

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

**A. 510(k) Number:**

K163522

**B. Purpose for Submission:**

To obtain a substantial equivalence determination for the FilmArray Warrior Control Panel M290.

**C. Measurand:**

Multi-analyte quality control materials

**D. Type of Test:**

FilmArray Warrior Control Panel M290 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, FilmArray NGDS Warrior Panel assay on the FilmArray 2.0 instrument, which detects biothreat pathogens: *Bacillus anthracis*, *Coxiella burnetii*, *Francisella tularensis*, *Yersinia pestis*, Ebola Virus and Marburg Virus.

**E. Applicant:**

Maine Molecular Quality Controls, Inc. (MMQCI)

**F. Proprietary and Established Names:**

FilmArray Warrior Control Panel M290

**G. Regulatory Information:**

1. Regulation section:

21 CFR 866.3920, Assayed quality control material for clinical microbiology assays

2. Classification:

Class II (Special Controls)

3. Product code:

PMN

4. Panel:

83- Microbiology

**H. Indication(s) for use:**

1. Indications for use(s):

FilmArray Warrior Control Panel M290 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 *Bacillus anthracis* (Chromosomal element, pXO1, pXO2), *Coxiella burnetii*, *Francisella tularensis*, *Yersinia pestis*, Ebola virus and Marburg virus on the FilmArray NGDS Warrior Panel performed on FilmArray 2.0 systems. FilmArray Warrior Control Panel M290 is composed of synthetic DNA specifically designed for and intended to be used solely with the FilmArray NGDS Warrior Panel assay. This product is not intended to replace manufacturer internal FilmArray NGDS Warrior Panel controls provided with the device.

2. Special conditions for use statement(s):

For *in vitro* diagnostic use only

For prescription use only

3. Special instrument requirements:

FilmArray Warrior Control Panel M290 was evaluated on FilmArray 2.0 instrument.

**I. Device Description:**

FilmArray Warrior Control Panel M290 is a quality control panel consisting of two Controls: FilmArray Warrior Positive Control and FilmArray Warrior Negative Control. The Positive Control contains non-infectious surrogate control material; a solution of synthetic DNA in buffers, stabilizers and preservatives. The DNA carries segments of all biothreat agents detected by the FilmArray NGDS Warrior Panel assay (see Table below) on FilmArray 2.0 systems. The Negative Control is comprised of non-specific DNA in buffers, stabilizers and preservatives. Each liquid control of FilmArray Warrior Control Panel M290 is processed separately according to FilmArray NGDS Warrior Panel assay manufacturer's Instructions for Use for Blood Samples.

The FilmArray Warrior Control Panel M290 is prepared nucleic acid concentrations of 5X-10X LoD for each of the organisms detected by the FilmArray NGDS Warrior Panel assay.

<b>Biothreat pathogens detected by FilmArray NGDS Warrior Panel</b>
<i>Bacillus anthracis</i> : Chromosomal element, pXO1, pXO2
<i>Coxiella burnetii</i>
<i>Francisella tularensis</i>
<i>Yersinia pestis</i>
<i>Ebola Virus</i>
<i>Marburg Virus</i>

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

FilmArray RP EZ Control Panel M265

2. Predicate 510(k) number(s):

K161573

3. Comparison with predicate:

Similarities		
Item	FilmArray Warrior Control Panel M290 (K163522)	FilmArray RP EZ Control Panel M265 (K161573)
Intended Use	FilmArray Warrior Control Panel M290 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 <i>Bacillus anthracis</i> (Chromosomal element, pXO1, pXO2), <i>Coxiella burnetii</i> , <i>Francisella tularensis</i> , <i>Yersinia pestis</i> , Ebola virus and Marburg virus on the FilmArray NGDS Warrior Panel performed on FilmArray 2.0 systems. FilmArray Warrior Control Panel M290 is composed of synthetic DNA specifically designed for and intended to be used solely with the FilmArray NGDS Warrior Panel assay. This product is not intended to replace manufacturer internal FilmArray NGDS Warrior Panel controls provided with the device.	FilmArray RP EZ Control Panel M265 is intended for use as external positive and negative, surrogate assayed quality control materials to monitor the performance of in vitro laboratory nucleic acid testing procedures for the qualitative detection of Adenovirus, Coronavirus, Human Metapneumovirus, Human Rhinovirus/ Enterovirus, Influenza A, Influenza A subtype H1, Influenza A subtype H3, Influenza A subtype H1-2009, Influenza B, Parainfluenza Virus, Respiratory Syncytial Virus, <i>Bordetella pertussis</i> , <i>Chlamydomphila pneumoniae</i> , and <i>Mycoplasma pneumoniae</i> on the FilmArray RP EZ assay performed on the FilmArray systems. The control panel also contains a negative control. This product is not intended to replace manufacturer controls provided with the device.
Physical format	Ready-to-Use Liquid	Same
Directions for Use	Process like patient Sample	Same
Composition	Synthetic DNA	Synthetic RNA transcripts
Number of targets monitored in one assay	Multiple	Same

