

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

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

K202382

**B. Purpose for Submission:**

To obtain a substantial equivalence determination for the FilmArray Global Fever Panel External Control Kit

**C. Measurand:**

Multi-analyte quality control materials

**D. Type of Test:**

FilmArray Global Fever Panel External Control Kit 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 Global Fever Panel on the FilmArray 2.0 systems.

**E. Applicant:**

BioFire Defense, LLC

**F. Proprietary and Established Names:**

FilmArray Global Fever Panel External Control Kit

**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):

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 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.

2. Special conditions for use statement(s):

For *in vitro* diagnostic use only

For prescription use only

3. Special instrument requirements:

The FilmArray Global Fever Panel External Control Kit were evaluated on the FilmArray 2.0 System.

**I. Device Description:**

The FilmArray Global Fever Panel External Control Kit contains Positive and Negative External Controls. 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     | <i>Leptospira</i> spp.                                                                  | Bacterial |
| Malaria           | <i>Plasmodium</i> spp.<br><i>Plasmodium falciparum</i><br><i>Plasmodium vivax/ovale</i> | Protozoan |
| Chikungunya fever | Chikungunya virus                                                                       | Viral     |

The External Controls are referenced in the Quick Guide and product literature as Control Injection Vials. The use of room-temperature stable External Controls contained within an injection vial simplifies the workflow and allows for use of the External Controls in settings where access to refrigeration may be limited. Each individually packaged, ready-to-use FilmArray Global Fever External Control is processed separately according to the Instructions for Use, and follows the procedure as outlined in the Quick Guide for the FilmArray Global Fever External Control Kit. Each External Control Injection Vial is intended for a single use.

The Global Fever Panel External Control Kit is designed to mitigate the risk of control contamination and misuse when evaluating clinical samples on the FilmArray 2.0 System.

- Negative External Controls are tested using the Negative External Control protocol, which monitors for contamination from both external control material and target pathogens; it will fail if either is detected.
- The Positive External Control contains DNA sequences that produce signature amplicon melting temperature (T<sub>m</sub>) values distinct from the amplicon T<sub>m</sub> values produced by each of the pathogens detected by the Global Fever Panel. By design, the Positive ECM will not be detected when using the Global Fever Panel Whole Blood Protocol, and reciprocally, amplified pathogen-specific nucleic acid will not be detected when using the Positive External Control Protocol. Through modification of the sequence between the inner primers for each ECM target, the T<sub>m</sub> value of the amplicon is shifted to higher or lower T<sub>m</sub> values relative to the expected Global Fever Panel target amplicon while running the same Global Fever Panel pouches with the same physical pouch manipulation in the FilmArray 2.0 Instrument. Positive External Control-specific pouch module software detects the expected shifted T<sub>m</sub> values as being from ECM amplicon, thereby evaluating the performance of the FilmArray 2.0 System. Also, the modification of the ECM sequence mitigates possible contamination events and does not cause false positives in clinical samples. In the unlikely event that Positive ECM or ECM amplicon is introduced into a patient sample, the resulting amplification T<sub>m</sub> value(s) is not detected within the pathogen(s) T<sub>m</sub> window in the Global Fever

Panel Whole Blood Protocol, where different Tm windows are used to detect amplified pathogen sequence.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

FilmArray Warrior Control Panel M290

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

K163522

3. Comparison with predicate:

| Similarities |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|--------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Item         | Device: FilmArray Global Fever Panel External Control Kit K202382                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Predicate: FilmArray Warrior Control Panel M290 K163522                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Intended Use | <p>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 <i>in vitro</i> 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 does not replace manufacturer internal controls provided as part of the Global Fever Panel device.</p> <p>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</p> | <p>FilmArray Warrior Control Panel M290 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 <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.</p> |

| <b>Similarities</b>              |                                                                                                |      |
|----------------------------------|------------------------------------------------------------------------------------------------|------|
|                                  | Injection Vial contains no DNA, and is non-reactive with the Global Fever Panel assays.        |      |
| <b>Technological Principles</b>  | Nested multiplex RT-PCR followed by melting analysis to confirm identity of amplified product. | Same |
| <b>Test Interpretation</b>       | Automated test interpretation and report generation. User cannot access raw data.              | Same |
| <b>Sample Preparation Method</b> | Process like patient sample.                                                                   | Same |
| <b>Composition</b>               | Synthetic DNA                                                                                  | Same |

