TRAINING UPDATE

Lab Location:	SGMC & WOMC	**Date Distributed:**	7/1/2021
Department:	Core Lab	**Due Date:**	8/1/2021

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

BioFire® FilmArray® Blood Culture Identification (BCID) Panel SGMC.M1018 v4

Description of change(s):

Note: In addition to removing the requirement to perform external QC each day of use, other info has been added to the SOP to help clarify –

- when a BCID should be performed
- what to say when calling the results

Please carefully review the highlighted sections of the SOP. The review quiz will focus on the changes.

Section	Reason
3.2, 8	Clarified criteria for performing BCID
6.3	Removed daily ext. QC to match IQCP
10.6	Added call instructions
16	Added IQCP info
Addendum A	Added BCID not done if gram is NOS

This revised SOP was implemented on June 29, 2021

Document your compliance with this training update by taking the quiz in the MTS system.

Technical SOP

Title	**BioFire® FilmArray® Blood Culture Identification (BCID) Panel**
Prepared by	Ron Master Date: 2/19/2021
Owner	Ron Master Date: 2/19/2021

Laboratory Approval	**Local Effective Date:**	
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		

TABLE OF CONTENTS

1. TEST INFORMATION

Assay	Method/Instrument	Test Code
BioFire® FilmArray® Blood Culture Identification (BCID) Panel	Multiplexed PCR / BioFire Torch Instrument	BCIDA/BCIDN

Synonyms/Abbreviations
BCID

Department
Microbiology

2. ANALYTICAL PRINCIPLE

The BioFire BCID Panel pouch is a closed system disposable that houses all the chemistry required to isolate, amplify, and detect nucleic acid from multiple bloodstream pathogens within a single blood culture sample. The rigid plastic component (fitment) of the BioFire BCID Panel 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 BioFire BCID Panel loads the sample into the BioFire BCID Panel pouch, places the pouch into the BioFire® FilmArray® Instrument, and starts the run. All other operations are automated.

The following gram-positive bacteria, gram-negative bacteria, and yeast are identified using the BioFire BCID Panel:

Gram-positive bacteria

- *Enterococcus*
- *Listeria monocytogenes*
- *Staphylococcus*
- *Staphylococcus aureus*
- *Streptococcus*
- *Streptococcus agalactiae*
- *Streptococcus pneumoniae*
- *Streptococcus pyogenes*

Gram-negative bacteria

- *Acinetobacter baumannii*
- *Enterobacteriaceae*
- *Enterobacter cloacae* complex
- *Escherichia coli*
- *Klebsiella oxytoca*
- *Klebsiella pneumoniae*
- *Serratia marcescens*

- *Proteus*
- *Haemophilus influenza*
- *Neisseria meningitidis* (encapsulated)
- *Pseudomonas aeruginosa*

Yeast

- *Candida albicans*
- *Candida glabrata*
- *Candida krusei*
- *Candida parapsilosis*
- *Candida tropicalis*

Antimicrobial resistance genes

- *mecA* – methicillin resistance
- *vanA/B* – vancomycin resistance
- KPC – carbapenem resistance

The BioFire® FilmArray® Blood Culture Identification (BCID) Panel also contains assays for the detection of genetic determinants of resistance to methicillin (mecA), vancomycin (vanA and vanB), and carbapenems (KPC) to aid in the identification of potentially antimicrobial resistant organisms in positive blood culture samples.

