

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION MEMORANDUM
ASSAY ONLY TEMPLATE**

A. 510(k) Number:

K161306

B. Purpose for Submission:

To obtain a substantial equivalence determination for a premarket notification for the BD BACTEC Standard Anaerobic/F (plastic) blood culture vial

C. Measurand:

Anaerobic microorganisms from blood

D. Type of Test:

Liquid culture medium for recovery of microorganisms from blood using fluorescent technology to detect the increased CO₂ produced by the growth of microorganisms

E. Applicant:

Becton, Dickinson and Company

F. Proprietary and Established Names:

BD BACTEC™ Standard Anaerobic/F Culture Vials
Soybean-Casein Digest Broth in a Plastic Vial

G. Regulatory Information:

1. Regulation section:

21 CFR 866.2560 Microbial Growth Monitor

2. Classification:

Class I

3. Product code:

MDB System, Blood Culturing

4. Panel:

83 Microbiology

H. Intended Use:

1. Intended use(s):

BD BACTEC Standard Anaerobic/F culture vials (prereduced enriched Soybean-Casein Digest broth with CO₂) are for anaerobic blood cultures. Principal use is with the BD BACTEC fluorescent series instruments for the qualitative culture and recovery of anaerobic microorganisms from blood.

2. Indication(s) for use:

Same as Intended Use

3. Special conditions for use statement(s):

Prescription use

Limitations:

Recovery of SPS Sensitive Organisms from Blood Samples

Peptostreptococcus anaerobius is SPS sensitive which may affect detection if an insufficient amount of sample is inoculated into the vial.

General Considerations

The default 5-day (120 hours) protocol was utilized for all analytical testing with the BD BACTEC Standard Anaerobic/F culture media and protocol lengths of >5 days have not been evaluated.

4. Special instrument requirements:

BACTEC fluorescent series instruments BACTEC 9050, BACTEC 9240, BACTEC FX, and BACTEC FX40 using software versions listed below:

| Instrument | Software Version |
|-------------------|-------------------------|
| BACTEC 9050 | V2.01 |
| BACTEC 9240 | V4.95 |
| BACTEC FX | V5.20 |
| BACTEC FX 40 | V2.51B |

I. Device Description:

The blood sample to be tested is inoculated into one or more vials which are inserted into the

BACTEC fluorescent series instrument for incubation and periodic reading. Each vial contains a chemical sensor which can detect increases in CO₂ produced by the growth of microorganisms. The sensor is monitored by the instrument every ten minutes for an increase in its fluorescence, which is proportional to the amount of CO₂ present. A positive reading indicates the presumptive presence of viable microorganisms in the vial. Detection is limited to microorganisms that will grow in a particular type of medium.

J. Substantial Equivalence Information:

1. Predicate device name(s):

BD BACTEC Standard Aerobic/F and Anaerobic /F Culture Vials
Soybean-Casein Digest Broth

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

K915796

3. Comparison with predicate:

Table 1: Comparison with Predicate Device

| Item | Device BD BACTEC Standard Anaerobic/F (Plastic) | Predicate BD BACTEC Standard Anaerobic/F (Glass) K915796 |
|----------------------|---|---|
| Similarities | | |
| Intended Use | Qualitative culture and recovery of anaerobic microorganisms from blood with the BD BACTEC fluorescent series instrument | Same (from Name and Intended Use sections) |
| Sample Type | Human blood | Same |
| Instrument | BD BACTEC fluorescent series | Same |
| Detection Technology | Continuous monitoring; measurement of CO ₂ increase; resins for absorption of antimicrobials; rocking agitation parameters | Same |
| Incubation | 35°C (± 1.5°C) up to 120 hours | Same |

| Differences | | |
|--------------------------|-------------------------------------|--------------------|
| Vial Material | Plastic | Glass |
| Vial Weight | Lighter than glass | -- |
| Vial Height | 5.0 inches | 5.6 inches |
| Sensor Adhesion Promoter | Yes | N/A |
| Vial Sensor | 2.6 gram per vial, specific for the | 1.75 gram per vial |

| Differences | | |
|--------------------|---|--|
| | plastic vial geometry | |
| Sensor Components | BCP (indicator) - 6.5 mg/gram of sensor Red dye- 4.0 mg/gram of sensor | BCP (indicator)- 1.8 mg/gram of sensor Red dye- 1.9 mg/gram of sensor |

