BD BACTEC™ Platelet Aerobic/F Culture vials
Intended Use:

BD BACTEC™ Platelet Aerobic/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™ Platelet Aerobic/F Culture vials support the growth of aerobic microorganisms (bacteria and fungi).

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 series instrument series for incubation and periodic reading. Each vial contains a chemical sensor which can detect increases in CO_2 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_2 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_2 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_2 are monitored by the **BD BACTEC** FX series instrument. Analysis of the rate and amount of CO_2 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 Aerobic/F culture vials contain the following active ingredients prior to processing:

List of Ingredients

Processed Water	40 mL
Soybean-Casein Digest Broth	3.0% w/v
Yeast Extract	0.3% w/v
Animal Tissue Digest	0.01% w/v
Sucrose	0.1% w/v
Hemin	0.0005% w/v
Menadione	0.00005% w/v
Pyridoxal HCl	0.001% w/v
Sodium Bicarbonate	0.04% w/v
Sodium Polyanetholsulfonate	0.035% w/v

All **BD BACTEC** media are dispensed with added CO_2.

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"1-4 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.

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

When collecting and preparing platelets follow current institutional standard operating procedures. It is recommended to test platelets no sooner than 24 hours after collection of the freshest unit in the pool.

PROCEDURE

Remove the flip-off cap from **BD BACTEC** vial top and inspect the vial for cracks, contamination, excessive cloudiness, and bulging or indented septum. **DO NOT USE** if any defect is noted. Before inoculating, swab the septum with alcohol (iodine is **NOT** recommended). Using a syringe and needle, aseptically withdraw 4 mL of platelet product from the sample bag. Insert the needle into the BACTEC vial and inoculate four (4) milliliters into the vial. **Inoculated vials should be placed in the BD BACTEC series instrument 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 series instrument, but rather it should be subcultured, Gram-stained and treated as a presumptively positive vial.

Positive vials will be determined by the **BD BACTEC** FX series instrument and identified as such within the default seven day protocol (see the appropriate **BD BACTEC** series instrument User's Manual). The sensor inside the bottle will not appear visibly different in positive and negative vials, however the **BD BACTEC FX** series instrument 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:

Bacillus cereus	ATCC 11778
Candida albicans	ATCC 10231
Escherichia coli	ATCC 25922
Klebsiella oxytoca	ATCC 33496
Pseudomonas aeruginosa	ATCC 27853
Serratia marcescens	ATCC 264
Staphylococcus aureus	ATCC 25923
Staphylococcus epidermidis	ATCC 12228
Streptococcus agalactiae	ATCC 12928

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

LIMITATIONS OF THE PROCEDURE

Please note that a negative vial may be due to no organisms being present in the sample or under inoculation of the vial. 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.

Precautions should be taken when removing platelet sample from the 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.5

General Considerations:

Quality control testing of platelet products 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_2 to be detected by the system or significant growth has occurred before placing the vial into the system.

The default 7-day (168 hours) protocol was utilized for all analytical testing with the BD BACTEC Platelet 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 vial is recommended.[6]

EXPECTED PERFORMANCE

Seeded laboratory studies have demonstrated that BD BACTEC Platelet Aerobic/F vials are capable of detecting contaminating microorganisms in Leukocyte Reduced Apheresis Platelets (LRAP) and a pool of up to six units of Leukocyte Reduced Whole Blood Platelet Concentrates (LRWBPC).

The following organisms were evaluated in the analytical studies: *Aspergillus brasiliensis, Bacillus cereus, Enterobacter cloacae, Escherichia coli, Klebsiella oxytoca, Pseudomonas aeruginosa, Serratia marcescens, Staphylococcus aureus, Staphylococcus epidermidis and Streptococcus agalactiae.*

PERFORMANCE CHARACTERISTICS

A total of 294 BD BACTEC Platelet Aerobic/F vials were evaluated for false positivity with un-seeded LRAP. One BD BACTEC Platelet Aerobic/F vial was positive and subculture positive; the remaining 293 vials were instrument negative and subculture negative.

A total of 528 BD BACTEC Platelet Aerobic/F vials were inoculated with seeded LRAP and 481 vials were instrument positive (Table 11). 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. There were no false negatives observed during this study. There were no false positives for the BD BACTEC Platelet Aerobic/F vials inoculated with either LRAP or LRWBPC (un-seeded and seeded).