Differences		
Item	FilmArray RP EZ Control Panel M265 (K163522)	FilmArray RP EZ Control Panel M265 (K161573)
Assay Steps Monitored	Amplification, detection, identification	Same plus reverse transcription

**K. Standard/Guidance Document Referenced (if applicable):**

None were referenced

**L. Test Principle:**

Not applicable

**M. Performance Characteristics (if/when applicable):**

1. External Site Testing:

Performance characteristics of the FilmArray Warrior Control Panel M290 on the FilmArray instrument 2.0 were evaluated at five clinical laboratory sites. Testing was conducted by multiple operators for over a six month period, consisting of three lots of FilmArray Warrior Control Panel M290 and nine FilmArray Warrior Panel pouch lots. A total of 310 external controls were tested (163 positive and 147 negative). The results are shown in the table below:

Summary of External Test Results								
External Site	Total Tests	Percent Total Correct Results	Correct Positive Control Result	Incorrect Positive Control Result	Percent Correct Positive Control	Correct Negative Control Result	Incorrect Negative control Result	Percent Correct Negative Control
A	41	100%	20	0	100%	21	0	100%
B	104	99.1%	58	1	98.3%	45	0	100%
C	51	100%	26	0	100%	25	0	100%
D	60	100%	31	0	100%	29	0	100%
E	54	98.1%	26	1	96.3%	27	0	100%
All Sites	310	99.4%	161	2	98.8%	147	0	100%

2. Analytical performance:

a. *Precision:*

An internal precision study for the FilmArray Warrior Control Panel M290 was conducted over multiple days by testing three FilmArray Warrior Control Panel M290 lots with four FilmArray Warrior Panel assay lots performed by three operators. The results are shown in the table below:

<b>FilmArray Warrior Control Panel Summary of Internal Precision Test Results</b>						
<b>Control</b>	<b>Control Lot #</b>	<b>No. of Tests</b>	<b>Invalid</b>	<b>Correct Results</b>	<b>Incorrect Results</b>	<b>Percent Correct<sup>1</sup></b>
FilmArray Warrior Positive Control	C18MAR16	20	0	20	0	100%
FilmArray Warrior Negative Control	A02NOV15	20	0	20	0	100%
FilmArray Warrior Positive Control	C01JUL16	20	0	20	0	100%
FilmArray Warrior Negative Control	B01JUL16	21	1	20	0	100%
FilmArray Warrior Positive Control	B15JUL16	22	2	20	0	100%
FilmArray Warrior Negative Control	A15JUL16	21	1	20	0	100%
	<b>TOTAL</b>	<b>124</b>	<b>4</b>	<b>120</b>	<b>0</b>	<b>100 %</b>

<sup>1</sup>The 4 Invalid samples were re-tested according to BioFire instructions and were not included in the Percent Correct analysis.

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

*b. Linearity/Assay Reportable Range:*

Not applicable

*c. Lot-to-Lot Testing:* A subset of testing in the internal precision study was used to demonstrate Lot-to-lot reproducibility by testing 3 lots of FilmArray Warrior Control Panel M290 using the same pouch lot on the same instrument at MMQCI. The results are shown in the table below:

<b>FilmArray Warrior Control Panel Summary of Lot-to-Lot Testing</b>				
<b>Control</b>	<b>Control Lot #</b>	<b>Number of Tests</b>	<b>Pouch Lot</b>	<b>Correct Results</b>
FilmArray Warrior Positive Control	C18MAR16	7	160314	7/7
FilmArray Warrior Negative Control	A02NOV15	7	160314	7/7
FilmArray Warrior Positive Control	C01JUL16	7	160314	7/7
FilmArray Warrior Negative Control	B01JUL16	8 (1 Invalid)	160314	7/7
FilmArray Warrior Positive Control	B15JUL16	7	160314	7/7
FilmArray Warrior Negative Control	A15JUL16	7	160314	7/7

*d. Within-run Testing:*

Within-run reproducibility was demonstrated in a separate study conducted by one operator testing one lot each of FilmArray Warrior Positive Control and FilmArray Warrior Negative Control with one lot of NGDS Warrior Panel pouches on the FilmArray 2.0, each within one day at MMQCI.

