510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K220870

B Applicant

BioFire Defense, LLC

C Proprietary and Established Names

BioFire Global Fever Panel, BIOFIRE SHIELD Control Kit for the BioFire Global Fever Panel

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
QMV	Class II	21 CFR 866.3966 - Device To Detect And Identify Selected Microbial Agents That Cause Acute Febrile Illness	MI - Microbiology
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 both the BioFire Global Fever Panel and the BIOFIRE SHIELD Control Kit for the Global Fever Panel on the FilmArray Torch instrument system.

B Measurand:

The BioFire Global Fever Panel detects and identifies the following pathogens: Chikungunya virus, Dengue virus, *Leptospira* spp., and *Plasmodium* spp., including species differentiation between *P. falciparum* and *P. vivax/ovale.*

C Type of Test:

The BioFire Global Fever Panel is a multiplexed nucleic acid-based test for the detection and identification of six pathogens which cause acute febrile illness (AFI) from whole blood specimens on BioFire FilmArray systems.

III Intended Use/Indications for Use:

A Intended Use(s):

BioFire Global Fever Panel Intended Use:

The BioFire Global Fever Panel is a qualitative, multiplexed, nucleic acid-based in vitro diagnostic test intended for use with BioFire FilmArray 2.0 and BioFire FilmArray Torch Systems. The BioFire Global Fever Panel detects and identifies selected bacterial, viral, and protozoan nucleic acids directly from EDTA whole blood collected from individuals with signs and/or symptoms of acute febrile illness or recent acute febrile illness and known or suspected exposure to the following target pathogens: chikungunya virus, dengue virus (serotypes 1, 2, 3 and 4), *Leptospira* spp., and *Plasmodium* spp. (including species differentiation of *Plasmodium falciparum* and *Plasmodium vivax/ovale*). Evaluation for more common causes of acute febrile illness (e.g., infections of the upper and lower respiratory tract or gastroenteritis, as well as non-infectious causes) should be considered prior to evaluation with this panel. Results are meant to be used in conjunction with other clinical, epidemiologic, and laboratory data, in accordance with the guidelines provided by the relevant public health authorities.

Positive results do not rule out co-infections with pathogens not included on the BioFire Global Fever Panel. Not all pathogens that cause acute febrile illness are detected by this test, and negative results do not rule out the presence of other infections. In the United States, patient travel history and consultation of the CDC Yellow Book should be considered prior to use of the BioFire Global Fever Panel as some pathogens are more common in certain geographical locations.

BIOFIRE SHIELD Control Kit for the BioFire Global Fever Panel Intended Use:

The BIOFIRE SHIELD Control Kit for the BioFire Global Fever Panel contains Positive and Negative External Controls intended for use as assayed quality controls to monitor the performance of in vitro diagnostic laboratory nucleic acid testing procedures for the qualitative detection of chikungunya virus, dengue virus (serotypes 1, 2, 3, and 4), *Leptospira* spp., and *Plasmodium* spp. (including species differentiation of *Plasmodium falciparum* and *Plasmodium vivax/ovale*) when using the BioFire Global Fever Panel on BioFire FilmArray 2.0 and BioFire FilmArray Torch Systems. The BIOFIRE SHIELD Control Kit for the BioFire Global Fever Panel is designed for and intended to be used solely with the BioFire Global Fever Panel. This product does not replace manufacturer internal controls provided as part of the BioFire Global Fever Panel device.

Both the Positive and Negative External Controls are provided in a FilmArray Control Injection Vial format. The Positive Control Injection Vial contains dried synthetic DNA segments in buffer and stabilizer to assess the presence of each individual assay on the BioFire Global Fever Panel. The Negative Control Injection Vial contains no DNA and is non-reactive with the BioFire Global Fever Panel assays.

B Indication(s) for Use:
Same as 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 Global Fever Panel and the BIOFIRE SHIELD Control Kit for the BioFire Global Fever Panel are for use with the FilmArray 2.0 or FilmArray Torch instrument systems.

IV Device/System Characteristics:

A Device Description:

The BioFire Global Fever Panel is a multiplexed nucleic acid-based test for the detection and identification of six pathogens which cause acute febrile illness (AFI) from whole blood specimens on BioFire FilmArray systems. The BioFire Global Fever Panel detects and identifies the following pathogens: chikungunya virus, dengue virus, *Leptospira* spp., and *Plasmodium* spp., including species differentiation between *P. falciparum* and *P. vivax/ovale*. The FilmArray Global Fever Panel simultaneously conducts six tests for the identification of bacterial, viral, and protozoan organisms from whole blood specimens collected in EDTA tubes. Results from the FilmArray Global Fever Panel are available within about one hour.

