AHC.M 1023 BioFire® FilmArray® Blood Culture Identification 2 (BCID2) Panel

Copy of version 2.0 (approved and current)

Last Approval or Periodic Review Completed	9/29/2022
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Effective Date	10/1/2022

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Organization	Adventist HealthCare

Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Approval	Lab Director	9/29/2022	2.0	Nicolas Cacciabeve	
Approval	Laboratory Operations Director	9/28/2022	2.0	Robert SanLuis Robert SanLuis	
Approval	Lab Director	8/29/2022	1.0	Nicolas Cacciabeve	
Approval	Laboratory Operations Director	8/19/2022	1.0	Robert SanLuis Robert SanLuis	

Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
2.0	Approved and Current	Major revision	9/28/2022	10/1/2022	Indefinite
1.0	Retired	Initial version	8/19/2022	9/13/2022	10/1/2022

Linked Documents

- AG.F 622 BioFire FilmArray® Blood Culture Identification Panel (BCID2) Target vs. Gram Reaction

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Technical SOP

Title	**BioFire® FilmArray® Blood Culture Identification 2 (BCID2) Panel**
Prepared by	Rob SanLuis Date: 8/18/2022
Owner	Rob SanLuis Date: 8/18/2022

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

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1. TEST INFORMATION

Assay	Method/Instrument	Test Code
BioFire® FilmArray® Blood Culture Identification 2 (BCID2) Panel	Multiplexed PCR / BioFire Torch Instrument	BCIDA/BCIDN

Synonyms/Abbreviations
BCID2, BCID

Department
Microbiology

2. ANALYTICAL PRINCIPLE

The BioFire BCID2 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 BCID2 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 BCID2 Panel loads the sample into the BioFire BCID2 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 BCID2 Panel:

Gram-positive bacteria

- *Enterococcus faecalis*
- *Enterococcus faecium*
- *Listeria monocytogenes*
- *Staphylococcus* spp.
  - *Staphylococcus aureus*
  - *Staphylococcus epidermidis*
  - *Staphylococcus lugdunensis*
- *Streptococcus* spp.
  - *Streptococcus agalactiae* (Group B)
  - *Streptococcus pneumonia*
  - *Streptococcus pyogenes* (Group A)

Gram-negative bacteria

- *Acinetobacter calcoaceticus-baumannii* complex
- *Bacteroides fragilis*
- *Haemophilus influenzae*

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- *Neisseria meningitidis* (encapsulated)
- *Pseudomonas aeruginosa*
- *Stenotrophomonas maltophilia*
- *Enterobacterales*
    - *Enterobacter cloacae* complex
    - *Escherichia coli*
    - *Klebsiella aerogenes*
    - *Klebsiella oxytoca*
    - *Klebsiella pneumonia* group
    - *Proteus spp.*
    - *Salmonella* spp.
    - *Serratia marcescens*

Yeast

- *Candida albicans*
- *Candida auris*
- *Candida glabrata*
- *Candida krusei*
- *Candida parapsilosis*
- *Candida tropicalis*
- *Cryptococcus neoformans/gattii*

Antimicrobial resistance genes

- *mecA/C*
- *mecA/C* and MREJ (MRSA)
- *vanA/B*
- KPC
- CTX-M (ESBL)
- IMP
- *mcr-1*
- VIM
- NDM
- OXA-48-like

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*), ß-lactams including penicillins, cephalosporins, monobactams, and carbapenems ($bla_{\text{CTX-M}}$, bla_{IMP}, bla_{KPC}, bla_{NDM}, $bla_{\text{OXA48-like}}$, bla_{VIM}) to aid in the identification of potentially antimicrobial-resistant organisms in positive blood culture samples. In addition, the panel includes an assay for the detection of the mobilized genetic determinant *mcr-1*, an emerging marker of public health importance. The antimicrobial resistance gene or marker detected may or may not be associated with the agent responsible for disease. Negative results for these select antimicrobial resistance gene and marker assays do not indicate susceptibility, as multiple mechanisms of resistance to methicillin, vancomycin, ß-lactams, and colistin exist.

