

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

### **Intended Use**

BD BACTEC™ Platelet Anaerobic/F Culture vials are used with the BD BACTEC™ FX instrument series for quality control testing 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™ Anaerobic/F Culture vials support the growth of anaerobic microorganisms.

### **Summary and Explanation of Test**

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.

### **Principle of the method/procedure.**

If microorganisms are present in the test sample inoculated into the BD BACTEC vial, CO<sub>2</sub> will be produced when the organisms metabolize the substrates present in the vial. Increases in the fluorescence of the vial sensor caused by the higher amount of CO<sub>2</sub> are monitored by the BD BACTEC FX series instrument. Analysis of the rate and amount of CO<sub>2</sub> increase enables the BD BACTEC FX series instrument to determine if the vial is positive; i.e., that the test sample contains viable organisms.

### **Reagents**

The **BD BACTEC Platelet Anaerobic/F Culture vials** contain the following active ingredients prior to processing:

#### **List of Ingredients**

|  |              |
|--|--------------|
| Processed Water.....                   | 40 mL        |
| Soybean-Casein Digest Broth.....       | 2.75% w/v    |
| Yeast Extract.....                     | 0.2% w/v     |
| Animal Tissue Digest.....              | 0.05% w/v    |
| Dextrose.....                          | 0.2% w/v     |
| Hemin.....                             | 0.0005% w/v  |
| Menadione.....                         | 0.00005% w/v |
| Sodium Citrate.....                    | 0.02% w/v    |
| Thiols.....                            | 0.1% w/v     |
| Sodium Pyruvate.....                   | 0.1% w/v     |
| Saponin.....                           | 0.26% w/v    |
| Antifoaming Agent.....                 | 0.01% w/v    |
| Sodium Polyanetholsulfonate (SPS)..... | 0.035% w/v   |

All **BD BACTEC** media are dispensed with added CO<sub>2</sub>. Platelet Anaerobic/F media are pre-reduced and dispensed with added CO<sub>2</sub> and N<sub>2</sub>. Composition may have been adjusted to meet specific performance requirements.

### **Warnings and Precautions**

For *in vitro* Diagnostic Use.

Rx Only

This Product Contains Dry Natural Rubber.

Not for use in the BD BACTEC 9000 series instrument

**Pathogenic microorganisms, including hepatitis viruses and Human Immunodeficiency Virus, may be present in clinical specimens. “Standard Precautions”<sup>1-4</sup> and institutional guidelines should be followed in handling all items contaminated with blood and other body fluids.**

Prior to use, each vial should be examined for evidence of damage, contamination or deterioration. Vials displaying evidence of damage or contamination such as leakage, cloudiness, discoloration (darkening), bulging or depressed septum should not be used.

Positive culture vials for subculturing or staining, etc.: Before sampling it is necessary to release gas which often builds up due to microbial metabolism. Sampling should be performed in a biological safety cabinet if possible, and appropriate protective clothing, including gloves and masks, should be worn. See Procedure section for more information on subculturing. To minimize the potential of leakage during inoculation of specimen into culture vials, use syringes with permanently attached needles or **BD Luer-Lok™** brand tips.

### **Storage Instructions**

The **BD BACTEC** vials are ready for use as received and require no reconstitution or dilution. Store at 2–25 °C, in a dry place **out of direct light**.

### **PLATELET PREPARATION FOR VIAL INOCULATION**

It is recommended to testing pre-storage pooled platelets no sooner than 24 hours after collection of the freshest unit in the pool. When collecting and preparing platelets follow current institutional standard operating procedures.<sup>6</sup>

### **PROCEDURE**

Remove the flip-off cap from **BD BACTEC** vial top and inspect the vial for cracks, contamination, excessive cloudiness, and bulging or indented stoppers. **Do not use** if any defect is noted. Before inoculating, swab the septum with alcohol (iodine is **not** recommended). Aseptically inject or draw directly 4 mL of specimen per vial. **Inoculated anaerobic vials should be placed in the BD BACTEC FX instrument series as soon as possible** for incubation and

monitoring. If placement of an inoculated vial into the instrument has been delayed and visible growth is apparent, it should not be tested in the **BD BACTEC FX** instrument series, but rather it should be subcultured, Gram-stained and treated as a presumptively positive bottle.