| Differences     |                                                                                                                                                 |                                                                                                                                               |
|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|
| Item            | Device: FilmArray Global Fever Panel External Control Kit K202382                                                                               | Predicate: FilmArray Warrior Control Panel M290 K163522                                                                                       |
| Targets         | <i>Leptospira</i> spp., <i>Plasmodium</i> spp., <i>Plasmodium falciparum</i> , <i>Plasmodium vivax/ovale</i> , Chikungunya virus, Dengue virus, | <i>Bacillus anthracis</i> , <i>Coxiella burnetii</i> , <i>Francisella tularensis</i> , <i>Yersinia pestis</i> , Ebola Virus and Marburg Virus |
| Physical format | External Control Material dried on Control Injection Vial filter                                                                                | Ready-to-use liquid                                                                                                                           |

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

None were referenced

**L. Test Principle:**

Not applicable

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

1. Analytical performance:

*a. Clinical Study Evaluation:*

A clinical study was performed with the Global Fever Panel External Control Kit on the FilmArray 2.0 instrument to assess the performance in a clinical laboratory setting. Testing consisted of alternating the Positive and Negative External Control Material (ECM) each day of testing and between each FilmArray instrument between July 2019 and January 2020. Multiple operators participated in testing at each of the 6 clinical study sites. Eight FilmArray Global Fever Panel pouch lots and 3 lots of quality controls were tested across all sites. A total of 317 external controls were tested (160 Positive Controls, 157 Negatives). Cp values for each analyte are provided for informational purposes only. The results are shown in the Tables below:

**Table 2: FilmArray Global Fever Panel Clinical Study Summary**

| Category     | #expected results/# tested <sup>1</sup> | Overall Percent Agreement | 95% Confidence Interval |
|--------------|-----------------------------------------|---------------------------|-------------------------|
| Positive ECM | 159/160 <sup>2</sup>                    | 99.4%                     | 96.6-99.9%              |
| Negative ECM | 155/157 <sup>2</sup>                    | 98.7%                     | 95.5-99.7%              |

<sup>1</sup>Expected result for the Global Fever Panel External Control Kit Positive Control is positive. Expected result for the Global Fever Panel External Control Kit Negative Control is negative.

<sup>2</sup>Site was directed to test a Positive and a Negative ECM on the same day. The Negative ECM run failed because all ECM analytes were Detected, and the Positive ECM run failed because all ECM analytes were Not Detected

**Table 3: Clinical Study Stratified by Site**

| Category     | Site                                    |                                         |                                         |                                         |                                         |                                         | All Sites                 | All Sites               |
|--------------|-----------------------------------------|-----------------------------------------|-----------------------------------------|-----------------------------------------|-----------------------------------------|-----------------------------------------|---------------------------|-------------------------|
|              | #1                                      | #2                                      | #3                                      | #4                                      | #5                                      | #6                                      | Overall Percent Agreement | 95% Confidence Interval |
|              | #expected results/# tested <sup>1</sup> | #expected results/# tested <sup>1</sup> | #expected results/# tested <sup>1</sup> | #expected results/# tested <sup>1</sup> | #expected results/# tested <sup>1</sup> | #expected results/# tested <sup>1</sup> |                           |                         |
| Positiv ECM  | 42/43                                   | 2/2                                     | 16/16                                   | 34/34                                   | 25/25                                   | 40/40                                   | 99.4% (159/160)           | 96.5-99.9%              |
| Negative ECM | 41/42                                   | 2/2                                     | 15/15                                   | 31/32                                   | 26/26                                   | 40/40                                   | 98.7% (155/157)           | 95.5-99.7%              |

<sup>1</sup>Expected result for the Global Fever Panel External Control Kit Positive Control is positive. Expected result for the Global Fever Panel External Control Kit Negative Control is negative.

