

## **510(k) Summary**

***BD BACTEC™ Platelet Aerobic/F Culture vials***  
***BD BACTEC™ Platelet Anaerobic/F Culture Vials***

**Summary Preparation Date:**

4/30/2018

**Submitted by:**

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**Proprietary Names:**

*For the instrument:*  
BD BACTEC™ FX instrument series

*For the media:*

***BD BACTEC™ Platelet Aerobic/F Culture Vials***  
***BD BACTEC™ Platelet Anaerobic/F Culture Vials***

**Common Names:**

*For the instrument:*  
***BACTEC FX***

*For the media:*

***Platelet Aerobic/F***  
***Platelet Anaerobic/F***

## **Regulatory Information**

*Regulation section: 21CFR 866.2560*

*Classification: Class I, non-exempt*

*Panel: Microbiology (83)*

*Product Code(s):MZC*

## **Predicate Device**

bioMerieux BacT/ALERT® BPA Culture Bottle

bioMerieux BacT/ALERT® BPN Culture Bottle

## **Device Establishment**

Becton Dickinson Caribe Ltd.

Vicks Drive Lot #6

Cayey, PR 00737

Registration Number: 2647876

## **Performance Standards**

21CFR 866.2560

## **Intended Use**

BD BACTEC™ Platelet Aerobic/F Culture Vials are used with the BD BACTEC™ FX instrument series for quality control of leukocyte reduced apheresis platelet (LRAP) units, both leukocyte reduced single and a pool of up to 6 units of leukocyte reduced whole blood platelet concentrates (LRWBPC). BD BACTEC™ Platelet Aerobic/F Culture vials support the growth of aerobic microorganisms (bacteria and fungi).

BD BACTEC™ Platelet Anaerobic/F Culture Vials are used with the BD BACTEC™ FX instrument series for quality control of leukocyte reduced apheresis platelet (LRAP) units, both leukocyte reduced single and a pool of up to 6 units of leukocyte reduced whole blood platelet concentrates (LRWBPC). BD BACTEC™ Platelet Anaerobic/F Culture Vials support the growth of anaerobic microorganisms.

## **Device Description**

The sample to be tested is inoculated into one or more vials which are inserted into the BD BACTEC FX instrument series for incubation and periodic reading. Each vial contains a chemical sensor which can detect increases in CO<sub>2</sub> 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 CO<sub>2</sub> 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.

## **Test Principle**

Leukocyte reduced apheresis platelet (LRAP) units, both leukocyte reduced single and a pool of up to 6 units of leukocyte reduced whole blood platelet concentrates (LRWBPC) are inoculated into one or more vials which are inserted into the BD BACTEC FX instrument series for 7 days incubation. Each vial contains a chemical sensor which can detect increases in CO<sub>2</sub> 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 CO<sub>2</sub> 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.

### **Substantial Equivalence<sup>1</sup>**

Becton Dickinson is establishing **BD BACTEC Platelet/F vials** are substantially equivalent to bioMerieux BacT/ Alert® BPA Culture Bottles (BK050037 and BD050043). Prepared plated media, (TSA II w/ 5% Sheep Blood Agar, Sabouraud Dextrose Agar, Emmons and CDC Anaerobe 5% Sheep Blood Agar) was utilized as the confirmatory reference method; confirming the absence of pre-existing bacteria in a platelet unit.

### **Analytical Performance**

#### **BD BACTEC Platelet Aerobic/F vials**

The data demonstrates that BD BACTEC Platelet Aerobic/F vials are capable of detecting the presence of microorganisms in leukocyte reduced apheresis platelets (LRAP) and in a pool of up to six (6) units of leukocyte reduced whole blood platelet concentrates (LRWBPC).

An evaluation to determine the ability of BD BACTEC Platelet Aerobic/F vials to detect selected microorganisms from seeded Leukocyte Reduced Apheresis Platelets (LRAP) and leukocyte reduced single units of whole blood platelet concentrates (LRWBPC) in a pool of up to six (6) units of leukocyte reduced whole blood platelet concentrates on the BD BACTEC™ FX Instrument series was performed at two investigational sites, BD R&D BACTEC™ Laboratory and Indiana University.

A total of 294 BD BACTEC Platelet Aerobic/F vials (98 vials from each of three lots) were evaluated for false positivity, (150 vials at Site 1 and 144 vials at Site 2) with un-seeded LRAP. One BD BACTEC Platelet Aerobic/F vial was instrument positive and sub-culture positive; the remaining 293 vials were instrument negative and subculture negative. There were no false positives observed in BD BACTEC Platelet Aerobic/F vials inoculated with un-seeded LRAP.

