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| BioFire FilmArray Blood Culture Identification 2 Panel | | | | | | | | |
| **Purpose** | This procedure provides instructions for performing Blood Culture Identification 2 Panel on the BioFire FilmArray system. | | | | | | | |
| **Policy Statements** | This procedure applies to all technical staff performing testing on the BioFire FilmArray. | | | | | | | |
| **Principle and Clinical Significance** | The BioFire® Blood Culture Identification 2 (BCID2) panel is a multiplexed nucleic acid diagnostic test intended for the use with the BioFire ®FilmArray Torch systems. The FilmArray BCID2 panel is capable of simultaneous qualitative detection and identification of multiple bacterial and yeast nucleic acids and select genetic determinants of antimicrobial resistance. The BCID2 assay is performed directly on blood culture samples identified as positive by a continuous blood culture system that demonstrates the presence of organisms as determined by Gram Stain. FilmArray BCID2 Panel results are available in about an hour. Timely diagnosis and administration of effective treatment can significantly reduce mortality, duration of hospital stays, and costs due to sepsis.  The following bacteria and yeast are identified using the FilmArray BCID2 panel:    The BioFire® BCID2 panel contains assays for the detection of genetic determinants associated with resistance to methicillin (*mecA/C* and *mecA/C* in conjunction with *MREJ*), vancomycin (*vanA* and *vanB*), β-lactams including penicillins, cephalosporins, monobactams and carbapenems (*bla*CTX-M, *bla*IMP,  *bla*KPC *bla*OXA48-like, *bla*NDM, *bla*VIM) to aid of the identification of potentially antimicrobial- resistant organisms in positive blood culture samples.  In addition, the panel includes an assay for the detection of mobilized genetic determinant mcr-1, an emerging marker of public health importance. The antimicrobial resistance gene detected may or may not be associated with the agent responsible for disease. Negative results for these select antimicrobial resistance gene assays do not indicate susceptibility, as multiple mechanisms of resistance to methicillin, vancomycin, β-lactams and colistin exist.  The following antimicrobial resistance markers are identified using the BCID2 panel:    The BioFire® BCID2 panel is indicated as an aid in the diagnosis of specific agents of bacteremia and fungemia and results should be used in conjunction with other clinical and laboratory findings. Positive results do not rule out co-infection with organisms not included in the FilmArray BCID2 panel. The BioFire BCID2 Panel is not intended to monitor treatment for bloodstream infection.  Subculture of positive blood cultures is necessary to recover organisms for susceptibility testing, to identify organisms in the blood culture that are not detected by the BioFire BCID2 panel, and for determination of species detected but not identified with complexes, group, or genera by the BioFire BCID2 Panel assays.  The BioFire BCID2 Panel pouch is a closed disposable system that stores all the necessary reagents for sample preparation, polymerase chain reaction (PCR), and detection in order to isolate, amplify, and detect nucleic acid from multiple pathogens and antimicrobial resistance genes contained in blood culture samples identified as positive by a continuous monitoring blood culture system. After sample collection, the user injects hydration solution and sample combined with the BioFire FilmArray Sample buffer into the pouch, places the pouch into a BioFire FilmArray Instrument Module, and starts a run. The entire run process takes about an hour. During a run, the BioFire system:   * Lyses the sample by agitation (bead beating) in addition to chemical lysis mediated by the Sample Buffer. * Extracts and purify all nucleic acids form the sample using magnetic bead technology. * Performs nested multiplex PCR by: * First performing a single, large volume, massively multiplexed reaction (PCR1) * Then performing multiple singleplex second-stage PCR reactions (PCR2) to amplify sequences within the OCR1 products. * Uses endpoint melting curve data to detect and generate a result for each target on the BioFire BCID2 Panel array. | | | | | | | |
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| **Workup Code** | BCID | | | | | | | |
| **Materials** |  | |  | |  | |  | |
|  | **Reagents** | | **Supplies** | | **Equipment** | | **Reagent storage** | |
|  | * Individually packaged BioFire BCID2 panel pouches * Single–use Sample Buffer ampoules * Single-use pre-filled Hydration Injection Vials (blue) * Single-use Sample Injection Vials (red) * External positive control: Microbiologics cat no. 8215 * External negative control: blood culture media * Household bleach | | * 1 ml syringes * Individually packaged Transfer Pipettes | | * FilmArray Torch and software * FilmArray Pouch Loading Station * Biosafety Hood * FilmArray Torch Printer | | * Store kit at room temperature-Do Not 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. * Once the pouch has been loaded, the run should be started within 60 minutes. | |
