



**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY**

**I Background Information:**

**A 510(k) Number**

K200010

**B Applicant**

Maine Molecular Quality Controls, Inc.

**C Proprietary and Established Names**

FilmArray BCID2 Control Panel M416

**D Regulatory Information**

Product Code(s)	Classification	Regulation Section	Panel
PMN	Class II	21 CFR 866.3920 - Assayed Quality Control Material for Clinical Microbiology Assays	MI - Microbiology

**II Submission/Device Overview:**

**A Purpose for Submission:**

To obtain a substantial equivalence determination for the FilmArray BCID2 Control Panel M416

**B Measurand:**

Multi-analyte quality control materials

**C Type of Test:**

FilmArray BCID2 Control Panel M416 is intended for *in vitro* diagnostic use as external assayed quality control materials to monitor the qualitative amplification, detection and identification steps of the laboratory nucleic acid test BioFire BCID2 Panel on the FilmArray 2.0 or FilmArray Torch systems. The BioFire BCID2 Panel on the FilmArray 2.0 or FilmArray Torch system detects multiple bacterial and yeast nucleic acids and select genetic determinants of antimicrobial resistance from positive blood cultures. Gram Positive Bacteria: *Enterococcus faecalis*, *Enterococcus faecium*, *Listeria monocytogenes*, *Staphylococcus* spp. (with specific differentiation of *Staphylococcus aureus*, *Staphylococcus epidermidis*, and *Staphylococcus*

*lugdunensis*), *Streptococcus* spp. (with specific differentiation of *Streptococcus agalactiae* (Group B), *Streptococcus pneumoniae*, and *Streptococcus pyogenes* (Group A)), Gram-negative Bacteria: *Acinetobacter calcoaceticus-baumannii* complex, *Bacteroides fragilis*, *Haemophilus influenzae*, *Neisseria meningitidis* (encapsulated), *Pseudomonas aeruginosa*, *Stenotrophomonas maltophilia*, *Enterobacterales* (with specific differentiation of *Enterobacter cloacae* complex, *Escherichia coli*, *Klebsiella aerogenes*, *Klebsiella oxytoca*, *Klebsiella pneumoniae* group, *Proteus* spp., *Salmonella* spp., and *Serratia marcescens*), Yeast: *Candida albicans*, *Candida auris*, *Candida glabrata*, *Candida krusei*, *Candida parapsilosis*, *Candida tropicalis*, and *Cryptococcus neoformans/gattii*, Resistance Markers: CTX-M, IMP, KPC, *mcr-1*, *mecA/C*, *mecA/C* and MREJ (MRSA), NDM, OXA-48-like, *vanA/B* and VIM

### III Intended Use/Indications for Use:

#### A Intended Use(s):

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 calcoaceticusbaumannii* 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 assay on FilmArray systems. FilmArray BCID2 Control Panel M416 is composed of synthetic DNA specifically designed for and intended to be used solely with the BioFire BCID2 Panel assay. This product is not intended to replace manufacturer controls provided with the device.

#### B Indication(s) for Use:

See Intended Use.

#### C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

For *in vitro* diagnostic use only

#### D Special Instrument Requirements:

The FilmArray BCID2 Control Panel was evaluated on the FilmArray 2.0 instrument.

### IV Device/System Characteristics:

## A Device Description:

FilmArray BCID2 Control Panel M416, P/N M416, is a quality control panel consisting of 2 controls, FilmArray BCID2 Positive Control, P/N M41718, and FilmArray BCID2 Negative Control, P/N M41818. The Positive Control contains non-infectious surrogate control material; a solution of synthetic DNA in buffers, stabilizers and preservatives. The DNA in the Positive Control carries nucleic acid corresponding to the genome segments of all the pathogens and antimicrobial resistance genes detected and identified by the BioFire Blood Culture Identification 2 (BCID2) Panel assay (see table below) on the FilmArray systems. The Negative Control contains only buffers, stabilizers and preservatives. Each liquid control of FilmArray BCID2 Control Panel M416 is processed separately according to BioFire BCID2 Panel assay manufacturer's Instructions for Use for patient samples (positive blood cultures) obtained from individuals suspected of sepsis. Each tube of control contains sufficient liquid for a single use.

