### FilmArray® Blood Culture Identification Panel Testing

### Purpose

This procedure provides instructions for testing positive blood culture samples using the FilmArray Blood Culture Identification Panel (BCID) Kit.

### Background

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.

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

**Gram-Positive Bacteria**

* *Enterococcus*
* *Listeria monocytogenes*
* *Staphylococcus*
* *Staphylococcus aureus*
* *Streptococcus*
* *Streptococcus agalactiae*
* *Streptococcus pneumonia*
* *Streptococcus pyogenes*

**Gram-Negative Bacteria**

* *Acinetobacter baumannii*
* *Enterobacteriaceae*
* *Enterobacter cloacae* complex
* *Escherichia coli*
* *Klebsiella oxytoca*
* *Klebsiella pneumonia*
* *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 FilmArray BCID Panel also contains assays for the detection of genetic determinants of resistance to methicillin (mecA), vancomycin (vanA and vanB), and carbapenems (blaKPC) to aid in the identification of potentially antimicrobial resistant organisms in positive blood culture samples.

### Principle of the Procedure

The FilmArray BCID 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 FilmArray BCID pouch contains reagents in freeze-dried form. The flexible plastic portion of the pouch is divided into discrete segments (blisters) where the required chemical processes are carried out. The user of the FilmArray BCID Panel loads the sample into the FilmArray BCID pouch, places the pouch into the FilmArray instrument, and starts the run. All other operations are automated.

The following is an overview of the operations and processes that occur during a FilmArray run:

1. Nucleic Acid Purification - Nucleic acid purification occurs in the first three blisters of the pouch. The sample is lysed by agitation (bead beating) and the liberated nucleic acid is captured, washed and eluted using magnetic bead technology. These steps require about ten minutes and the bead-beater apparatus can be heard as a high pitched whine during the first minute of operation.
2. 1st Stage Multiplex PCR - The purified nucleic acid solution is combined with a preheated master mix to initiate thermocycling for multiplex PCR. The effect of 1st stage PCR is to enrich for the target nucleic acids present in the sample.
3. 2nd Stage PCR - The products of first stage PCR are diluted and mixed with fresh PCR reagents containing a double stranded DNA binding dye (LCGreen® Plus, BioFire Diagnostics, LLC). This solution is distributed over the 2nd stage PCR array. The individual wells of the array contain primers for different assays (each present in triplicate) that target specific nucleic acid sequences from each of the pathogens detected, as well as control template material. These primers are ‘nested’ or internal to the specific products of the 1st stage multiplex reaction, which enhances both the sensitivity and specificity of the reactions.
4. DNA Melting Analysis – After 2nd stage PCR, the temperature is slowly increased and fluorescence in each well of the array is monitored and analyzed to generate a melt curve. The temperature at which a specific PCR product melts (melting temperature or Tm) is consistent and predictable and the FilmArray software automatically evaluates the data from replicate wells for each assay to report results. For a description of data interpretation and reporting see the Interpretation of Results section of this booklet.

### 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.**

* Sample Volume – 200 uL
* 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 200 uL.
* 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.

### Materials

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

### 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.

**Monitoring Test System Performance**

The FilmArray software will automatically fail the run if the melting temperature (Tm) for either the DNA Process Control or the PCR2 Control is outside an acceptable range (77.6-81.6 for the DNA Process Control and 74.2-78.2 for the PCR2 Control). If required by local, state, or accrediting organization quality control requirements, users can monitor the system by trending Tm values for the control assays and maintaining records according to standard laboratory quality control practices. The PCR2 Control is used in all pouch types and can therefore be used to monitor the system when multiple pouch types (e.g., RP and BCID) are used on the same FilmArray instrument. The Tm values for the DNA Process Control can only be evaluated for FilmArray runs with the BCID Panel.

Good laboratory practice recommends running external positive and negative controls regularly. Uninnoculated blood culture media can be used as an external negative control. Previously characterized positive blood culture samples or samples spiked with well characterized organisms can be used as external positive controls. External controls should be used in accordance with the appropriate accrediting organization requirements, as applicable.

### Procedure

Refer to the FilmArray Blood Culture Identification Panel Quick Guide, the FilmArray Training 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.
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.

**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.**

1. Gently pinch the textured plastic tab on the side of the ampoule until the seal snaps.
2. 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.
3. Invert the positive blood culture bottle several times to mix.
4. Wipe the bottle septum with alcohol and air dry.
5. Tilt the bottle and hold in the tilted position to allow the bottle resin to settle (approximately 10 seconds).
6. Using a syringe, withdraw 200 uL of blood culture sample through the bottle septum, taking care to avoid drawing resin beads into the sample, or the formation of bubbles.
7. 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 (>200 uL) 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 (200 uL) 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.**

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

**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.

### Interpretation

The FilmArray Software automatically analyzes and interprets the assay results and displays the final results in a test report (see the FilmArray Blood Culture Identification Panel Quick Guide to view an example of a test report). The analyses performed by the FilmArray Software and details of the test report are described below.