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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)
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.**

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.

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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 2 (BCID2) Panel pouches	BioFire FLM1-ASY-0147

4.2 Reagent Preparation and Storage

Assay Kit	
Kit Contents	BioFire® FilmArray® Blood Culture Identification (BCID2) 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

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6. QUALITY CONTROL

6.1 Controls Used

Controls	Supplier and Catalog Number
Maine Molecular BCID2 Panel	M416 Positive & Negative

6.2 Control Preparation and Storage

Control	
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 positive and negative controls are tested with each new kit lot number or shipment or every 31 days, whichever is more frequent.

IQCP completed and approved.

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

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- **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 2 (BCID2) External QC Form.
- Record all Internal quality control results on the BioFire FilmArray Blood Culture Identification 2 (BCID2) 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 2 (BCID2) Panel.
- All positive blood cultures tested using the FilmArray® Blood Culture Identification 2 (BCID2) 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

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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

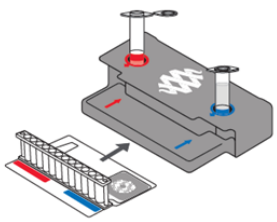
Individually packaged Transfer Pipettes
8 mL 13x100 mm sterile tubes

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 

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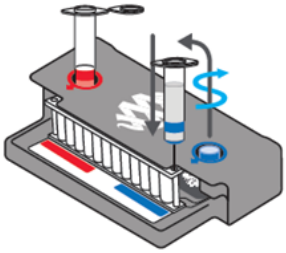
8.1	Specimen / Reagent Preparation
4.	Place a blue-capped Hydration Injection Vial in the blue well of the Pouch Loading Station.
5.	Place a red-capped Sample Injection Vial in the red well of the Pouch Loading Station.
Hydrate Pouch	
1.	Twist and lift the Hydration Injection Vial, leaving blue cap in 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.
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. 

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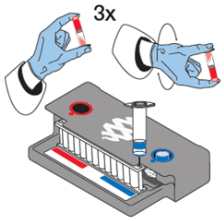
8.2	Test Run
3.	Invert the ampoule over the red-capped Sample Injection Vial and re-position thumb and forefinger to grip the bottom of the ampoule. Dispense Sample Buffer using a slow, forceful squeeze, followed by a second squeeze. **Avoid squeezing the ampoule additional times as this will generate 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.
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	

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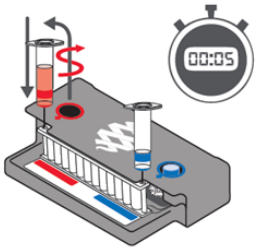
8.2	Test Run
1.	Slowly twist the Sample Injection Vial so it loosens from its red cap and **pause for 5 seconds.**  Lift the Sample Injection Vial, leaving the red cap in the well of the Pouch Loading Station.
2.	Insert the cannula tip into the port in the pouch fitment located directly below the red 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.
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.

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8.2	Test Run
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 BCID2 Sunquest label. • This will facilitate identifying the BCID2 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

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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.
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.

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BioFire BCID2 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.

Antimicrobial Resistance Genes and Applicable Bacteria:

BioFire BCID2 Panel AMR Gene Result	*Enterococcus faecalis*	*Enterococcus faecium*	*Staphylococcus aureus*	*Staphylococcus epidermidis*	*Staphylococcus lugdunensis*	*Acinetobacter baumanii* complex	*Enterobacterales*	*Enterobacter cloacae* complex	*Escherichia coli*	*Klebsiella aerogenes*	*Klebsiella oxytoca*	*Klebsiella pneumoniae* group	*Proteus* spp.	*Salmonella* spp.	*Serratia marcescens*	*Pseudomonas aeruginosa*
vanA/B	×	×														
mecA/C				×	×											
***mecA/C* and MREJ (MRSA)**			×													
mcr-1								×	×	×	×	×		×		
CTX-M						×	×	×	×	×	×	×	×	×	×	×
IMP						×	×	×	×	×	×	×	×	×	×	×
KPC						×	×	×	×	×	×	×	×	×	×	×
NDM						×	×	×	×	×	×	×	×	×	×	×
OXA-48-like							×	×	×	×	×	×	×	×	×	
VIM						×	×	×	×	×	×	×	×	×	×	×