## B Pathogens and antimicrobial resistance genes found in FilmArrayBCID2 Control Panel M416, detected by BioFire BCID2 Panel assay.

Antimicrobial resistance genes	
CTX-M	<i>mecA/C</i> and MREJ (MRSA)
IMP	NDM
KPC	OXA-48-like
<i>mcr-1</i>	<i>vanA/B</i>
<i>mecA/C</i>	VIM
Gram Positive Bacteria	
<i>Enterococcus faecalis</i>	<i>Streptococcus</i> spp.
<i>Enterococcus faecium</i>	<i>Streptococcus agalactiae</i> (Group B)
<i>Listeria monocytogenes</i>	<i>Streptococcus pneumoniae</i>
<i>Staphylococcus</i> spp.	<i>Streptococcus pyogenes</i> (Group A)
<i>Staphylococcus aureus</i>	
<i>Staphylococcus epidermidis</i>	
<i>Staphylococcus lugdunensis</i>	
Gram Negative Bacteria	
<i>Acinetobacter calcoaceticus-baumannii</i> complex	Enteric bacteria
<i>Bacteroides fragilis</i>	<i>Enterobacter cloacae</i> complex
<i>Haemophilus influenzae</i>	<i>Escherichia coli</i>
<i>Neisseria meningitidis</i>	<i>Klebsiella aerogenes</i>
<i>Pseudomonas aeruginosa</i>	<i>Klebsiella oxytoca</i>
<i>Stenotrophomonas maltophilia</i>	<i>Klebsiella pneumoniae</i> group
	<i>Salmonella</i> spp
	<i>Serratia marcescens</i>
Yeast	
<i>Candida albicans</i>	<i>Candida parapsilosis</i>
<i>Candida auris</i>	<i>Candida tropicalis</i>
<i>Candida glabrata</i>	<i>Cryptococcus neoformans/gattii</i>
<i>Candida krusei</i>	

**C Principle of Operation:**

Not applicable

**V Substantial Equivalence Information:**

**A Predicate Device Name(s):**

FilmArray Pneumonia/Pneumoniaplus Control

**B Predicate 510(k) Number(s):**

K190222

**C Comparison with Predicate(s):**

Device & Predicate Device(s):	K200010	K190222
Device Trade Name	FilmArray BCID2 Control Panel M416	FilmArray Pneumonia/Pneumoniaplus Control
General Device Characteristic Similarities		
Intended Use/ Indications For Use	<p>FilmArray BCID2 Control Panel M416 is intended for use as an external positive and negative assayed quality control to monitor the performance of <i>in vitro</i> laboratory nucleic acid testing procedures for the qualitative detection of antimicrobial resistance genes: CTX-M, IMP, KPC, <i>mcr-1</i>, <i>mecA/C</i>, <i>mecA/C</i> and MREJ (MRSA), NDM, OXA-48-like, vanA/B, VIM; Gram positive and Gram-negative bacteria: <i>Enterococcus faecalis</i>, <i>Enterococcus faecium</i>, <i>Listeria monocytogenes</i>, <i>Staphylococcus</i> spp., <i>Staphylococcus aureus</i>, <i>Staphylococcus epidermidis</i>, <i>Staphylococcus lugdunensis</i>, <i>Streptococcus</i> spp., <i>Streptococcus agalactiae</i> (Group B), <i>Streptococcus pneumoniae</i>, <i>Streptococcus pyogenes</i> (Group A), <i>Acinetobacter calcoaceticus baumannii</i> complex, <i>Bacteroides fragilis</i>, Enteric bacteria, <i>Enterobacter cloacae</i> complex, <i>Escherichia coli</i>, <i>Klebsiella aerogenes</i>, <i>Klebsiella oxytoca</i>, <i>Klebsiella pneumoniae</i> group,</p>	<p>FilmArray Pneumonia/Pneumoniaplus Control is intended for use as an external positive and negative assayed quality control to monitor performance of <i>in vitro</i> laboratory nucleic acid testing procedures for the qualitative detection of bacteria: <i>Acinetobacter calcoaceticus-baumannii</i> complex, <i>Enterobacter cloacae</i> complex, <i>Escherichia coli</i>, <i>Haemophilus influenzae</i>, <i>Klebsiella aerogenes</i>, <i>Klebsiella oxytoca</i>, <i>Klebsiella pneumoniae</i> group, <i>Moraxella catarrhalis</i>, <i>Proteus</i> spp., <i>Pseudomonas aeruginosa</i>, <i>Serratia marcescens</i>, <i>Staphylococcus aureus</i>, <i>Streptococcus agalactiae</i>, <i>Streptococcus pneumoniae</i>, <i>Streptococcus pyogenes</i>, <i>Chlamydia pneumoniae</i>, <i>Legionella pneumophila</i>, <i>Mycoplasma pneumoniae</i>; antimicrobial resistance genes: CTX-M, IMP, KPC, <i>mecA/C</i> and MREJ, NDM, OXA-48 like, VIM; and viruses: Adenovirus, Coronavirus, Human Metapneumovirus, Human Rhinovirus/Enterovirus, Influenza A, Influenza B, Middle East Respiratory Syndrome Coronavirus (MERS-CoV), Parainfluenza Virus and Respiratory Syncytial Virus on the FilmArray</p>

