine Molecular cat no. M262- Store frozen -25°C to -15°C * Alternate controls-Zeptometrix NATrol ME Controls NATMEC-BIO | | | | * FilmArray System including: * FilmArray Instrument and software * FilmArray Pouch Loading Station compatible with the use of the FilmArray Injection Vials | |
| **Specimen** | CSF specimens collected via lumbar puncture, and should not be centrifuged.Minimum Sample Volume - 200 μL of CSF specimen is required for testing. Bloody samples are acceptable.If sharing tube with other testing, aliquot 0.5 mL to snap cap tube before performing other testing (e.g. CSF Culture, HSVPP or EVPCR).Specimens should be processed and tested with the FilmArray ME Panel as soon as possible, though they may be stored for up to one day at room temperature, or under refrigeration for up to seven days. | | | | | | | |
| **Special Safety Precautions** | Microbiologists are subject to occupational risks associated with specimen handling. Refer to the safety policies located in the safety section of the *Microbiology Procedure Manual***.**   1. [*Biohazard Containment*](file:///G:\Lab%20Procedures\Microbiology\1NEW%20Micro%20Procedure%20Manual.%20(same%20as%20in%20Starnet)\MCVI%203%20Safety\MCVI%203.1%20Biohazard%20Containment.docx) 2. [*Biohazardous Spills*](file:///G:\Lab%20Procedures\Microbiology\1NEW%20Micro%20Procedure%20Manual.%20(same%20as%20in%20Starnet)\MCVI%203%20Safety\MCVI%203.4%20Biohazardous%20Spills.docx) 3. [*Safety in the Microbiology Laboratory*](file:///G:\Lab%20Procedures\Microbiology\1NEW%20Micro%20Procedure%20Manual.%20(same%20as%20in%20Starnet)\MCVI%203%20Safety\MCVI%203.2%20Safety%20in%20the%20Microbiology%20Lab.docx) | | | | | | | |
| **Storage** | * Store kit at room temperature-Do Not Refrigerate of Freeze. * Avoid storage near heating or cooling vents. * All kit components should be stored and used together. Do not mix components from one kit with another kit. * Do not remove from packaging until sample is ready to be tested. | | | | | | | |
| **Quality Control** | Two process controls are included in each pouch:  1. RNA Process Control-The RNA Process Control assay targets an RNA transcript from the yeast *Schizosaccharomyces pombe*. The yeast is present in the pouch in a freeze-dried form and becomes rehydrated when sample is loaded. The control material is carried through all stages of the test process, including lysis, nucleic acid purification, reverse transcription, 1st stage PCR, dilution, 2nd stage PCR and DNA melting. A positive control result indicates that all steps carried out in the FilmArray ME pouch were successful.  2. PCR2 Control-The PCR2 Control assay detects a DNA target that is dried into wells of the array along with the corresponding primers. A positive result indicates that 2nd stage PCR was successful.  Both control assays must be positive for the test run to pass. When either control fails, the Controls field of the test report (upper right hand corner) will display Failed and all results will be listed as Invalid. If the controls fail, the sample should be retested using a new pouch.  **External Quality Controls**  Perform QC using external positive and negative controls every 30 days using perform QC using Maine Molecular cat no. M262.   * Rotate use of torch modules for testing  1. Clean hood and supplies with 10% bleach dilution followed by water. Use loading station labeled for QC use. 2. Obtain controls from freezer and allow the control to be tested to come to room temperature (approximately 30 minutes). 3. Use control as provided. Do not dilute. 4. Invert the tube 5-10 times, then vortex 3-5 second. 5. Tap the tube in the hood several times to ensure that no control material is caught in the cap before opening the tube. 6. Aspirate the controls using the FilmArray transfer pipette and analyze as a patient sample. 7. Record results on the FilmArray ME Quality Control worksheet and Log. File results in the binder.   **Acceptable results:**  **Positive:** all organisms and resistance markers detected  **Negative:** all organisms and resistance markers NOT detected  **New Lot/Shipment Quality Control:**  Perform QC using external positive and negative controls with each new lot or shipment before putting into service.  Record and file results on the BioFire ME Quality Control Log  Notify Technical Specialist or Technical Director with unacceptable or undesirable results.  **Wipe Testing:**  To be performed every 30 days to monitor for contamination.   