| **Sample** | Positive Blood Culture samples that demonstrate the presence of organisms as determined by Gram stain. Sample volume is 0.2 mL. Samples should be processed and tested as soon as possible after being flagged as positive by the culture instrument. However, samples may be stored for up to 24 hours at room temperature prior to testing.  **Do not** perform if patient has had a previous positive blood cultures run on BioFire FilmArray with **same** Gram stain morphology per hospital admission.  **Do not** perform on a related bottle (other bottle with same accession number) with the **same** Gram stain morphology.  **Do not** perform if no organisms are seen on the Gram Stain.  **Do not** perform on patients that are deceased or collected during an autopsy (MCAL or SCAL).  **Do not** perform on patients readmitted to the Emergency department for follow up on a positive blood culture when BioFire FilmArray BCID had already been performed. | | | | | | | |
| **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* *Policy 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. [*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)  * [*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)  1. Wear appropriate personal protective equipment (PPE) including disposable gloves and lab coats. 2. Handle all samples and waste materials as if they were capable of transmitting infectious agents. 3. Change gloves often when handling reagents or samples. 4. Dispose of materials used in this assay, including reagents, used buffer vials in biohazardous waste. 5. Sample buffer will form hazardous compounds and fumes when mixed with bleach or other disinfectants. | | | | | | | |
| **Quality Control** | There are two **internal process controls** included in each pouch.   1. DNA Process Control-The DNA Process Control assay targets DNA from the yeast *Schizosaccharomyces pombe*. The control material is carried through all stages of the test process, including lysis, nucleic acid purification, 1st stage PCR, dilution, 2nd stage PCR, and DNA melting. A positive control result indicated that all steps carried out in the pouch were successful. 2. PCR2 Control-The PCR2 Control assay detects a DNA target that is dried into the wells of the array along with the corresponding primers. A positive result indicated that 2nd stage PCR was successful.   Both control assays must be positive for the test run to pass. If either control fails, the Controls field of the test report will display FAILED and all results will be listed as INVALID. The sample should be retested using a new pouch.  **External Quality Controls:**  Perform QC using external positive (Microbiologics cat. No. 8215) and negative (blood culture media) controls every 30 days   * Rotate use of torch modules for testing  1. Clean hood and supplies with 10% bleach dilution followed by water 2. Aliquot approximately 1-2 mL blood culture media into a sterile snap cap falcon tube.   NOTE: This will be used as rehydration fluid AND negative control material   1. Ensure pellet is at the bottom of the positive control tube. 2. With a sterile transfer pipette rehydrate the inactivated positive control pellet with approximately 200uL blood culture media (can use transfer pipettes included in kit) 3. Vortex for 10 seconds at full speed to mix. 4. Quick spin the vial to ensure all target material is on the bottom. 5. Aspirate the controls using the FilmArray transfer pipette and analyze as a patient sample. 6. Record results on the FilmArray BCID 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 FilmArray BCID Quality Control Log   **Acceptable results:**  **Positive:** all organisms and resistance markers detected  **Negative:** all organisms and resistance markers NOT detected  **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 Supervisor, Technical Specialist or Technical Director with unacceptable or undesirable results. | | | | | | | |
| **Laboratory Precautions** | 1. Prevent organism contamination 2. All samples contain high concentrations of organisms and should be processed in a bio-safety hood. 3. Prior to processing a sample, **thoroughly clean** both the work area and Pouch Loading Station using freshly prepared 10% bleach dilution. Wipe disinfected surfaces with water. 4. Use **clean gloves** to remove materials from bulk packaging bags and **reseal** bulk packaging bags when not in use. 5. Samples and pouches should be handled **one** at a time under the hood. 6. Change gloves and clean work area between **each sample**. 7. Prevent amplicon contamination 8. Discard pouches in a zipped biohazard bag placed into a biohazard container that is not near the instrument immediately after the run has completed. 9. Avoid excessive handling of pouches after test runs. 10. Change gloves immediately after handling used pouches. 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. 13. Blood Culture media may contain non-viable organisms and /or nucleic acids at levels that can be detected by the BioFire BCID2 Panel. 14. The presence of non-viable organisms or nucleic acids may lead to false positive test results. The organism involved and frequency of such occurrences may change in the future. Typically, these false positives will present with more than one positive result because the BCID2 panel will also detect the organism that is growing in the culture bottle. 15. Do not use media that contains charcoal. | | | | | | | |