	<p><i>Proteus</i> spp., <i>Salmonella</i> spp., <i>Serratia marcescens</i>, <i>Haemophilus influenzae</i>, <i>Neisseria meningitidis</i>, <i>Pseudomonas aeruginosa</i> and <i>Stenotrophomonas maltophilia</i>; and yeast pathogens: <i>Candida albicans</i>, <i>Candida auris</i>, <i>Candida glabrata</i>, <i>Candida krusei</i>, <i>Candida parapsilosis</i>, <i>Candida tropicalis</i>, and <i>Cryptococcus neoformans/gattii</i> on the BioFire Blood Culture Identification 2 (BCID2) Panel assay on FilmArray systems. FilmArray BCID2 Control Panel M416 is composed of synthetic DNA specifically designed for and intended to be used solely with the BioFire BCID2 Panel assay. This product is not intended to replace manufacturer controls provided with the device.</p>	<p>Pneumonia Panel or Pneumonia Panel plus assays performed on FilmArray systems. FilmArray Pneumonia/ Pneumoniaplus Control is composed of synthetic DNA and RNA specifically designed for and intended to be used solely with the FilmArray Pneumonia Panel and FilmArray Pneumonia Panel plus assays. This product is not intended to replace manufacturer controls provided with the device.</p>
Physical format	Ready-to-Use Liquid	Same
Directions for Use	Process like patient sample	Same
Number of targets monitored in one assay	Multiple, >30 targets	Same
<b>General Device Characteristic Differences</b>		
Targets	<p>CTX-M, IMP, KPC, <i>mcr-1</i>, <i>mecA/C</i>, <i>mecA/C</i> and MREJ (MRSA), NDM, OXA-48-like, vanA/B, VIM; Gram positive and Gram-negative bacteria: <i>Enterococcus faecalis</i>, <i>Enterococcus faecium</i>, <i>Listeria monocytogenes</i>, <i>Staphylococcus</i> spp., <i>Staphylococcus aureus</i>, <i>Staphylococcus epidermidis</i>, <i>Staphylococcus lugdunensis</i>, <i>Streptococcus</i> spp., <i>Streptococcus agalactiae</i> (Group B), <i>Streptococcus pneumoniae</i>, <i>Streptococcus pyogenes</i> (Group A), <i>Acinetobacter calcoaceticus baumannii</i> complex, <i>Bacteroides fragilis</i>, Enteric bacteria, <i>Enterobacter cloacae</i> complex, <i>Escherichia coli</i>, <i>Klebsiella aerogenes</i>, <i>Klebsiella oxytoca</i>, <i>Klebsiella pneumoniae</i> group, <i>Proteus</i> spp., <i>Salmonella</i> spp., <i>Serratia marcescens</i>, <i>Haemophilus influenzae</i>, <i>Neisseria</i></p>	<p><i>Acinetobacter calcoaceticus-baumannii</i> complex, <i>Enterobacter cloacae</i> complex, <i>Escherichia coli</i>, <i>Haemophilus influenzae</i>, <i>Klebsiella aerogenes</i>, <i>Klebsiella oxytoca</i>, <i>Klebsiella pneumoniae</i> group, <i>Moraxella catarrhalis</i>, <i>Proteus</i> spp., <i>Pseudomonas aeruginosa</i>, <i>Serratia marcescens</i>, <i>Staphylococcus aureus</i>, <i>Streptococcus agalactiae</i>, <i>Streptococcus pneumoniae</i>, <i>Streptococcus pyogenes</i>, <i>Chlamydia pneumoniae</i>, <i>Legionella pneumophila</i>, <i>Mycoplasma pneumoniae</i>; antimicrobial resistance genes: CTX-M, IMP, KPC, <i>mecA/C</i> and MREJ, NDM, OXA-48 like, VIM; and viruses: Adenovirus, Coronavirus, Human Metapneumovirus, Human Rhinovirus/Enterovirus, Influenza A, Influenza B, Middle East Respiratory Syndrome Coronavirus (MERS-CoV), Parainfluenza Virus and Respiratory Syncytial Virus</p>