All vials inoculated with seeded platelets will be subcultured; both instrument positive and instrument negative vials (vials that remain negative throughout the 7 day protocol). Vials inoculated with un-seeded platelets (false positive testing) that are instrument positive will be subcultured to determine if organism is present; vials are instrument negative (remain negative throughout the 7 day protocol), will not be subcultured.

Vials entered into the instrument will be automatically tested every ten minutes for the duration of the testing protocol period. Positive vials will be determined by the **BD BACTEC FX** instrument series and identified as such (see the appropriate **BD BACTEC FX** instrument series User's Manual). The sensor inside the bottle will not appear visibly different in positive and negative vials, however the

**BD BACTEC FX** instrument series can determine a difference in fluorescence.

**Subculturing:** Prior to subculturing, put the vial in an upright position, and place an alcohol wipe over the septum. To release pressure in the vial, insert a sterile needle with an appropriate filter or pledget through the alcohol wipe and septum. The needle should be removed after the pressure is released and before sampling the vial for subculture. The insertion and withdrawal of the needle should be done in a straight-line motion, avoiding any twisting motions-

## QUALITY CONTROL

Quality control requirements must be performed in accordance with applicable local, state and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control procedures. It is recommended that the user refer to pertinent CLSI guidance and CLIA regulations for appropriate Quality Control practices.

**DO NOT USE** culture vials past their expiration date.

**DO NOT USE** culture vials that exhibit any cracks or defects; discard the vial in the appropriate manner.

Quality Control Certificates are provided with each carton of media. Quality Control Certificates list test organisms, including ATCC® cultures specified in the CLSI Standard M22, Quality Control for Commercially Prepared Microbiological Culture Media. The range of time to-detection in hours for each of the following organisms is ≤ 72 h:

|                                   |            |
|-----------------------------------|------------|
| <i>Clostridium perfringens</i>    | ATCC 13124 |
| <i>Enterobacter cloacae</i>       | ATCC 35030 |
| <i>Klebsiella oxytoca</i>         | ATCC 33496 |
| <i>Propionibacterium acnes</i>    | ATCC 6919  |
| <i>Serratia marcescens</i>        | ATCC 264   |
| <i>Staphylococcus aureus</i>      | ATCC 25923 |
| <i>Staphylococcus epidermidis</i> | ATCC 12228 |
| <i>Streptococcus agalactiae</i>   | ATCC 12928 |

For information on Quality Control for the **BD BACTEC FX** instrument series, refer to the appropriate **BD BACTEC FX** instrument series User's Manual.

### **LIMITATIONS OF THE PROCEDURE**

Please note that a negative vial may be due to zero organisms being present or under inoculation of the vial. Per FDA guidance recommends utilizing more than one type of culture vial; Aerobic and Anaerobic.

#### **Contamination**

Care must be taken to prevent contamination of the sample during collection and inoculation into the BD BACTEC vial. A contaminated sample will give a positive reading, but will not indicate a relevant clinical result. Such a determination must be made by the user based on such factors as type of organisms recovered, occurrence of the same organism in multiple cultures, patient history, etc.

Great precaution should be taken when removing platelet unit and inoculating in BD vial to reduce contamination

A Gram-stained smear from culture medium may contain small numbers of nonviable organisms derived from media constituents, staining reagents, immersion oil, glass slides, and specimens used for inoculation. In addition, the patient specimen may contain organisms that will not grow in the culture medium or in media used for subculture. Such specimens should be subcultured to special media as appropriate.<sup>5</sup>

#### **General Considerations:**

Quality control testing of platelets will be achieved by adding 4 mL of platelets. Platelets may contain antimicrobials or other inhibitors which may slow or prevent the growth of microorganisms. False negative readings may result when certain organisms are present which do not produce enough CO<sub>2</sub> to be detected by the system or significant growth has occurred before placing the vial into the system.

Due to the nature of biological materials in media products and inherent organism variability, the user should be cognizant of potential variable results.

The default 7-day (168 hours) protocol was utilized for all analytical testing with the BD BACTEC Standard/10 Aerobic/F culture media and protocol lengths of >7 days have not been evaluated.

Per FDA guidance more than one type of culture vial should be utilized for testing; Aerobic and Anaerobic Culture vials are recommended.