| **Procedure-Prepare the Pouch** | 1. Thoroughly clean the work area, the vortex andthe FilmArray Pouch Loading Station with freshly prepared 10% bleach dilution (or suitable disinfectant) followed by a water rinse. 2. Change gloves. 3. Remove Pouch, Sample Injection Vial (RED), Hydration Injection Vial (BLUE), and a Sample Buffer ampoule 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. 4. Remove the pouch from its vacuum-sealed package by tearing or cutting the notched outer packaging and opening the protective aluminum canister. The pouch may still be used even if the vacuum seal is not intact. 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. Label the pouch and the red vial with the small accession label. Do not cover the bar code. Slide the pouch into the FilmArray pouch loading station. | | | | | | | |
| **Procedure-Hydrate 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.      1. 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.  **NOTE:** record any hydration failures in the problem log.   1. Discard tip into the sharps container. | | | | | | | |
| **Procedure-Prepare Sample Mix** | 1. Hold the Sample Buffer ampoule so that the tip is facing up. 2. Firmly pinch the textured plastic tab on the side of the ampoule until the seal snaps. 3. 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.      1. Using the provided transfer pipette up to the second line, transfer 0.2 ml of sample from sterile labeled snap cap tube used during sub culturing directly to labeled sample buffer in the sample injection vial. Discard pipette in an appropriate biohazard sharps container and tightly close the lid of the sample injection vial.      1. Remove the sample injection vial from the FilmArray pouch loading station and gently invert the vial at least three times to mix. 2. Return the sample injection vial to the FilmArray pouch loading station. | | | | | | | |
| **Procedure-Load Sample Mix** | 1. Slowly twist the sample injection vial counter clockwise so it loosens from its red cap and pause for 3-5 seconds to let any drops fall. Lift the sample injection vial, leaving the red cap in the well of the Pouch Loading Station. 2. Insert the cannula tip into the port in the pouch sample port located directly below the red arrow of the 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.      1. 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.   **NOTE:** record any hydration failures in the problem log.   1. Discard the sample injection vial and the hydration injection vial in an appropriate biohazard sharps container. 2. Change gloves. 3. Remove the pouch from the FilmArray pouch loading station. | | | | | | | |
| **Procedure – Run Pouch** | 1. With clean gloves select an available module on the touch screen. 2. Scan the barcode on the pouch.      1. Enter or Scan the Sample ID. 2. Insert the pouch into the module; the module will grab onto the pouch and pull it into the chamber.   **NOTE:** make sure that the pouch fitment label is lying flat and not folded.   1. Enter the username and password, then select **Next**. 2. Review the information on the screen, verify correctness and select **Start Run**. 3. **Discard gloves.** | | | | | | | |
| **Procedure – Completion of Run** | 1. At the end of the run, the status of the module changes to “Finished” and the pouch is partially ejected. 2. Place pouch in a zipped biohazard bag and discard in Biohazard waste bin that is **not** located near the instrument. 3. The report will print automatically upon completion of the run.   **NOTE:**   * If the report does not print, proceed to Select the “Finished” module to review the report (or select the **Browse Runs** tab to view the report) and select **Print**. * If for any reason the report needs to be printed on a different printer, insert a thumb drive, view the report and save the report to print from another computer. | | | | | | | |