The BioFire Global Fever Panel was previously cleared under DEN200043 for use with BioFire FilmArray 2.0 systems. Please refer to DEN200043 for additional information regarding the BioFire Global Fever Panel. In this 510(k) submission, the FilmArray Torch system is being added as an additional instrument system for use with the BioFire Global Fever Panel. The FilmArray Torch is a modular configuration of the FilmArray 2.0 that minimizes instrument footprint by stacking up to twelve individual FilmArray Torch Modules on top of a single FilmArray Torch System Base.

The BIOFIRE SHIELD Control Kit for the BioFire Global Fever Panel is an assayed quality control intended for monitoring the diagnostic performance of the BioFire Global Fever Panel. The Control Kit consists of Positive and Negative External Controls in a FilmArray Control Injection Vial format. The Positive External Control contains external assayed quality control material consisting of a set of non-infectious DNA segments dried on the filter of a FilmArray Control Injection Vial and detected by the Global Fever Panel. Analysis of the controls is carried out by specific pouch modules that are included in the BioFire Global Fever Panel Pouch Module Package. The Positive External Control has been optimized to be detected by all pathogen assays contained in the Global Fever Panel (Table 1). The Negative External Control

contains no nucleic acid, and a successful run will be negative for all assays on the panel. These controls are not intended to replace the internal FilmArray Global Fever Panel pouch controls (RNA process control and second stage PCR array control). The Global Fever Panel External Control Kit contains no biological hazards and is 100% non-infectious.

Table 1: Pathogens Detected by the FilmArray Global Fever Panel

Disease	Pathogen Assay Result	Type
Leptospirosis	*Leptospira* spp.	Bacterial
Malaria	*Plasmodium* spp. *Plasmodium falciparum* *Plasmodium vivax/ovale*	Protozoan
Chikungunya fever	Chikungunya virus	Viral
Dengue fever	Dengue virus	

The BioFire SHIELD Control Kit for the Global Fever Panel was previously cleared for use with FilmArray 2.0 instrument system under K202382 as the FilmArray Global Fever Panel External Control Kit. The information contained in this 510(k) submission is provided to support equivalent performance of the external control material on the FilmArray Torch instrument system.

V Substantial Equivalence Information:

A Predicate Device Name(s):
FilmArray Global Fever Panel and FilmArray Global Fever Panel External Control Kit

B Predicate 510(k) Number(s):
DEN200043, K202382

C Comparison with BioFire Global Fever Panel

Device & Predicate Device(s):	K220870	DEN200043
Device Trade Name	BioFire Global Fever Panel	BioFire Global Fever Panel
General Device Characteristic Similarities		
Intended Use/Indications For Use	The BioFire Global Fever Panel is a qualitative, multiplexed, nucleic acid-based in vitro diagnostic test intended for use with BioFire FilmArray 2.0 and BioFire FilmArray Torch Systems. The BioFire Global Fever Panel detects and identifies selected	Same

	bacterial, viral, and protozoan nucleic acids directly from EDTA whole blood collected from individuals with signs and/or symptoms of acute febrile illness or recent acute febrile illness and known or suspected exposure to the following target pathogens: chikungunya virus, dengue virus (serotypes 1, 2, 3 and 4), *Leptospira* spp., and *Plasmodium* spp. (including species differentiation of *Plasmodium falciparum* and *Plasmodium vivax/ovale*). Evaluation for more common causes of acute febrile illness (e.g., infections of the upper and lower respiratory tract or gastroenteritis, as well as non-infectious causes) should be considered prior to evaluation with this panel. Results are meant to be used in conjunction with other clinical, epidemiologic, and laboratory data, in accordance with the guidelines provided by the relevant public health authorities. Positive results do not rule out co-infections with pathogens not included on the BioFire Global Fever Panel. Not all pathogens that cause acute febrile illness are detected by this test,	