1. Clean the hood and supplies with 10% bleach dilution followed by water 2. Prepare a sterile cryovial or conical by aliquoting approximately 500µL nuclease free water. 3. Set up the loading block as if testing a patient specimen 4. Soak a culturette swab in the nuclease free water for approximately 1 minute. 5. Swab working areas including processing hood surface, vortex and any other high touch surfaces in the **sample prep** area. 6. Using a biohazard pad as a barrier, break swab off into the red sample injection vial, add the sample buffer to the vial and test as a patient specimen. 7. Positive results are cause for alert and decontamination. Stop reporting patient results, and consult Technical Specialist to discuss contaminant testing. 8. See [the FilmArray Torch Operator’s Manual](file:///G:\LAB\Microbiology\BioFire%20FilmArray\htfa-prt-0001_filmarray_torch_operator_s_manual_ivd_en.pdf) for decontamination instructions 9. Record and file results on the wipe testing log in the FilmArray binder   **Desirable results:**  All organisms and resistance markers NOT detected  Notify Technical Specialist or Technical Director with unacceptable or undesirable results. | | | | | | | |
| **Laboratory Precautions** | Due to the sensitive nature of the FilmArray ME panel, it is important to guard against contamination of the specimen and work area by carefully following the testing process.   1. Prevent organism contamination 2. Samples may contain high concentrations of organisms and should be processed in a biosafety hood. 3. A biosafety cabinet that is used for performing CSF culture should not be used for sample preparation or pouch loading. 4. Prior to processing a sample, thoroughly clean both the work area and FilmArray Pouch Loading Station using freshly prepared 10% bleach dilution. Wipe disinfected surfaces with water. 5. Use clean gloves to remove materials from bulk packaging bags and reseal bulk packaging bags when not in use. 6. Samples and pouches should be handled one at a time 7. Change gloves and clean work area between each sample 8. Prevent amplicon contamination 9. Discard pouches in biohazard container immediately after the run has completed. 10. Avoid excessive handling of pouches after test runs. 11. Avoid exposing pouches to sharp edges or anything that might cause a puncture. 12. If liquid is observed on the exterior of a pouch, immediately contain and discard in a biohazard container. The instrument/Module and work space must be decontaminated. | | | | | | | |
| **Procedure-Prepare the Pouch** | 1. Enter the Mycology room, place sample in rack by hood, remove standard lab coat and don a disposable lab coat. Wear paper face mask while processing and transporting the sample. 2. Thoroughly clean the work area, the FilmArray Pouch Loading Station and the exterior of the CSF sample with freshly prepared 10% bleach dilution (or suitable disinfectant) followed by a water rinse. 3. Change gloves. 4. Remove FilmArray Pouch, Sample Injection Vial (RED), Hydration Injection Vial (BLUE), Sample Buffer ampoule and a transfer pipette from the box. Avoid touching the open well of the Sample Injection vial and the tip of the Sample Buffer ampoule as this may introduce contamination. Remove vials and ampoule by squeezing the package to expel the vial. Avoid reaching into package to grab vial and ampoule. 5. Place the blue-capped hydration injection vial in the blue well of the FilmArray Pouch Loading Station. 6. Place the red-capped sample injection vial in the red well of the FilmArray pouch loading station. 7. If necessary, transfer sample to labeled snap cap tube with 1 ml sterile disposable pipette so the kit pipette can reach sample. 8. Remove the pouch from its vacuum-sealed package by tearing or cutting the notched outer packaging and opening the protective aluminum canister. 9. Label the pouch and the red vial with the small CID label. Do not cover the bar code. Slide the pouch into the FilmArray pouch loading station. | | | | | | | |
| **Procedure-Hydrate the Pouch** | 1. Twist counterclockwise and lift the hydration injection vial, leaving blue cap in the well of the FilmArray pouch loading station. 2. Insert the cannula tip into the port in the pouch located directly below the blue arrow of the FilmArray pouch loading station. Push down forcefully in a firm and quick motion until you hear a faint “pop” and feel an ease in resistance. The correct volume of liquid will be pulled into the pouch by vacuum. 3. Discard tip into the sharps container. 4. Verify that the pouch has been hydrated: Flip the barcode label down and check to see that fluid has entered the reagent wells (located at the base of the rigid plastic part of the pouch). Small air bubbles may be seen. If the pouch fails to hydrate (dry reagents appear as white pellets), repeat Step 2 to verify that the seal of the port was broken or retrieve a new pouch and repeat from Step 2 of the prepare pouch section. | | | | | | | |