| **Organism Interpretation/**  **Antimicrobial Resistance Interpretation** | **Results Interpretation for Gram-Positive Bacteria**   1. The BioFire BCID2 Panel contains assays for the specific detection of ***Enterococcus faecalis*** and **Enterococcus *faecium, Listeria monocytogenes*** as well as clinically important ***Staphylococci (S. aureus, S. epidermidis and S. lugdunensis***) and ***Streptococci*** (***S. pyogenes, S. agalactiae***, and ***S. pneumoniae)***. Results for the bacteria are reported as Detected or Not Detected based on the individual corresponding assay result. If the assay is positive the result will be Detected and if the assay is negative, the result will be Not Detected. 2. The BioFire BCID2 Panel contains four assays for the detection of ***Staphylococcus*** species. Species-specific genus-level are included for the detection of ***Staphylococcus aureus****,* ***Staphylococcus epidermidis*** and **Staphylococcus lugdunensis**. The fourth assay is a genus-level assay designed to react with ***Staphylococcus*** species not specifically identified by one of the other assays. If all four assays are negative, the test will be ***Staphylococcus*** spp Not Detected. Alternatively, if any of the four assays are positive, the test result will be ***Staphylococcus*** spp Detected and results for each species–specific assay will also be reported independently. 3. Based on testing and sequence analysis, it is predicted that five species within the ***Staphylococcus*** genus (***S. equorum, S fluerettii, S. lentus, S. muscae and S. rostri)*** may not be detected, even at positive blood culture levels. Sequence analysis predicts a low rick of cross-reactivity between the ***Staphylococcus*** assay and ***Aerococcus viridans, Enterococcus cecorum*** and ***Granulicatella adiacens***. 4. The BioFire BCID2 Panel contains four assays for the detection of ***Streptococcus*** species. Species-specific assays are included for the detection of ***Group A Strep (S. pyogenes),*** ***Group B (S. agalactiae***), and ***S. pneumoniae***. The fourth assay is a genus-level assay (***Streptococcus***) designed to react with most Viridans group and other ***Streptococcus*** species that are not specifically identified by the one the assays on the panel. If all four assays are negative, the test result will be ***Streptococcus*** spp Not Detected. Alternatively, if any of the four assays are positive, the test result will be ***Streptococcus*** spp. Detected and results for each species-specific assay will also be reported independently. 5. Based on testing and sequence analysis, all species with the ***Streptococcus*** genus will be amplified by one or more of the assays on the panel at positive blood culture levels. However, there are some species (***Streptococcus equi, S. entericus, S. halitosis, S. hyovaginalis, S. minor and S. pantholopis)*** and variant sequences identified as ***S. minor, S. oralis, S. sobrinus, S. suis and S. uberis*** that may be amplified less efficiently than others and may not be detected.   **Results Interpretation for Gram-Negative Bacteria**   1. The BioFire BCID2 Panel contains assays for specific detection of many Gram-negative species. Species are identified individually for ***Bacteroides fragilis***, ***Escherichia coli, Haemophilus influenzae, Klebsiella aerogenes, Klebsiella oxytoca, N. meningitidis***,  ***Pseudomonas aeruginosa, Serratia marcescens*** and ***Stenotrophomonas maltophilia*** or as a complex, group, or genusfor ***Acinetobacter calcoaceticus-baumannii*** ***complex***, ***Enterobacter cloacae complex, Klebsiella pneumoniae*** group, ***Proteus*** spp, ***Salmonella*** spp. Each of these are reported as Detected or Not Detected based on individual corresponding assay results. If the assay is positive the result will be Detected and if the assay is negative, the result will be Not Detected. 2. The BioFire BCID2 Panel contains ten assays for the detection of most species within multiple families of the order ***Enterobacterales***. Two assays are designed to react with relevant species within the families: **Enterobacteriaceae, Erwiniaceae, Hafniaceae, Morganlleaceae, Yersiniaceae**. The eight other assays are for the detection of specific species, genera or groups of species within the ***Enterobacterales*** order including ***Enterobacter cloacae complex, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca***, ***Klebsiella pneumoniae*** group, ***Proteus*** spp, ***Salmonella*** spp and ***Serratia marcescens***. If all ten assays are negative, the test result will be ***Enterobacterales*** Not Detected. Alternatively, if any of the ten assays are positive, the test result will be ***Enterobacterales*** Detected and results for the genus, complex, group or species specific assays will also be reported independently. 3. Based on testing and sequence analysis, each of the gram-negative assays is specific for detection of the indicated genus, complex, group or species with the exception of the cross-reactivity’s noted:  * ***Bacteroides xylanisolvens*** and ***Bacteroides caccae*** can be misidentified as ***Bacteroides fragilis.*** * The ***Enterobacter cloacae complex*** is comprised of multiple species ***(E. asburiae, E. cloacae, E. hormaechei, E. kobei, E. ludwigii and E. mori).*** The assay may cross react with ***E. bugandensis and Trabulsiella guamensis.*** * The ***E. coli*** assay cross reactswith ***Shigella species (S. sonnei, S. boydii, S. dysenteriae and S. flexneri)*** which are practically indistinguishable from E. coli but are only very rarely isolated from blood culture. Cross reactivity may also occur with ***E. fergusonii.*** * ***Haemophilus aegyptius*** will be detected as ***Haemophilus influenzae.