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

Not Applicable

L. Test Principle:

The BD BACTEC Standard Anaerobic/F medium is an enriched soybean- casein digest broth, with each vial containing 40 mL of broth. The formulation is specifically designed to enhance the recovery of facultative and anaerobic microorganisms from blood. Sodium polyanetholesulfonate (SPS) is added to the medium as an anticoagulant and compliment fixation inhibitor.

Each BD BACTEC Standard Anaerobic/F blood culture medium vial contains a chemical sensor in a silicon rubber base that can detect increases in CO₂ produced by the growth of microorganisms. Three to seven mL of blood is inoculated into the BD BACTEC Standard Anaerobic/F blood culture medium vial, which is inserted into the BD BACTEC Fluorescent Series instrument for incubation, agitation and periodic measurement. When microorganisms are present in the blood sample, they metabolize nutrients in the culture medium, releasing CO₂ into the medium. A dye in the sensor reacts with the CO₂, modulating the amount of light that is absorbed by the fluorescent material in the sensor. The instrument’s photo detectors monitor the sensor every 10 minutes and measure the level of fluorescence, which is proportional to the amount of CO₂ present in the vial. Positivity of a vial is determined by algorithms resident in the instrument rack’s microprocessor. The algorithms use the rate of CO₂ production as well as the absolute increase in CO₂ to interpret the data.

Culture vials flagged as presumptively positive are removed from the instrument for subculture and Gram stain in order to identify the microorganisms for further evaluation and proposed patient treatment. Culture vials that are not flagged as positive remain in the instrument until the test protocol has been completed and negative bottles are discarded at the end of protocol (120 hours).

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

The BACTEC Standard Anaerobic/F (plastic) vial was evaluated across three lots in the Time To Detection (TTD) and the Percent Recovery (Detection) studies.

Different lots of key raw materials were used to manufacture each lot of culture media. The actual inoculum level of 0, 1, 2-10, and >10 CFU were used in the analysis. The actual inoculum level was determined on the basis of growth observed on non-selective agar plate. The inoculum of 0 CFU indicates that no growth was observed on non-selective agar. However, growth can be observed in the vials due to difference in inoculum volume required between agar and BACTEC vial and sampling imprecision at this low inoculum level. The time to detection results are presented in Table 2.

Table 2: Precision/Reproducibility: Lot to Lot Difference

| Lot | Bld Vol (mL) | Median Time to Detection in Hours (95% CI) | | | |
|-----|--------------|--|-------------------------|-------------------------|-------------------------|
| | | 0 CFU | 1 CFU | 2-10 CFU | >10 CFU |
| 1 | 3 | 24.698 (10.215, 39.18) | 18.76 (14.318, 26.174) | 19.838 (15.979, 23.734) | 17.907 (16.085, 19.707) |
| | 7 | 12.104 (9.881, 33.126) | 22.054 (16.337, 28.057) | 19.748 (15.785, 23.759) | 17.837 (16.125, 19.274) |
| 2 | 3 | 28.694 (12.237, 39.521) | 19.134 (13.975, 24.257) | 18.317 (14.671, 23.253) | 17.721 (15.87, 19.421) |
| | 7 | 25.319 (10.215, 32.455) | 21.382 (14.779, 27.385) | 19.338 (15.478, 22.362) | 17.565 (15.96, 19.141) |
| 3 | 3 | 16.088 (10.858, 24.478) | 23.102 (12.337, 41.13) | 20.075 (15.88, 24.674) | 17.683 (15.736, 19.377) |
| | 7 | 15.582 (10.382, 21.504) | 19.67 (14.921, 25.923) | 18.08 (15.296, 22.473) | 17.633 (15.92, 19.029) |

The percent recovery results stratified by lot (combining blood volumes, inoculum levels, organisms, and instruments) are shown in Table 3.