	and negative results do not rule out the presence of other infections. In the United States, patient travel history and consultation of the CDC Yellow Book should be considered prior to use of the BioFire Global Fever Panel as some pathogens are more common in certain geographical locations.	
Specimen Type	Whole blood (collected in EDTA tube)	Same
Pathogens Detected	Chikungunya virus, dengue virus (serotypes 1, 2, 3, and 4), *Leptospira* spp., *Plasmodium* spp. (including species differentiation of *P. falciparum* and *P. vivax/ovale*.	Same
Analyte	RNA/DNA	Same
Technological Principles	Highly multiplexed, nested, nucleic acid amplification test with melt analysis	Same
Time to Result	~1 hour	Same
Test Interpretation	Automated test interpretation and report generation; user cannot access raw data	Same
Controls	Two controls are included in each reagent pouch to control for sample processing and both stages of PCR and melt analysis	Same
Assayed External Controls	BIOFIRE SHIELD Control Kit for the BioFire Global Fever Panel	Same
User Complexity	Moderate	Moderate

General Device Characteristic Differences		
Instrumentation	BioFire FilmArray 2.0 or BioFire FilmArray Torch systems	BioFire FilmArray 2.0 systems
System Configuration	Up to 12 FilmArray Torch Modules to one System and up to eight FilmArray 2.0 modules to one computer with mouse, barcode scanner, and FilmArray Pouch Loading Station.	Up to eight FilmArray 2.0 modules to one computer with mouse, barcode scanner, and FilmArray Pouch Loading Station.

Comparison with FilmArray Global Fever Panel External Control Kit

Device & Predicate Device(s):	K220870	K202382
Device Trade Name	BIOFIRE SHIELD Control Kit for the BioFire Global Fever Panel	FilmArray Global Fever Panel External Control Kit
General Device Characteristic Similarities		
Intended Use	The BIOFIRE SHIELD Control Kit for the BioFire Global Fever Panel contains Positive and Negative External Controls intended for use as assayed quality controls to monitor the performance of in vitro diagnostic laboratory nucleic acid testing procedures for the qualitative detection of chikungunya virus, dengue virus (serotypes 1, 2, 3, and 4), *Leptospira* spp., and *Plasmodium* spp. (including species differentiation of *Plasmodium falciparum* and *Plasmodium vivax/ovale*) on the	The FilmArray Global Fever Panel External Control Kit contains Positive and Negative External Controls intended for use as assayed quality controls to monitor the performance of in vitro diagnostic laboratory nucleic acid testing procedures for the qualitative detection of FilmArray Global Fever Panel targets on FilmArray 2.0 systems. The Global Fever Panel External Control Kit is designed for and intended to be used solely with the FilmArray Global Fever Panel. This product

	BioFire Global Fever Panel performed on BioFire FilmArray® 2.0 and BioFire FilmArray Torch Systems. The BIOFIRE SHIELD Control Kit for the BioFire Global Fever Panel is designed for and intended to be used solely with the BioFire Global Fever Panel. This product does not replace manufacturer internal controls provided as part of the BioFire Global Fever Panel device. Both the Positive and Negative External Controls are provided in a FilmArray Control Injection Vial format. The Positive Control Injection Vial contains dried synthetic DNA segments in buffer and stabilizer to assess the presence of each individual assay on the BioFire Global Fever Panel. The Negative Control Injection Vial contains no DNA and is non-reactive with the BioFire Global Fever Panel assays.	does not replace manufacturer internal controls provided as part of the Global Fever Panel device. Both the Positive and Negative External Controls are provided in a FilmArray Control Injection Vial format. The Positive Control Injection Vial contains dried synthetic DNA segments in buffer and stabilizer to assess the presence of each individual assay on the FilmArray Global Fever Panel. The Negative Control Injection Vial contains no DNA, and is non-reactive with the Global Fever Panel assays.
Physical Format	External control material dried on Control Injection Vial filter	Same
Composition	Tm-shifted synthetic DNA (positive control only)	Same
Targets Monitored	Chikungunya virus, dengue virus (serotypes 1, 2, 3, and 4), *Leptospira* spp., and	Same

	Plasmodium spp. (including species differentiation of *P. falciparum* and *P. vivax/ovale*.	
Test Interpretation	Automated test interpretation and report generation; user cannot access raw data	Same
Reagent Storage	Room temperature	Same
General Device Characteristic Differences		
Instrumentation	BioFire Global Fever Panel run on FilmArray 2.0 **or** FilmArray Torch systems	BioFire Global Fever Panel run on FilmArray 2.0 systems