3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	N/A
Specimen Collection and/or Timing	See Blood Culture with Automated Detection, BACTEC FX, SOP SGMC.M1008
Special Collection Procedures	See Blood Culture with Automated Detection, BACTEC FX, SOP SGMC.M1008
Other	N/A

3.2 Specimen Type & Handling

Criteria	
Type -Preferred	Blood culture samples identified as positive by a continuous monitoring blood culture system. Results are intended to be interpreted in conjunction with Gram stain results.
-Other Acceptable	None
Collection Container	BACTEC blood culture vial
Volume - Optimum	0.2 mL (200 µL)
- Minimum	0.2 mL (200 µL)

Criteria	
Transport Container and Temperature	BACTEC blood culture vial at Room Temperature
Stability & Storage Requirements	Room Temperature: 8 hours (15-25°C)
	Refrigerated: Not Acceptable
	Frozen: Not Acceptable
Timing Considerations	Must test within 8 hours
Unacceptable Specimens & Actions to Take	Any other than positive blood culture vial. Do not use blood culture media that contains charcoal (e.g., BacT/ALERT FA FAN® Aerobic). Reject specimen
Compromising Physical Characteristics	Refrigerated or frozen
Other Considerations	**Only test the first positive (Gram stain positive) bottle for each patient unless the Gram morphology changes from the initial positive. Do not test NOS bottles.** Using a subculture unit, add ≥ 300 mL of the positive blood culture into a sterile 8-mL 13x100 mm tube.

NOTE: Labeling requirements for all reagents, calibrators and controls include: (1) Open date, (2) Substance name, (3) Lot number, (4) Date of preparation, (5) Expiration date, (6) Initials of tech, and (7) Any special storage instructions. Check all for visible signs of degradation.

4. REAGENTS

The package insert for a new lot of kits must be reviewed for any changes before the kit is used. A current Package Insert is included as a Related Document.

4.1 Reagent Summary

Reagents / Kits	Supplier & Catalog Number
Individually packaged BioFire® FilmArray® Blood Culture Identification (BCID) Panel pouches	BioFire FLM1-ASY-0149

4.2 Reagent Preparation and Storage

Assay Kit	
Kit Contents	BioFire® FilmArray® Blood Culture Identification (BCID) Panel Kit, each pouch contains: • 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 All kit components should be stored and used together. Do not use components from one kit with those of another kit.
Storage	Store the test kit, including reagent pouches and buffers, at room temperature (15–25ºC). Avoid storage of any materials near heating or cooling vents or in direct sunlight. DO NOT REFRIGERATE.
Stability	Unopened material is stable through the expiration date when stored at room temperature (15–25ºC). Do not remove pouches from their packaging until a sample is ready to be tested. Once the pouch packaging has been opened, the pouch should be loaded as soon as possible (within approximately 30 minutes).
Preparation	See Section 8.1

5. CALIBRATORS/STANDARDS

N/A

6. QUALITY CONTROL

6.1 Controls Used

Controls	Supplier and Catalog Number
Maine Molecular BCID Panel	Maine Molecular / M235
External positive control	M2362816
External negative control	M2370016

6.2 Control Preparation and Storage

Control	Maine Molecular BCID Panel M235
Preparation	Allow control to come to room temperature (18-25°C) Do not dilute. Immediately before use, mix the control by vortexing for 3-5 seconds and then shake the tube down firmly to remove any droplets caught in the cap.
Storage/Stability	2-8°C Unopened material is stable through the expiration date when stored refrigerated. Each control vial is single use, discard after use.

6.3 Frequency

External Controls are ~~run daily, each day of use and~~ with each new kit lot number or shipment or every 31 days, whichever is more frequent.

Internal QC results are checked and recorded for each patient test. The FilmArray instrument will not report a patient result unless all internal controls yield acceptable results.

6.4 Tolerance Limits and Criteria for Acceptable QC

A. Tolerance Limits

Tolerance Limits	
External Positive Control	Detected
External Negative Control	Not Detected
Internal Controls	
DNA Process Control	Passes if Meets the Assigned Acceptance Criteria
PCR2 Control	Passes if Meets the Assigned Acceptance Criteria

- **If the control result is Failed, then the results for all of the tests on the panel are displayed as Invalid and the sample will need to be retested with a new pouch.**

B. Criteria for Acceptable QC
- All controls must yield acceptable results.
- Controls and patient data must be reviewed for acceptability and for atypical or unexpected results or trends prior to reporting patient results.
- DO NOT release results from runs with unacceptable controls or with unusual patterns, trends or distribution in patient values.