Table 3: Percent of Positive Results by Lot

| Lot | Total | Positive | Percent Recovery (95% CI) |
|-----|-------|----------|---------------------------|
| 1 | 280 | 244 | 87.14% (82.52%, 90.72%) |
| 2 | 280 | 245 | 87.50% (82.91%, 91.03%) |
| 3 | 280 | 245 | 87.50% (82.91%, 91.03%) |

Similar performance was observed among the lots and there were no statistically significant differences across all three lots in the precision study.

b. *Linearity/assay reportable range:*

Not Applicable

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

Quality Control

An internal validation study across three lots with inoculum at 10-100 CFU per vial was conducted using the organisms listed below:

| | |
|---------------------------------|------------|
| <i>Clostridium histolyticum</i> | ATCC 19401 |
| <i>Streptococcus pneumoniae</i> | ATCC 6305 |
| <i>Clostridium perfringens</i> | ATCC 13124 |
| <i>Escherichia coli</i> | ATCC 25922 |

| | |
|-------------------------------|------------|
| <i>Bacteroides fragilis</i> * | ATCC 25285 |
| <i>Staphylococcus aureus</i> | ATCC 25923 |
| <i>Bacteroides vulgatus</i> | ATCC 8482 |

*CLSI recommended strain

B. fragilis was evaluated by testing eight replicates for each lot while the rest of the QC isolates were evaluated by testing seven replicates each. All organisms were detected ≤ 72 hours, with mean ranges from 7.6 hours (*Clostridium histolyticum*) to 24.8 hours (*Staphylococcus aureus*).

d. *Detection limit:*

Microbial Detection Limit (MDL, target inoculum level 0- 1, 1- 10 CFU/vial)

The microbial detection limit study was conducted to assess the capability of the culture media to detect low numbers of organisms (expected target level of 0-1 and 1-10 CFU/vial) when present in blood. The study included 13 organisms (six anaerobes and seven facultative anaerobes) tested at two blood volumes (3 and 7 mL), each at challenging target inoculum levels of 0-1 and 1-10 CFU/vial across three lots with BACTEC FX and BACTEC 9240:

13 org x 2 blood vol. x 2 inoculum vol. x 3 lots x 2 instrument types = 312

Results are provided in Table 4. The percent recovery, difference between predicate and modified bottles with 95% two-sided bootstrap confidence intervals stratified by organism are presented for all inoculum levels combined (Target 0-1, and 1-10 CFU per vial).

Table 4: Microbial Detection Limit (MDL) Difference by Organism

| Organism Name | # of Samples | Percent Recovery for Modified | Percent Recovery for Predicate | Difference between percent recovery of Modified and Predicate | 95% CI (low) | 95% CI (high) |
|--|--------------|-------------------------------|--------------------------------|---|--------------|---------------|
| <i>Bacteroides fragilis</i> | 24 | 79.17 | 75 | 4.17 | -20.28 | 28.61 |
| <i>Bacteroides vulgatus</i> | 24 | 62.5 | 91.67 | -29.17 | -50.71 | -7.62 |
| <i>Clostridium perfringens</i> | 24 | 70.83 | 79.17 | -8.33 | -28.06 | 11.39 |
| <i>Enterococcus faecalis</i> | 24 | 79.17 | 83.33 | -4.17 | -25.71 | 17.38 |
| <i>Escherichia coli</i> | 24 | 79.17 | 66.67 | 12.5 | -11.48 | 36.48 |
| <i>Fusobacterium nucleatum</i> | 24 | 70.83 | 62.5 | 8.33 | -14.52 | 31.19 |
| <i>Porphyromonas asaccharolytica</i> | 24 | 66.67 | 58.33 | 8.33 | -7.66 | 24.32 |
| <i>Staphylococcus aureus</i> | 24 | 62.5 | 70.83 | -8.33 | -31.19 | 14.52 |
| <i>Staphylococcus epidermidis</i> | 24 | 79.17 | 66.67 | 12.5 | -14.12 | 39.12 |
| <i>Streptococcus agalactiae</i> (Strep. group B) | 24 | 83.33 | 75 | 8.33 | -14.52 | 31.19 |
| <i>Streptococcus pneumoniae</i> | 24 | 62.5 | 41.67 | 20.83 | 0.9 | 40.77 |
| <i>Streptococcus pyogenes</i> (Strep. group A) | 24 | 87.5 | 83.33 | 4.17 | -17.38 | 25.71 |
| <i>Veillonella parvula</i> | 24 | 75 | 91.67 | -16.67 | -38.78 | 5.45 |
| All | 312 | 73.72% | 72.73% | 0.96 | -4.51 | 6.43 |