*** * ***Klebsiella grimontii*** and ***K. michiganensis*** cross reacts with the ***K. oxytoca*** assay. ***K. pneumoniae*** and ***Raoultella ornithinolytica*** can be misidentified as ***K. oxytoca*** by standard lab methods leading to apparent false negative ***K. oxytoca*** results. * The ***Salmonella*** assay will react with both species of ***Salmonella (S. bongori and S. enterica),*** including all known subspecies and serotypes. There is low risk of cross-reactivity with ***Plesiomonas shigelloides.***   **Results Interpretation for Yeast**   1. The BioFire BCID2 detected species-specific assays for ***Candida albicans***, ***Candida glabrata,*** ***Candid krusei,*** ***Candida parapsilosis***, ***Candida tropicalis, Candida auris*** and ***Cryptococcus neoformans/gattii***. Results for all yeast are reported as Detected and Not Detected based on individual corresponding assay results. If the assay is positive the result will be Detected and if the assay is negative, the result will be Not Detected.   **Results Interpretation for Antimicrobial Resistance Genes**   1. The BioFire BCID2 Panel contain assays for the specific detection of several genetic determinants of resistance to multiple classes of antibiotics found in select gram-positive or gram negative bacteria. Results for the Antimicrobial Resistance Genes are not reported unless an applicable bacterium is also detected, therefore the results are based on multiple assays. 2. Antimicrobial Resistance can occur via multiple mechanisms. A Not Detected result for a genetic marker of Antimicrobial Resistance does not indicate susceptibility to associated antimicrobial drugs or drug classes. A Detected result cannot be definitively linked to the microorganism detected. Culture is required to obtain susceptibility testing. 3. The mecA/C is intended to aid in the identification of methicillin-resistant ***Staphylococcus epidermidis*** and ***Staphylococcus lugdunensis.*** When the ***Staphylococcus epidermidis*** and ***Staphylococcus lugdunensis*** assays are positive, the mecA/C result will be reported as Detected or Not Detected. 4. The ***mecA/C*** and **MREJ** are both considered for the ***Staphylococcus aureus*** and ***Staphylococcus*** assays. Detection of ***Staphylococcus aureus*** and positive ***mecA/C*** and **MREJ results are indicative of Methicillin Resistant *Staphylococcus aureus (MRSA).*** | | | | | | | |
| **Interpretation of FilmArray printout/ Results** | **BioFire BCID2 two-page report contains a Run Summary, Result Summary and Run Details section.**   1. **Run Summary**: Sample ID, Organisms Detected, Applicable Antimicrobial Resistance Genes Detected, Controls:  * **Organisms Detected field**: Any organism with a Detected result will be listed in the field. If all of the tests were negative, **None** will be displayed in the Detected field. * **Applicable Antimicrobial Resistance Genes Detected field**: Any applicable Antimicrobial Resistance Genes with a positive result will listed as Detected. If all applicable Antimicrobial Resistance Genes are negative, None will be listed in the corresponding field. * Controls are listed as Passed, Failed, or Invalid.  1. **Result Summary:** Lists the result for each target tested by the panel. Possible results are Detected, Not Detected, N/A and Invalid. 2. **Run Details:** Provides additional information about the run including: pouch information (type, lot number, serial number), run status. 3. Result speciated organisms with appropriate codes that correlate with Gram stain morphology. Refer to table 1. **Organisms Identified/Result Codes** for appropriate codes. See Troubleshooting/Resulting if gram stain does not correlate with FilmArray results. 4. If more than 4 distinct organisms are detected, retesting is recommended. | | | | | | | |
| **Critical Values** | All BioFire Film Array results, positive, negative or invalid are critical and will be called to the provider (MD, DO, CNP, PA). Call all positive results to Pharmacy at 6-8532. | | | | | | | |
| **Troubleshooting/Resulting Invalids** | If gram stain does not correlate with FilmArray results, staining reaction does not match or organism is absent from gram stain, re-stain the slide once. **Do not enter results from FilmArray that do not correlate with the gram stain.**  Record **all** issues on the FilmArray Torch Problem Log  **Invalid results:**   1. Repeat test. 2. If results are invalid on repeat, call provider to notify them of invalid FilmArray results. 3. Add code **UNRB** on Observations line 2. 4. Document phone call code on Observations line 3.   **Example:**  Observations 1. Gram Negative Rods being isolated and identified.  2. Unresolved: This sample is inhibitory to amplification.  3. Called to and read back by Rachel L RN at 1400 1/23/2019. Gram Stain  **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   **NOTE:** See the FilmArray Torch User manual for additional scenarios that may require Troubleshooting. | | | | | | | |
