

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 FilmArray[®] Blood Culture Identification Panel on the FilmArray[®] instrument.

FilmArray[®] BCID Control Panel M235 v1.1 cannot be cloned, sold, or transferred without the explicit written consent of MMQCI.

PRODUCT SUMMARY and PRINCIPLE:

FilmArray[®] BCID Control Panel M235 v1.1 is comprised of synthetic DNA suspended in a non-infectious solution of buffers, preservatives and stabilizers.

Best practice is to establish a quality control program for every assay performed by the laboratory.^{1, 2} 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:

The FilmArray[®] BCID Control Panel M235 v1.1 is comprised of 12 tubes, 200µL each, of synthetic DNA suspended in a non-infectious solution of buffers, preservatives and stabilizers. Table 1 lists the pathogens that are monitored by the FilmArray[®] BCID Control Panel M235 v1.1 when tested by the FilmArray[®] Blood Culture Identification Panel on the FilmArray[®] instrument.

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 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.

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. Prepare and hydrate a pouch according to FilmArray[®] Instructions.
4. Immediately before use, mix the control by briefly vortexing the tube for 3 - 5 seconds and then shake the tube down firmly to remove any droplets caught in the cap.
5. Aspirate the control using the FilmArray[®] transfer pipette.
6. Analyze the control as you would a patient sample by adding the control to the FilmArray[®] Sample Buffer.
7. Discard after use according to your local and federal regulations.

PRECAUTIONS and WARNINGS:

- Do not dilute.
- 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 any biological material of human origin.

EXPECTED VALUES:

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. Recoveries may vary depending on instrumentation, reagents and systematic or random errors. The expected results when the controls are analyzed are listed in Table 1.

Table 1: FilmArray[®] Result Summary Interpretation

Assay	M23618 Call	M23718 Call
Antimicrobial Resistance Genes		
KPC – carbapenem-resistance gene	Detected	N/A
mecA – methicillin-resistance gene	Detected	N/A
vanA/B – vancomycin-resistance genes	Detected	N/A
Gram Positive Bacteria		
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
Gram Negative Bacteria		
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
Yeast		
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

ORDERING INFORMATION:

FilmArray[®] BCID Control Panel M235 v1.1

Part Number: M235v1.1

Kit Contains: 12 tubes x 200 µL

6 each of M23618v1.1 & M23718v1.1

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1. ISO 15189: Medical laboratories – Particular requirements for quality and competence.
2. CAP Molecular Pathology Checklist; Commission on Laboratory Accreditation, Laboratory Accreditation Program, Mol.20000