	<i>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</i>	
Composition	Synthetic DNA transcripts	Synthetic DNA, and RNA transcripts

**VI Standards/Guidance Documents Referenced:**

None Referenced

**VII Performance Characteristics (if/when applicable):**

**A Analytical Performance:**

1. Precision/Reproducibility:

A multi-site reproducibility study was performed with the FilmArray BCID2 Control Panel on FilmArray instrument 2.0 and FilmArray Torch systems. Testing consisted of three positive and three negative controls run per day and spanned a period of 10 different days. Multiple operators participated in testing at each of the three locations. Three lots each of external control material and three lots of BioFire BCID2 Panel pouch lots were tested across all sites, a total of 185 external controls were tested. Of the 185 controls tested, 2 gave an Invalid result and were retested according to BioFire Instructions for Use. Correct results were obtained for the retests. The Invalids were not included in the Percent Correct analysis in the table below. Out of 183 tests with valid pouch controls, the correct analytes were detected (for positive controls) or not detected (for negative controls) in 180 tests, for an overall correct call rate of 98%. Additional precision data can be found in the product labeling.

The results suggest that there are no significant differences between different users and different sites on different days. External reproducibility studies for the FilmArray BCID2 Control Panel are acceptable.

*Precision*

An internal precision study for the FilmArray BCID2 Control Panel was conducted over twenty different days by testing three FilmArray BCID2 Control Panel lots with three BioFire BCID2 Panel assay lots performed by four operators using two FilmArray 2.0 instruments. All controls gave correct results except for 2 positive controls which gave false negative results and upon retesting gave the correct result. The results are shown in the table below:

**Table: FilmArray BCID2 Control Precision Summary**

Category	#expected results/ #tested <sup>1</sup>	Overall Percent Agreement	95% Confidence Interval
FilmArray BCID2BCID2 Negative Control	60/60	100%	94% to 100%
FilmArray BCID2BCID2 Positive Control	60/62*	96.8%	89% to 99.1%

<sup>1</sup>Expected result for the FilmArray BCID2 Positive Control is positive. Expected result for the FilmArray BCID2 Negative Control is negative.

\* Two Positive controls gave initial false negative results, all produced the correct results upon a single retest

There appears to be no significant differences in mean Cp value when testing different control lots on different days. Precision studies are acceptable.

#### *Within-run Testing*

Within-run precision was demonstrated in a separate study conducted by one operator testing one lot of FilmArray BCID2 Control with one lot of BioFire BCID2 pouches on the FilmArray 2.0, each within one day. The results are shown in the tables below:

**Table: FilmArray BCID2 Control Panel Summary of Within-run Precision**

Control	#expected results/ #tested <sup>1</sup>	Overall Percent Agreement	95% Confidence Interval
FilmArray BCID2 Positive Control	6/6	100%	61%-100%
FilmArray BCID2 Negative Control	6/6	100%	61%-100%

<sup>1</sup>Expected result for the FilmArray BCID2 Positive Control is positive. Expected result for the FilmArray BCID2 Negative Control is negative.

Within-run reproducibility studies for the FilmArray BCID2 Control are acceptable.

#### *Lot-to-Lot Testing*

Lot-to-lot reproducibility was demonstrated by testing three lots of FilmArray BCID2 Positive Control using the same pouch lot. Results are shown in the following tables.