| **Limitations** | 1. The performance of the BioFire BCID2 Panel has not been established for the screening of blood or blood products. 2. Results of this test must be correlated with the clinical history, epidemiological data and other data available to the clinician evaluated the patient. 3. The BioFire BCID2 Panel is a qualitative test and does not provide a quantitative value for the organism in the sample. 4. This test has not been validated for testing samples other than positive blood culture samples that demonstrate the presence of organisms by gram stain. 5. Blood cultures must be tested within 24 hours of being flagged as positive by a continuous monitoring blood culture instrument. 6. In some cases, the Gram stain result and the results of the BioFire BCID2 Panel may be discrepant. In these cases, the BioFire BCID2 Panel should be confirmed by culture before reporting. 7. This product should not be used to test blood culture media that contains charcoal. 8. Any blood culture media may contain non-viable organisms and/or nucleic acid at levels that can be detected by the BioFire BCID2 Panel leading to false positive results. 9. The FilmArray BCID Panel may not distinguish mixed cultures when two or more species of the same genes of organisms group are present (e.g. *S. aureus* and *S. hominis*) 10. In mixed cultures, the FilmArray BCID Panel may not identify all targeted organisms in the specimen, depending on the concentration of each target present. 11. Antimicrobial resistance can occur via multiple mechanisms. A Not Detected result for the FilmArray antimicrobial resistance genes assays does not indicate antimicrobial susceptibility. Subculturing and standard susceptibility testing of isolates is required to determine antimicrobial susceptibility. 12. The results for the FilmArray antimicrobial resistance gene assays do not specifically link the resistance gene to the associated organism. 13. Discrepancies between the BioFire BCID2 Panel test result and other microbial identification methods may be caused by the inability to reliably differentiate closely related species based on standard phenotypic microbial identification methods of the design of other molecular assays. 14. The detection of bacterial, yeast and antimicrobial resistance gene nucleic acid is dependent upon proper sample collection, handling, transportation, storage and preparation. 15. A negative BioFire BCID2 Panel result does not exclude the possibility of bloodstream infection. Negative rest results may occur from sequence variants in the region targeted by the assay, the presence of inhibitors, technical error, sample mix-up or an infection caused by an organism not detected by the panel. 16. There is a risk of false positive values resulting from cross-contamination by target organisms. 17. If more than 4 distinct organisms are detected, retesting is recommended. 18. BioFire BCID2 Panel assays can cross react with several organisms, typically closely related or near neighbor species to those detected by the panel. 19. The BioFire BCID2 Panel may cross react C. tropicalis with high titers of C parapsilosis and the C parapsilosis may cross react with high titers of C. tropicalis. Detected results for both in the same sample may be due to cross-reactivity or due to both organisms being present. 20. Borderline oxacillin-resistant *Staphylococcus aureus* (BORSA) and moderately resistant *S. aureus* (MODSA) strains demonstrate reduced susceptibility to oxacillin due to hyper production of *β*-lactamases or modification of penicillin-binding proteins. BORSA and MODSA strains do not contain the *mec*A or *mec*C gene. A *mec*A/C and MREJ (MRSA) Not Detected result will be reported by the BioFire BCID2 Panel for these strains. 21. The *van*A/B result is not reported in the absence of *Enterococcus faecalis* or *E faecium* detection and will therefore not be reported for blood cultures containing other vancomycin-resistant Enterococci or vancomycin-resistant *Staphylococcus aureus* (VRSA). | | | | | | | |
| **Method Performance Specifications** | 1. For *in vitro* diagnostic use only 2. BioFire BCID2 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 BCID2 Panel in conjunction with patient signs and symptoms, results from Gram stain 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. | | | | | | | |
| **Organisms Identified/Result codes** | Table 1. Organisms Identified/Result codes   |  |  |  |  | | --- | --- | --- | --- | | **Gram Positive Cocci in Clusters** | | | | | *Staphylococcus* spp*.* **STSP** | *Staphylococcus aureus* **MSSA or MRSA, see resistance genes section** | *Staphylococcus epidermidis* **SEPI** | *Staphylococcus lugdunensis* **SLUG** | | **Gram positive cocci in Pairs and/or Chains** | | | | | *Streptococcus spp.