**Assay Interpretation**

When 2nd stage PCR is complete, the FilmArray instrument performs a high resolution DNA melting analysis on the PCR products and measures the fluorescence signal generated in each well (for more information see FilmArray Operator’s Manual). The FilmArray software then performs several analyses and assigns a final assay result.

**Analysis of melt curves.** The FilmArray software evaluates the DNA melt curve for each well of the 2nd stage PCR array to determine if a PCR product was present in that well. If the melt profile indicates the presence of a PCR product, then the analysis software calculates the melting temperature (Tm) of the curve. The Tm value is then compared against the expected Tm range for the assay. If the software determines that the melt curve is positive and the Tm falls inside the assay-specific Tm range, the melt curve is called positive. If the software determines that the melt curve is negative or is not in the appropriate Tm range, the melt curve is called negative.

**Analysis of replicates.** Once melt curves have been identified, the software evaluates the three replicates for each assay to determine the assay result. For an assay to be called positive, at least two of the three associated melt curves must be called positive, and the Tm for at least two of the three positive melt curves must be similar (within 1°C). Assays that do not meet these criteria are called negative.

**Organism Interpretation**

Interpretations for many of the organisms are based on the results of a single assay (see Table 2). Interpretations for Haemophilus influenzae and the Staphylococcus, Streptococcus, and Enterobacteriaceae groups rely on the results of several assays. The antimicrobial resistance genes are also based on the result of a single assay; however, the test results are only reported when specific organisms are also detected in the same sample. This section provides an explanation of the test results and guidelines for actions to be taken based on the test result. This section also contains information about known assay limitations (e.g., cross-reactivity, strains that are not detected) that may be important in the interpretation of the test result and in correlating the FilmArray results with the result of standard culture and biochemical identification.

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 rare cases, the Gram stain result and FilmArray BCID Panel results may be discrepant (for example, detection of a gram-positive cocci by FilmArray BCID when gram-positive cocci were not observed in the Gram stain). In these cases, the results should be used in conjunction with other clinical and laboratory findings.

**Single Assay Interpretations**

Organisms listed in Table 1 are considered to be Detected if a single corresponding assay is positive.

Table 1. FilmArray BCID Panel Single Assay Interpretations

| **Bacteria** | **Yeast** |
| --- | --- |
| *Acinetobacter baumannii* | *Candida albicans* |
| *Enterococcus* | *Candida glabrata* |
| *Listeria monocytogenes* | *Candida krusei* |
| *Neisseria meningitidis* | *Candida parapsilosis* |
| *Pseudomonas aeruginosa* | *Candida tropicalis* |

***Acinetobacter baumannii***

*Acinetobacter baumannii* is part of the *Acinetobacter calcoaceticus-baumannii* (ACB) complex. In addition to *A. baumannii*, the complex includes *A. calcoaceticus, A. pittii* (genomospecies 3), and *A. nosocomialis* (genomospecies 13TU). These species are genetically and phenotypically related and cannot be reliably differentiated from each other using current microbial identification methods. The BCID Panel Abaumannii assay detects *A. baumannii*; however, it also detects some strains of the non-*baumannii* species with varying sensitivity. Discrepancies between the BCID Panel test result and microbial identification may be caused by misidentification of non-*baumannii* members of the ACB complex as *A. baumannii*. No cross-reactivity with other *Acinetobacter* species outside of the ACBcomplex is expected.

***Enterococcus***

The Enterococcus assay detects the major species associated with *Enterococcus* bloodstream infections (*E. faecium* and *E. faecalis*) as well as several less common species of varying clinical relevance including: *E. avium*, *E. casseliflavus*, E. *durans*, E*. gallinarum*, and *E. hirae*. *E. dispar* and *E. saccharolyticus* are detected with reduced sensitivity and *E. raffinosus*, which is occasionally isolated from clinical specimens, will not be detected by the BCID Panel.

Limited cross-reactivity with coagulase-negative staphylococci has been observed. Sequence analysis and empirical testing suggest that this cross-reactivity may occur when select species (*S. haemolyticus*, *S. epidermidis*, and *S. capitis*) are in the blood culture at a very high concentration.

***Listeria monocytogenes***

There are 12 known serovars of *L. monocytogenes*, however; only three serovars (1/2a, 1/2b and 4b) account for more than 90% of human cases of listeriosis. The BCID Panel is designed to detect all known serovars. Sequence analysis predicts that cross-reactivity with some strains of atypical *Listeria innocua* is possible.

***Neisseria meningitidis***

The BCID Panel detects encapsulated strains of *N. meningitidis*. Unencapsulated strains are generally considered non-virulent species of the normal nasopharyngeal flora and are not detected by the BCID Panel.

***Pseudomonas aeruginosa***

The Paeruginosa assay detects *P. aeruginosa* and does not cross-react with other *Pseudomonas* species or closely-related bacteria.