VI Standards/Guidance Documents Referenced:

- IEC 62304:2006/A1:2016, 'Medical device software – Software life-cycle processes'
- ISO 14971:2007/(R)2010, 'Medical devices – Application of risk management to medical devices'
- ISO 15223-1:2016 'Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements'
- Assay Migration Studies for In Vitro Diagnostic Devices, Guidance for Industry and FDA Staff (April 2013)
- Bundling Multiple Devices or Multiple Indications in a Single Submission, Guidance for Industry and Food and Drug Administration Staff (June 22, 2007)
- Deciding When to Submit a 510(k) for a Change to an Existing Device, Guidance for Industry and FDA Staff (October 2017)
- General Principle of Software Validation, Final Guidance for Industry and FDA Staff (January 11, 2002)
- Guidance for Industry and Food and Drug Administration Staff – Highly Multiplexed Microbiological/Medical Countermeasure In Vitro Nucleic Acid Based Diagnostic Devices (August 27, 2014)
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, Guidance for Industry and FDA Staff (May 11, 2005)
- Off-The-Shelf Software Use in Medical Devices, Guidance for Industry and FDA Staff (September 27, 2019)
- Statistical Guidance on Reporting Results from Studies Evaluating Diagnostic Tests, FDA Guidance Document (March 13, 2007)
- Molecular Diagnostic Methods for Infectious Diseases, Clinical and Laboratory Standards Institute (CLSI) Guideline, MM03-Ed3 (February 2015)

- User Protocol for Evaluation of Qualitative Test Performance, Clinical and Laboratory Standards Institute (CLSI) Approved Guideline – Second Edition, EP12-A2 (January 2008)
- User Verification of Performance for Precision and Trueness, Clinical and Laboratory Standards Institute (CLSI) Approved Guideline – Second Edition EP15-A2 (April 2006)

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Performance of the BioFire Global Fever Panel on BioFire FilmArray Torch System

A reproducibility study was performed to establish equivalent analyte detection of the BioFire Global Fever Panel on the BioFire FilmArray 2.0 and FilmArray Torch systems. Reproducibility of BioFire Global Fever Panel test results between the two instrument systems was directly compared. The study incorporated potential variation introduced by different instruments (three), days (five), replicates (six), systems/modules, and reagent kit lots. The site variable was simulated using three different FilmArray Torch and three different FilmArray 2.0 systems.

Briefly, three contrived whole blood samples were prepared with different mixtures of panel analytes: *Leptospira interrogans*, dengue virus, and *Plasmodium falciparum*. For each analyte, one sample was spiked at a Moderate Positive (3×LoD) level, another sample at a Low Positive (1×LoD) level, and the third sample was not spiked (negative). Six aliquots (replicates) of each sample were tested on each system on five different days, providing a total of 90 replicate test results per sample per FilmArray platform. On each test day, two operators per system used three FilmArray 2.0 instruments and three FilmArray Torch modules; three BioFire Global Fever Panel pouch reagent lots were rotated daily.

Reproducibility was assessed by comparing the observed test results (Detected/Not Detected) to the expected test results (Detected for spiked samples, Not Detected for unspiked samples). The overall agreement between observed and expected results for the FilmArray 2.0 platform was 99.4% and the overall agreement for the FilmArray Torch platform was 98.9%. Detection rates and percent agreement between observed and expected test results are shown in Table 2 below.

Table 2: Reproducibility of the BioFire Global Fever Panel on FilmArray Platforms