### **EXPECTED RESULTS**

Seeded laboratory studies have demonstrated that BD BACTEC Platelet Anaerobic/F vials are capable of detecting contaminating microorganisms in the seeded Leukocyte Reduced Apheresis Platelet LRAP units at concentrations of <1 CFU/mL and 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.

The following organisms were evaluated in the analytical studies: *Clostridium perfringens*, *Enterobacter cloacae*, *Escherichia coli*, *Klebsiella oxytoca*, *Propionibacterium acnes*, *Serratia marcescens*, *Staphylococcus aureus*, *Staphylococcus epidermidis* and *Streptococcus agalactiae*.

## **PERFORMANCE CHARACTERISTICS**

A total of 216 BD BACTEC Platelet Anaerobic/F vials were evaluated for false positivity with un-seeded LRAP. There were no false positives observed in BD BACTEC Platelet Anaerobic/F vials inoculated with un-seeded LRAP.

A total of 432 BD BACTEC Platelet Anaerobic/F vials were inoculated with seeded LRAP, of these 432 compliant vials, there were two false positives<sup>(\*)</sup> and 426 true positives (Table 13). Upon subculture, all instrument positive vials produced pure growth with morphology consistent with the organism that was used in seeding the LRAP unit (true positives in set). There were four instrument negative BD BACTEC Platelet Anaerobic/F vials; one vial each of *Escherichia coli*, *Staphylococcus epidermidis*, *Serratia marcescens* and *Clostridium perfringens* that exhibited no growth upon terminal subculture. There were no false negatives observed during this study.

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%.