***Candida albicans, Candida glabrata, Candida krusei, Candida parapsilosis, and Candida tropicalis***

Species-specific assays are included in the BCID Panel for each of the five most common *Candida* species associated with candidemia (*Candida albicans*, *Candida glabrata*, *Candida krusei*, *Candida parapsilosis*, and *Candida tropicalis*). Based on *in silico* analysis and empirical testing, each assay is specific for detection of the indicated species with the following exceptions:

*Candida albicans* is closely related to *Candida dubliniensis* and misidentification of these species by laboratory methods does occur. Cross-reactivity between the Calbicans assay and *C. dubliniensis* has not been observed but sequence analysis predicts that cross-reactivity with *C. dubliniensis* is possible.

The BCID Panel assay for detection of *C. parapsilosis* cross-reacts with *Candida orthopsilosis*. Prior to being designated as unique species, *C. orthopsilosis* and *C. metapsilosis* were classified as Group II and Group III *Candida parapsilosis,* respectively. Both are closely related to *Candida parapsilosis* and can be misidentified as *Candida parapsilosis* using standard identification methods. The BCID Panel assay for *C. parapsilosis* will not detect *C. metapsilosis*; however, amplification of *C. orthopsilosis* is predicted by sequence analysis and has been confirmed. *In silico* analysis suggests that cross-reactivity with *C. multigemmis* may also be possible, though this cross-reactivity has not been observed.

**NOTE**: *Candida krusei* is also known as *Issatchenkia orientalis* and *Pichia kudriavzevkii*, therefore reactivity with isolates identified as these species does not represent cross-reactivity.

Multiple Assay Interpretations

***Haemophilus influenzae***

The BCID Panel contains two different assays (Hinfluenzae1 and Hinfluenzae2) for the detection of *H. influenzae*. If either or both of the assays are positive, the test result will be *Haemophilus influenzae* Detected. If both the Hinfluenzae1 and Hinfluenzae2 assays are negative, the test result will be *Haemophilus influenzae* Not Detected.

***Staphylococcus***

The BCID Panel contains three assays for the detection of *Staphylococcus* species. The *Staphylococcus aureus* assay and two multi-species assays (Staphylococcus1 and Staphylococcus2). The Saureus assay detects all strains of *S. aureus* and does not cross-react with other organisms, including other species of *Staphylococcus*. The multi-species assays detect the most prevalent coagulase-negative *Staphylococcus* (CoNS) species encountered in blood culture specimens and can also react with high levels of *S. aureus*.

The FilmArray Software integrates the results of the three *Staphylococcus* assays into a final *Staphylococcus* test result. If all three assays are negative, the test result will be *Staphylococcus* Not Detected. If any of the three assays is positive, the result will be *Staphylococcus* Detected. Results for the Saureus assay (positive or negative) determine the *Staphylococcus aureus* test result (Detected or Not Detected, respectively). Table 6 (see Antimicrobial Resistance Genes Interpretation section below) provides a summary of the interpretation of these three assays as well as the results for the *mecA* assay.

As stated above, the two multi-species assays (Staphlyococcus1 and Staphylococcus2) detect the most commonly encountered CoNS recovered for positive blood cultures. However, this is a large and diverse group and detection by BCID Panel assays is variable. The table below summarizes the ability of the BCID Panel to detect various species of *Staphylococcus*. The species in the detected column are expected to be reliably detected by the BCID Panel at organism concentrations observed in positive blood cultures (~ 5x106 CFU/mL). The species listed in the reduced sensitivity column have been shown to be detected at higher concentrations (~107 to 108 CFU/mL) but may not always be detected in positive blood cultures. The species listed in the Not Detected column are unlikely to be detected by the BCID Panel due to sequence mismatches with the BCID Panel assays.

**Table 2. Summary of BCID Panel Reactivity with Staphylococcia**

| **Detected** | **Detected with**  **Reduced Sensitivity** | **Not Detected** |
| --- | --- | --- |
| *S. aureus* | *S. capitis* | *S*. *auricularis* |
| *S. caprae* | *S. pasteuri* | *S*. *carnosus* |
| *S. cohnii* | *S. saprophyticus* | *S*. *lentus* |
| *S. epidermidis* | *S. simulans* | *S. pettenkoferi* |
| *S. haemolyticus* | *S. warneri* | *S*. *pseudointermedius* |
| *S. hominis* |  | *S*. *schleiferi* |
| *S. lugdunensis* | *S*. *sciuri* |
| *S. xylosus* |  |

a See Analytical Reactivity (Inclusivity) section of FilmArray Blood Culture Identification (BCID) Panel Instruction Booklet for additional *in silico* reactivity predictions.

Note: CoNS are often contaminating organisms and may be present at lower concentrations in polymicrobial

blood cultures than in single organism cultures.

Note: Multiple *Staphylococcus* species may be present in a single sample. The presence of multiple *Staphylococcus* species cannot be determined by BCID Panel test results

***Streptococcus***

The BCID Panel contains four assays for the detection of *Streptococcus* species. Species-specific assays are included for the detection of Group A Strep (Spyogenes), Group B Strep (Sagalactiae), and Spneumoniae. The fourth assay is a multi-species assay (Streptococcus) designed to react with select Viridans group and other *Streptococcus* species encountered in blood culture specimens. However, the BCID Panel may not detect all *Streptococcus* species.