Platelet Aerobic - Apheresis

Platelet Aerobic/F Culture Vial with Leukocyte Reduced Apheresis Platelets							
Organism	***ATCC***	***CFU/mL***	***Mean TTD (hr)***	***Range (hr)***	***Instrument Positive***	***True Positive in Set***	***Agreement***
Aspergillus brasiliensis	16404	2	63.5	(40.3 - 153.5)	12	12	100%
Aspergillus brasiliensis	16404	18	53.4	(38.8 - 80.6)	12	12	100%
Aspergillus brasiliensis	16404	30	37.7	(33.3 - 44.8)	12	12	100%
Aspergillus brasiliensis	16404	68	36.7	(32.6 - 43.5)	12	12	100%
Bacillus cereus	11778	<1	11.2	(10.7 - 11.4)	7	7	100%
Bacillus cereus	11778	<1	11.2	(10.7 - 11.6)	5	5	100%
Bacillus cereus	11778	<1	11.2	(10.6 - 12.1)	10	10	100%
Bacillus cereus	11778	2	10.3	(9.8 - 10.8)	12	12	100%
Bacillus cereus	11778	2	10.4	(9.9 - 11.1)	12	12	100%
Bacillus cereus	11778	3	11.2	(11 - 11.5)	6	6	100%
Enterobacter cloacae	35030	2	12	(11.4 - 12.8)	12	12	100%
Enterobacter cloacae	35030	33	11.3	(10.9 - 12.1)	12	12	100%
Enterobacter cloacae	35030	68	10.6	(10.3 - 10.8)	12	12	100%
Enterobacter cloacae	35030	408	10.7	(10.3 - 10.8)	12	12	100%
Escherichia coli	25922	<1	12.3	(11.4 - 13.1)	11	11	100%
Escherichia coli	25922	12	10.7	(10.5 - 11)	12	12	100%
Escherichia coli	25922	18	11.1	(10.9 - 11.6)	12	12	100%
Escherichia coli	25922	198	10.3	(10.1 - 10.6)	12	12	100%
Klebsiella oxytoca	33496	4	13	(12.5 - 13.5)	12	12	100%
Klebsiella oxytoca	33496	49	11.9	(11.6 - 12.1)	12	12	100%
Klebsiella oxytoca	33496	234	11.8	(11.7 - 12.2)	12	12	100%

Platelet Aerobic/F Culture Vial with Leukocyte Reduced Apheresis Platelets							
Organism	***ATCC***	***CFU/mL***	***Mean TTD (hr)***	***Range (hr)***	***Instrument Positive***	***True Positive in Set***	***Agreement***
Klebsiella oxytoca	33496	335	11.2	(10.9 - 11.5)	12	12	100%
Pseudomonas aeruginosa	27853	1	17.2	(16.7 - 17.6)	12	12	100%
Pseudomonas aeruginosa	27853	14	16.7	(16.1 - 17.6)	12	12	100%
Pseudomonas aeruginosa	27853	16	15.4	(14.7 - 15.9)	12	12	100%
Pseudomonas aeruginosa	27853	107	14.8	(14.2 - 15.7)	12	12	100%
Serratia marcescens	264	<1	13.3	(12.3 - 15.3)	12	12	100%
Serratia marcescens	264	1	13	(12.1 - 13.9)	12	12	100%
Serratia marcescens	264	2	12.7	(12.3 - 13.2)	11	11	100%
Serratia marcescens	264	45	11.2	(10.8 - 11.6)	12	12	100%
Staphylococcus aureus	25923	2	16	(15.2 - 16.7)	12	12	100%
Staphylococcus aureus	25923	18	14.6	(14.1 - 15.1)	12	12	100%
Staphylococcus aureus	25923	44	15.7	(14.6 - 16.4)	12	12	100%
Staphylococcus aureus	25923	230	14.9	(14.4 - 15.6)	12	12	100%
Staphylococcus epidermidis	12228	2	17.7	(17.1 - 18.7)	11	11	100%
Staphylococcus epidermidis	12228	4	17.9	(16.7 - 20.2)	12	12	100%
Staphylococcus epidermidis	12228	5	17.8	(17.2 - 18.6)	12	12	100%
Staphylococcus epidermidis	12228	54	16.5	(15.9 - 18.2)	12	12	100%
Streptococcus agalactiae (Strep. group B)	12928	2	10.8	(10.5 - 11.3)	12	12	100%
Streptococcus agalactiae (Strep. group B)	12928	11	11	(10.8 - 11.2)	12	12	100%
Streptococcus agalactiae (Strep. group B)	12928	25	9.9	(9.4 - 10.3)	12	12	100%
Streptococcus agalactiae (Strep. group B)	12928	41	9.8	(9.7 - 9.9)	12	12	100%
Total Agreement					481	481	100%

A total of 282 BD BACTEC Platelet Aerobic/F vials were evaluated for false positivity with un-seeded LRWPBC. There were no false positives observed in BD BACTEC Platelet Aerobic/F vials inoculated with un-seeded LRWPBC.

A total of 576 BD BACTEC Platelet Aerobic/F vials were inoculated from the seeded pool of six LRWBPC. 513 vials were compliant and 474 vials were instrument positive (Table 12). 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). 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.