**Table 4: Clinical Study Crossing Point (Cp) Summary**

| ECM Assay              | Cp   |       |      |              |         |
|------------------------|------|-------|------|--------------|---------|
|                        | Mean | StDev | CV   | Range        | Δ Range |
| CHIKV 1                | 16.5 | 1.0   | 6.4% | 13.5 to 19.7 | 6.2     |
| CHIKV 2                | 16.6 | 1.1   | 6.6% | 13.0 to 19.3 | 6.3     |
| DENV 1                 | 17.7 | 1.2   | 6.5% | 14.2 to 20.9 | 6.7     |
| DENV 2_1               | 16.1 | 1.1   | 6.9% | 13.3 to 19.1 | 5.8     |
| DENV 2_2               | 15.9 | 1.1   | 6.7% | 12.7 to 18.8 | 6.1     |
| DENV 3                 | 16.7 | 1.3   | 7.6% | 12.8 to 19.6 | 6.8     |
| DENV 4                 | 18.0 | 1.1   | 6.0% | 14.8 to 21.5 | 6.7     |
| <i>Lepto</i> 1         | 17.4 | 1.1   | 6.2% | 14.0 to 20.1 | 6.1     |
| <i>Plas falciparum</i> | 17.7 | 1.1   | 6.4% | 14.2 to 20.5 | 6.3     |
| <i>Plas ovale</i>      | 15.2 | 1.1   | 7.4% | 12.6 to 18.9 | 6.3     |
| <i>Plas spp</i>        | 17.7 | 1.0   | 5.8% | 14.6 to 20.7 | 6.1     |
| <i>Plas vivax</i>      | 15.2 | 1.1   | 7.4% | 12.6 to 18.9 | 6.3     |
| yRNA                   | 15.0 | 1.0   | 6.8% | 11.7 to 16.8 | 5.1     |
| PCR2                   | 19.0 | 1.6   | 8.6% | 17.5 to 24.5 | 7.0     |

*b. Multi-Site Reproducibility:*

A multi-site reproducibility study was performed with the Global Fever Panel External Control Kit on the FilmArray 2.0 instrument. Testing included 2 operators, 3 test sites, 3 FilmArray Global Fever Panel pouch lots, 3 lots of quality controls and 3 FilmArray 2.0 systems over 5 days. A total of 270 external controls were tested (135 Positive and 135 Negatives ECM). Cp values for each analyte are provided for informational purposes only. The results are shown in the Tables below:

**Table 5: Reproducibility Stratified by Site**

| Category     | Site                                    |                                         |                                         | All Sites                 | All Sites               |
|--------------|-----------------------------------------|-----------------------------------------|-----------------------------------------|---------------------------|-------------------------|
|              | #1                                      | #2                                      | #3                                      | Overall Percent Agreement | 95% Confidence Interval |
|              | #expected results/# tested <sup>1</sup> | #expected results/# tested <sup>1</sup> | #expected results/# tested <sup>1</sup> |                           |                         |
| Positive ECM | 42/45                                   | 45/45                                   | 45/45                                   | 97.8% (132/135)           | 93.7-99.2%              |
| Negative ECM | 45/45                                   | 44/45 <sup>2</sup>                      | 44/45 <sup>3</sup>                      | 98.5% (133/135)           | 94.8-99.6%              |

<sup>1</sup>Expected result for the Global Fever Panel External Control Kit Positive Control is positive. Expected result for the Global Fever Panel External Control Kit Negative Control is negative.

<sup>2</sup>Unexpected detection of pathogen amplicon for an off-panel assay, suspected laboratory contamination

<sup>3</sup>Unexpected detection of pathogen amplicon for DENV 2\_1 assay.