The FilmArray Software integrates the results of all four *Streptococcus* assays into a final *Streptococcus* result as shown in the table below. If all of the assays are negative, the test result will be *Streptococcus* Not Detected. Alternatively, if any of the four assays are positive, the test result will be *Streptococcus* Detected. Results for each species-specific assay are also reported independently.

**Table 3. Possible Assay Results and Corresponding Streptococcus Test Results**

| **FilmArray BCID Interpretations** | **Streptococcus Assay** | **Sagalactiae Assay** | **Spneumoniae Assay** | **Spyogenes Assay** | **Description** |
| --- | --- | --- | --- | --- | --- |
| *Streptococcus* Not Detected  *Streptococcus agalactiae* Not Detected  *Streptococcus pneumoniae* Not Detected  *Streptococcus pyogenes* Not Detected | Negative | Negative | Negative | Negative | No *Streptococcus* species detected |
| ***Streptococcus* Detected**  *Streptococcus agalactiae* Not Detected  *Streptococcus pneumoniae* Not Detected  *Streptococcus pyogenes* Not Detected | **Positive** | Negative | Negative | Negative | *Streptococcus* species detected  (not *S. agalactiae*, *S. pneumoniae*, or *S. pyogenes*) |
| ***Streptococcus* Detected**  ***Streptococcus agalactiae* Detected**  *Streptococcus pneumoniae* Not Detected  *Streptococcus pyogenes* Not Detected | Any result | **Positive** | Negative | Negative | *Streptococcus agalactiae* detected |
| ***Streptococcus* Detected**  *Streptococcus agalactiae* Not Detected  ***Streptococcus pneumoniae* Detected**  *Streptococcus pyogenes* Not Detected | Any result | Negative | **Positive** | Negative | *Streptococcus pneumoniae* detected |
| ***Streptococcus* Detected**  *Streptococcus agalactiae* Not Detected  *Streptococcus pneumoniae* Not Detected  ***Streptococcus pyogenes* Detected** | Any result | Negative | Negative | **Positive** | *Streptococcus pyogenes* detected |

Note: Multiple *Streptococcus* species assays may be positive in a single sample. If this occurs, the test result for each species with a positive assay will be reported as Detected.

*Streptococcus agalactiae*, *Streptococcus pneumoniae*, *Streptococcus pyogenes* are three of the most important streptococci to identify from blood cultures and each is detected by the BCID Panel with a species-specific assay. The gene target for each assay is either found only in the species of interest or is highly conserved within the species of interest. No cross-reactivity with other streptococci is predicted for these assays.

The multi-species Streptococcus assay reacts with the following species at levels observed in positive blood cultures: *S. anginosus*, *S. bovis, S. constellatus*, *S. dysgalactiae*, *S. equinis, S. gallolyticus, S. gordonii*, *S. intermedius*, *S. mitis, S. mutans*, *S. oralis, S. parasanguinis*, S. *pseudopneumoniae*, *S. salivarius,* and *S. sanguinis.*

Streptococci that are not listed here are rare and have not been tested. The Streptococcus assay may demonstrate variable to no reactivity with those species.

***Enterobacteriaceae***

The BCID Panel includes seven assays to detect members of the *Enterobacteriaceae* family. Six genus/species specific assays are included for the detection of *Enterobacter cloacae* (and other *E. cloacae* complex species); *Escherichia coli, Klebsiella oxytoca*, *Klebsiella pneumoniae, Proteus* spp*.,* and *Serratia marcescens*. A seventh assay (the Enteric assay) will react with some (not all) species detected by the other six assays; however, its primary function is to detect other less common, but clinically relevant members of the *Enterobacteriaceae* family. Combined, these seven assays will detect many, but not all *Enterobacteriaceae*.

As described for the other multi-assay interpretations, a positive result for any of the seven *Enterobacteriaceae*-associated assays will generate an *Enterobacteriaceae* Detected result. Each specific genus/species assay result will also be reported independently as shown in Table 4. Results for the Enteric assay are not reported independently, but are incorporated into the *Enterobacteriaceae* test result. Negative results for all seven assays will generate an *Enterobacteriaceae* Not Detected result.