C. Corrective Action
- All rejected runs must be effectively addressed and include the following documentation:
  - Control(s) that failed (e.g., positive control with negative result) and/or atypical or unexpected patient results
  - Actions taken
  - Statement of what was done with the patient samples from the affected run/batch,
  - Date and initials of the person recording the information.
- Patient samples in failed analytical runs must be reanalyzed.

NOTE: The laboratory director or designee may override rejection of partial or complete runs. Justification for the override must be documented in detail.

6.5 Documentation

- Record all External quality control results on the BioFire FilmArray Blood Culture Identification Panel (BCID) External QC Form.
- Record all Internal quality control results on the BioFire FilmArray Blood Culture Identification (BCID) Internal QC Log
- Quality control records are reviewed daily at the bench, weekly by the Group Lead or designee, and monthly by the Supervisor/Manager or designee.
- Refer to complete policies and procedures for QC documentation and for record retention requirements in the Laboratory QC Program.

6.6 Quality Assurance Program

- The laboratory participates in CAP proficiency testing.
- Only the first positive blood culture for each patient will be tested using the FilmArray® Blood Culture Identification (BCID) Panel.
- All positive blood cultures tested using the FilmArray® Blood Culture Identification (BCID) Panel must also be inoculated onto solid media and sent to Chantilly for identification and antimicrobial susceptibility testing as per the Blood Culture with Automated Detection, BACTEC FX, SOP SGMC.M1008

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

BioFire® FilmArray® Torch Systems
BioFire FilmArray Software

7.2 Equipment

Pouch Loading Station compatible with the use of the Injection Vials

7.3 Supplies

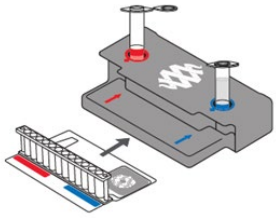
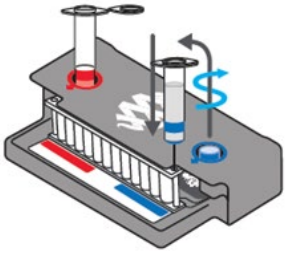
Individually packaged Transfer Pipettes
8 mL 13x100 mm sterile tubes

8. PROCEDURE

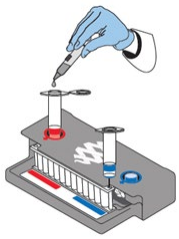
NOTE: For all procedures involving specimens, buttoned lab coats, gloves, and face protection are required minimum personal protective equipment. Report all accidents to your supervisor.

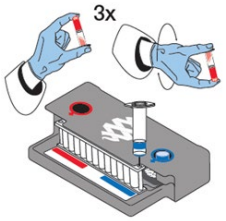
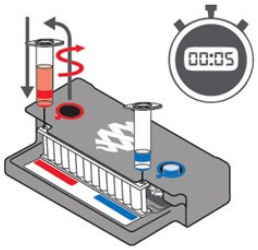
Refer to BioFire® FilmArray® Torch Systems Maintenance procedures for required maintenance.

Only test the first positive (Gram stain positive) bottle for each patient unless the Gram morphology changes from the initial positive. Do NOT test NOS bottles.

8.1	Specimen / Reagent Preparation
Prepare Pouch	
1.	Thoroughly clean the work area and the Pouch Loading Station with freshly prepared 10% bleach (or suitable disinfectant) followed by a water rinse.
2.	Don clean gloves. 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 Pouch Loading Station so that the red and blue labels on the pouch align with the red and blue arrows on the Pouch Loading Station 
4.	Place a blue-capped Hydration Injection Vial in the blue well of the Pouch Loading Station.
5.	Place a red-capped Sample Injection Vial in the red well of the Pouch Loading Station.
Hydrate Pouch	
1.	Twist and lift the Hydration Injection Vial, leaving blue cap in the well of the Pouch Loading Station.
2.	Insert the cannula tip into the port in the pouch located directly below the blue 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 liquid will be pulled into the pouch by vacuum. 
3.	Verify that the pouch has been hydrated.