<b>FilmArray Warrior Control Panel Summary of Within-run Reproducibility Results</b>				
<b>Control</b>	<b>Control Lot#</b>	<b>Number of Tests</b>	<b>Pouch Lot</b>	<b>Correct Results</b>
FilmArray Warrior Positive Control	C01JUL16	6	151216	6/6
FilmArray Warrior Negative Control	B01JUL16	6	151216	6/6

Within-run reproducibility studies for the FilmArray Warrior Control Panel M290 are acceptable.

e. *Linearity/assay reportable range:*

Not applicable

f. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

*Traceability:*

Not applicable

*Stability:*

*Open Vial Stability:* Not applicable because FilmArray Warrior Control Panel M290 is packaged for single use.

*Closed Vial Real-time Stability:* An accelerated stability study was performed to establish the shelf life stability claims for the FilmArray Warrior Control Panel M290. Based on this study, the FilmArray Warrior Control Panel M290 is expected to be stable until the expiration date (12 months) when stored frozen (-20°C or colder) and unopened. This product is 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 Warrior Control Panel M290 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 Warrior Control Panel M290 on dry ice with overnight delivery, ensuring that the control material remains frozen upon receipt. The frozen control material is then to be stored at -20°C, as indicated in the FilmArray Warrior Control Panel M290 Package insert. A shipping study was performed to confirm the shipping process and to investigate the outcome of a possible shipping delay and subsequent arrival with no dry ice. The study evaluated two (2) lots of the FilmArray Warrior Positive Control placed in dry ice and was stored for five (5) days at ambient temperature then tested using the FilmArray Warrior Panel Assay. To simulate a shipping delay, two (2) lots of the FilmArray

Warrior Positive Control were stored for up to 5 days at ambient temperature and tested using the FilmArray Warrior Panel Assay.

The study demonstrated that the FilmArray Warrior Control Panel M290 is stable for two (2) days on dry ice in MMQCI's standard shipping box. FilmArray Warrior Positive Control is stable after five (5) days at ambient temperatures of approximately 19-21°C. The FilmArray Warrior Positive Control should be stored frozen (–20°C or colder) as indicated in the package insert.

*Expected Values:*

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

**FilmArray Warrior Control Panel M290 Result Summary**

<b>FilmArray Warrior Positive Control</b>	
<i>Bacillus anthracis</i>	Detected
pXO1	Detected
pXO2	Detected
<i>Coxiella burnetii</i>	Detected
<i>Francisella tularensis</i>	Detected
<i>Yersinia pestis</i>	Detected
Ebola virus	Detected
Marburg virus	Detected
<b>FilmArray Warrior Negative Control</b>	
<i>Bacillus anthracis</i>	Not Detected
pXO1	Not Detected
pXO2	Not Detected
<i>Coxiella burnetii</i>	Not Detected
<i>Francisella tularensis</i>	Not Detected
<i>Yersinia pestis</i>	Not Detected
Ebola virus	Not Detected
Marburg virus	Not Detected

*Matrix Effects:*

A study was performed to evaluate potential matrix effects of the FilmArray Warrior Control Panel M290. To confirm that clinical matrix (blood) does not significantly affect the results of the FilmArray NGDS Warrior Panel assay, inactivated *Francisella tularensis* was spiked into the FilmArray Warrior Negative Control, which contains the identical matrix found in the FilmArray Warrior Positive Control, and whole blood to simulate a clinical sample. Both sample types were tested in triplicate by the FilmArray NGDS Warrior Panel assay.

Results demonstrated that the FilmArray Warrior Control Panel M290 matrix has no effect on the assay. Study results are shown in the table below:

Biothreat Pathogen Analyte	Spiked <i>Francisella tularensis</i> Crossing Point (Cp) Data									
		Whole Blood			Mean Cp	MMQCI Matrix			Mean Cp	
FTT2	Positive	22.4	21.2	22.0	21.9	Positive	21.5	21.1	22.2	21.6
FTT3	Positive	27.0	27.0	27.0	27.0	Positive	23.8	27.0	25.0	25.3
PCR2	Positive	18.3	18.2	18.5	18.3	Positive	18.3	18.2	18.1	18.2
YeastRNA	Positive	17.7	20.9	18.7	19.1	Positive	18.9	20.8	19.0	19.6

g. *Detection limit:*

Not applicable

h. *Analytical Reactivity (Inclusivity):*

Not applicable

i. *Cross Reactivity:*

Not applicable

j. *Interference:*

Not applicable

k. *Assay cut-off:*

Not applicable.

3. Comparison studies:

a. *Method comparison with predicate device:*

Not applicable.

4. Clinical Studies:

a. *Clinical Sensitivity:*

Not applicable

b. *Clinical specificity:*

Not applicable

*c. Other clinical supportive data (when a. and b. are not applicable):*

Not applicable.

5. Clinical cut-off:

Not Applicable

**N. Proposed Labeling:**

The labeling is sufficient and satisfies the requirements of 21 CFR Parts 801 and 809 and the special controls for this device type.

**O. Conclusion:**

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