| **Procedure-Prepare Sample Mix** | 1. Hold the Sample Buffer ampoule so that the tip is facing up. 2. Gently pinch the textured plastic tab on the side of the ampoule until the seal snaps. 3. Re-position thumb and forefinger to grip between the textured plastic tab and the bottom of the ampoule, then invert the ampoule over the red-capped sample injection vial and re-position thumb and forefinger to grip the bottom of the ampoule. Dispense sample buffer using a slow, forceful squeeze, followed by a second squeeze. Squeezing the ampoule additional times will generate excessive bubbles, which should be avoided. 4. Vortex the patient specimen for 10 seconds. 5. Using the transfer pipette provided in the test kit, draw sample to the second line (approximately 0.2 mL). Add sample to the red sample injection vial. 6. Tightly close the lid of the sample injection vial and mix by gently inverting at least three times. | | | | | | | |
| **Procedure-Load Sample Mix** | 1. Slowly unscrew the sample injection vial so it loosens from its red cap and pause for 3-5 seconds.   **NOTE:** If any droplets form at the end of the needle, carefully wipe the tip off the on inner edge of the red screw cap from the vial (still in the block)   1. Remove the sample injection vial leaving cap in pouch loading station and insert the cannula tip into the port in the pouch fitment located directly below the red arrow of the FilmArray pouch loading station. Push down forcefully in a firm and quick motion until you hear a faint “pop” and feel an ease in resistance. The correct volume of the liquid will be pulled into the pouch by vacuum. 2. Verify that the sample has been loaded. Flip the barcode label down and check to see that fluid has entered the reagent well next to the sample loading port. If the pouch fails to pull sample from the sample injection vial, the pouch should be discarded. Retrieve a new pouch and repeat from the prepare pouch section. 3. Discard the sample injection vial and the hydration injection vial in an appropriate biohazard sharps container. 4. Change gloves. 5. Remove and discard disposable lab coat in garbage can after each use. Don standard lab coat. Do not store disposable lab coat near standard lab coat. 6. Remove the pouch from the FilmArray pouch loading station and walk to BioFire Instrument. | | | | | | | |
| **Procedure-Run Pouch** | 1. Ensure that the FilmArray torch system is on. 2. Select an available module on the touch screen. 3. Scan the barcode on the FilmArray pouch using the barcode scanner. If the barcode cannot be scanned the required information can be manually entered into the appropriate fields. 4. Enter the sample ID (CID). This can be done manually or scanned in by the using the barcode scanner when a barcoded sample ID is used. 5. Insert the pouch into the module. 6. If necessary, select and/or confirm a protocol from the protocol drop down list. 7. Enter the operator user name and password (micro and micro), then select next. 8. Review the entered run information on the screen. If correct, select start run. 9. Thoroughly clean the work area and the FilmArray Pouch Loading Station with freshly prepared 10% bleach dilution (or suitable disinfectant) followed by a water rinse. 10. At the end of the run, the status of the module changes to finished and the pouch is partially ejected. 11. Select the finished module on the dashboard to view the report. 12. Wearing gloves, remove the pouch from the module, place in a biohazard bag, seal and immediately discard the pouch in the biohazard container under the GeneXpert. 13. Change gloves. | | | | | | | |
