

510(k) Summary

BD BACTEC™ Platelet Aerobic/F Culture vials

BD BACTEC™ Platelet Anaerobic/F Culture Vials

Summary Preparation Date:

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Submitted by:

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Proprietary Names:

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

Common Names:

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 Devices

BACT/ ALERT® BPA Culture Bottle;
BK200472

BACT/ ALERT® BPN Culture Bottle;
BK200472

Purpose of the Traditional 510(k) notice:

To include safety measure language extending platelet unit shelf life to seven days.

- To include data supporting large volume testing of 8 mL, with 48 hours or more from sample collection.

The modified BD BACTEC™ Platelet Aerobic/F Culture Vials and BD BACTEC™ Platelet Anaerobic/F Culture Vials have similar intended uses, principles of operation, and technological characteristics to its predicate the BACT/ ALERT® BPA Culture Bottle and BACT/ ALERT® BPN Culture Bottle, BK200472, cleared May 20, 2020.

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).

- BD BACTEC FX instrument Systems are used as a safety measure, to extend dating beyond day 5 and up to day 7 for the following:
 - Large volume delayed sampling (LVDS) of platelets no sooner than 48 hours after collection
 - Secondary culture no sooner than day 4 after platelet collection.
- BD BACTEC FX Instrument Systems are used to extend dating to five days for the following:
 - Large volume, delayed sampling of platelets no sooner than 36 hours after collection; OR
 - Secondary culture no sooner than day 3 after platelet collection

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.

- BD BACTEC FX instrument Systems are used as a safety measure, to extend dating beyond day 5 and up to day 7 for the following:
 - Large volume delayed sampling (LVDS) of platelets no sooner than 48 hours after collection
 - Secondary culture no sooner than day 4 after platelet collection.
- BD BACTEC FX Instrument Systems are used to extend dating to five days for the following:
 - Large volume, delayed sampling of platelets no sooner than 36 hours after collection; OR
 - Secondary culture no sooner than day 3 after platelet collection

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 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 specific type of medium.

Technological Characteristics

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 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.

Performance Data

Summary of analytical studies for BD BACTEC Platelet Aerobic/F vials.

- o Instrument time to detection:
 - A total of 30 Platelet Aerobic/F vials stored at 20°-25°C were seeded with organisms and evaluated for time to detection. Organisms were detected in all vials in less than 168 hours.
- o False positive:
 - A total of 78 Platelet Aerobic/F vials stored at 20°-25°C were evaluated for false positivity. There were no false positives (instrument positive vials, subculture negative) observed throughout the testing; false positive rate = 0%
- o False negative:
 - A total of 30 Platelet Aerobic/F vials stored at 20-25C were seeded with organisms and evaluated for time to detection. Organisms were detected in all vials in less than 168 hours. There were no false negatives observed throughout the testing; false negative rate = 0%.

Summary of analytical studies for BD BACTEC Platelet Anaerobic/F vials.

- Instrument time to detection:
 - o A total of 30 Platelet Anaerobic/F vials stored at 20°-25°C were seeded with organisms and evaluated for time to detection. Organisms were detected in all vials in less than 168 hours.
- False positive:
 - o A total of 78 Platelet Aerobic/F vials stored at 20°-25°C were evaluated for false positivity. There were no false positives (instrument positive vials, subculture negative) observed throughout the testing; false positive rate = 0%
- False negative:

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BD BACTEC™ Platelet Aerobic/F Culture Vials and BD BACTEC™ Platelet Anaerobic/F Culture Vials Traditional 510(k)
BK200530

- A total of 30 Platelet Anaerobic/F vials stored at 20°-25°C were seeded with organisms and evaluated for time to detection. Organisms were detected in all vials in less than 168