| UnityPoint Health METHODIST | Page 1 of 9 | Section: UPM MICRO | Policy #: 04.017 |
|---|---|---|---|
| | Approved by: see signature block at end of document | | Date: 2/26/18<br>Review by: 2/26/18 |
| MICROBIOLOGY LABORATORY | Supersedes: 10/27/17<br>Date Revised: 6/8/16, 6/23/16, 10/27/17, 2/26/18 | | |
| | Primary Responsible Parties: Marsha Bishoff<br>Secondary Responsible Parties: Audrey Davis | | |
| | CAP Standard: | | |
| SUBJECT: BIOFIRE BLOOD CULTURE IDENTIFICATION PANEL | | | |

**Multiplexed Nucleic Acid Test**
**Film Array**

## PRINCIPLE

The FilmArray BCID Panel is a multiplexed nucleic acid test intended for use with the FilmArray Instrument for the simultaneous qualitative detection and identification of multiple bacterial and fungal nucleic acids in positive blood culture samples.

## CLINICAL SIGNIFICANCE

Blood cultures are essential in the diagnosis and treatment of the etiologic agents of sepsis. Bacterial sepsis constitutes one of the most serious infectious diseases and; therefore, the expeditious detection and identification of blood borne bacterial pathogens is an important function of the diagnostic microbiology laboratory.

## SPECIMEN

Human blood culture samples identified as positive by a continuous monitoring blood culture system that demonstrates the presence of organisms as determined by Gram stain. For optimal results, only the anaerobic bottle should be used for testing.

Sample Volume – 0.2 mL

Samples should be collected from a blood culture bottle in a tilted position to allow the bottle resin to settle (approximately 10 seconds). Sample should be collected from the blood culture bottle using a syringe that is capable of measuring 0.2 mL. Blood culture 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 8 hours at room temperature or in the culture instrument prior to testing.

**REAGENT**

| Materials Provided | Materials Required But Not Provided |
|---|---|
| Each kit contains sufficient reagents to test 30 or 6 specimens:<br>Individually packaged FilmArray BCID pouches<br>Single-use (1.0 mL) Sample Buffer ampoules<br>Single-use pre-filled (1.5 mL) Hydration Injection Vials (blue)<br>Single-use Sample Injection Vials (red)<br>Individually packaged Transfer Pipettes | FilmArray System including:<br>FilmArray Instrument<br>FilmArray Pouch Loading Station compatible with the use of the FilmArray Injection Vials<br>**Note:** Previous versions of Pouch Loading Station should not be used with the FilmArray Injection Vials. |

**Kit reagents must be stored at 15 – 25 °C and kit components kept sealed until ready for use.**

**QUALITY CONTROL**

**Process Controls**
Two process controls are included in each pouch:

1. **DNA Process Control**
   The DNA Process Control assay targets DNA from the yeast *Schizosaccharomyces pombe*. The yeast is present in the pouch in a freeze-dried form and is hydrated and introduced into the test when the sample is loaded. 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 indicates 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 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. An IQCP has been developed for this assay, please see IQCP folder in the technical coordinator's office. The plan will be reviewed on a yearly basis and

adapted according to the risk assessment changes.

**PROCEDURE:**
Video or the FilmArray Operator's Manual for more details and pictorial representations of these instructions. Gloves and other Personal Protective Equipment (PPE) should be used when handling pouches and samples. Only one FilmArray BCID pouch should be prepared at a time. Once sample is added to the pouch, it should be promptly transferred to the instrument to start the run. After the run is complete, the pouch should be discarded in a biohazard container.

**Prepare Pouch**

1. Thoroughly clean the work area and the FilmArray Pouch Loading Station with freshly prepared 10% bleach (or suitable disinfectant) followed by a water rinse.
2. Remove the pouch from its vacuum-sealed package by tearing or cutting the notched outer packaging and opening the protective aluminum canister.

**NOTE: If the vacuum seal of the pouch is not intact, the pouch may still be used. Attempt to hydrate the pouch using the steps in the Hydrate Pouch section. If hydration is successful, continue with the run. If hydration fails, discard the pouch and use a new pouch to test the sample.**

3. Slide the pouch into the FilmArray Pouch Loading Station so that the red and blue labels on the pouch align with the red and blue arrows on the FilmArray Pouch Loading Station.
4. Place a blue-capped Hydration Injection Vial in the blue well of the FilmArray Pouch Loading Station.
5. Place a red-capped Sample Injection Vial in the red well of the FilmArray Pouch Loading Station.