Analyte (Source / ID)		Concentration Tested (copies/mL)	Expected Result	Detection Rate (n/N) % Agreement with Expected Result							
				FilmArray 2.0 Platform				FilmArray Torch Platform			
				System 1	System 2	System 3	All FA 2.0 Systems [95% CI]	System 1	System 2	System 3	All FA Torch Systems [95% CI]
Leptospira interrogans* serovar *icterohaemorrhagiae (ATTC / 23581)		3×LoD (1.0E+03)	Detected	30/30 100%	30/30 100%	30/30 100%	**90/90 100%** [95.9-100%]	30/30 100%	30/30 100%	30/30 100%	**90/90 100%** [95.9-100%]
		1×LoD (3.4E+02)	Detected	29/30 96.7%	29/30 96.7%	28/30 93.3%	**86/90 95.6%** [89.1-98.3%]	29/30 96.7%	28/30 93.3%	28/30 93.3%	**85/90 94.4%** [87.6-97.6%]
		Negative	Not Detected	30/30 100%	30/30 100%	30/30 100%	**90/90 100%** [95.9-100%]	30/30 100%	30/30 100%	30/30 100%	**90/90 100%** [95.9-100%]
Dengue virus DENV-2 New Guinea C (Zeptometrix / 0810089CF)		3×LoD (1.0E+03)	Detected	30/30 100%	30/30 100%	30/30 100%	**90/90 100%** [95.9-100%]	30/30 100%	30/30 100%	30/30 100%	**90/90 100%** [95.9-100%]
		1×LoD (3.4E+02)	Detected	30/30 100%	30/30 100%	30/30 100%	**90/90 100%** [95.9-100%]	30/30 100%	29/30 96.7%	30/30 100%	**89/90 98.9%** [94.0-99.8%]
		Negative	Not Detected	30/30 100%	30/30 100%	30/30 100%	**90/90 100%** [95.9-100%]	30/30 100%	30/30 100%	29/30 [1] 96.7%	**89/90 98.9%** [94.0-99.8%]
Plasmodium falciparum IPC 4884 (BEI / MRA-1238)	***Plasmodium* spp. Detection Results**	3×LoD (5.4E+02)	Detected	30/30 100%	30/30 100%	30/30 100%	**90/90 100%** [95.9-100%]	30/30 100%	30/30 100%	30/30 100%	**90/90 100%** [95.9-100%]
		1×LoD (1.8E+02)	Detected	30/30 100%	30/30 100%	30/30 100%	**90/90 100%** [95.9-100%]	30/30 100%	30/30 100%	30/30 100%	**90/90 100%** [95.9-100%]
		Negative	Not Detected	30/30 100%	30/30 100%	30/30 100%	**90/90 100%** [95.9-100%]	30/30 100%	30/30 100%	30/30 100%	**90/90 100%** [95.9-100%]
	***Plasmodium falciparum* Detection Results**	3×LoD (5.4E+02)	Detected	30/30 100%	30/30 100%	30/30 100%	**90/90 100%** [95.9-100%]	30/30 100%	29/30 96.7%	30/30 100%	**89/90 98.9%** [94.0-99.8%]
		1×LoD (1.8E+02)	Detected	30/30 100%	28/30 93.3%	29/30 96.7%	**87/90 96.7%** [90.7-98.9%]	30/30 100%	28/30 93.3%	28/30 93.3%	**86/90 95.6%** [89.1-98.3%]
		Negative	Not Detected	30/30 100%	30/30 100%	30/30 100%	**90/90 100%** [95.9-100%]	30/30 100%	30/30 100%	30/30 100%	**90/90 100%** [95.9-100%]
Overall Agreement with Expected Result				**1073/1080 99.4%** [98.7-99.7%]				**1068/1080 98.9%** [98.1-99.4%]			

[1]There was one unexpected dengue virus Detected result for the FilmArray Torch platform for an overall agreement of 98.9% (89/90). The unexpected dengue virus Detected result may have been the result of contamination introduced during sample preparation, handling, and/or sample loading.

A second assessment of reproducibility was conducted based on variability in the melt temperature (Tm) of the amplification products measured as standard deviation. Variability in the melt temperatures for the assays evaluated with both FilmArray Platforms was within the expected range (≤0.5°C) for each simulated site, the Tm standard deviation varying between 0.2°C and 0.3°C.Melt temperature means, standard deviations, and coefficient of variation (CV) are shown in Table 3 below.