The study showed the percent recovery for all organisms combined was 73.72% for the plastic vial and 72.73% for the predicate glass vial. However, a statistically significant difference of -29.17% was observed with *Bacteroides vulgatus*. This difference can be explained by the finding that the actual inoculum for the target 0-1 CFU per vial was determined to be “zero” for nine of the twelve plastic vials. The percent recovery was 100% for both the glass and plastic vials at actual inoculum of 2-10 CFU for *Bacteroides vulgatus*. The MDL study demonstrated that the modified plastic device performed equivalently when compared to the predicate glass device at low target inoculum levels.

e. *Analytical specificity:*

Not applicable

f. *Assay cut-off:*

Not applicable

2. Comparison studies:

Performance of the BD BACTEC Standard Anaerobic/F (plastic) blood culture vials was evaluated in seeded internal analytical studies to demonstrate comparable performance to

the predicate device, the BD BACTEC Standard Anaerobic/F (glass) blood culture vials. Comparison results were acceptable. The comparisons were made using the following parameters: time to detection, percent recovery, false negative rate, and false positive. For statistical analysis, 95% two-sided bootstrap confidence intervals for differences were used.

a. *Method comparison with predicate device:*

Instrument Time to Detection (TTD) study

The TTD (in hours) was recorded as part of the combined Percent recovery and the Microbial Detection Limit studies using the BD BACTEC FX and 9240 instruments at three inoculum levels, across two blood volumes (3 mL and 7 mL) over three media lots. The Percent Recovery study represented the standard inoculum of 10 to 100 CFU per vial and the Microbial Detection Limit study represented the challenge inoculum levels of 0 to 1 and 1 to 10 CFU per vial.

The TTD data was also analyzed by target inoculum level, blood volume or lot numbers. The results are shown in Tables 5-7.

Table 5: Summary of TTD Study Results by Target Inoculum Levels and Blood Volumes*

| Target CFU | Bld. Vol. | Median of TTD for Modified (95% CI) | Median of TTD for Predicate (95% CI) | Median of TTD difference** (95% CI) |
|------------|-----------|-------------------------------------|--------------------------------------|-------------------------------------|
| 0 to 1 | 3 | 16.815 (12.626, 22.692) | 17.017 (12.437, 23.84) | -0.667 (-1.584, -0.083) |
| | 7 | 19.608 (14.307, 23.756) | 19.992 (14.307, 24.925) | -0.667 (-1.834, -0.167) |
| 1 to 10 | 3 | 20.111 (17.29, 21.981) | 21.238 (17.973, 23.005) | -0.667 (-1.25, -0.335) |
| | 7 | 19.595 (17.062, 21.439) | 20.007 (17.676, 21.769) | -0.418 (-0.751, -0.168) |
| 10 to 100 | 3 | 17.752 (16.648, 18.857) | 18.587 (17.475, 19.505) | -0.42 (-0.583, -0.335) |
| | 7 | 17.666 (16.67, 18.557) | 18.128 (17.237, 18.97) | -0.334 (-0.418, -0.25) |