**Hydrate Pouch**

1. Twist 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. 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.

**Prepare Sample Mix**

1. Hold the Sample Buffer ampoule so that the tip is facing up.

> **NOTE: Use care to avoid touching the tip during handling, as this may introduce contamination.**

2. Gently 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.
4. Invert the positive blood culture bottle several times to mix.
5. Wipe the bottle septum with alcohol and air dry.
6. Tilt the bottle and hold in the tilted position to allow the bottle resin to settle (approximately 10 seconds).
7. Using a syringe, withdraw 0.2 mL of blood culture sample through the bottle septum, taking care to avoid drawing resin beads into the sample, or the formation of bubbles.
8. Add sample directly to Sample Buffer in the Sample Injection Vial. Discard syringe in an appropriate biohazard sharps container and Return the Sample Injection Vial to the FilmArray Pouch Loading Station.

Alternately: Draw the desired amount of blood culture sample (>0.2 mL) from the bottle into the syringe and transfer to a sterile secondary container. Draw the blood culture sample from the secondary container to the second line of the Transfer Pipette (0.2 mL) and add the sample to Sample Buffer in the Sample Injection Vial. Tightly close the lid of the Sample Injection Vial.

> **NOTE: DO NOT use the Transfer Pipette to mix the sample once it is added to the Sample Injection Vial.**

9. Remove the Sample Injection Vial from the FilmArray Pouch Loading Station and gently invert the vial at least three times to mix.
10. Return the Sample Injection Vial to the FilmArray Pouch Loading Station.

**Load Sample Mix**

1. Slowly twist the Sample Injection Vial so it loosens from its red cap and pause for 3-5 seconds. Lift the Sample Injection Vial, leaving the red cap in the well of the FilmArray Pouch Loading Station.
2. 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 liquid will be pulled into the pouch by vacuum.
3. 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.

4. Discard the Sample Injection Vial and the Hydration Injection Vial in an appropriate biohazard sharps container.
5. Record the Sample ID in the provided area on the pouch label (or affix a barcoded Sample ID) and remove the pouch from the FilmArray Pouch Loading Station.

**Run Pouch**

The FilmArray software includes a step-by-step on-screen tutor that shows each step of the test.

1. Ensure that the computer and FilmArray instrument(s) are on and the FilmArray software is launched.
2. Open the lid of an available instrument (if not already open).

**NOTE: An available instrument is indicated by a constant green light on the front of the instrument.**

3. Insert the pouch into the instrument. Position the pouch so that the array is on the right with the film directed downward into FilmArray instrument. The red and blue labels on the pouch should align with the red and blue arrows on the FilmArray instrument. The pouch will click into place. If inserted correctly, the barcode is visible and the label is readable on the top of the pouch. The instrument and software must detect that the pouch has been inserted correctly before continuing to the next step.

**NOTE: If the pouch does not slide into the instrument easily, gently push the lid of the instrument back to be sure that it is completely open.**

4. Scan the barcode on the FilmArray pouch using the barcode scanner. Pouch identification (Lot Number and Serial Number), Pouch Type and Protocol are preprogrammed in the rectangular barcode located on the FilmArray pouch. The information will be automatically entered when the barcode is scanned. If it is not possible to scan the barcode, the pouch Lot Number, Serial Number, Pouch Type and Protocol can be manually entered from the information provided on the pouch label into the appropriate fields. To reduce data entry errors, it is strongly recommended that the pouch information be entered by scanning the barcode.

**NOTE: The barcode cannot be scanned prior to placing the pouch in the instrument.**

5. Enter the Sample ID. The Sample ID can be entered manually or scanned in by using the barcode scanner when a barcoded Sample ID is used.
6. If necessary, select a protocol from the Protocol drop down list (the protocol is usually selected automatically).
7. Enter a user name and password in the Name and Password fields.
8. Close the FilmArray instrument lid.
9. Click the Start Run button on the screen.

Once the run has started, the screen displays a list of the steps being performed by the instrument and the number of minutes remaining in the run.

**NOTE: The bead-beater apparatus can be heard as a high-pitched noise (whine) during the first minute of operation.**

10. When the run is finished, follow the on-screen instructions to open the instrument and remove the pouch.
11. Immediately discard the pouch in a biohazard container.
12. Results are automatically displayed in the report section of the screen. The run file is automatically saved in the FilmArray database and the report can be printed and/or saved as a PDF file.

## REPORTING RESULTS

### FilmArray BCID Test Report

The FilmArray BCID test report is automatically displayed upon completion of a run and contains three sections, the Run Summary, the Results Summary, and the Run Details (see the FilmArray Blood Culture Identification Panel Quick Guide to view an example of a test report). The test report can be saved as a PDF or printed.

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. Any organism with a Detected result will be listed in the corresponding field of the summary. If all of the tests were negative then None will be displayed in the Detected field. Antimicrobial resistance genes with a result of Detected or Not Detected will be listed in the corresponding field of the summary. Controls are listed as Passed, Failed or Invalid. See the Controls Field section below for detailed information about the interpretation of controls and appropriate follow-up in the case of control failures.

The Results Summary – Interpretations section of the test report lists the result for each target tested by the panel. Possible results for each organism are Detected, Not Detected, or Invalid. Possible results for antimicrobial resistance genes are Detected, Not Detected, N/A, or Invalid. See Results Summary section below for detailed information about interpretation of test results and appropriate follow-up for Invalid results.