A total of 528 BD BACTEC Platelet Aerobic/F vials were inoculated with seeded LRAP (176 vials from each of three lots). Twenty-four of these vials were deemed non-compliant. Of the remaining 504 compliant vials, 481 vials were instrument positive (Table 5). Upon subculture, all instrument positive vials produced pure growth with morphology consistent with the organism used in seeding the LRAP unit (true positives in set). The organism concentration in the seeded LRAP units was a low inocula that targeted 1 CFU/mL. The mean time to detection for the organisms evaluated in this study ranged from 9.8 to 63.5 hours. The overall range in time to detection was 9.4 to 153.5 hours. There were no false negatives observed during this study. There were twenty-three instrument negative BD BACTEC Platelet Aerobic/F vials (*Bacillus cereus* n=20, *Escherichia coli* n=1, *Serratia marcescens* n=1, and *Staphylococcus epidermidis* n=1) that exhibited no growth upon terminal subculture.

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<sup>1</sup> The term “substantial equivalence” as used in this 510(k) notification is limited to the definition of substantial equivalence as found in the Federal Food, Drug and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

The data demonstrates that BD BACTEC Platelet Aerobic/F vials are capable of detecting contaminating microorganisms from seeded Leukocyte Reduced Apheresis Platelets (LRAP) at concentrations of <1 CFU/mL.

A total of 282 BD BACTEC Platelet Aerobic/F vials (94 vials from each of three lots) were evaluated for false positivity (144 vials at Site 1 and 138 vials at Site 2) with un-seeded LRWBPC. There were no false positives observed in BD BACTEC Platelet Aerobic/F vials inoculated with un-seeded LRWBPC.

A total of 576 BD BACTEC Platelet Aerobic/F vials (192 vials from each of three lots) were inoculated from the seeded pool of six LRWBPC. Sixty-three of these vials were deemed non-compliant. Of the remaining 513 compliant vials, 474 vials were instrument positive (Table 6). Upon subculture, all instrument positive vials produced pure growth with morphology consistent with the organism that was used to seed the pool of six LRWBPC (true positives in set). The organism concentration in the seeded pool of six LRWBPC units was a low inocula that targeted 1 CFU/mL. The mean time to detection for the organisms evaluated in this study ranged from 9.5 to 48.5 hours. The overall range in time to detection was 9.3 to 55.8 hours. There were no false negatives observed during this study. There were thirty instrument negative BD BACTEC Platelet Aerobic/F vials (*Aspergillus brasiliensis* n = 2, *Bacillus cereus* n=23, *Escherichia coli* n =1, *Serratia marcescens* n= 3, *Staphylococcus epidermidis* n =1) that exhibited no growth upon terminal subculture.

The data demonstrates that BD BACTEC Platelet Aerobic/F vials are capable of detecting contaminating microorganisms in a pool of up to six units of Leukocyte Reduced Whole Blood Platelet Concentrates (LRWBPC) at concentrations of <1 CFU/mL.

#### **BD BACTEC Platelet Anaerobic/F vials**

The data demonstrates that BD BACTEC Platelet Anaerobic/F vials are capable of detecting the presence of microorganisms in leukocyte reduced apheresis platelets (LRAP) and in a pool of up to six (6) units of leukocyte reduced whole blood platelet concentrates (LRWBPC).

A total of 216 BD BACTEC Platelet Anaerobic/F vials (72 vials from each of three lots) were evaluated for false positivity (108 vials/site) with un-seeded LRAP. There were no false positives observed in BD BACTEC Platelet Anaerobic/F vials inoculated with un-seeded LRAP.

The false positive rate for BD BACTEC Platelet Anaerobic/F vials inoculated with LRAP (un-seeded and seeded) is 0.3% (2/648). The overall false positive rate for BD BACTEC Platelet Anaerobic/F vials inoculated with either LRAP or LRWBPC (un-seeded and seeded) is 0.1% (2/1392).

The data demonstrates that BD BACTEC Platelet Aerobic/F vials are capable of detecting contaminating microorganisms from seeded Leukocyte Reduced Apheresis Platelets (LRAP) at concentrations of <1 CFU/mL

A total of 228 BD BACTEC Platelet Anaerobic/F vials (76 vials from each of three lots) were evaluated for false positivity (120 vials at Site 1 and 108 vials at Site 2) with un-seeded LRWBPC. There were no false positives observed in BD BACTEC Platelet Anaerobic/F vials inoculated with un-seeded LRWBPC.

There were no false negatives observed during this study. There were twelve instrument negative BD BACTEC Platelet Anaerobic/F vials (*Clostridium perfringens* n=1, *Serratia marcescens* n= 7, *Staphylococcus epidermidis* n =4) that exhibited no growth upon terminal subculture.

The data demonstrates that BD BACTEC Platelet Anaerobic/F vials are capable of detecting contaminating microorganisms in a pool of up to six units of Leukocyte Reduced Whole Blood Platelet Concentrates (LRWBPC) at concentrations of <1 CFU/mL