## Platelet Anaerobic/F Culture Vial with Apheresis Platelets

| Organism   | ATCC  | CFU/mL | Mean TTD (hr) | Range (hr)      | Instrument Positive | True Positive in Set | Agreement |
|--|-------|--------|---------------|-----------------|---------------------|----------------------|-----------|
| <i>Clostridium perfringens</i>                   | 13124 | <1     | 6.9           | ( 6.9 - 7 ) *   | 10                  | 10                   | 100%      |
| <i>Clostridium perfringens</i>                   | 13124 | 1      | 10.5          | ( 10.1 - 10.8 ) | 12                  | 12                   | 100%      |
| <i>Clostridium perfringens</i>                   | 13124 | 3      | 7             | ( 7 - 7.1 ) *   | 11                  | 11                   | 100%      |
| <i>Clostridium perfringens</i>                   | 13124 | 19     | 9             | ( 8.7 - 9.2 )   | 12                  | 12                   | 100%      |
| <i>Enterobacter cloacae</i>                      | 35030 | 2      | 11.9          | ( 11.4 - 13.1 ) | 12                  | 12                   | 100%      |
| <i>Enterobacter cloacae</i>                      | 35030 | 33     | 11            | ( 10.6 - 11.4 ) | 12                  | 12                   | 100%      |
| <i>Enterobacter cloacae</i>                      | 35030 | 68     | 10.5          | ( 10.3 - 10.6 ) | 12                  | 12                   | 100%      |
| <i>Enterobacter cloacae</i>                      | 35030 | 408    | 10.5          | ( 10.3 - 10.8 ) | 12                  | 12                   | 100%      |
| <i>Escherichia coli</i>                          | 25922 | <1     | 11.6          | ( 11.1 - 12.1 ) | 11                  | 11                   | 100%      |
| <i>Escherichia coli</i>                          | 25922 | 12     | 10.1          | ( 9.9 - 10.5 )  | 12                  | 12                   | 100%      |
| <i>Escherichia coli</i>                          | 25922 | 18     | 10.6          | ( 10.3 - 11.1 ) | 12                  | 12                   | 100%      |
| <i>Escherichia coli</i>                          | 25922 | 198    | 9.8           | ( 9.7 - 10.1 )  | 12                  | 12                   | 100%      |
| <i>Klebsiella oxytoca</i>                        | 33496 | 4      | 12.1          | ( 11.6 - 12.8 ) | 12                  | 12                   | 100%      |
| <i>Klebsiella oxytoca</i>                        | 33496 | 49     | 10.8          | ( 10.6 - 10.9 ) | 12                  | 12                   | 100%      |
| <i>Klebsiella oxytoca</i>                        | 33496 | 234    | 11.1          | ( 10.8 - 11.3 ) | 12                  | 12                   | 100%      |
| <i>Klebsiella oxytoca</i>                        | 33496 | 335    | 10.6          | ( 10.5 - 10.8 ) | 12                  | 12                   | 100%      |
| <i>Propionibacterium acnes</i>                   | 6919  | <1     | 82.2          | ( 78.2 - 86.7 ) | 12                  | 12                   | 100%      |
| <i>Propionibacterium acnes</i>                   | 6919  | 8      | 71.5          | ( 70.1 - 72.6 ) | 12                  | 12                   | 100%      |
| <i>Propionibacterium acnes</i>                   | 6919  | 18     | 82.3          | ( 78.7 - 84.7 ) | 12                  | 12                   | 100%      |
| <i>Propionibacterium acnes</i>                   | 6919  | 39     | 71.9          | ( 70.7 - 73.3 ) | 12                  | 12                   | 100%      |
| <i>Serratia marcescens</i>                       | 264   | <1     | 14.6          | ( 12.8 - 18.6 ) | 12                  | 12                   | 100%      |
| <i>Serratia marcescens</i>                       | 264   | 1      | 14.2          | ( 12.7 - 16.4 ) | 12                  | 12                   | 100%      |
| <i>Serratia marcescens</i>                       | 264   | 2      | 13.6          | ( 12.7 - 14.4 ) | 11                  | 11                   | 100%      |
| <i>Serratia marcescens</i>                       | 264   | 45     | 11.8          | ( 11.4 - 12.1 ) | 12                  | 12                   | 100%      |
| <i>Staphylococcus aureus</i>                     | 25923 | 2      | 15            | ( 13.7 - 16.6 ) | 12                  | 12                   | 100%      |
| <i>Staphylococcus aureus</i>                     | 25923 | 18     | 13.8          | ( 12.9 - 14.4 ) | 12                  | 12                   | 100%      |
| <i>Staphylococcus aureus</i>                     | 25923 | 44     | 15.6          | ( 14.6 - 16.6 ) | 12                  | 12                   | 100%      |
| <i>Staphylococcus aureus</i>                     | 25923 | 230    | 13.8          | ( 13.1 - 15.1 ) | 12                  | 12                   | 100%      |
| <i>Staphylococcus epidermidis</i>                | 12228 | 2      | 22.3          | ( 20.1 - 25.6 ) | 12                  | 12                   | 100%      |
| <i>Staphylococcus epidermidis</i>                | 12228 | 4      | 20            | ( 18.6 - 21.6 ) | 12                  | 12                   | 100%      |
| <i>Staphylococcus epidermidis</i>                | 12228 | 5      | 20.3          | ( 18.1 - 22.1 ) | 11                  | 11                   | 100%      |
| <i>Staphylococcus epidermidis</i>                | 12228 | 54     | 18.7          | ( 17.6 - 19.1 ) | 12                  | 12                   | 100%      |
| <i>Streptococcus agalactiae (Strep. group B)</i> | 12928 | 2      | 10.4          | ( 10.1 - 10.6 ) | 12                  | 12                   | 100%      |
| <i>Streptococcus agalactiae (Strep. group B)</i> | 12928 | 11     | 10.5          | ( 10.2 - 10.7 ) | 12                  | 12                   | 100%      |
| <i>Streptococcus agalactiae (Strep. group B)</i> | 12928 | 25     | 9.5           | ( 9.2 - 9.7 )   | 12                  | 12                   | 100%      |
| <i>Streptococcus agalactiae (Strep. group B)</i> | 12928 | 41     | 9.6           | ( 9.4 - 9.7 )   | 12                  | 12                   | 100%      |
| <b>Total Agreement</b>                           |       |        |               |                 | 428                 | 428                  | 100%      |

A total of 228 BD BACTEC Platelet Anaerobic/F vials were evaluated for false positivity with un-seeded LRWPBC. There were no false positives observed in BD BACTEC Platelet Anaerobic/F vials inoculated with un-seeded LRWBPC.

A total of 516 BD BACTEC Platelet Anaerobic/F vials were inoculated with the seeded pool of six LRWBPC. Of the 456 compliant vials, 444 were instrument positive. Upon subculture, all instrument positive vials produced pure growth with morphology consistent with the organism.

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.