**Table: FilmArray BCID2 Control Panel Summary of Lot-to-Lot Reproducibility**

Summary of Lot-to-Lot Testing			
Control Lot #	Number of Tests	Pouch Lot	Correct Results
C19JUN19A	6	604119	6/6
D20JUN19A	6	604119	6/6
B24JUN19A	6	604119	6/6

Lot-to-Lot reproducibility studies for the FilmArray BCID2 Control Panel are acceptable. Additional data is provided in the product labeling.

2. Linearity:

Not applicable

3. Analytical Specificity/Interference:

Not applicable

4. Assay Reportable Range:

Not applicable

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

*Open Vial Stability*

Not applicable because FilmArray BCID2 Control is packaged for single use.

*Real-Time Stability Program*

Real-time stability studies are ongoing to support product claims and to monitor potential assay modifications for which the FilmArray BCID2 Control is indicated for use. Real-time stability study protocols and acceptance criteria were reviewed and found to be acceptable.

*Shipping Stability*

MMQCI ships the FilmArray BCID2 Control on dry ice with overnight delivery (U.S.) or 4-7 days (ex-U.S.), ensuring that the control material remains cold upon receipt. The control material is then expected to be stored at 2-8°C upon receipt, as indicated in the FilmArray BCID2 Control package insert. A shipping study was performed to confirm the shipping process and to investigate the outcome of a possible shipping delay and consequent arrival with the gel packs no longer frozen or cold. The study evaluated two lots of the FilmArray BCID2 Positive control that was placed with 2 frozen gel packs. After 2 days, some vials were returned to the refrigerator at 2-8°C, and subsequently tested using the BioFire BCID2 Panel assay, thus representing usual customer receipt of product. To simulate a shipping delay, the remaining 'shipped' vials from the 2 lots of the FilmArray BCID2 Positive Control were removed from the shipping box after 2 days and stored for up to 6 days at ambient room temperature. The vials were then returned to the refrigerator and subsequently tested using the BioFire BCID2 Panel assay.

The study demonstrated that the FilmArray BCID2 Positive Control is stable for two days on frozen gel packs in MMQCI's standard shipping box. FilmArray BCID2 Positive Control is stable after six days at ambient temperatures of approximately 19-21°C. The FilmArray BCID2 Positive Control should be stored frozen (2-8°C) as indicated in the package insert.



6. Detection Limit:

Not applicable

7. Assay Cut-Off:

Not applicable

**B Comparison Studies:**

1. Method Comparison with Predicate Device:

Not applicable

2. Matrix Comparison:

The matrix of the FilmArray BCID2 Control Panel is synthetic, which allows for reproducible manufacturing, stability, provides a non-infectious material for the laboratory staff and carries the control DNA through the extraction process. Since the matrix is not identical to that of the routine BCID2 assay sample, blood culture media, a test was performed to investigate the effect of the matrix on the assay.

To confirm that the matrix has no effect on the assay or control, genomic DNA *Streptococcus pneumoniae* was spiked into the FilmArray BCID2 Negative Control, which contains the identical matrix found in the FilmArray BCID2 Positive Control, and tested in triplicate with the BioFire BCID2 assay. The same inactivated pathogen was spiked into BD BACTEC Ped. Plus/F Culture Vial with negative whole blood to simulate a clinical sample, which will also be tested in triplicate with the BioFire BCID2 assay.

Results demonstrated that samples prepared with FilmArray BCID2 Control whole blood showed no inhibition and/or false negative results.

**C Clinical Studies:**

1. Clinical Sensitivity:

Not applicable

2. Clinical Specificity:

Not applicable

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

Not applicable

**D Clinical Cut-Off:**

Not applicable

**E Expected Values/Reference Range:**

FilmArray BCID2 Control is a qualitative control and the expected results are listed in the tables below.

**Tables: FilmArray BCID2 Positive & Negative Result Summary**

Result Summary		
	Positive Control	Negative Control
<b>Antimicrobial resistance genes</b>		
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
<b>Gram Positive Bacteria</b>		
<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
<b>Gram Negative Bacteria</b>		
<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

<b>Result Summary</b>		
<i>Pseudomonas aeruginosa</i>	Detected	Not Detected
<i>Stenotrophomonas maltophilia</i>	Detected	Not Detected
<b>Yeast</b>		
<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

**VIII Proposed Labeling:**

The labeling supports the finding of substantial equivalence for this device.

**IX Conclusion:**

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.