| **Interpretation** | 1. The FilmArray Software automatically analyzes and interprets the assay results and displays the final results in a test report. 2. The **Run Summary** section of the test report provides the Sample ID, time and date of the run, control results and an overall summary of the test results.   **NOTE:** Any organism with a Detected result will be listed in the corresponding field of the summary.   1. Controls are listed as Passed, Failed or Invalid. See **Table 1** below for Internal Control Result Interpretation. 2. The **Result Summary** section of the test report lists the result for each target tested by the panel. See **Table 2** below for Result Interpretation.   **NOTE:** If **two** or more distinct organisms are detected, repeat testing from the original sample. Only report results if both runs match. Consult with the Technical Specialist or Technical Director if results do **NOT** match upon repeat.   1. The **Run Details** section provides additional information about the run.   Table 1 provides a summary and explanation of the possible control results and follow-up actions.  **Table 1. Interpretation of Controls Field on the FilmArray ME Panel Test Report**   |  |  |  |  | | --- | --- | --- | --- | | **Control Result** | **Explanation** | **Action Required** | **Outcome** | | Passed | The run was successfully completed  AND  Both pouch controls were successful. | None | Report the results provided on the test report. | | Failed | The run was successfully completed  BUT  At least one of the pouch controls (RNA Process Control and/or PCR2 Control) failed. | Repeat the test using a new pouch. | Accept the results of the repeat testing. If the error persists, contact Technical Support for further instruction. | | Invalid | The controls are invalid because the run did not complete.  (Typically this indicates a software or hardware error). | Note any error codes displayed during the run and the Run Status field in the Run Details section of the report. Refer to the FilmArray Operator’s Manual or contact Technical Support for further instruction.  Once the error is resolved, repeat the test or repeat the test using another instrument. | Accept the valid results of the repeat testing. If the error persists, contact Technical Support for further instruction. | | | | | | | | |
| **Limitations** | 1. False negative results may occur when the concentration of organism(s) in the specimen is below the device limit of detection. In the prospective clinical study, two specimens were positive by standard of care culture and negative with the FilmArray ME Panel. 2. Due to the small number of positive prospective and retrospective specimens for certain organisms, performance characteristics for *Escherichia coli*, *Haemophilus influenzae*, *Listeria monocytogenes*, *Neisseria meningitidis*, *Streptococcus agalactiae*, Cytomegalovirus, and Human parechovirus were established primarily using contrived clinical specimens. 3. Due to the small number of positive specimens collected for certain organisms during the prospective clinical study, performance characteristics for HSV-1, HSV-2, Human parechovirus, Varicella, HHV-6 and *C. neoformans/gattii* were also established with retrospective clinical specimens. 4. The FilmArray Meningitis/Encephalitis (ME) Panel performance has only been established on the FilmArray, FilmArray 2.0, and FilmArray Torch systems. 5. This test is a qualitative test and does not provide a quantitative value for the organism(s) in the specimen. 6. Results from this test must be correlated with the clinical history, epidemiological data, and other data available to the clinician evaluating the patient. 7. The performance of this test has not been established for CSF specimens from patients without signs and/or symptoms of meningitis and/or encephalitis 8. The performance of this test has not been specifically evaluated for CSF specimens from immunocompromised individuals. 9. The effect of antibiotic treatment on test performance has not been evaluated. 10. The performance of this test has not been established for monitoring treatment of infection with any of the panel organisms. 11. This test is not intended for use with CSF collected from indwelling medical devices (e.g., CSF shunts). 12. CSF specimens should not be centrifuged before testing. 13. The effect of interfering substances has only been evaluated for those listed in the labeling. Interference by substances other than those described in the Interference section below could lead to erroneous results. 14. A negative FilmArray ME Panel result does not exclude the possibility of CNS infection and should not be used as the sole basis for diagnosis, treatment, or other management decisions. There is a risk of false negative values due to the presence of sequence variants or rearrangements in the gene targets of the assay, procedural errors, inhibitors in specimens, technical error, sample mix-up, or infection caused by an organism not detected by the FilmArray ME 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. 