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BCID2 Resistance Targets		
Target	**Organisms**	**Resistance Type**
Van A/B	*Enterococcus faecalis*	VRE - vancomycin resistance
	Enterococcus faecium	VRE - vancomycin resistance
mecA/C + MREJ	*Staphylococcus aureus*	MRSA - methicillin resistance
mec A/C	*Staphylococcus epidermidis*	MRSE - methicillin resistance
	Staphylococcus lugdunensis	methicillin resistance
CTX-M	*Acinetobacter baumannii* complex	ESBL - extended-spectrum beta-lactamase
	Enterobacterales	ESBL - extended-spectrum beta-lactamase
	Escherichia coli	ESBL - extended-spectrum beta-lactamase
	Klebsiella pneumoniae group	ESBL - extended-spectrum beta-lactamase
	Klebsiella oxytoca	ESBL - extended-spectrum beta-lactamase
	Klebsiella (Enterobacter) aerogenes	ESBL - extended-spectrum beta-lactamase
	Enterobacter cloacae complex	ESBL - extended-spectrum beta-lactamase
	Proteus species	ESBL - extended-spectrum beta-lactamase
	Salmonella species	ESBL - extended-spectrum beta-lactamase
	Serratia marcescens	ESBL - extended-spectrum beta-lactamase
	Pseudomonas aeruginosa	ESBL - extended-spectrum beta-lactamase
KPC,NDM,IMP,VIM	*Acinetobacter baumannii* complex	CRAB - carbapenem resistance
KPC,NDM,IMP,VIM,OXA	Enterobacterales	CRE - carbapenem resistance
KPC,NDM,IMP,VIM,OXA	*Escherichia coli*	CRE - carbapenem resistance
KPC,NDM,IMP,VIM,OXA	*Klebsiella pneumoniae* group	CRE - carbapenem resistance
KPC,NDM,IMP,VIM,OXA	*Klebsiella oxytoca*	CRE - carbapenem resistance
KPC,NDM,IMP,VIM,OXA	*Klebsiella (Enterobacter) aerogenes*	CRE - carbapenem resistance
KPC,NDM,IMP,VIM,OXA	*Enterobacter cloacae* complex	CRE - carbapenem resistance
KPC,NDM,IMP,VIM,OXA	*Proteus* species	CRE - carbapenem resistance
KPC,NDM,IMP,VIM,OXA	*Salmonella* species	CRE - carbapenem resistance
KPC,NDM,IMP,VIM,OXA	*Serratia marcescens*	CRE - carbapenem resistance
KPC,NDM,IMP,VIM	*Pseudomonas aeruginosa*	CRPA - carbapenem resistance
mcr-1	*Escherichia coli*	colistin resistance
	Klebsiella pneumoniae group	colistin resistance
	Klebsiella oxytoca	colistin resistance
	Klebsiella (Enterobacter) aerogenes	colistin resistance
	Enterobacter cloacae complex	colistin resistance
	Salmonella species	colistin resistance
Note:	*Proteus* species and *Serratia marcescens*	are intrinsically resistant to colistin

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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 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”
Discrepant results between gram stain slide and BCID2 results	See section 13 and Addendum A for how to handle discrepant results.
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

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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 BCID2
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 "THIS IS A CRITICAL RESULT and give the Gram stain result and state that 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