**Table 4. Possible Assay Results and the Corresponding *Enterobacteriaceae* Test Results**

| **FilmArray BCID Interpretations** | **Enteric Assay** | **Ecloacae Assay** | **E. coli Assay** | **Koytoca Assay** | **Kpneumoniae Assay** | **Proteus Assay** | **Smarcescens Assay** | **Description** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| *Enterobacteriaceae Not Detected*  *Enterobacter cloacae complex* Not Detected  *Escherichia coli* Not Detected  *Klebsiella oxytoca* Not Detected  *Klebsiella pneumoniae* Not Detected  *Proteus* Not Detected  *Serratia marcescens* Not Detected | Neg | Neg | Neg | Neg | Neg | Neg | Neg | No *Enterobacteriaceae* species detecteda |
| ***Enterobacteriaceae Detected***  *Enterobacter cloacae complex* Not Detected  *Escherichia coli* Not Detected  *Klebsiella oxytoca* Not Detected  *Klebsiella pneumoniae* Not Detected  *Proteus* Not Detected  *Serratia marcescens* Not Detected | **Pos** | Neg | Neg | Neg | Neg | Neg | Neg | *Enterobacteriaceae* species detected  (not *E. cloacae* complex species, *E. coli*, *K. oxytoca*, *K. pneumoniae*, *Proteus*, or *S. marcescens*) |
| ***Enterobacteriaceae* Detected**  ***Enterobacter cloacae complex* Detected**  *Escherichia coli* Not Detected  *Klebsiella oxytoca* Not Detected  *Klebsiella pneumoniae* Not Detected  *Proteus* Not Detected  *Serratia marcescens* Not Detected | Any result | **Pos** | Neg | Neg | Neg | Neg | Neg | *E. cloacae* complex species detected |
| ***Enterobacteriaceae* Detected**  *Enterobacter cloacae complex* Not Detected  ***Escherichia coli* Detected**  *Klebsiella oxytoca* Not Detected  *Klebsiella pneumoniae* Not Detected  *Proteus* Not Detected  *Serratia marcescens* Not Detected | Any result | Neg | **Pos** | Neg | Neg | Neg | Neg | *E. coli* detected |
| ***Enterobacteriaceae* Detected**  *Enterobacter cloacae complex* Not Detected  *Escherichia coli* Not Detected  ***Klebsiella oxytoca* Detected**  *Klebsiella oxytoca* Not Detected  *Klebsiella pneumoniae* Not Detected  *Proteus* Not Detected  *Serratia marcescens* Not Detected | Any result | Neg | Neg | **Pos** | Neg | Neg | Neg | *K. oxytoca* detected |
| ***Enterobacteriaceae* Detected**  *Enterobacter cloacae complex* Not Detected  *Escherichia coli* Not Detected  *Klebsiella oxytoca* Not Detected  ***Klebsiella pneumoniae* Detected**  *Proteus* Not Detected  *Serratia marcescens* Not Detected | Any result | Neg | Neg | Neg | **Pos** | Neg | Neg | *K. pneumoniae* detected |
| ***Enterobacteriaceae* Detected**  *Enterobacter cloacae complex* Not Detected  *Escherichia coli* Not Detected  *Klebsiella oxytoca* Not Detected  *Klebsiella pneumoniae* Not Detected  ***Proteus* Detected**  *Serratia marcescens* Not Detected | Any result | Neg | Neg | Neg | Neg | **Pos** | Neg | *Proteus* species detected |
| ***Enterobacteriaceae* Detected**  *Enterobacter cloacae complex* Not Detected  *Escherichia coli* Not Detected  *Klebsiella oxytoca* Not Detected  *Klebsiella pneumoniae* Not Detected  *Proteus* Not Detected  ***Serratia marcescens* Detected** | Any result | Neg | Neg | Neg | Neg | Neg | **Pos** | *S. marcescens* detected |

Note: Multiple *Enterobacteriaceae* assays may be positive in a single sample. If this occurs, the test result for each species with a positive assay will be reported as Detected.

a *Morganella* spp., *Providencia* spp., *Rahnella* spp., *Yersinia* spp., *Tatumella* spp., and some *Serratia* spp. are not detected by the *Enterobacteriaceae* assays.

***Enterobacter cloacae* complex**

The *Enterobacter cloacae* complex is comprised of six species (*E. asburiae*, *E. cloacae*, *E. hormaechei*, *E. kobei*, *E. ludwigii*, and *E. nimipressuralis*) that may all be identified as *E. cloacae* by phenotypic laboratory methods. Of the six complex species, the BCID Panel Ecloacae assay detects *E. cloacae* (subspecies *cloacae* and *dissolvens*), *E. asburiae*, and *E. hormaechei*. Detection of *E. kobei, E. ludwigii*, and *E. nimipressuralis* is not expected and the clinical significance of these species is uncertain.

Cross-reactivity with the closely related *Enterobacter cancerogenus* (which has previously been described as a member of the *E. cloacae* complex; also known as *E. taylorae*) is possible. Cross-reactivity with the clinically important *Enterobacter aerogenes* and two former *Enterobacter* species (*Cronobacter* *sakazakii* and *Pantoea* *agglomerans*) has not been observed.

***Escherichia coli***

The BCID Panel *E. coli* assay cross-reacts with *Shigella* species (*S. boydii*, *S. dysenteriae*, *S. flexneri*, and *S. sonnei*); which are practically indistinguishable from *E. coli* by both phenotypic and genetic analyses, but are only very rarely isolated from blood culture. Cross-reactivity has also been observed with *Escherichia fergusonii*, a rare but potentially emerging pathogen.

***Klebsiella oxytoca***

The BCID Panel Koxytoca assay does not cross-react with other *Klebsiella* or *Enterobacteriaceae* species. However, *K. pneumoniae* or *Raoultella ornithinolytica* can be misidentified as *K. oxytoca* by standard laboratory methods leading to instances of apparent false negative *K. oxytoca* results. Similarly, a few variant strains of *K. oxytoca* have been identified that will not be detected as *K. oxytoca* by the BCID Panel; however, these variants are detected by the Enteric assay and reported as *Enterobacteriaceae* Detected.