* **STRE** | *Streptococcus agalactiae* **BSB** | *Streptococcus pneumoniae* **SPNE** | *Streptococcus pyogenes* **BSA** | | *Enterococcus faecalis* **EF** | *Enterococcus faecium* **EFM** |  |  | | **Gram positive rods** | | | | | *Listeria monocytogenes* **LMON** | | | |  |  |  |  |  | | --- | --- | --- | --- | | **Gram Negative Rods** | | | | | *Acinetobacter calcoaceticus-baumannii complex* **AANI** | *Bacteroides fragilis* **BAFR** | *Enterobacterales*  **EBAL** | *Haemophilus influenzae* **HFLU** | | *Enterobacter cloacae complex* ***ENCLC*** | *Escherichia coli-****EC*** | *Klebsiella oxytoca****-KLOX*** | *Klebsiella pneumoniae-****KLPN*** | | Klebsiella aerogenes **ENAE** | *Proteus-****PROT*** | *Serratia marcescens-****SMAR*** | *Pseudomonas aeruginosa-****PSAR*** | | *Salmonella* Spp **SALM** | *Stenotrophomonas aeruginosa* **PSMA** |  |  | | **Gram Negative Cocci** | | | | | *Neisseria meningitidis* **NMEN** | | | |  |  |  |  |  | | --- | --- | --- | --- | | **Yeast** | | | | | *Candida albicans-****CALB*** | *Candida glabrata-****TGLA*** | *Candida krusei-*  ***CKRU*** | *Candida parapsilosis-****CPAR*** | | *Candida tropicalis-****CTRP*** | Candida auris  **CAUR** | Cryptococcus neoformans/gattii  **CRYNG** | |  |  |  |  |  | | --- | --- | --- | --- | | **Antimicrobial Resistance genes** | | | | | **Carbapenemases** |  |  |  | |  | IMP **IMPD** | KPC **KPCD** | OXA-48-like **OXAD** | |  | NDM **NDMD** | VIM  **VIMM** |  | | **Colistin Resistance** | mcr-1 **MCR1** |  |  | | **ESBL** | CTX-M **CTX** |  |  | | **Methicillin resistance** | mecA/C **MECAC** | mecA/C and MREJ **MECAM** | | | **Vancomycin resistance** | vanA/B **VAND** |  |  |  |  |  |  |  | | --- | --- | --- | --- | | **Miscellaneous reporting codes** | | | | | BioFire PCR results  **-BPCR** | Detected by BioFire  **-DETBC** | BioFire Testing in process **-BFTP** | No Organism detected  **-NODP** | | Invalid results  **-UNRB** | Further id to follow  **-FID** |  |  |   Use code **DETEC** after each organism and/or resistance gene.  Use code **BPCR** after each call statement.  Use code **FID** if the organism is not speciated.  Use code **NODP** when no organism is detected by the BioFire FilmArray PCR Panel.  Use code **BFTP** when resulting the Gram stain, have determined that BCID is needed and are waiting for BioFire FilmArray BCID panel results. | | | | | | | |
|  |  | | | | | | | |
| **Result Reporting** | 1. When an organism(s) is/are detected, record culture results in Sunquest **Microbiology Result Entry** in Observations. 2. Read **Run Summary** on FilmArray BCID Panel printout. If Gram stain correlates, **replace** gram stain results with Organisms detected results by adding codes from **Table 1: Organisms Identified/Result Codes** shown above. 3. Add Antimicrobial Resistance Genes codes when applicable. Use **Table 1: Organisms Identified/Result Codes** shown above. Absence of antimicrobial genes will not be reported. 4. Do not add code for genus identification if the organism is speciated. Example: Organisms Detected: *Streptococcus-Streptococcus pneumoniae*. Only report the *Streptococcus pneumoniae* 5. Add code **DETBC** after results. 6. Non speciated results will have the code **FID** (Further identification to follow) added. 7. Use code **NODP** when no organism are detected by the BioFire FilmArray Multi-Plex PCR. 8. Use code **BFTP** when resulting the Gram stain, have determined that BCID is needed and are waiting for BioFire FilmArray BCID panel results. Remove code when adding BioFire FilmArray results. 9. Add documentation of results phoned to provider and pharmacy, when applicable. Add code **BPCR.** 10. Add code **GMS** when no organisms are detected and Gram stain results are called.     Figure 1. BioFire FilmArray 2 page printout      **Example 1:** Use code **MSSA-DETBC** on line 1. Add code **BPCR** after call statement.  Observations: 1. *Staphylococcus aureus, Methicillin Sensitive-* Detected by  BioFire FilmArray PCR  2. Called to and read back by Dr. Schmitt at 1300 12/11/2021.  BioFire PCR results.  3. Called to Pharmacy (Jill) at 1300 12/11/2021. BioFire PCR results.  Figure 2. MRE Observations results    **Example 2:**  **If only the genus is detected**, for example, use code **PROT-DETBC**. Add code **FID** on line 2. Add code **BPCR** after call statement.  Observations: 1. *PROTEUS SPECIES* Detected by BioFire FilmArray PCR  2. Further identification to follow  3. Called to and read back by Dr Heaton at 1005 8/6/2019.  BioFire PCR Results.  4. Called to Pharmacy (Jill) at 1000 8/6/2019 BioFire PCR results.    Figure 3. Only species detected      The next day, after organism is speciated, enter results on line 2 and add Isolated code.      Figure 4. Only species detected next day results    **Example 3: If only the genus *Staphylococcus* is detected**, use code **STSP-DETBC.**  On line 2, add code **FID**.  On line 3, add code **BPCR** after call statements.  Observations: 1. *STAPHLYOCOCCUS SPECIES* Detected by BioFire  FilmArray PCR  2. Further identification to follow  3. Called to and read back by Dr. Schmitt at 1300 12/11/2021.  BioFire PCR Results.  4. Called to Pharmacy (Jack) at 1300 12/112/021. BioFire  PCR Results.  Figure 5. Only Staphylococcus species detected.    The next day, after organism is speciated, enter results on line 2 and add Isolated code.  Figure 6. Only species detected, next day results    **Example 4:** **If Klebsiella pneumoniae group is detected and KPC resistance genes are detected**: Use code **KLPN-DETBC** on line 1. On line 2, use **KPCD-DETBC**. Add code **BPCR** after call statement.  