8.1	Specimen / Reagent Preparation
4.	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.

8.2	Test Run
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. **Avoid squeezing the ampoule additional times as this will generate excessive bubbles.** 
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 subculture unit, add ≥ 300 uL of the positive blood culture into a sterile 8-mL 13x100 mm tube, taking care to avoid drawing resin beads into the sample, or the formation of bubbles.
8.	Draw the blood culture sample from the 8-mL 13x100 mm tube to the second line of the Transfer Pipette (200 uL) and add sample directly into 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.	Tightly close the lid of the Sample Injection Vial.

8.2	Test Run
10.	Remove the Sample Injection Vial from the Pouch Loading Station and gently invert the vial at least three times to mix. 
11.	Return the Sample Injection Vial to the Pouch Loading Station.
Load Sample Mix	
1.	Slowly twist the Sample Injection Vial so it loosens from its red cap and **pause for 5 seconds.**  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 fitment 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 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 Pouch Loading Station.
6.	Discard gloves.
Run Pouch - BioFire® FilmArray® Torch	
1.	Ensure that the BioFire Torch system is on.
2.	Don clean gloves. Select an available Module on the touch screen.

8.2	Test Run
3.	Scan the barcode on the 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 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.
4.	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.
5.	Insert the pouch into the Module. Ensure that the pouch fitment label is lying flat on top of pouch and not folded over. As the pouch is inserted, the Module will grab onto the pouch and pull it into the chamber.
6.	If necessary, select and/or confirm a protocol from the protocol drop-down list.
7.	Enter operator user name and password, then select Next. **NOTE: The font color of the username is red until the user name is recognized by the software.**
8.	Review the entered run information on the screen. If correct, select Start Run. 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.**
9.	At the end of the run, the status of the Module changes to Finished and the pouch is partially ejected. Do not remove the pouch until after the next step. One copy of the report will print automatically.
10.	Select the Finished Module on the Dashboard to view the report. Select Print to print a second copy of the report.
11.	Remove the pouch from the Module and immediately discard the pouch in a biohazard container. **NOTE: Once the pouch has been removed, the report can only be viewed through the Browse Runs feature.**
12.	Staple 1 copy of the Report to the Positive Blood Culture Worksheet. On the second copy of the report: • Place a patient label (must include the patient's name), preferably use the BCID Sunquest label. • This will facilitate identifying the BCID report if it gets separated from the blood culture plates. • Send this copy to Chantilly with the plates and Batch List.

NOTE: In the event that the test system becomes inoperable, notify supervision or designee for further direction. Patient specimens must be stored in a manner that maintains the integrity of the specimen.

9. CALCULATIONS

N/A

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

The Internal Control field on the test report will display "Controls: Passed / Failed / or Invalid". The Control field will display **Passed** only if the run completed successfully (no instrument or software errors) and both of the internal control assays (DNA Process Control and PCR2 Control) were successful. 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.

The table below provides a summary and explanation of the possible control results and follow-up actions.

Control Result	Explanation	Action Required	Outcome
Passed	The run was successfully completed AND Both pouch (internal) 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 (internal) 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.

Control Result	Explanation	Action Required	Outcome
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 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. 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. 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.

BioFire BCID Panel Test Report
The test report can be saved as a PDF or printed.

Once a run has completed, it is possible to edit the Sample ID. Sample ID is the only field of the report that can be changed.

10.2 Rounding

N/A

10.3 Units of Measure

N/A

10.4 Clinically Reportable Range (CRR)

N/A

10.5 Review Patient Data

- Review patient results for unusual patterns, trends or distribution.
- Report atypical or unexpected results or trends for this test to appropriate supervisory personnel, prior to releasing results.