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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 2 (BCID2) Panel simultaneously tests a single positive blood culture sample to provide results for 33 different organisms and organism groups that cause bloodstream infections and 10 genetic markers that are known to confer antimicrobial resistance. 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 BCID2 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
- **Polymicrobial blood cultures with 3 or more distinct organisms are possible but rare.** If Detected repeat the BCID2 before reporting the results. In addition, ensure the gram stain correlates the findings, see note below.
- **In some cases, the Gram stain result and results from the FilmArray BCID2 Panel may be discrepant**
    - **Example 1**: A Blood Culture turned positive and you observe gram negative rods on the gram stain slide which triggered performing BCID2. The BCID2 detected both a gram-positive and gram-negative organisms but the gram positive was not seen on the slide. **Action:** Make new slides to confirm the initial gram stain findings. Decontaminate work surfaces and repeat the BCID using aseptic technique. If the gram stain is still discordant, in the LIS utilize **"HIDE"** for that particular discordant result and report the other results, document on QV form for follow-up. Send the culture out for identification as per procedure.
    - **Example 2**: Bacteria (Organism) seen on the Gram Stain but the BCID2 does not detect the organism. **Action:** The BCID2 does not detect all possible organisms so it is possible to report gram stain results with a Negative BCID2. Send the culture out for identification as per procedure.

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14. LIMITATIONS OF METHOD

- The performance of the BioFire BCID2 Panel has not been established for the screening of blood or blood products.
- Results from this test must be correlated with clinical history, epidemiological data, and other data available to the clinician evaluating the patient.
- BioFire BCID2 Panel performance has only been established on the BioFire 2.0 and BioFire Torch systems.
- The BioFire BCID2 Panel is a qualitative test and does not provide a quantitative value for the organism(s) in the specimen.
- This test has not been validated for testing samples other than human blood culture samples identified as positive by a continuous monitoring blood culture system.
- Blood culture samples must be tested within 24 hours of being flagged as positive by a continuous monitoring blood culture system.
- All identification results provided by the BioFire BCID2 Panel are intended to be interpreted in conjunction with results obtained from Gram stain of the positive blood culture. Gram reaction (gram-positive or gram-negative) and cellular morphology (gram positive cocci in clusters, pairs, or chains, gram-negative rods) should be considered in correlation with the BioFire BCID2 Panel results.
- In some cases, the Gram stain result and results of the BioFire BCID2 Panel may be discrepant (for example, detection of gram-positive cocci by the BioFire BCID2 Panel when gram-positive cocci were not observed in the Gram stain). In these cases, the BioFire BCID2 Panel results should be confirmed (e.g., by culture) before reporting, unless the result is concordant with other laboratory, epidemiological, or clinical findings, **see above in section 13 for examples.**
- The performance of this test was found to be equivalent for the specific blood culture bottle types evaluated in the clinical study and analytically. Performance for other blood culture bottle types was not evaluated.
- 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 BioFire BCID2 Panel.
- 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 test results. Typically, these false positives may present with more than one positive result because the BioFire BCID2 Panel may also detect the organism that is growing in the culture bottle.
- The BioFire BCID2 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., Staphylococcus aureus and Staphylococcus hominis).
- In mixed cultures, the BioFire BCID2 Panel may not identify all targeted organisms in the specimen, depending upon the concentration of each target present. In particular, false negative results for Pseudomonas aeruginosa or Stenotrophomonas spp. may occur if another organism is present in the blood culture. Conversely, standard subculture methods may also

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not identify all organisms in a mixed culture, depending upon the concentration and growth characteristics of each organism present.

- Antimicrobial resistance can occur via multiple mechanisms. A Not Detected result for the antimicrobial resistance gene assays does not indicate antimicrobial susceptibility. Subculturing and standard susceptibility testing of isolates are required to determine antimicrobial susceptibility.
- The results for the antimicrobial resistance gene assays do not specifically link the resistance gene to the applicable bacteria detected. In mixed cultures, the resistance gene may be associated with any of the applicable bacteria detected or an organism that was not detected by the panel.
- 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 or the design of other molecular assays.
- The detection of bacterial, yeast, and antimicrobial resistance gene nucleic acid is dependent upon proper sample collection, handling, transportation, storage, and preparation. Failure to observe proper procedures in any one of these steps can lead to incorrect results. There is a risk of false positive or false negative values resulting from improperly collected, transported, or handled samples.
- A negative BioFire BCID2 Panel result does not exclude the possibility of bloodstream infection. Negative test 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. Test results may also be affected by concurrent antibacterial/antifungal therapy or levels of organism in the sample that are below the limit of detection for the test (especially in the case of mixed cultures). Negative results should not be used as the sole basis for diagnosis, treatment, or other management decisions.
- There is a risk of false positive values resulting from cross-contamination by target organisms, their nucleic acids or amplified product, or from non-specific signals in the assay. Particular attention should be given to the Laboratory Precautions noted under the Warnings and Precautions section.
- False positives and false negatives can be the result of a variety of sources and causes. It is important that results be used in conjunction with other clinical, epidemiological, or laboratory information.
- If four or more distinct organisms are detected in a specimen, retesting is recommended to confirm the polymicrobial result.
- Cross-reactivity with organisms other than those listed in the Analytical Specificity section below may lead to erroneous results.
- The effect of interfering substances has only been evaluated for those listed in the labeling. Interference by substances other than those described in the Interference section below could lead to erroneous results.
- BioFire BCID2 Panel assays can cross-react with several organisms, typically closely related or near-neighbor species to those detected by the panel. All confirmed or predicted cross-