15. The detection of organism nucleic acid is dependent upon proper sample collection, handling, transportation, storage, and preparation. Failure to observe proper procedures in any one of these steps can lead to incorrect results. There is a risk of false positive and false negative results caused by improperly collected, transported, or handled specimens. The RNA process control and the PCR 2 control will not indicate whether or not nucleic acid has been lost due to inadequate collection, transport or storage of specimens. 16. Positive and negative predictive values are highly dependent on prevalence. False positive results are more likely for low prevalence analytes. 17. Viral, bacterial, and yeast nucleic acid may persist *in vivo* independently of organism viability. Detection of organism targets does not imply that the corresponding organisms are infectious or the causative agents for clinical symptoms. 18. HHV-6 or CMV can exist in latent form that is reactivated during infection due to other pathogens, including agents not detected by the FilmArray ME panel that may cause meningitis/encephalitis (e.g., Mycobacterium tuberculosis or HIV). When detected by the FilmArray ME, HHV-6 or CMV should be considered as the likely cause of meningitis/encephalitis only in appropriate clinical settings and following expert consultation. 19. Viral shedding into the CSF often occurs in cases of zoster (shingles; caused by reactivation of VZV). VZV may not be the cause of CNS disease in these cases. 20. Organism and amplicon contamination may produce erroneous results for this test. Particular attention should be given to the Laboratory Precautions noted under the Warnings and Precautions section. 21. Some organisms detected by the FilmArray ME Panel, such as S. pneumoniae and H. influenzae can be shed from the respiratory tract of healthy individuals. HSV-1 may also be shed from individuals with active or recurrent cold sores. Particular attention should be given to the Laboratory Precautions noted under the Warnings and Precautions section. Caution should also be exercised during specimen collection and testing to prevent contamination leading to false positive results. 22. If two or more organisms are detected in a specimen, retesting is recommended to confirm the polymicrobial result. 23. Cross-reactivity with organisms in addition to those listed in the Analytical Specificity section may lead to erroneous results. Cross-reactivity with human rhinoviruses may occur, but rhinoviruses are rarely present in human cerebrospinal fluid and are not a recognized cause of meningitis. Caution should be exercised during specimen collection and testing to prevent contamination with rhinovirus associated with respiratory infections 24. Only E. coli strains possessing the K1 capsular antigen will be detected. All other E. coli strains/serotypes will not be detected. 25. Only encapsulated strains of N. meningitidis will be detected. Unencapsulated N. meningitidis will not be detected. | | | | | | | |
| **Method Performance Specifications** | 1. For *in vitro* diagnostic use only 2. BioFire ME panel pouches are only for use with BioFire 2.0 and BioFire Torch systems. 3. A trained healthcare professional should carefully interpret the results from the FilmArray ME Panel in conjunction with patient signs and symptoms and other diagnostic tests. 4. Pouches are stored under vacuum in individually-wrapped canister. To preserve the integrity of the pouch vacuum for proper operation, be sure that an instrument/module is available and operational before unwrapping any pouches for loading. 5. Always check the expiration date on the pouch and do not use a pouch after its expiration date. 6. Samples with significant amounts of blood are acceptable for testing. 7. Interference has been seen with samples with a high protein value. | | | | | | | |