10.6 Repeat Criteria and Resulting

IF the result is …	THEN…
If the control result is Failed	The results for all of the tests on the panel are displayed as Invalid and the sample will need to be retested with a new pouch.
If Detected results are reported for 3 or more organisms in a sample	Retest the sample is to confirm the polymicrobial result.
Detected	Report result as "Detected"
Not Detected	Report result as "Not Detected"
Invalid	Do not report and contact supervisor. Typically, this indicates a software or hardware error
N/A (Antimicrobial Resistance Genes only)	Organism that contains the resistance gene is Not Detected, result for resistance gene is not reported.

Message Code	Message
Detected	DET
Not Detected	NTD

Replacement of Failed Pouches
BioFire will replace failed pouches. We must document the following information on the BioFire Failed Pouches for Credit Log and submit to BioFire in order to be reimbursed.

Date
Initials
Assay – RP, RP2.1, or BCID
Instrument S/N - SGMC-TB010179, WOMC-TB010182
Pouch Lot #
Error Categories - Hydration Failure, Loss of Vacuum, Control Failure, Software Error, Instrument Error, Others
Comments - in comments it is important to put any code number for the errors – software and instrument. And any further information if you are reporting an "others" errors.

To Look up an error code
1. Select Browse Runs in the top menu
2. Use the search icon to search for runs
3. Select a single run from the table
4. Select View Report
5. Click on actions
6. Select show run details
7. Look for an Error code

Result Reporting

- BioFire is interfaced with Sunquest to upload results. See Addendum A.

Call the Nursing Unit **and** state the following:
"THIS IS A CRITICAL RESULT. The Gram stain result is ___*provide result*__. **The BCID results have been resulted and are available in Cerner".** Document as per the Critical Call procedure.

11. EXPECTED VALUES

11.1 Reference Ranges

Not Detected

11.2 Critical Values

Detected

11.3 Standard Required Messages

N/A

12. CLINICAL SIGNIFICANCE

Sepsis (defined as system inflammatory response syndrome in response to infection) is the 11th leading cause of death in the United States [1]. Life-threatening bacterial and fungal sepsis currently strikes approximately 240 out of 100,000 people per year in the U.S. (750,000 total cases), with severe sepsis (associated with acute organ dysfunction) in 95 out of 100,000 people [2]. Timely diagnosis and administration of effective treatment can significantly reduce mortality, duration of hospital stays, and costs due to sepsis. The FilmArray Blood Culture Identification (BCID) Panel simultaneously tests a single positive blood culture sample to provide results for 24 different organisms and organism groups that cause bloodstream infections and three genetic markers that are known to confer antimicrobial resistance (see Table 1). The test can be performed on blood culture bottles that are flagged as positive by a continuously monitoring blood culture instrument. Results are intended to be interpreted in conjunction with Gram stain results. FilmArray BCID Panel results are available within about one hour. Rapid identification of the organism(s) in the blood culture, along with information about antimicrobial resistance gene status for select microorganisms, may aid the physician in making appropriate treatment decisions.

13. PROCEDURE NOTES

- **FDA Status:** Approved/cleared
- **Validated Test Modifications:** None

NOTE: Polymicrobial blood cultures with 3 or more distinct organisms are possible but rare. If Detected results are reported for 3 or more organisms in a sample, a retest of the sample is recommended to confirm the polymicrobial result.

NOTE: In some cases, the Gram stain result and results from the FilmArray BCID Panel may be discrepant (for example, detection of gram-positive cocci by the FilmArray BCID Panel when gram-positive cocci are not observed in the Gram stain). In these cases, the FilmArray BCID Panel results should be confirmed (e.g. by culture) before reporting, unless the result is concordant with other laboratory, epidemiological, or clinical findings.