Platelet Aerobic - LRWBPC

Organism	*ATCC*	*CFU/mL*	*Mean TTD (hr)*	*Range (hr)*	*Instrument Positive*	*True Positive in Set*	*Agreement*
Aspergillus brasiliensis	16404	<1	48.5	(39.3 - 55.8)	12	12	100%
Aspergillus brasiliensis	16404	1	43	(36.6 - 52.9)	12	12	100%
Aspergillus brasiliensis	16404	11	32.9	(31.6 - 35.8)	12	12	100%
Aspergillus brasiliensis	16404	18	31.2	(30.6 - 32.8)	10	10	100%
Bacillus cereus	11778	<1	11.1	(10.5 - 11.8)	12	12	100%
Bacillus cereus	11778	<1	11.4	(11 - 11.7)	4	4	100%
Bacillus cereus	11778	<1	10.9	(10.4 - 12.2)	12	12	100%
Bacillus cereus	11778	<1	11.9	(11.3 - 12.1)	4	4	100%
Bacillus cereus	11778	1	11.2	(10.6 - 12.7)	5	5	100%
Enterobacter cloacae	35030	<1	11.4	(10.8 - 12)	12	12	100%
Enterobacter cloacae	35030	10	10.8	(10.5 - 11.3)	12	12	100%
Enterobacter cloacae	35030	16	10.5	(10.3 - 10.7)	12	12	100%
Enterobacter cloacae	35030	65	9.8	(9.4 - 10.1)	12	12	100%
Escherichia coli	25922	1	11.4	(10.9 - 12.8)	11	11	100%
Escherichia coli	25922	1	11	(10.6 - 11.6)	12	12	100%
Escherichia coli	25922	9	10.6	(10.3 - 11)	12	12	100%
Escherichia coli	25922	11	9.8	(9.6 - 10.1)	12	12	100%
Klebsiella oxytoca	33496	<1	12.8	(12.3 - 13.3)	12	12	100%
Klebsiella oxytoca	33496	2	14.5	(14.2 - 15)	12	12	100%
Klebsiella oxytoca	33496	16	11.5	(11.2 - 11.9)	12	12	100%
Klebsiella oxytoca	33496	16	13.1	(12.9 - 13.4)	12	12	100%
Pseudomonas aeruginosa	27853	<1	17.2	(16.3 - 18.6)	12	12	100%
Pseudomonas aeruginosa	27853	9	15.5	(15.1 - 16.4)	12	12	100%
Pseudomonas aeruginosa	27853	18	14.7	(14.2 - 15.2)	12	12	100%
Pseudomonas aeruginosa	27853	19	14.5	(14.2 - 14.7)	12	12	100%
Serratia marcescens	264	<1	20.2	(13.4 - 29.4)	9	9	100%
Serratia marcescens	264	<1	12.8	(11.9 - 14.3)	12	12	100%
Serratia marcescens	264	1	13.7	(12.4 - 15.4)	12	12	100%
Serratia marcescens	264	2	12.4	(11.8 - 12.9)	12	12	100%
Serratia marcescens	264	4	12.2	(11.7 - 13.2)	12	12	100%
Staphylococcus aureus	25923	<1	15.1	(14.3 - 16.6)	12	12	100%
Staphylococcus aureus	25923	6	14.5	(14.1 - 14.9)	12	12	100%
Staphylococcus aureus	25923	11	13.2	(13 - 13.5)	12	12	100%
Staphylococcus aureus	25923	17	13.4	(13.1 - 13.7)	12	12	100%
Staphylococcus epidermidis	12228	<1	18.9	(17.7 - 20.3)	11	11	100%
Staphylococcus epidermidis	12228	3	19.2	(18.6 - 20.6)	12	12	100%
Staphylococcus epidermidis	12228	5	16.7	(15.7 - 17.2)	12	12	100%
Staphylococcus epidermidis	12228	5	17.9	(17.3 - 18.5)	12	12	100%
Streptococcus agalactiae (Strep. group B)	12928	<1	10.8	(10.4 - 11.1)	12	12	100%
Streptococcus agalactiae (Strep. group B)	12928	<1	10	(9.8 - 10.3)	12	12	100%
Streptococcus agalactiae (Strep. group B)	12928	4	10.7	(10.5 - 11.1)	12	12	100%
Streptococcus agalactiae (Strep. group B)	12928	23	9.5	(9.3 - 9.7)	12	12	100%

Organism	*ATCC*	*CFU/mL*	*Mean TTD (hr)*	*Range (hr)*	*Instrument Positive*	*True Positive in Set*	*Agreement*
Total Agreement					474	474	100%

AVAILABILITY

BD BACTEC™ Platelet Aerobic/F Culture Vials (442051).

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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.