### Platelet Anaerobic/F Culture Vial with Leukocyte Reduced Whole Blood Platelet Concentrates

| <i>Organism</i>                                  | <i>ATCC</i> | <i>CFU/mL</i> | <i>Mean TTD (hr)</i> | <i>Range (hr)</i> | <i>Instrument Positive</i> | <i>True Positive in Set</i> | <i>Agreement</i> |
|--|-------------|---------------|----------------------|-------------------|----------------------------|-----------------------------|------------------|
| <i>Clostridium perfringens</i>                   | 13124       | <1            | 9.9                  | ( 9.5 - 10.5 )    | 11                         | 11                          | 100%             |
| <i>Clostridium perfringens</i>                   | 13124       | 1             | 10                   | ( 9.5 - 10.6 )    | 12                         | 12                          | 100%             |
| <i>Clostridium perfringens</i>                   | 13124       | 3             | 9.5                  | ( 9.1 - 9.8 )     | 12                         | 12                          | 100%             |
| <i>Clostridium perfringens</i>                   | 13124       | 3             | 9.6                  | ( 8.9 - 13.1 )    | 12                         | 12                          | 100%             |
| <i>Enterobacter cloacae</i>                      | 35030       | <1            | 11.2                 | ( 10.9 - 11.4 )   | 12                         | 12                          | 100%             |
| <i>Enterobacter cloacae</i>                      | 35030       | 10            | 10.5                 | ( 10.3 - 10.8 )   | 12                         | 12                          | 100%             |
| <i>Enterobacter cloacae</i>                      | 35030       | 16            | 10.3                 | ( 10.2 - 10.7 )   | 12                         | 12                          | 100%             |
| <i>Enterobacter cloacae</i>                      | 35030       | 65            | 9.6                  | ( 9.4 - 9.9 )     | 12                         | 12                          | 100%             |
| <i>Escherichia coli</i>                          | 25922       | 1             | 10.9                 | ( 10.6 - 12.1 )   | 12                         | 12                          | 100%             |
| <i>Escherichia coli</i>                          | 25922       | 1             | 10.4                 | ( 10.1 - 10.7 )   | 12                         | 12                          | 100%             |
| <i>Escherichia coli</i>                          | 25922       | 9             | 10                   | ( 9.7 - 10.2 )    | 12                         | 12                          | 100%             |
| <i>Escherichia coli</i>                          | 25922       | 11            | 9.4                  | ( 9.1 - 9.7 )     | 12                         | 12                          | 100%             |
| <i>Klebsiella oxytoca</i>                        | 33496       | <1            | 12                   | ( 11.5 - 12.6 )   | 12                         | 12                          | 100%             |
| <i>Klebsiella oxytoca</i>                        | 33496       | 2             | 11.7                 | ( 11.2 - 12.1 )   | 12                         | 12                          | 100%             |
| <i>Klebsiella oxytoca</i>                        | 33496       | 16            | 10.7                 | ( 10.4 - 11.1 )   | 12                         | 12                          | 100%             |
| <i>Klebsiella oxytoca</i>                        | 33496       | 16            | 10.7                 | ( 10.4 - 11.1 )   | 12                         | 12                          | 100%             |
| <i>Propionibacterium acnes</i>                   | 6919        | 1             | 82.5                 | ( 78.6 - 87.6 )   | 12                         | 12                          | 100%             |
| <i>Propionibacterium acnes</i>                   | 6919        | 9             | 71.2                 | ( 69.2 - 74.2 )   | 12                         | 12                          | 100%             |
| <i>Propionibacterium acnes</i>                   | 6919        | 16            | 69.1                 | ( 67.6 - 71.1 )   | 12                         | 12                          | 100%             |
| <i>Propionibacterium acnes</i>                   | 6919        | 18            | 72.1                 | ( 70.2 - 74.7 )   | 12                         | 12                          | 100%             |
| <i>Serratia marcescens</i>                       | 264         | <1            | 22.8                 | ( 13.2 - 54.7 )   | 6                          | 6                           | 100%             |
| <i>Serratia marcescens</i>                       | 264         | <1            | 13.5                 | ( 12.9 - 14.1 )   | 12                         | 12                          | 100%             |
| <i>Serratia marcescens</i>                       | 264         | 1             | 14.1                 | ( 12.6 - 17.2 )   | 11                         | 11                          | 100%             |
| <i>Serratia marcescens</i>                       | 264         | 2             | 13.2                 | ( 12.7 - 13.5 )   | 12                         | 12                          | 100%             |
| <i>Serratia marcescens</i>                       | 264         | 4             | 13                   | ( 12.7 - 13.5 )   | 12                         | 12                          | 100%             |
| <i>Staphylococcus aureus</i>                     | 25923       | <1            | 14.9                 | ( 14.1 - 15.5 )   | 12                         | 12                          | 100%             |
| <i>Staphylococcus aureus</i>                     | 25923       | 6             | 14.8                 | ( 13.9 - 15.2 )   | 12                         | 12                          | 100%             |
| <i>Staphylococcus aureus</i>                     | 25923       | 11            | 13.5                 | ( 12.9 - 14.1 )   | 12                         | 12                          | 100%             |
| <i>Staphylococcus aureus</i>                     | 25923       | 17            | 14.2                 | ( 13.2 - 15.2 )   | 12                         | 12                          | 100%             |
| <i>Staphylococcus epidermidis</i>                | 12228       | <1            | 21.7                 | ( 19.8 - 23.7 )   | 9                          | 9                           | 100%             |
| <i>Staphylococcus epidermidis</i>                | 12228       | <1            | 22.1                 | ( 20.6 - 24.6 )   | 11                         | 11                          | 100%             |
| <i>Staphylococcus epidermidis</i>                | 12228       | 3             | 23                   | ( 20.6 - 28.2 )   | 12                         | 12                          | 100%             |
| <i>Staphylococcus epidermidis</i>                | 12228       | 5             | 19.9                 | ( 19.1 - 21.1 )   | 12                         | 12                          | 100%             |
| <i>Staphylococcus epidermidis</i>                | 12228       | 5             | 20.7                 | ( 18.6 - 22.7 )   | 12                         | 12                          | 100%             |
| <i>Streptococcus agalactiae</i> (Strep. group B) | 12928       | <1            | 10.2                 | ( 9.9 - 10.4 )    | 12                         | 12                          | 100%             |
| <i>Streptococcus agalactiae</i> (Strep. group B) | 12928       | <1            | 9.5                  | ( 9.3 - 9.8 )     | 12                         | 12                          | 100%             |
| <i>Streptococcus agalactiae</i> (Strep. group B) | 12928       | 4             | 10.4                 | ( 10.1 - 10.8 )   | 12                         | 12                          | 100%             |
| <i>Streptococcus agalactiae</i> (Strep. group B) | 12928       | 23            | 9                    | ( 9 - 9.2 )       | 12                         | 12                          | 100%             |