*For all lots combined

**Median of the difference between Modified and Predicate devices

Table 6: Summary of TTD Results by Blood Volumes*

| Blood Volume (mL) | Median of TTD for Modified (95% CI) | Median of TTD for Predicate (95% CI) | Median of TTD difference (95% CI) |
|-------------------|-------------------------------------|--------------------------------------|-----------------------------------|
| 3 | 18.138 (17.131, 19.087) | 19.05 (17.909, 19.945) | -0.501 (-0.585, -0.417) |
| 7 | 18.005 (17.184, 18.864) | 18.533 (17.754, 19.309) | -0.361 (-0.5, -0.252) |

*For all lots and target inoculum levels combined

Table 7: Summary of TTD Results by Lot Numbers*

| Lot # | Median of TTD for Modified (95% CI) | Median of TTD for Modified (95% CI) | Median of TTD difference (95% CI) |
|--------------|--|--|--|
| Lot 1 | 18.169 (17.122, 19.27) | 18.395 (17.314, 19.489) | -0.168 (-0.253, -0.085) |
| Lot 2 | 18.228 (17.057, 19.41) | 19.064 (17.957, 20.164) | -0.584 (-0.751, -0.422) |
| Lot 3 | 17.807 (16.719, 18.875) | 18.724 (17.586, 19.755) | -0.584 (-0.75, -0.418) |

*For all blood volumes and target inoculum levels combined

In addition, for all inoculum levels data combined, it was observed that the estimated median for the modified plastic vial and the predicate glass vial was 17.91 hours and 19.30 hours respectively; the median TTD difference was -0.5 hours (95% CI, -0.584, -0.417), favoring the modified plastic vial.

The TTD study demonstrated that the modified plastic device performed equivalently when compared to the predicate glass device when stratified by target inoculum level, blood volume or lot numbers.

Percent Recovery (Detection) Study

The percent recovery (detection) was evaluated in a study of 528 paired sets at the standard inoculum level of 10 to 100 CFU/vial on four instruments across three lots using a diverse set of microorganisms frequently isolated in blood.

$$22 \text{ org} \times 3 \text{ lots} \times 2 \text{ blood vol} \times 4 \text{ instruments} = 528 \text{ paired sets}$$

Of the 528 paired sets, 504 sets recovered 21 organisms in both the plastic vial and the glass vial and 24 sets were negative by both vials. The study showed that the sodium polyanetholesulfonate (SPS) sensitive *Peptostreptococcus anaerobius* at actual inoculum level of 37 CFU/vial across blood volumes of 3 and 7 mL was not detected in either vials. Percent recovery was 95.5%.

The performance of each organism at inoculum of 10 to 100 CFU per vial is shown in Table 8.

