



FilmArray BCID2 Control Panel M416

INTENDED USE:

The FilmArray BCID2 Control Panel M416 is intended for use as an external positive and negative assayed quality control to monitor the performance of *in vitro* laboratory nucleic acid testing procedures for the qualitative detection of antimicrobial resistance genes: CTX-M, IMP, KPC, *mcr-1*, *mecA/C*, *mecA/C* and MREJ (MRSA), NDM, OXA-48-like, *vanA/B*, VIM; Gram positive and Gram negative bacteria: *Enterococcus faecalis*, *Enterococcus faecium*, *Listeria monocytogenes*, *Staphylococcus* spp., *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Staphylococcus lugdunensis*, *Streptococcus* spp., *Streptococcus agalactiae* (Group B), *Streptococcus pneumoniae*, *Streptococcus pyogenes* (Group A), *Acinetobacter calcoaceticus-baumannii* complex, *Bacteroides fragilis*, Enteric bacteria, *Enterobacter cloacae* complex, *Escherichia coli*, *Klebsiella aerogenes*, *Klebsiella oxytoca*, *Klebsiella pneumoniae* group, *Proteus* spp., *Salmonella* spp., *Serratia marcescens*, *Haemophilus influenzae*, *Neisseria meningitidis*, *Pseudomonas aeruginosa* and *Stenotrophomonas maltophilia*; and yeast pathogens: *Candida albicans*, *Candida auris*, *Candida glabrata*, *Candida krusei*, *Candida parapsilosis*, *Candida tropicalis*, and *Cryptococcus neoformans/gattii* on the BioFire® Blood Culture Identification 2 (BCID2) Panel on the BioFire FilmArray® systems. This product is not intended to replace manufacturer controls provided with the device.

PRODUCT SUMMARY and PRINCIPLE:

FilmArray BCID2 Control Panel M416 is comprised of 2 controls, FilmArray BCID2 Positive Control and FilmArray BCID2 Negative Control. FilmArray BCID2 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 BCID2 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 BCID2 Control Panel M416 is comprised of 12 tubes, 6 tubes of positive control and 6 tubes of negative control, 200µL each. FilmArray BCID2 Positive Control contains synthetic DNA suspended in a non-infectious solution of buffers, preservatives and stabilizers. FilmArray BCID2 Negative Control contains buffers and preservatives. Table 1 lists the antimicrobial resistance markers and pathogens that are monitored by the FilmArray BCID2 Control Panel M416 when tested by the BioFire BCID2 Panel on the BioFire FilmArray systems.

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 BCID2 Pouch using the control as you would use a patient specimen, according to BioFire BCID2 Panel Quick Guide or Instructions for Use.
5. Discard after use according to your local and federal regulations.

PRECAUTIONS, WARNINGS and LIMITATIONS:

- Use the control as provided. Do not dilute or transfer to another tube.
- This product is intended for *in vitro* diagnostic use only.
- This product is only for use with BioFire BCID2 Panel on the BioFire FilmArray systems. It 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 BCID2 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 BCID2 Control Panel M416 cannot be cloned, sold, or transferred without the explicit written consent of MMQCI

STORAGE and STABILITY:

FilmArray BCID2 Control Panel M416 should be stored at 2 - 8°C. Unopened FilmArray BCID2 Control Panel M416 is stable through the expiration date printed on the kit label when consistently stored refrigerated (2° – 8°C). FilmArray BCID2 Positive Control and FilmArray BCID2 Negative Control are for single use. Discard after use according to your local and federal regulations.

EXPECTED VALUES:

Table 1 lists the expected results when the controls are analyzed by BioFire BCID2 Panel. The laboratory should follow Good Laboratory Practice (GLP) and establish its own performance characteristics for FilmArray BCID2 Control Panel M416 in demonstrating adequate system performance.