Observations: 1. KLEBSIELLA PNEUMONIAE-Detected by BioFire Film Array PCR  2. KPC Detected by BioFire Film Array PCR  3. Called to and read back by L6 (Dr. Schmitt) at 1300 12/11/2021  BioFire PCR results  4. Called to and read back by Pharmacy (Jack) at 1300 12/11/2021  BioFire PCR results  Figure 7. MRE Observations results with KPC    **Example 5:** **If Klebsiella pneumoniae group is detected and no resistance genes are detected**: Use code **KLPN-DETBC** on line 1. Add code **BPCR** after call statement.  Observations: 1. KLEBSIELLA PNEUMONIAE-Detected by BioFire Film Array PCR  2. Called to and read back by L6 (DR Heaton) at 1320 3/15/19  BioFire PCR results  3. Called to and read back by Pharmacy (Jill ) at 1206 3/15/19  BioFire PCR results  Figure 8. MRE Observations results with KPC not detected    **Example 6:** **If the result is Staphylococcus aureus and mecA/C and MREJ (MRSA)**  **are detected**, on line 1 enter code **MRSA-DETBC**. On line 2 add  code **MECAM–DETBC**. Add code **BPCR** after call statement.    Observations: 1. *Methicillin Resistant Staphylococcus aureus* -Detected by BioFire  FilmArray PCR.  2. mecA/C and MREJ (MRSA) Detected by BioFire FilmArray PCR  4. Called to and read back by L6 (Dr Monica Ray) at 1320 3/15/19  BioFire PCR results  5. Called to and read back by L6 (Dr Monica Ray) at 1206 3/15/19  BioFire PCR results  Figure 9. MRE Observations with *Staph aureus* and mecA/C and MREJ detected    **Example 7:** **If the result is Staphylococcus aureus with no resistance genes detected**,  on line 1 enter code **MSSA-DETBC**. Add code **BPCR** after call statement.    Observations: 1. Staph aureus, Methicillin Sensitive-Detected by BioFire  FilmArray PCR.  2. Called to and read back by L6 (Dr. Schmitt) at 1300 12/11/2021  BioFire PCR results  3. Called to and read back by Pharmacy (Jill) at 1300 12/11/2021  BioFire PCR results  Figure 10. MRE Observations *Staph aureus* with mecA/C not detected results    **Example 8: If no organisms** are detected by BioFire FilmArray,enter code **NODP** on observation line 2. **Do not repeat the test**. Call provider with **both** Gram Stain and BioFire result. Do not call Pharmacy with negative BioFire results. Enter code **GMS** and **BPCR** with ‘called to’ statement.  Observations: 1. Gram Negative Rods being isolated and identified.  2. No Organism detected by BioFire FilmArray Multi-Plex PCR  3. Called to and read back by Dr Heaton at 1000 8/6/2019.  Gram stain. BioFire PCR Results.      Figure 11. MRE Observation with No Organisms Detected     1. Call **all** results to provider (MD, DO, CNP, PA) 2. Call all positive results to pharmacy at 6-8532. This is the St Paul PICU pharmacist that will relay the results to the pharmacist on either campus. 3. Do not final. Click on **Save** twice when all results and calls are documented. 4. Document your initials, tech code and which bottle the panel was performed on the FilmArray Report. 5. Staple BioFire FilmArray report to Bactec printout. 6. Day shift: use workup code BCID and enter organism codes. 7. Day shift: add code **BBID** to Billing tab whenever a FilmArray is performed. This will be added instead of the ID1 code. Only add ID1 bill code when performing identification on un-speciated results, e.g. Staphylococcus species. 8. Day shift: add code **BBID2** to Billing tab when a second FilmArray BCID panel is performed due to a second morphology. 9. Day shift: confirm all *Klebsiella* spp. detected on BioFire FilmArray with a MALDI identification. Document in Workup. If discrepant, leave BioFire FilmArray result on line 1 and add the isolated organism on another result line. Record on BioFire problem log.   Figure 12. Workup | | | | | | |
| **References** | BioFire FilmArray Application and Training Guide BioFire Diagnostics, LLC 515 Colorow Drive Salt Lake City UT 84108 May 2016  BioFire Blood Culture Identification (BCID2) Panel RFIR-PTR-0841-02 June 2020 | | | | | | | |
| **Alternate Methods** | 1. Perform identification on Vitek MS or Vitek2 from subcultures. | | | | | | | |
| **Customer and Technical Support** | Web information at [www.biofiredx.com](http://www.biofiredx.com). Email at [support@biofiredx.com](mailto:support@biofiredx.com). Call at 1-800-735-6544 or fax to 801-588-0507. | | | | | | | |
| **Training Plan/ Competency Assessment** | |  |  | | --- | --- | | **Training Plan** | **Initial Competency Assessment** | | 1. Employee must read the procedure. 2. Employee will demonstrate the ability to perform procedure, record results, and document corrective action after instruction by the trainer. | 1. Direct observation | | | | | | | | |
| **Proficiency Testing** | **API:** Blood Pathogen Panel, 3 shipments - 5 samples each. | | | | | | | |
| **Historical Record** |  |  | |  | |  | | |
|  | **Version** | **Written/Revised by:** | | **Effective Date:** | | **Summary of Revisions** | | |
| 1 | Susan DeMeyere | | 1/17/2021 | | Initial Version | | |
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