



## FilmArray® BCID Control Panel M235 v1.1

**INTENDED USE:**

The FilmArray® BCID Control Panel M235 v1.1 is intended for *in vitro* use as a quality control to monitor the detection and identification of multiple pathogens and antibiotic resistance genes associated with blood stream infections when tested by the BioFire® FilmArray® Blood Culture Identification (BCID) Panel on the BioFire® FilmArray® instrument.

**PRODUCT SUMMARY and PRINCIPLE:**

FilmArray BCID Control Panel M235 v1.1 is comprised of 2 controls. FilmArray® BCID Positive Control and FilmArray® BCID Negative Control. FilmArray BCID Positive Control contains surrogate control material composed of synthetic nucleic acid corresponding to genome segments of the pathogens and antimicrobial resistance markers listed in Table 1. FilmArray BCID Negative Control contains no nucleic acid.

Routine use of quality controls that are consistent lot to lot assists the laboratory in identifying shifts, trends, and increased frequency of random errors caused by variations in the test system, such as failing reagents. Early investigation can prevent failed assay runs.

**COMPOSITION:**

FilmArray BCID Control Panel M235 v1.1 is comprised of 12 tubes, 6 tubes of positive control and 6 tubes of negative control, 200µL each. FilmArray BCID Positive Control contains synthetic DNA suspended in a non-infectious solution of buffers, preservatives and stabilizers. FilmArray BCID Negative Control contains buffers and preservatives. Table 1 lists the antimicrobial resistance markers and pathogens that are monitored by the FilmArray BCID Control Panel M235 v1.1.

**INSTRUCTIONS FOR USE:**

1. Allow the control to be tested to come to room temperature (18° – 25°C).
2. Use the control as provided. **DO NOT DILUTE.**
3. Immediately before use, mix the control thoroughly by first inverting several times followed by vortexing the tube for 3-5 seconds. Tap the tube several times on the bench to remove any control caught in the cap before opening the tube.
4. Prepare and run a BioFire BCID Pouch using the control as you would use a patient specimen, according to BioFire BCID Panel Quick Guide or Instructions for Use.
5. Discard after use according to your local and federal regulations.

**PRECAUTIONS and WARNINGS:**

- Use the control as provided. Do not dilute or transfer to another tube.
- This product is intended for *in vitro* analytical testing and is provided for Research Use only, not for use in diagnostic procedures.
- This product does not contain the entire genome of the pathogens listed in Table 1.
- This product is not intended for use as a substitute for the internal controls provided in the BioFire BCID Panel assay.
- This product is red in appearance.
- This product does not contain any biological material of human or animal origin. Universal Precautions are NOT required when handling this product.
- Quality control materials should be used in accordance with local, state, federal regulations and accreditation requirements.
- FilmArray BCID Control Panel M235 v1.1 cannot be cloned, sold, or transferred without the explicit written consent of MMQCI

**STORAGE and STABILITY:**

FilmArray BCID Control Panel M235 v1.1 should be stored at 2 – 8°C. Unopened FilmArray BCID Control Panel M235 v1.1 is stable through the expiration date printed on the kit label when consistently stored refrigerated (2° – 8°C). FilmArray BCID Positive Control and FilmArray BCID Negative Control are for single use. Discard after use according to your local and federal regulations.

**EXPECTED VALUES:**

Table 1 lists the expected results of the FilmArray BCID Control Panel M235 v1.1. The laboratory should follow Good Laboratory Practice (GLP) and establish its own performance characteristics for FilmArray BCID Control Panel M235 v1.1 in demonstrating adequate system performance.

**Table 1: FilmArray Result Summary Interpretation**

Assay	Positive Control	Negative Control
<b>Antimicrobial Resistance Genes</b>		
KPC – carbapenem-resistance gene	Detected	N/A
mecA – methicillin-resistance gene	Detected	N/A
vanA/B – vancomycin-resistance genes	Detected	N/A
<b>Gram Positive Bacteria</b>		
Enterococcus	Detected	Not Detected
Listeria monocytogenes	Detected	Not Detected
Staphylococcus	Detected	Not Detected
Staphylococcus aureus	Detected	Not Detected
Streptococcus	Detected	Not Detected
Streptococcus agalactiae	Detected	Not Detected
Streptococcus pneumoniae	Detected	Not Detected
Streptococcus pyogenes	Detected	Not Detected
<b>Gram Negative Bacteria</b>		
Acinetobacter baumannii	Detected	Not Detected
Enterobacteriaceae	Detected	Not Detected
Enterobacter cloacae complex	Detected	Not Detected
Escherichia coli	Detected	Not Detected
Klebsiella oxytoca	Detected	Not Detected
Klebsiella pneumoniae	Detected	Not Detected
Proteus	Detected	Not Detected
Serratia marcescens	Detected	Not Detected
Haemophilus influenzae	Detected	Not Detected
Neisseria meningitidis	Detected	Not Detected
Pseudomonas aeruginosa	Detected	Not Detected
<b>Yeast</b>		
Candida albicans	Detected	Not Detected
Candida glabrata	Detected	Not Detected
Candida krusei	Detected	Not Detected
Candida parapsilosis	Detected	Not Detected
Candida tropicalis	Detected	Not Detected

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**ORDERING INFORMATION:**

FilmArray® BCID Control Panel M235 v1.1

**Part Number: M235v1.1**

Kit Contains: 12 tubes x 200µL

6 Positive controls and 6 Negative controls