| **Result Reporting** | 1. Results will automatically transmit to the LIS. 2. Log into Sunquest to release results. 3. Select Result Entry from Menu options 4. In the Configuration field select TORCH from the dropdown box.      1. Click on the  button located in the lower right corner to populate the transmitted results. 2. Ensure the correct specimen ID (accession number) is shown. Review messages located on the top and results. Compare results to the FilmArray report.    1. If you have a positive **Alert Value**: Click on the analyte, press tab and add the code **RP**, press tab, enter semi-colon, and record who the result was relayed to with the time/date.      1. If all results match, click  button located on the lower left corner. Click  when the “Verify Release Destination” window opens. 2. The code **SURE** (Semi-urgent result) will automatically append to all positive results. 3. All results positive for HHV6 and CMV will automatically have the following comment attached: **MEPNLC** that will state: WARNING: The FilmArray ME Panel does not distinguish between latent and active CMV and HHV-6 infections. Detection of these viruses may indicate primary infection, secondary reactivation, or the presence of latent virus. Results should always be interpreted in conjunction with other clinical, laboratory, and epidemiological information. 4. Open Lab Inquiry, search for the report by accession, review results.    1. Print results if positive or invalid. Attach to instrument report. 5. Verify accession, CID, and patient name match on print out and label. Place in the FilmArray result binder. | | | | | | | |
| **Alert values** | **Alert Values:**  Report any positiveresult by telephone to the physician or patient’s nurse.   1. Add the code **RP**, press tab, enter semi-colon, and record who the result was relayed to with the time/date. 2. The code **SURE** (Semi-urgent result) will automatically append. 3. All results positive for HHV6 and CMV will automatically have the following comment attached: **MEPNLC** that will state: WARNING: The FilmArray ME Panel does not distinguish between latent and active CMV and HHV-6 infections. Detection of these viruses may indicate primary infection, secondary reactivation, or the presence of latent virus. Results should always be interpreted in conjunction with other clinical, laboratory, and epidemiological information. | | | | | | | |
| **Troubleshooting** | **Invalid results:**   1. Repeat test. 2. If results are invalid on repeat, call provider to notify them of invalid FilmArray results. 3. See reporting instructions below.   **Broken or leaked pouch:**   1. Follow the decontamination procedure outline in the instrument manual. 2. Perform wipe testing before patient testing 3. If wipe test is negative proceed with testing | | | | | | | |
| **Reporting Invalid Results** | **NOTE:** If Invalid results are obtained after testing the original sample twice, the results will be reported as unresolved.  **NOTE:** Invalid results will NOT be transmitted to the LIS, the report must be generated manually.   1. Call invalid results to the patient’s provider or RN. 2. Click on **Result Entry** and switch to manual resulting mode. 3. Under configuration select **MEPNL**. 4. Click on the first analyte and enter **unresolved** (UNRE), tab and enter the code **SIA,** and the following comment will append: “This sample is inhibitory to amplification and the results are inconclusive. Consider repeat collection if clinically indicated.” 5. Press tab and add the code **RP**, press tab, enter semi-colon, and record who the result was relayed to with the time/date. 6. Click on each additional analyte and enter the code **HIDE.** See example below. 7. Click  button located on the lower left corner. Click  when the “Verify Release Destination” window opens. See the example below in **Figure 2**.   **Figure 2: Reporting Invalid Results**     1. Record invalid results on the problem log. | | | | | | | |
| **References** | FilmArray Meningitis/Encephalitis Panel (ME) CE-IVD Instruction Booklet (RFIT-PRT-0276), BioFire Diagnostics, LLC. | | | | | | | |
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| **Training Plan/ Competency Assessment** | **Training Plan** | | | | **Initial Competency Assessment** | | | |
| 1. Employee must read the procedure. 2. Employee will observe trainer performing the procedure. 3. Employee will demonstrate the ability to perform procedure, record results and document corrective action after instruction by the trainer. | | | | 1. Direct observation. | | | |
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| **Historical Record** |  |  | |  | |  | | |
|  | **Version** | **Written/Revised by:** | | **Effective Date:** | | **Summary of Revisions** | | |
| 1 | Susan DeMeyere | | 11/1/2022 | | Initial Version | | |
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