***Klebsiella pneumoniae***

The BCID Panel Kpneumoniae assay detects *K. pneumoniae* (including three subspecies; ssp. *pneumoniae*, ssp. *ozaenae*, and ssp. *rhinosclermatis*) and *K. variicola. K. variicola* is a closely related species to *K. pneumoniae* that has been isolated from clinical specimens. The Kpneumoniae assay does not cross-react with *Klebsiella oxytoca*. However, the closely related *Raoultella* (formerly *Klebsiella*) *ornithinolytica* can be misidentified as *K. oxytoca* and exhibits cross-reactivity with the Kpneumoniae assay.

***Proteus***

The BCID Panel Proteus assay detects four of five characterized species within the genus (*P. mirabilis*, *P. hauseri*, *P. penneri*, and *P. vulgaris*). *P. mirabilis*, *P. penneri*, and *P. vulgaris* are considered opportunistic human pathogens, with *P. mirabilis* being the most common. The fifth species in the genus, *P. myxofaciens*, is not a known human pathogen and detection is not expected.

***Serratia marcescens***

*Serratia marcescens* is the primary human pathogen within the *Serratia* genus, though rare cases of human infection with other *Serratia* species (*S*. *plymuthica, S. liquefaciens*,*S*. *rubidaea*,*S. odorifera,* *S. ficaria* and *S. fonticola*) have been described. The BCID Panel Smarcescens assay was designed to detect *S. marcescens*, but will exhibit variable reactivity with select *Serratia* species as well. Based on sequence analysis and empirical testing, *S. ficaria* and *S. entomophila* (non-human pathogen) can be reliably detected. Reactivity with *S. odorifera* and *S. rubidaea* (rare human pathogens) is also possible, depending on the amount of organism in the specimen. *S. liquefaciens,* *S. plymuthica, S. fonticola*, *S. grimesii,* and *S. proteamaculans* will not be detected.

In addition to *Serratia* species, cross-reactivity has also been observed between the Smarcescens assay and a specific strain of *Pseudomonas aeruginosa* (ATCC25619), the soil bacterium *Pseudomonas putida*, and *Raoultella ornithinolytica* (commonly misidentified by standard laboratory methods as *Klebsiella oxytoca*).

**Other *Enterobacteriaceae***

If any of the species specific assays described above are positive, the *Enterobacteriaceae* result will be Detected. However, the *Enterobacteriaceae* family includes many additional species that are not covered by the species specific assays. The BCID Enteric assay detects many, but not all species of *Enterobacteriaceae* that may be associated with human infection, including *Cedeceae davisiae*, *Citrobacter* spp., *Cronobacter (Enterobacter) sakazakii*, *Enterobacter* spp. *(including E. aerogenes*), *Escherichia* spp*.*, *Kluyvera ascorbata*, *Leclercia adecarboxylata*, *Raoultella* spp., *Salmonella* spp., *Shigella* spp., and *Yokenella regensburgei*.

Detection of some other *Enterobacteriaceae* may only occur when the organism is present in a blood culture at high levels (>1x108 CFU/mL) including *Hafnia alvei*,and some *Serratia* spp. The BCID Enteric assay may also react with members of the *Enterobacteriaceae* family that are rare human pathogens (*Edwardsiella* spp. and *Erwinia* spp.) as well as species typically classified as plant pathogens (*Brenneria* spp., *Dickeya* spp., *Pectobacterium* spp., etc.).

Sequence analysis and testing indicate that the BCID Enterobacteriaceae assays will not detect *Morganella* *morganii*, *Providencia* spp., *Rahnella* spp., *Serratia liquefaciens*, *Tatumella ptyseos*, *Yersinia* spp. and others (see Table 5 below).

**Table 5. Summary of BCID Panel Reactivity with *Enterobacteriaceae*a**

| **Detected** | **Detected with**  **Reduced Sensitivity** | **Not Detected** |
| --- | --- | --- |
| *Cedeceae* spp. | *Edwardsiella spp.* | *Morganella morganii* |
| *Citrobacter* spp. | *Enterobacter gergoviae* | *Providencia* spp. |
| *Cronobacter* spp. | *Hafnia alvei* | *Rahnella* spp. |
| *Enterobacter* spp. | *Pantoea* spp. | *Serratia liquefaciens* |
| *Escherichia* spp. | *Salmonella bongori* | *Serratia plymuthica* |
| *Klebsiella* spp. | *Serratia fonticola* | *Tatumella ptyseos* |
| *Kluyvera* spp. | *Serratia odorifera* | *Yersinia enterocolitica* |
| *Leclercia adecarboxylata* | *Serratia rubidaeae* |  |
| *Proteus* spp. |  |
| *Raoultella* spp*.* |
| *Salmonella* spp. |
| *Shigella* spp. |
| *Serratia marcescens, S. ficaria, and S. entomophila* b |
| *Yokenella regensbergei* |

a See Analytical Reactivity (Inclusivity) section of FilmArray Blood Culture Identification (BCID) Panel Instruction Booklet for additional *in silico* reactivity predictions.

b Insect pathogen

Antimicrobial Resistance Genes Interpretation. The test results for antimicrobial resistance genes are only reported when an associated organism (as shown in Table 6) is detected in the same test. Tables 7, 8, and 9 provide detailed listing of the assay results and the corresponding BCID Panel test results.