The Run Details section provides additional information about the run including: pouch

information (type, lot number, and serial number), Run Status (Completed, Incomplete, Aborted, Instrument Error, Instrument Communication Error, or Software Error), the protocol that was used to perform the test, the identity of the operator that performed the test, and the instrument used to perform the test.

Once a run has completed, it is possible to edit the Sample ID. If this information has been changed, an additional section called Change History will be added to the test report. This Change History section lists the field that was changed, the original entry, the revised entry, the operator that made the change, and the date that the change was made. Sample ID is the only field of the report that can be changed.

**PROCEDURALNOTES/PROBLEM-SOLVING TIPS**

The BCID panel will only be run once the blood gram stain shows gram negative bacilli or gram positive cocci. Also, only one panel will be run per patient in a seven day time frame, unless a second positive bottle shows different gram stain morphology, or is requested by a clinician.

Due to false positive results with *Candida parapsilosis*, do NOT report this organism unless yeast is seen in the gram stain.

If a definitive ID (genus and species) is produced by the Biofire Film Array, no further identification work up is necessary. i.e. Biofire result of *E. coli* is acceptable, no further I.D required; result of *Enterobacteriaceae* needs further I.D; result of *S. pneumoniae* does not require optochin disk; yeast does not need an API.

**Control Field**

The Controls field on the test report will display Passed, Failed, or Invalid. The Controls field will display Passed only if the run completed successful ly (no instrument or software errors) and both of the pouch control assays (DNA Process Control and PCR2 Control) were successful. The Controls field will display Failed if the run was completed successfully (no instrument or software errors) but one or both of the pouch control assays failed (0 or 1 positive replicates for either of the controls, each of which is tested in triplicate). If the control result is Failed, then the result for all of the tests on the panel are displayed as Invalid and the sample will need to be retested with a new pouch.

Table 10 provides a summary and explanation of the possible control results and follow-up actions.

**Table 10. Interpretation of Controls Field on the FilmArray BCID Test Report**

| | | | |
|---|---|---|---|
| Passed | The run was successfully completed<br>AND<br>Both pouch controls were successful. | None | Report the results provided on the test report. |

| | | | |
|---|---|---|---|
| Failed | The run was successfully completed<br>BUT<br>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.<br>(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.<br>Once the error is resolved, repeat the test or repeat the test using another instrument.<br>If the error occurred in the first 30 seconds of the run, the same pouch may be used for the repeat test (within 60 minutes of pouch loading) using the same instrument or another instrument, as available.<br>If the error occurred later in the run or you are unsure when the error occurred, return to the original sample to load a new pouch. Repeat the test with the new pouch on the same instrument or another instrument, as available. | Accept the valid results of the repeat testing. If the error persists, contact Technical Support for further instruction. |

**REFERENCES**

FilmArray Blood Culture Identification Panel (BCID) Instruction Booklet (RFIT-PRT-0369), BioFire Diagnostics, LLC.

MMCI Laboratory is a CAP accredited facility, as of 7/1/11 the responsibility of new and/or substantially revised policies and procedures will be restricted the Laboratory Director whose name appears on the CLIA certificate, whose signature appears below. The biennial review will be

completed by the Administrative Director.

| ***POLICY CREATION :*** | | |
|---|---|---|
| ***Author:*** | ***Teresa Nuese, MT*** | ***June 7, 2016*** |
| ***Medical Director:*** | ***Devendra Trivedi, MD*** | ***June 8, 2016*** |

| ***MEDICAL DIRECTOR*** | | |
|---|---|---|
| **DATE** | **NAME** | **SIGNATURE** |
| February 12, 2017 | Elizabeth A. Bauer-Marsh, M.D. | |
| ***SECTION MEDICAL DIRECTOR*** | | |
| June 8, 2016 | Lori Racsa, DO | |
| | | |

| **REVISION HISTORY** | | | |
|---|---|---|---|
| **Rev** | **Description of Change** | **Author** | **Effective Date** |
| 0 | Initial Release | T. Nuese | 6/8/16 |
| 1 | Changed indexing from 11.015 to 04.017 | T. Nuese | 6/23/16 |
| 2 | Added reagent storage requirements, added comment of false positive results of C. parapsiolosis | T Nuese | 9/28/17 |
| 3 | Added comment for definitive ID. Added 7 day time frame for performing test. General reformatting. | A Davis | 02/15/18 |

**Reviewed by**

| **Lead** | **Date** | **Coordinator/ Manager** | **Date** | **Medical Director** | **Date** |
|---|---|---|---|---|---|
| | | | 6/7/16 | | 6/8/16 |
| | | | 6/23/16 | | 6/23/16 |
| | | | 9/28/17 | | 10/27/17 |
| Marsha Bishoff | 2/21/18 | | 2/15/18 | | 2/26/18 |