Table 3. Summary of Tm (°C) Analyses for BioFire Global Fever Panel Assays

Analyte	Assay	FA Platform	Observed Tm (°C)											
			Simulated Site 1			Simulated Site 2			Simulated Site 3			Overall		
			Mean	±StDev	CV	Mean	±StDev	CV	Mean	±StDev	CV	Mean	±StDev	CV
Controls														
RNA Process Control	Yeast RNA	FA 2.0	82.0	0.3	0.4%	82.1	0.3	0.4%	82.1	0.3	0.4%	82.1	0.3	0.4%
		Torch	82.4	0.2	0.2%	82.3	0.2	0.2%	82.3	0.2	0.2%	82.3	0.2	0.2%
PCR2 Control	PCR2	FA 2.0	76.0	0.3	0.4%	76.0	0.2	0.3%	76.1	0.2	0.3%	76.0	0.2	0.3%
		Torch	76.3	0.2	0.3%	76.2	0.2	0.3%	76.2	0.2	0.3%	76.2	0.2	0.3%
Bacteria														
Leptospira interrogans	Lepto 1	FA 2.0	81.7	0.3	0.4%	81.7	0.3	0.4%	81.8	0.2	0.2%	81.8	0.3	0.4%
		Torch	82.0	0.2	0.2%	81.9	0.2	0.2%	81.9	0.2	0.2%	82.0	0.2	0.2%
Viruses														
Dengue virus Type 2	DENV 2_1	FA 2.0	80.3	0.3	0.4%	80.3	0.2	0.2%	80.4	0.2	0.2%	80.3	0.2	0.2%
		Torch	80.6	0.2	0.2%	80.5	0.2	0.2%	80.5	0.2	0.2%	80.5	0.3	0.4%
Protozoa														
Plasmodium falciparum	Plas spp.	FA 2.0	79.1	0.3	0.4%	79.2	0.3	0.4%	79.3	0.2	0.3%	79.2	0.2	0.3%
		Torch	79.5	0.2	0.3%	79.4	0.2	0.3%	79.4	0.2	0.3%	79.4	0.2	0.3%
	Plas falciparum	FA 2.0	74.2	0.3	0.4%	74.3	0.2	0.3%	74.3	0.2	0.3%	74.3	0.2	0.3%
		Torch	74.6	0.2	0.3%	74.5	0.2	0.3%	74.5	0.2	0.3%	74.5	0.2	0.3%

BioFire FilmArray 2.0 and Torch Systems met the reproducibility acceptance criteria showing an overall agreement between expected and observed results of ≥95%, and Tm variability of ≤0.5°C.

Performance of the BIOFIRE SHIELD Control Kit for the BioFire Global Fever Panel on BioFire FilmArray Torch System

Performance of the BIOFIRE SHIELD Control Kit on the BioFire FilmArray 2.0 system was established in K202382. Reproducibility of the BIOFIRE SHIELD Control Kit on the BioFire FilmArray Torch platform was evaluated by testing Positive External Controls and Negative External Controls on three BioFire FilmArray Torch systems. Testing included two operators per system for a total of 135 replicates for each control type over five days. Reproducibility was evaluated by calculating the percent agreement between observed test results (Passed or Failed) and expected test results (Passed) for

both negative and positive SHIELD controls. The expected percent agreement for controls was 99.6%. Results are summarized in Table 4 below.

Table 4: Reproducibility of the BIOFIRE SHIELD Control Kit on the FilmArray Torch Platform

External Control Type	Expected Result	Observed/Expected (Percent Agreement)			
		System 1	System 2	System 3	All Operators [95% Confidence Interval]
Positive	Passed [1]	45/45 (100%)	45/45 (100%)	45/45 (100%)	135/135 (100%) [97.2-100%]
Negative	Passed [2]	44/45[3] (97.8%)	45/45 (100%)	45/45 (100%)	134/135 (99.3%) [95.9-99.9%]
Overall Agreement with Expected Result		269/270 (99.6%) [97.9-99.9%]			

[1] All Global Fever Panel assays have a positive amplicon melt in the PEC melt range.
[2] All Global Fever Panel assays have no melt in both the PEC melt range and in the organism/virus melt range.
[3]One single unexpected dengue virus Detected result was observed for a Negative External Control on System 1. The failure was due to detection of Positive External Control amplicon and may been due to contamination with Positive External Control during control preparation and pouch loading.

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):

   Not applicable.

6. Detection Limit:

   Not applicable.

7. Assay Cut-Off:

   Assay cut-offs remain unchanged from the previously cleared version of the Global Fever panel (see DEN200043).

B Comparison Studies:

1. Method Comparison with Predicate Device:

   Not applicable.

2. Matrix Comparison:

   Not applicable.

C Clinical Studies:

1. Clinical Sensitivity:

   Clinical performance of the BioFire Global Fever Panel was established in DEN200043. Please refer to the published decision summary for additional details.

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:

Expected values of the BioFire Global Fever Panel were established in DEN200043. Please refer to the published decision summary for additional details.

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.