14. LIMITATIONS OF METHOD

- In mixed cultures, the FilmArray BCID Panel may not identify all detectable organisms in the specimen, depending upon the concentration of each target present.
- The FilmArray BCID Panel may not distinguish mixed cultures when two or more species of the same genus or organism group are present in a specimen (e.g., *S. aureus* and *S. epidermidis*).
- FilmArray BCID Panel performance has only been established on the FilmArray, FilmArray 2.0, and FilmArray Torch systems.
- This test is a qualitative test and does not provide a quantitative value for the organism(s) in the sample.
- The performance of this test has primarily been evaluated with the BD BACTEC Plus Aerobic/F blood culture bottle. Other media have been assessed analytically for interference with detection of organisms at positive blood culture levels.
- This product should not be used to test blood culture media that contain charcoal. Charcoal containing media may contain non-viable organisms and/or nucleic acid at levels that can be detected by the FilmArray BCID Panel.
- Antimicrobial resistance can occur via multiple mechanisms. A Not Detected result for the FilmArray antimicrobial resistance gene assays does not indicate antimicrobial susceptibility. Subculturing and standard susceptibility testing of isolates is required to determine antimicrobial susceptibility.
- The results for the FilmArray antimicrobial resistance gene assays do not specifically link the resistance gene to the associated organism. In mixed growth, the FilmArray BCID Panel does not specifically attribute vanA/B mediated vancomycin resistance to a specific *Enterococcus* spp.; mecA-mediated methicillin resistance to either *S. aureus* or other *Staphylococcus* spp.; or KPC mediated carbapenem-resistance to *Enterobacteriaceae*, *Acinetobacter baumannii* or *Pseudomonas aeruginosa*.
- The FilmArray BCID Panel does not contain assays for obligate anaerobic organisms that might be recovered in blood culture.
- Blood culture samples must be tested within 8 hours of being flagged as positive by a continuously monitoring blood culture instrument.
- This test has not been validated for testing samples other than blood culture samples identified as positive by a continuously monitoring blood culture system.
- Results from this test must be correlated with the clinical history, epidemiological data, and other data available to the clinician evaluating the patient.

- The FilmArray BCID Panel does not detect all species in the *Enterobacteriaceae* family. *Morganella* spp., *Providencia* spp., *Rahnella* spp., and *Yersinia* spp. will not be detected.
- Based on sequence analysis, the FilmArray BCID Panel may not detect *S. pneumoniae* serotypes 11A and 19, or may detect these serotypes with reduced sensitivity compared to other serotypes.
- The FilmArray BCID Panel will not detect encapsulated *Neisseria meningitidis* containing the variant ctrA gene sequences.
- The FilmArray BCID Panel does not detect all species of *Enterococcus, Proteus, Staphylococcus or Streptococcus*.

14.1 Analytical Measurement Range (AMR)

N/A

14.2 Precision

N/A

14.3 Interfering Substances

See manufacturer's Instruction Booklet for data.

14.4 Clinical Sensitivity/Specificity/Predictive Values

See manufacturer's Instruction Booklet for data.

15. SAFETY

Refer to the safety manuals and Safety Data Sheet (SDS) for detailed information on safety practices and procedures and a complete description of hazards.

16. RELATED DOCUMENTS

Blood Culture with Automated Detection, BACTEC FX, SOP SGMC.M1008
BioFire FilmArray Blood Culture Identification Panel (BCID) External QC Form (AG.F564)
BioFire Failed Pouches for Credit Log (AG.F565)
FilmArray Torch Maintenance Record (AG.F516)
BioFire FilmArray Blood Culture Identification (BCID) Internal QC Log (AG.F575)
BioFire® FilmArray® Torch Systems Maintenance procedure
FilmArray® Blood Culture Identification (BCID) Panel Individual Quality Control Plans (VC 950, VC 951)

17. REFERENCES

FilmArray® Blood Culture Identification (BCID) Panel Instruction Booklet, RFIT-PRT-0369-04 July 2018, BioFire Diagnostics, LLC.
FilmArray® Torch Specification Sheet, HTFA-PRT-0058-01, QS-339B-01