Table 8: Percent Recovery (10- 100 CFU/vial) Summary by Organism

| Organism Name | # of Samples | Percent Recovery for Modified | Percent Recovery for Predicate | Difference between percent recovery of Modified and Predicate | 95% CI (low) | 95% CI (high) |
|--|---------------------|--------------------------------------|---------------------------------------|--|---------------------|----------------------|
| <i>Bacteroides fragilis</i> | 24 | 100 | 100 | 0 | -11.55 | 11.55 |
| <i>Bacteroides ovatus</i> | 24 | 100 | 100 | 0 | -11.55 | 11.55 |
| <i>Bacteroides thetaiotaomicron</i> | 24 | 100 | 100 | 0 | -11.55 | 11.55 |
| <i>Bacteroides vulgatus</i> | 24 | 100 | 100 | 0 | -11.55 | 11.55 |
| <i>Clostridium histolyticum</i> | 24 | 100 | 100 | 0 | -11.55 | 11.55 |
| <i>Clostridium novyi</i> | 24 | 100 | 100 | 0 | -11.55 | 11.55 |
| <i>Clostridium perfringens</i> | 24 | 100 | 100 | 0 | -11.55 | 11.55 |
| <i>Enterococcus faecalis</i> | 24 | 100 | 100 | 0 | -11.55 | 11.55 |
| <i>Enterococcus faecium</i> | 24 | 100 | 100 | 0 | -11.55 | 11.55 |
| <i>Escherichia coli</i> | 24 | 100 | 100 | 0 | -11.55 | 11.55 |
| <i>Fingoldia magna</i> | 24 | 100 | 100 | 0 | -11.55 | 11.55 |
| <i>Fusobacterium nucleatum</i> | 24 | 100 | 100 | 0 | -11.55 | 11.55 |
| <i>Klebsiella pneumoniae</i> | 24 | 100 | 100 | 0 | -11.55 | 11.55 |
| <i>Peptoniphilus asaccharolyticus</i> | 24 | 100 | 100 | 0 | -11.55 | 11.55 |
| <i>Peptostreptococcus anaerobius</i> | 24 | 0 | 0 | 0 | -11.55 | 11.55 |
| <i>Porphyromonas asaccharolytica</i> | 24 | 100 | 100 | 0 | -11.55 | 11.55 |
| <i>Staphylococcus aureus</i> | 24 | 100 | 100 | 0 | -11.55 | 11.55 |
| <i>Staphylococcus epidermidis</i> | 24 | 100 | 100 | 0 | -11.55 | 11.55 |
| <i>Streptococcus agalactiae (Strep. group B)</i> | 24 | 100 | 100 | 0 | -11.55 | 11.55 |
| <i>Streptococcus pneumoniae</i> | 24 | 100 | 100 | 0 | -11.55 | 11.55 |
| <i>Streptococcus pyogenes (Strep. group A)</i> | 24 | 100 | 100 | 0 | -11.55 | 11.55 |
| <i>Veillonella parvula</i> | 24 | 100 | 100 | 0 | -11.55 | 11.55 |
| All | 528 | 95.45% | 95.45% | 0 | -0.52 | 0.52 |

The percent recovery for all the inoculum levels is shown in Table 9.

Table 9: Summary of Percent Recovery Studies by Inoculum Levels

| CFU/mL | # | Percent Recovery For Modified | Percent Recovery For Predicate | Difference between Modified and Predicate | 95% CI (low) | 95% CI (high) |
|--------------------|-----|-------------------------------|--------------------------------|---|--------------|---------------|
| 10 to 100 | 528 | 95.45% | 95.45% | 0 | -0.52 | 0.52 |
| 0 to 1, 1 to 10 | 312 | 73.72% | 72.73% | 0.96 | -4.51 | 6.43 |
| Overall (Combined) | 840 | 87.38% | 87.02% | 0.36 | -1.69 | 2.4 |

The percent recovery study demonstrated that the modified plastic vial performed equivalently when compared to the predicate glass vial.

False Positive Rates (Instrument-positive, subculture-negative)

False positivity was assessed with vials inoculated with fresh human blood of 2, 4, 6, 8, and 10 mL, but no organisms were added to the vials. There were a total of 240 pair sets across three lots using BACTEC FX and BACTEC 9240 to be completed at the protocol of 120 hours incubation.

$$40 \text{ vials} \times 3 \text{ lots} \times 2 \text{ instruments} = 240 \text{ vials per device}$$

The results are indicated in Table 10.

Table 10: Summary of False Positive Study

| # of Vials | Percent Recovery for Modified | Percent Recovery for Predicate | Difference between percent recovery of Modified and Predicate | 95% CI (low) | 95% CI (high) |
|------------|-------------------------------|--------------------------------|---|--------------|---------------|
| 240 | 0 | 0 | 0 | -1.15 | 1.15 |

No instrument false positive signals were detected. The modified device performed equivalently when compared to the predicate device in the false positive study.

False Negative Rates (Instrument-negative, subculture-positive)

All inoculated paired sets (528 from the Recovery study + 312 from the Microbial Detection Limit study =840) that were instrument negative at the end of protocol (120 hours) were subcultured onto appropriate culture media plates. This combined data set was evaluated for the false negative rates. A false negative is a vial that was instrument-negative at the end of protocol (120 hours) yet contains viable organisms upon subculturing onto appropriate culture media. There were a total of 70 paired sets where both the modified and the predicate devices were negative at 120 hours; there were 36 sets where the predicate device only detected (i.e., 36 plastic vials subcultured) and 39 vials where the new device detected (i.e., 39 glass vials subcultured).