**Table 6: Reproducibility Crossing Point (Cp) Summary**

| ECM Assay               | Observed Cp |     |       |        |     |       |        |     |      |           |     |       |
|-------------------------|-------------|-----|-------|--------|-----|-------|--------|-----|------|-----------|-----|-------|
|                         | Site 1      |     |       | Site 2 |     |       | Site 3 |     |      | All Sites |     |       |
|                         | Mean        | SD  | CV    | Mean   | SD  | CV    | Mean   | SD  | CV   | Mean      | SD  | CV    |
| Yeast RNA               | 16.4        | 0.8 | 4.9%  | 15.7   | 0.6 | 3.8%  | 15.5   | 0.4 | 2.6% | 15.9      | 0.7 | 4.4%  |
| PCR2                    | 21.0        | 2.3 | 11.0% | 20.5   | 2.3 | 11.2% | 19.5   | 1.7 | 8.7% | 20.3      | 2.2 | 10.8% |
| CHIKV 1                 | 18.7        | 1.0 | 5.3%  | 17.1   | 1.0 | 5.8%  | 17.3   | 1.0 | 5.8% | 17.7      | 1.2 | 6.8%  |
| CHIKV 2                 | 18.4        | 0.8 | 4.3%  | 17.1   | 0.7 | 4.1%  | 17.3   | 0.7 | 4.0% | 17.6      | 0.9 | 5.1%  |
| DENV 1                  | 19.3        | 0.8 | 4.1%  | 18.0   | 0.8 | 4.4%  | 18.3   | 0.8 | 4.4% | 18.5      | 1.0 | 5.4%  |
| DENV 2_1                | 16.6        | 0.9 | 5.4%  | 15.4   | 0.8 | 5.2%  | 15.4   | 0.8 | 5.2% | 15.8      | 1.0 | 6.3%  |
| DENV 2_2                | 17.2        | 0.7 | 4.1%  | 16.1   | 0.7 | 4.3%  | 16.3   | 0.8 | 4.9% | 16.5      | 0.9 | 5.5%  |
| DENV 3                  | 18.3        | 1.0 | 5.5%  | 17.1   | 0.9 | 5.3%  | 17.5   | 1.1 | 6.3% | 17.6      | 1.1 | 6.3%  |
| DENV 4                  | 19.7        | 0.7 | 3.6%  | 18.4   | 0.5 | 2.7%  | 18.6   | 0.6 | 3.2% | 18.9      | 0.9 | 4.8%  |
| Lepto 1                 | 18.8        | 0.8 | 4.3%  | 17.5   | 0.7 | 4.0%  | 17.8   | 0.8 | 4.5% | 18.0      | 0.9 | 5.0%  |
| Plas falciparum         | 19.2        | 0.8 | 4.2%  | 17.9   | 0.8 | 4.5%  | 18.2   | 0.8 | 4.4% | 18.4      | 1.0 | 5.4%  |
| Plas ovale <sup>a</sup> | 17.9        | 1.0 | 5.6%  | 16.1   | 0.9 | 5.6%  | 16.3   | 0.9 | 5.5% | 16.8      | 1.2 | 7.1%  |
| Plas vivax <sup>a</sup> |             |     |       |        |     |       |        |     |      |           |     |       |
| Plas spp                | 19.5        | 0.8 | 4.1%  | 18.3   | 0.7 | 3.8%  | 18.4   | 0.7 | 3.8% | 18.7      | 0.9 | 4.8%  |

<sup>a</sup> Assays are co-spotted in one PCR2 well. During the test run, overall fluorescence is measured for the PCR2 well, and therefore the two assays have the same amplification curve. Each assay does have a distinct T<sub>m</sub> value identified during the melt evaluation at the end of the test run.

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

*c. Precision:*

A precision study for the Global Fever Panel External Control Kit was conducted over fourteen days by testing one Global Fever Panel External Control Kit lot with one FilmArray Global Fever Panel pouch lot performed by one operator using one FilmArray 2.0 instrument. A total of 90 external controls were tested (45 Positive and 45 Negatives ECM). Cp values for each analyte are provided for informational purposes only. The results are shown in the Tables below:

**Table 7: Global Fever Panel External Control Kit Precision Summary**

| Category     | #expected results/<br>#tested <sup>1</sup> | Overall Percent Agreement | 95% Confidence Interval |
|--------------|--------------------------------------------|---------------------------|-------------------------|
| Positive ECM | 45/45                                      | 100%                      | 92.1-100%               |
| Negative ECM | 45/45                                      | 100%                      | 92.1-100%               |

<sup>1</sup>Expected result for the Global Fever Panel External Control Kit Positive Control is positive. Expected result for the Global Fever Panel External Control Kit Negative Control is negative.