**Table 6. Antimicrobial Resistance Genes and Associated Organisms**

| **Antimicrobial Resistance Genes** | **Associated Organism** |
| --- | --- |
| *mecA* | *Staphylococcus* |
| *vanA/B\** | *Enterococcus* |
| KPC | Any *Enterobacteriaceae,*  *A. baumannii,* and/or  *P. aeruginosa* |

*\*NOT* reported with *Staphylococcus*. Vancomycin-resistant *Staphylococcus aureus* (VRSA) is possible but extremely rare.

The results for each of the antimicrobial resistance genes will be listed as either:

**Detected** – when an appropriate organism is detected and the antimicrobial resistance gene assay is positive.

**Not Detected** – when an appropriate organism is detected and the antimicrobial resistance gene assay is negative.

**N/A** – when NO appropriate organism is detected regardless of the result for the antimicrobial resistance gene assay.

**NOTE**: A Not Detected result for any of the antimicrobial resistance genes does not indicate susceptibility, as resistance may occur by other mechanisms.

**Table 7. Possible Assay Results and Corresponding *Staphylococcus* and *mecA* Test Results**

| **FilmArray BCID Test Results** | **Staphylococcus 1/2 Assays** | **Saureus Assay** | **mecA Assaya** | **Description** |
| --- | --- | --- | --- | --- |
| *Staphylococcus* Not Detected  *Staphylococcus aureus* Not Detected  *mecA* N/A | Negative | Negative | Any result | No *Staphylococcus* species detected; *mecA* results not applicable |
| ***Staphylococcus* Detected**  *Staphylococcus aureus* Not Detected  *mecA* Not Detected | **Positive** | Negative | Negative | *Staphylococcus* species detected  **AND**  *mecA* not detected |
| ***Staphylococcus* Detected**  *Staphylococcus aureus* Not Detected  ***mecA* Detected** | **Positive** | Negative | **Positive** | *Staphylococcus* species (not *S. aureus*) detected  **AND**  *mecA* detectedb |
| ***Staphylococcus* Detected**  ***Staphylococcus aureus* Detected**  *mecA* Not Detected | Any result | **Positive** | Negative | *Staphylococcus aureus* detected  **OR**  *Staphylococcus aureus* and one or more other *Staphylococcus* species detected  AND  *mecA* not detected |
| ***Staphylococcus* Detected**  ***Staphylococcus aureus* Detected**  ***mecA* Detected** | Any result | **Positive** | **Positive** | *Staphylococcus aureus* detected  **OR**  *Staphylococcus aureus* and one or more other *Staphylococcus* species detected  **AND**  *mecA* detectedb |

a The BCID Panel mecA assay will detect the *mecA* gene from all known SCCmec types, including the recently described mecALGA251/*mecC* variant (SCCmec type XI).

b The *mecA* gene may not be from the *Staphylococcus* (or *S. aureus*) that was detected or may be from only one of multiple *Staphylococcus* spp. that were detected in the culture. Subculturing and AST testing is required in order to assign a resistant and/or susceptible phenotype to each isolate recovered from the blood culture sample.

**Table 8. Possible Assay Results and Corresponding *vanA/B* Test Results**

| **FilmArray BCID Test Result** | **Enterococcus**  **Assay** | **vanA/B Assay** | **Description** |
| --- | --- | --- | --- |
| *Enterococcus* Not Detected  *vanA/B* N/A | Negative | Any result | No *Enterococcus* species detected; *vanA/B* results not applicable |
| ***Enterococcus* Detected**  *vanA/B* Not Detected | **Positive** | Negative | *Enterococcus* species detected  **AND**  *vanA/B* not detected |
| ***Enterococcus* Detected**  ***vanA/B* Detected** | **Positive** | **Positive** | *Enterococcus* species detected  **AND**  *vanA/B* detecteda |

a Subculturing and AST testing is required in order to assign a resistant and/or susceptible phenotype to isolates recovered from the blood culture sample.