One isolate of *Streptococcus agalactiae* at actual inoculum level of 0 CFU with 7 mL of

blood was instrument negative subculture positive in the predicate glass vial. There were no false negatives in the plastic vials. The study results demonstrated no significant difference between the plastic vials and the glass vials.

Note that the SPS sensitive *Peptostreptococcus anaerobius* was both instrument and subculture negative; therefore, it was not included in the false negative rates. However, this information is noted in the limitation and performance characteristic sections of the package insert:

Limitations:

Recovery of SPS Sensitive Organisms from Blood Samples

Peptostreptococcus anaerobius is SPS sensitive which may affect detection if an insufficient amount of sample is inoculated into the vial.

Performance

Peptostreptococcus anaerobius (24 sets) was not detected in either **BD BACTEC Standard Anaerobic/F** medium contained in a plastic vial or the **BD BACTEC Standard Anaerobic/F** medium contained in a glass vial at actual inoculum level of 37 CFU/vial with blood volumes of 3 and 7 mL. All paired replicates demonstrated no growth upon terminal subculture.

BD BACTEC Instrument Compatibility Study

The BACTEC instrument compatibility study was evaluated from the Percent Recovery study (i.e., 528 paired sets) dataset across four fluorescent- series instruments: BD BACTEC FX, FX40, 9240, and 9050. The study included 3 and 7 mL of blood at inoculum level of 10-100 CFU per vial. The BACTEC instrument compatibility study is demonstrated in Table 11:

Table 11: Summary of Instrument Compatibility Study

| Instrument | Blood Volume (mL) | Median Time to Detection in Hours (95% CI) | | |
|------------|-------------------|--|--------------------------|--------------------------|
| | | TTD Median for Modified | TTD Median for Predicate | Median of TTD difference |
| FX | 3 | 17.803 (15.674, 19.692) | 18.636 (16.136, 20.362) | -0.419 (-0.752, -0.253) |
| | 7 | 17.633 (15.872, 19.193) | 18.131 (16.23, 19.497) | -0.335 (-0.502, -0.168) |
| FX40 | 3 | 17.922 (15.852, 20.286) | 18.756 (16.434, 21.211) | -0.334 (-0.501, -0.168) |
| | 7 | 17.464 (15.684, 19.315) | 18.018 (16.287, 19.839) | -0.251 (-0.418, -0.087) |
| 9240 | 3 | 17.299 (15.36, 19.278) | 18.195 (15.777, 20.03) | -0.583 (-0.833, -0.394) |
| | 7 | 17.278 (15.61, 18.86) | 18.035 (16.027, 19.588) | -0.667 (-1, -0.417) |
| 9050 | 3 | 17.916 (15.75, 20.167) | 18.833 (16.417, 21.25) | -0.5 (-0.917, -0.333) |
| | 7 | 18.25 (15.917, 20.417) | 18.5 (16.083, 20.334) | -0.083 (-0.416, 0.25) |

The study demonstrated that the four instruments performed equivalently and they are compatible with BD BACTEC Standard Anaerobic/F culture medium in plastic vials.

b. Matrix comparison:

In seeded analytical studies, the performance of BD BACTEC Standard Anaerobic/F culture medium in plastic vial was compared to that in glass vial, with two human blood volumes, 22 common blood bloodstream bacteria across four fluorescent series instruments: BACTEC FX, FX40, BACTEC 9240, and BACTEC 9050.

3. Clinical studies:

Not applicable; seeded analytical studies to compare the new plastic blood culture vials to the glass blood culture vials (predicate).

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

5. Expected values/Reference range:

Seeded analytical studies demonstrated equivalent performance of the BD BACTEC Standard Anaerobic/F (plastic) blood culture medium when compared to the BD BACTEC Standard Anaerobic/F (glass) blood culture medium.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

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