| <i>Organism</i>        | <i>ATCC</i> | <i>CFU/mL</i> | <i>Mean TTD (hr)</i> | <i>Range (hr)</i> | <i>Instrument Positive</i> | <i>True Positive in Set</i> | <i>Agreement</i> |
|------------------------|-------------|---------------|----------------------|-------------------|----------------------------|-----------------------------|------------------|
| <b>Total Agreement</b> |             |               |                      |                   | 444                        | 444                         | 100%             |

## **AVAILABILITY**

BD BACTEC™ Platelet Anaerobic/F Culture Vials (442052).

## **REFERENCES:**

1. Clinical and Laboratory Standards Institute. 2005. Approved Guideline M29-A3. Protection of laboratory workers from occupationally acquired infections, 3rd ed. CLSI, Wayne, Pa.
2. Garner, J.S. 1996. Hospital Infection Control Practices Advisory Committee, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. Guideline for isolation precautions in hospitals. *Infect. Control Hospital Epidemiol.* 17:53-80.
3. U.S. Department of Health and Human Services. 2007. Biosafety in microbiological and biomedical laboratories, HHS Publication (CDC), 5th ed. U.S. Government Printing Office, Washington, D.C.
4. Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC). *Official Journal L262*, 17/10/2000, p. 0021-0045.
5. Clinical and Laboratory Standards Institute. 2004. Approved Standard M22-A3. Quality control of commercially prepared microbiological culture media, 3rd ed. CLSI, Wayne, Pa.
6. Food and Drug Administration. 2015, Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion  
<https://www.fda.gov/downloads/biologicsbloodvaccines/guidancecomplianceregulatoryinformation/guidances/blood/ucm425952.pdf>.

Technical Information: In the United States contact BD Technical Service and Support at 1.800.638.8663 or [www.bd.com](http://www.bd.com).