ORDERING INFORMATION:

FilmArray BCID2 Control Panel M416
Part Number: M416
 Kit Contains: 12 tubes x 200µL
 6 Positive controls and 6 Negative controls

Table 1: FilmArray BCID2 Positive & Negative Control Result Summary

	Positive Control	Negative Control
Antimicrobial resistance genes		
CTX-M	Detected	N/A
IMP	Detected	N/A
KPC	Detected	N/A
<i>mcr-1</i>	Detected	N/A
<i>mecA/C</i>	Detected	N/A
<i>mecA/C</i> and MREJ (MRSA)	Detected	N/A
NDM	Detected	N/A
OXA-48-like	Detected	N/A
<i>vanA/B</i>	Detected	N/A
VIM	Detected	N/A
Gram Positive Bacteria		
<i>Enterococcus faecalis</i>	Detected	Not Detected
<i>Enterococcus faecium</i>	Detected	Not Detected
<i>Listeria monocytogenes</i>	Detected	Not Detected
<i>Staphylococcus</i> spp.	Detected	Not Detected
<i>Staphylococcus aureus</i>	Detected	Not Detected
<i>Staphylococcus epidermidis</i>	Detected	Not Detected
<i>Staphylococcus lugdunensis</i>	Detected	Not Detected
<i>Streptococcus</i> spp.	Detected	Not Detected
<i>Streptococcus agalactiae</i> (Group B)	Detected	Not Detected
<i>Streptococcus pneumoniae</i>	Detected	Not Detected
<i>Streptococcus pyogenes</i> (Group A)	Detected	Not Detected
Gram Negative Bacteria		
<i>Acinetobacter calcoaceticus-baumannii</i> complex	Detected	Not Detected
<i>Bacteroides fragilis</i>	Detected	Not Detected
Enteric bacteria	Detected	Not Detected
<i>Enterobacter cloacae</i> complex	Detected	Not Detected
<i>Escherichia coli</i>	Detected	Not Detected
<i>Klebsiella aerogenes</i>	Detected	Not Detected
<i>Klebsiella oxytoca</i>	Detected	Not Detected
<i>Klebsiella pneumoniae</i> group	Detected	Not Detected
<i>Proteus</i> spp.	Detected	Not Detected
<i>Salmonella</i> spp.	Detected	Not Detected
<i>Serratia marcescens</i>	Detected	Not Detected
<i>Haemophilus influenzae</i>	Detected	Not Detected
<i>Neisseria meningitidis</i>	Detected	Not Detected
<i>Pseudomonas aeruginosa</i>	Detected	Not Detected
<i>Stenotrophomonas maltophilia</i>	Detected	Not Detected
Yeast		
<i>Candida albicans</i>	Detected	Not Detected
<i>Candida auris</i>	Detected	Not Detected
<i>Candida glabrata</i>	Detected	Not Detected
<i>Candida krusei</i>	Detected	Not Detected
<i>Candida parapsilosis</i>	Detected	Not Detected
<i>Candida tropicalis</i>	Detected	Not Detected
<i>Cryptococcus neoformans/gattii</i>	Detected	Not Detected

REPRESENTATIVE PERFORMANCE DATA:

Three lots of FilmArray BCID2 Positive Control and three lots of FilmArray BCID2 Negative Control were tested using the BioFire BCID2 Panel assay on BioFire FilmArray systems at 3 external clinical laboratory sites, incorporating 3 unique pouch lots and multiple operators and instruments. A total of 185 external controls were tested over 10 days at each site. Two Controls gave initial Invalid results and three Positive controls gave 1 or more initial false negative results. All produced the correct results upon retesting for an overall correct result rate of 98.4%.

Site	Total Tests	Invalid	Correct Positive Control Result	Incorrect Positive Control Result	Percent Correct Positive Control	Correct Negative Control Result	Incorrect Negative Control Result	Percent Correct Negative Control	Total Percent Correct
1	63	2*	30	1	96.8%	30	0	100.0%	98.4%
2	60	0	30	0	100.0%	30	0	100.0%	100.0%
3	62	0	30	2	93.8%	30	0	100.0%	96.8%
All Sites	185	2	90	3	96.8%	90	0	100.0%	98.4%

* Invalid results were not included in percent correct.