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BioFire® JI Control Panel M420

English

INTENDED USE:

The BioFire® JI Control Panel M420 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 gram-positive and gram-negative bacteria: *Anaerococcus prevotii/vaginalis*, *Clostridium perfringens*, *Cutibacterium avidum/granulosum*, *Enterococcus faecalis*, *Enterococcus faecium*, *Finegoldia magna*, *Parvimonas micra*, *Peptoniphilus*, *Peptostreptococcus anaerobius*, *Staphylococcus aureus*, *Staphylococcus lugdunensis*, *Streptococcus* spp., *Streptococcus agalactiae*, *Streptococcus pneumoniae*, *Streptococcus pyogenes*, *Bacteroides fragilis*, *Citrobacter*, *Enterobacter cloacae* complex, *Escherichia coli*, *Haemophilus influenzae*, *Kingella kingae*, *Klebsiella aerogenes*, *Klebsiella pneumoniae* group, *Morganella morganii*, *Neisseria gonorrhoeae*, *Proteus* spp., *Pseudomonas aeruginosa*, *Salmonella* spp., and *Serratia marcescens*, antimicrobial resistance genes: CTX-M, IMP, KPC, *mecA/C* and MREJ (MRSA), NDM, OXA-48-like, *vanA/B*, VIM; and yeast pathogens: *Candida* and *Candida albicans* on the BioFire® Joint Infection (JI) Panel on the BioFire® systems. BioFire JI Control Panel M420 is composed of synthetic DNA specifically designed for and intended to be used solely with the BioFire JI Panel assay. This product is not intended to replace manufacturer controls provided with the device.

PRODUCT SUMMARY and PRINCIPLE:

BioFire JI Control Panel M420 is comprised of 2 controls, BioFire® JI Positive Control and BioFire® JI Negative Control. BioFire JI 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. BioFire JI Negative Control contains no nucleic acid.

Quality controls can be used for routine monitoring of test systems, validation, verification, proficiency assessment, and training procedures. Routine use of quality controls assists the laboratory in identifying shifts, trends, and increased frequency of random errors caused by variations in the test system, such as failing reagents or malfunctioning equipment. Early investigation can prevent failed assay runs.

COMPOSITION:

BioFire JI Control Panel M420 is comprised of 12 single use tubes, 6 tubes of positive control and 6 tubes of negative control, 200µL each. BioFire JI Positive Control contains synthetic DNA suspended in a non-infectious solution of buffers, preservatives and stabilizers. BioFire JI Negative Control contains buffers and preservatives. Table 1 lists the pathogens and antimicrobial resistance markers that are monitored by the BioFire JI Control Panel M420 when tested with the BioFire JI Panel on the BioFire Systems.

INSTRUCTIONS FOR USE:

1. Allow the control to come to room temperature (18° – 25°C) for approximately 15 minutes.
2. Use the control as provided. **DO NOT DILUTE.**
3. Prepare and hydrate a pouch according to BioFire Instructions.
4. 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.
5. Prepare Sample Mix according to BioFire instructions, being sure to invert the control and sample buffer mixture **at least 3 times.** Load and run a BioFire JI Pouch, using the control as you would use a patient specimen, according to BioFire JI Quick Guide or Instructions for Use.
6. 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 the BioFire JI Panel on the BioFire 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 JI 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.
- BioFire JI Control Panel M420 cannot be cloned, sold, or transferred without the explicit written consent of MMQCI.

ORDERING INFORMATION:

BioFire® JI Control Panel M420

Part Number: M420

CONT Kit Contains: 12 tubes x 200µL

6 Positive (+) controls and 6 Negative (-) controls

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STORAGE and STABILITY:

BioFire JI Control Panel M420 should be stored at 2° – 8°C. Unopened BioFire JI Control Panel M420 is stable through the expiration date printed on the kit label when consistently stored refrigerated (2° – 8°C). BioFire JI Positive Control and BioFire JI 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 JI Panel. The laboratory should follow Good Laboratory Practice (GLP) and establish its own performance characteristics for BioFire JI Control Panel M420 in demonstrating adequate system performance.

Table 1: BioFire JI Positive & Negative Control Result Summary

	Positive Control	Negative Control
Gram Positive Bacteria		
<i>Anaerococcus prevotii/vaginalis</i>	Detected	Not Detected
<i>Clostridium perfringens</i>	Detected	Not Detected
<i>Cutibacterium avidum/granulosum</i>	Detected	Not Detected
<i>Enterococcus faecalis</i>	Detected	Not Detected
<i>Enterococcus faecium</i>	Detected	Not Detected
<i>Finegoldia magna</i>	Detected	Not Detected
<i>Parvimonas micra</i>	Detected	Not Detected
<i>Peptoniphilus</i>	Detected	Not Detected
<i>Peptostreptococcus anaerobius</i>	Detected	Not Detected
<i>Staphylococcus aureus</i>	Detected	Not Detected
<i>Staphylococcus lugdunensis</i>	Detected	Not Detected
<i>Streptococcus</i> spp.	Detected	Not Detected
<i>Streptococcus agalactiae</i>	Detected	Not Detected
<i>Streptococcus pneumoniae</i>	Detected	Not Detected
<i>Streptococcus pyogenes</i>	Detected	Not Detected
Gram Negative Bacteria		
<i>Bacteroides fragilis</i>	Detected	Not Detected
<i>Citrobacter</i>	Detected	Not Detected
<i>Enterobacter cloacae</i> complex	Detected	Not Detected
<i>Escherichia coli</i>	Detected	Not Detected
<i>Haemophilus influenzae</i>	Detected	Not Detected
<i>Kingella kingae</i>	Detected	Not Detected
<i>Klebsiella aerogenes</i>	Detected	Not Detected
<i>Klebsiella pneumoniae</i> group	Detected	Not Detected
<i>Morganella morganii</i>	Detected	Not Detected
<i>Neisseria gonorrhoeae</i>	Detected	Not Detected
<i>Proteus</i> spp.	Detected	Not Detected
<i>Pseudomonas aeruginosa</i>	Detected	Not Detected
<i>Salmonella</i> spp.	Detected	Not Detected
<i>Serratia marcescens</i>	Detected	Not Detected
Antimicrobial resistance genes		
CTX-M	Detected	N/A
IMP	Detected	N/A
KPC	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
Yeast		
<i>Candida</i>	Detected	Not Detected
<i>Candida albicans</i>	Detected	Not Detected

REPRESENTATIVE PERFORMANCE DATA:

Three lots of BioFire JI Positive Control and three lots of BioFire JI Negative Control were tested using the BioFire® JI Panel assay on BioFire Systems at 3 clinical laboratory sites, incorporating 3 unique BioFire JI Panel assay pouch lots, multiple operators and instruments. A total of 181 controls were tested over 10 days at the 3 sites. One control test gave an Invalid result. All other controls gave correct results for a correct result rate of 100%.

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
1	61	1*	30	0	100.0%	30	0	100.0%
2	60	0	30	0	100.0%	30	0	100.0%
3	60	0	30	0	100.0%	30	0	100.0%
All Sites	181	1*	90	0	100.0%	90	0	100.0%

* Invalid results were not included in percent correct.



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