**Table 8: Precision Crossing Point (Cp) Summary**

| ECM Assay                                                        | Mean Cp | SD  | CV   | Cp Range |         |         |
|------------------------------------------------------------------|---------|-----|------|----------|---------|---------|
|                                                                  |         |     |      | Minimum  | Maximum | Max-Min |
| RNA Process Control                                              | 16.0    | 0.7 | 4.4% | 15.0     | 18.5    | 3.5     |
| PCR2 Control                                                     | 19.0    | 0.2 | 1.1% | 18.5     | 19.5    | 1.0     |
| CHIKV 1                                                          | 18.8    | 0.8 | 4.3% | 17.4     | 20.4    | 3.0     |
| CHIKV 2                                                          | 18.4    | 0.6 | 3.3% | 17.2     | 19.8    | 2.6     |
| DENV 1                                                           | 19.0    | 0.7 | 3.7% | 17.8     | 20.7    | 2.9     |
| DENV 2_1                                                         | 15.9    | 0.7 | 4.4% | 15.0     | 17.7    | 2.7     |
| DENV 2_2                                                         | 17.1    | 0.6 | 3.5% | 15.9     | 19.0    | 3.1     |
| DENV 3                                                           | 18.3    | 0.8 | 4.4% | 15.7     | 20.0    | 4.3     |
| DENV 4                                                           | 19.5    | 0.8 | 4.1% | 18.2     | 21.0    | 2.8     |
| <i>Lepto</i> 1                                                   | 18.5    | 0.6 | 3.2% | 17.5     | 19.9    | 2.4     |
| <i>Plas falciparum</i>                                           | 18.9    | 0.7 | 3.7% | 17.8     | 21.0    | 3.2     |
| <i>Plas ovale</i> <sup>1</sup><br><i>Plas vivax</i> <sup>1</sup> | 17.5    | 1.1 | 6.3% | 15.6     | 19.7    | 4.1     |
| <i>Plas spp</i>                                                  | 19.5    | 0.8 | 4.1% | 18.4     | 21.7    | 3.3     |

<sup>1</sup> Assays are co-spotted in one PCR2 well. During the test run, overall fluorescence is measured for the PCR2 well, and therefore the two assays have the same amplification curve. Each assay does have a distinct Tm value identified during the melt evaluation at the end of the test run.

d. *Linearity/assay reportable range:*

Not applicable

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

*Traceability:*

Not applicable

*Stability:*

*Open Vial Stability:*

Not applicable because FilmArray Global Fever External Control Kitis 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 the FilmArray Global Fever External Control Kit is indicated for use. Real-time stability study protocols and acceptance criteria were reviewed and found to be acceptable.

*Shipping Stability:*

A FilmArray Global Fever External Control Kit shipping stability study was performed to confirm the shipping process and to investigate the outcome of a possible shipping delay. The study evaluated the Global Fever External Control Kit at low and high temperatures for a predefined amount of time prior to being stored at  $30\pm 2^{\circ}\text{C}$ .

The study demonstrated that the FilmArray Global Fever External Control Kit is stable for nine months at  $18\text{-}30^{\circ}\text{C}$  as indicated in the package insert.

*Expected Values:*

When performed properly, FilmArray Global Fever Panel External Controls should yield the result 'Passed'. Note that there are individual protocols for the FilmArray Global Fever Panel Positive and Negative External Controls; therefore, it is necessary to ensure that the appropriate protocol is selected prior to running the test.

If the result is 'Failed', the operator will be instructed to retest the External Control once, either immediately (Positive External Control) or after decontaminating the workspace (Negative External Control). If the result is 'Invalid', the operator will be instructed to retest the External Control once and to contact Technical Support if the

problem persists.

*f. Detection limit:*

Not applicable

*g. Analytical Reactivity (Inclusivity):*

Not applicable

*h. Cross Reactivity:*

Not applicable

*i. Interference:*

Not applicable

*j. Assay cut-off:*

Not applicable.

2. Comparison studies:

*a. Method comparison with predicate device:*

Not applicable.

3. 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.

4. Clinical cut-off:

Not Applicable.

**N. Proposed Labeling:**

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

**O. Conclusion:**

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