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reactive species have been identified in Table 130 and Table 131 in the Analytical Specificity (Cross-Reactivity and Exclusivity) section in the IFU.

- The BioFire BCID2 Panel C. tropicalis assay may cross-react with high titers of *C. parapsilosis* present in a sample and the *C. parapsilosis* assay may cross-react with high titers of *C. tropicalis*. Detected results for both *C. tropicalis* and *C. parapsilosis* in the same sample may be due to cross-reactivity or may be due to both organisms being present in the blood culture.
- Borderline oxacillin-resistant *Staphylococcus aureus* (BORSA) and moderately *resistant S. aureus* (MODSA) strains demonstrate reduced susceptibility to oxacillin due to hyperproduction of β-lactamases or modification of penicillin-binding proteins respectively. BORSA and MODSA strains do not contain the mecA or mecC gene. A mecA/C and MREJ (MRSA) Not Detected result will be reported by the BioFire BCID2 Panel for these strains.
- The vanA/B result is not reported in the absence of *Enterococcus faecalis* or *Enterococcus faecium* detection and will therefore not be reported for blood cultures containing other vancomycin-resistant Enterococci or vancomycin-resistant *Staphylococcus aureus* (VRSA).
- Continuous monitoring blood culture systems may falsely signal positive in a low percentage of bottles (estimated to be near 1%) when no organisms are growing in the sample. This may be due to hyperleukocytosis (very high white blood cell counts).
- The performance of the BioFire BCID2 Panel has not been established for monitoring the treatment of infection with any of the panel organisms.

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.

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16. RELATED DOCUMENTS

Blood Culture with Automated Detection, BACTEC FX, SOP SGMC.M1008
BioFire FilmArray Blood Culture Identification Panel (BCID2) External QC Form (AG.F564)
BioFire Failed Pouches for Credit Log (AG.F565)
FilmArray Torch Maintenance Record (AG.F516)
BioFire FilmArray Blood Culture Identification (BCID2) Internal QC Log (AG.F575)
BioFire FilmArray® Blood Cult ID Panel (BCID2) Target vs. Gram Reaction (AG.F622)
BioFire® FilmArray® Torch Systems Maintenance procedure

17. REFERENCES

FilmArray® Blood Culture Identification 2 (BCID2) Panel Instruction Booklet, RFIT-PRT-0841-03 July 2021, BioFire Diagnostics, LLC.
FilmArray® Torch Specification Sheet, HTFA-PRT-0058-01, QS-339B-01

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
1	9/28/22	6.3	Updated QC frequency	R SanLuis	R SanLuis
1	9/28/22	10.6, 13, and 14	Added discrepant results reporting information	D Collier R SanLuis	R SanLuis
1	9/28/22	Addendum A	Section C – Added FIN # to instructions Section E – Handling discordant results	R SanLuis	R SanLuis

19. ADDENDA

Addendum	Title
A	BioFire BCID2 Order/Result Processing in Sunquest

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Addendum A

BioFire BCID2 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. Utilize the current FIN (Account Number) to 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.

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- 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**
3. For "positive organanisms" reported on BCID2 when the GS is discordant, report as "HIDE" in the LIS, see section 13 notes for additional information.

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

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