**Table 9. Possible Assay Results and the Corresponding KPC Test Results**

| **FilmArray BCID Test Results** | **Abaumannii**  **Assay** | **Enterobacteriaceae-associated Assays** | **Paeruiginosa Assay** | **KPC Assaya** | **Description** |
| --- | --- | --- | --- | --- | --- |
| *Acinetobacter baumannii* Not Detected  *Enterobacteriaceae* Not Detected  *Pseudomonas aeruginosa* Not Detected  KPC N/A | Negative | Negative | Negative | Any result | No *A. baumannii, Enterobacteriaceae* species or *P. aeruginosa* detected;  KPC results not applicable |
| ***Acinetobacter baumannii* Detected**  *Enterobacteriaceae* Not Detected  *Pseudomonas aeruginosa* Not Detected  KPC Not Detected | **Positive** | Negative | Negative | Negative | *A. baumannii* detected;no *Enterobacteriaceae* species or *P. aeruginosa* detected  **AND**  KPC not detectedb |
| ***Acinetobacter baumannii* Detected**  *Enterobacteriaceae* Not Detected  *Pseudomonas aeruginosa* Not Detected  **KPC Detected** | **Positive** | Negative | Negative | **Positive** | *A. baumannii* detected*;* no *Enterobacteriaceae* species or *P. aeruginosa* detected  **AND**  KPC detectedc |
| *Acinetobacter baumannii*NotDetected  ***Enterobacteriaceae* Detected**  *Pseudomonas aeruginosa* Not Detected  KPC Not Detected | Negative | **Any Positive** | Negative | Negative | *Enterobacteriaceae* species detected*;* no *A. baumannii* or *P. aeruginosa* detected  **AND**  KPC not detectedb |
| *Acinetobacter baumannii*NotDetected  ***Enterobacteriaceae* Detected**  *Pseudomonas aeruginosa* Not Detected  **KPC Detected** | Negative | **Any Positive** | Negative | **Positive** | *Enterobacteriaceae* species detected*;* no *A. baumannii* or *P. aeruginosa* detected  **AND**  KPC detectedc |
| *Acinetobacter baumannii*NotDetected  *Enterobacteriaceae* NotDetected  ***Pseudomonas aeruginosa* Detected**  KPC Not Detected | Negative | Negative | **Positive** | Negative | *P. aeruginosa* detected*;* no *A. baumannii* or *Enterobacteriaceae* species detected  **AND**  KPC not detectedb |
| *Acinetobacter baumannii*NotDetected  *Enterobacteriaceae* NotDetected  ***Pseudomonas aeruginosa* Detected**  **KPC Detected** | Negative | Negative | **Positive** | **Positive** | *P. aeruginosa* detected*;* no *A. baumannii* or *Enterobacteriaceae* species detected  **AND**  KPC detectedc |

a The BCID Panel KPC assay will detect types 2-13 of the *bla*KPC gene

b When KPC is Not Detected, the following warning statement will be printed on the test report in red text ‘**WARNING**: A Not Detected result for the KPC gene does not indicate susceptibility to carbapenems. Gram negative bacteria can be resistant to carbapenems by mechanisms other than carrying the KPC gene.’ This special warning has been added to the report because there are multiple mechanisms for resistance to carbapenems. In particular, *Acinetobacter baumannii*, and *Pseudomonas aeruginosa* are commonly resistant to carbapenems, but only rarely carry the KPC gene.

c The KPCgene detected may not be from the *A. baumannii*, *Enterobacteriaceae*, and/or *P. aeruginosa* that was detected or may be from only one of multiple applicable organisms detected. Subculturing and AST testing is required in order to assign a resistant and/or susceptible phenotype to each isolate recovered from the blood culture sample.

**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 than 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.

**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 successfully (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 GI Test Report

| **Control Result** | **Explanation** | **Action Required** | **Outcome** |
| --- | --- | --- | --- |
| Passed | The run was successfully completed  AND  Both pouch controls were successful. | None | Report the results provided on the test report. |
| Failed | The run was successfully completed  BUT  At least one of the pouch controls (RNA Process Control and/or PCR2 Control) failed. | Repeat the test using a new pouch. | Accept the results of the repeat testing. If the error persists, contact technical support for further instruction. |
| Invalid | The controls are invalid because the run did not complete.  (Typically this indicates a software or hardware error). | Note any error codes displayed during the run and the Run Status field in the Run Details section of the report. Refer to the FilmArray Operator’s Manual or contact Technical Support for further instruction.  Once the error is resolved, repeat the test or repeat the test using another instrument.  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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### Result Reporting

The Results Summary – Interpretations section provides a complete list of the test results. Possible results for each organism include Detected, Not Detected, N/A and Invalid. Table 2 provides an explanation for each interpretation and any follow-up necessary to obtain a final result.

Table 11. Reporting of Results and Required Actions

| **Result** | **Explanation** | **Action** |
| --- | --- | --- |
| Detected | The run was successfully completed  AND  The pouch controls were successful (Passed)  AND  The assay(s) for the organism (or antimicrobial resistance gene) were POSITIVE | Report results.  NOTE: 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. |
| Not Detected | The run was successfully completed  AND  The pouch controls were successful (Passed)  AND  The assay(s) for the organism (or antimicrobial resistance gene) were NEGATIVE | Report results. |
| Invalid | The pouch controls were not successful (Failed)  OR  The run did not complete successfully  (Run Status displayed as: Aborted, Incomplete, Instrument Error, Software Error, or Instrument Communication Error) | See Table 11 Interpretation of Controls Field on the FilmArray Test Report for instruction. |
| N/A  (Antimicrobial Resistance Genes only) | The run was successfully completed  AND  The pouch controls were successful (Passed)  AND  The assay(s) for the organism(s) associated with the antimicrobial resistance gene were NEGATIVE so the results of the antimicrobial resistance gene are not applicable to the test results. | Report Results |

### References/Related Documents

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