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
1	5/4/21	8, 16	Add maintenance SOP	L Barrett	R Master
		8.2	Add to label report with patient name	L Barrett	R Master
		19	Deleted maintenance, re-numbered addenda	L Barrett	R Master
		Add. A	Corrected worksheet codes	L Barrett	R Master
2	5/25/21	Add. A	Step C- added changing collect date if second BCID is ordered for the same blood culture order.	M Sabonis	R Master
3	6/23/21	3.2, 8	Clarified criteria for performing BCID	R Master	R Master
		6.3	Removed daily ext. QC to match IQCP	L Barrett	
		10.6	Added call instructions	Z Morrow	
		16	Added IQCP info	L Barrett	
		Add. A	Added BCID not done if gram is NOS	Z Morrow	

19. ADDENDA

Addendum	Title
A	BioFire BCID Order/Result Processing in Sunquest

Addendum A

BioFire BCID Order/Result Processing in Sunquest

Sunquest method codes: **WOMC**: WOBF **SGMC**: SGBF

A. When aerobic or anaerobic bottle is positive, utilze the Sunquest special worksheet to deterimne if BCID test qualifies.
   - If patient appears on worksheet, then BCID is **not** indicated
   - If patient does not appear on worksheet, then BCID is indicated
   - When you pull a blood culture bottle perform the gram stain, and if you do not see any organisms (NOS) – DO NOT run a BCID

   How to generate Sunquest special worksheet report:

   FUNCTION: **WO**
   Printer: Enter Sunquest printer for report to print
   Option: **3 SPECIAL**
   Hospital ID: SGMC will enter **SGAH**; WOMC will enter **WAH**
   Complete or Incomplete: select **Complete**
   Date: **T-6**
   Worksheet/Tests: **BCIDS** (SGMC) or **BCIDW** (WOMC)
   All test: <N>
   Include composed text: <N>
   Include preliminary result: <N>
   Print Rack numbers: <N>

B. To perform a BCID, order the appropriate test based on the type of Blood Culture bottle using Sunquest GUI Order Entry.
   - Aerobic bottle - Order BCIDA [Blood culture Aero PCR]
   - Anaerobic bottle - Order BCIDN [Blood culture ANA PCR]

C. Place order under a new accession number using the same collect date/time as the XBLC.
   Note: If ordering a **second BCID test on the same XBLC accession** number, then you must enter the same collect time as the XBLC but add 1 minute. This is so the results for the first and second BCID post s**eparately** in Cerner and don't combine into one result.
   - For the receive date/time, use the defaults of current date/time. BCID orders are defined as Gen Lab tests. They cannot be ordered along with Microbiology cultures.
   - A collection label will print to the lab label printer associated with the device location that you logged into in Sunquest, not a Micro Media label.

D. Using the new accession # label, perform Blood culture BCID testing according to BioFire BCID SOP. Sunquest autofiling is turned on.
   - If autofiling is turned on: Results will automatically file into Sunquest upon completion and transmit to Cerner.

- If autofiling is turned off: Results will automatically transmit to Sunquest upon completion and are held. Results are then reviewed and released before they are sent to Cerner.

E. Resulting in Sunquest

1. If you need to manually enter results into Sunquest
   - Access Sunquest GUI Result Entry.
   - Resulting mode: Select MANUAL (similar to MEM in SmarTerm)
   - Configuration: from the drop down menu, select the following:
     If at WOMC, select **WO_MAN_BCID**
     If at SGMC, select **SG_MAN_BCID**
   - **Note,** there are three target genes that are not always reported out.
     KPCG – KPC [carbapenem-resistance gene]
     MECAG - mecA [methicillin-resistance gene]
     VABG - van A/B [vancomycin-resistance genes]

   If the instrument printout displays a result of "N/A" for any of these targets then report as "HIDE" in Sunquest.
2. If autoverification is turned off – or – troubleshooting
   Access Sunquest GUI Result Entry.
   - Resulting mode: Select INTERFACED (similar to OEM in SmarTerm)
   - Configuration: from the drop down menu, select the following:
     If at WOMC, select **WOBF_BCID**
     If at SGMC, select **SGBF_BCID**

F. Perform OFC (Online file clean up) in Sunquest once per shift.