

## BD BACTEC™ Plastic Blood Culture Bottles

BD Diagnostics has announced 510(k) clearance from the U.S. Food and Drug Administration (FDA) for BD BACTEC™ blood culture bottles in plastic for Plus Aerobic/F, Plus Anaerobic/F and Peds Plus/F culture media. Obtaining 510(k) clearance allows increased in convenience and safety for customers without compromising the performance and quality of the BACTEC blood culture results.

Tom Polen, President of BD Diagnostic Systems, said BD was pleased to offer their customers the convenience of plastic, while continuing to deliver outstanding performance and rapid time-to-detection that drive better sepsis and healthcare-associated infection diagnostics.

BD seeded studies have shown that all three different media in plastic bottles (BD BACTEC™ Plus Aerobic/F, BD BACTEC™ Plus Anaerobic/F and BD BACTEC™ Peds Plus™/F) have equivalent performance to the media contained in glass bottles.



***Improved Handling: Reduced Size & Weight – 100% Performance***

The table below shows the *similarities* and *differences* between the plastic and glass blood culture bottles.<sup>1,2,3</sup>

Similarities			
No.	Item	Plastic/ Glass	
1.	Intended Use	i) Plus Aerobic/F media: Qualitative aerobic culture and recovery of microorganisms (bacteria & yeast) from blood ii) Plus Anaerobic/F media: Qualitative anaerobic culture and recovery of microorganisms from blood iii) Peds Plus/F media: Qualitative aerobic culture and recovery of microorganisms (bacteria & yeast) from blood	
2.	Sample Type	Human blood	
3.	Sample Volume	i) Plus Aerobic/F & Plus Anaerobic/F media: 3 – 10 mL ii) Peds Plus/F media: 0.5 – 5.0 mL	
4.	Instrument	BD BACTEC fluorescent series	
5.	Growth Medium	Same formulation of enriched soybean casein digest broth	
6.	Detection Technology	i) Continuous monitoring ii) Measurement of CO <sub>2</sub> increase iii) Resins for absorption of antimicrobials iv) Rocking agitation parameters	
7.	Incubation	35°C (± 1.5°C) up to 120 hours	
Differences			
No.	Item	Plastic	Glass
1.	Bottle Material	Multilayer polycarbonate/nylon/polycarbonate plastic	Glass
2.	Bottle Weight	20.9 g	113 g
3.	Bottle Height	5.0 inches	5.6 inches
4.	Bottle Sensor	2.60 g specific for the plastic bottle geometry	1.75 g
5.	Sensor Adhesion Promoter	Inert adhesion promoter for the adhesion of sensor to the polycarbonate surface of the plastic bottle	Not required
6.	Indicator	i) Plus Aerobic/F & Plus Anaerobic/F media: Bromocresol Purple indicator (BCP) - 2.50 mg/g of sensor Radglo Red Dye - 1.54 mg/g of sensor ii) Peds Plus/F media: BCP - 6.50 mg/g of sensor Radglo Red Dye - 4.00 mg/g of sensor	i) Plus Aerobic/F & Plus Anaerobic/F media: Bromocresol Purple indicator (BCP) - 1.00 mg/g of sensor Radglo Red Dye - 1.09 mg/g of sensor ii) Peds Plus/F media: BCP - 1.80 mg/g of sensor Radglo Red Dye - 1.09 mg/g of sensor

Reference:

1. Pre-market clearance 510(k) BD BACTEC™ Plus Aerobic/F. [https://www.accessdata.fda.gov/cdrh\\_docs/pdf11/K113558.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf11/K113558.pdf).
2. Pre-market clearance 510(k) BD BACTEC™ Plus Anaerobic/F. [https://www.accessdata.fda.gov/cdrh\\_docs/pdf14/K141810.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf14/K141810.pdf).
3. Pre-market clearance 510(k) BD BACTEC™ Peds Plus™/F. [http://www.accessdata.fda.gov/cdrh\\_docs/pdf15/K151866.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf15/K151866.pdf).



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