

## 510(k) Summary

### **BACT/ALERT® BPA and BPN Culture Bottles used with the BACT/ALERT® Microbial Detection Systems**

#### **510(k) Submission Information:**

Submitter's Name: bioMérieux, Inc.  
595 Anglum Road  
Hazelwood, MO 63042

Contact Person : Mary Beth Anheuser  
Staff Regulatory Affairs Specialist  
314-731-8516

Alternative Contact Person : Nathan Hardesty  
Manager, Regulatory Affairs  
314-731-8666

Fax Number : 314-731-8689

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#### **Device Name :**

Formal/Trade Name(s): BacT/ALERT® BPA Culture Bottle  
BacT/ALERT® BPN Culture Bottle

Common Name(s): BacT/ALERT® BPA Culture Bottle  
BacT/ALERT® BPN Culture Bottle

Classification Name: Microbial Growth Monitor

Regulation: Class I, not exempt from premarket notification per  
21 CFR 866.2560

Product Code: MZC

**Predicate Device(s):** BacT/ALERT® BPA Culture Bottle (BK180266)  
BacT/ALERT® BPN Culture Bottle (BK180266)

### **Description of the Device(s):**

**BacT/ALERT® BPA** (color-coded blue) – BacT/ALERT BPA disposable culture bottles contain 40 mL of media and an internal sensor that detects carbon dioxide as an indicator of microbial growth. The BacT/ALERT BPA culture bottle does not require venting. The media formulation consists of pancreatic digest of casein (1.7% w/v), papaic digest of soybean meal (0.3% w/v), sodium polyanethol sulfonate (SPS) (0.035% w/v), pyridoxine HCl (0.001% w/v), and other complex amino acid and carbohydrate substrates in purified water. Bottles are prepared with an atmosphere of CO<sub>2</sub> in oxygen under vacuum. The composition of the media may be adjusted to meet specific performance requirements.

**BacT/ALERT® BPN** (color-coded purple) – BacT/ALERT BPN disposable culture bottles contain 40 mL of media and an internal sensor that detects carbon dioxide as an indicator of microbial growth. The media formulation consists of pancreatic digest of casein (1.36% w/v), papaic digest of soybean meal (0.24% w/v), sodium polyanethol sulfonate (SPS) (0.035% w/v), menadione (0.00005% w/v), hemin (0.0005% w/v), yeast extract (0.376% w/v), pyridoxine hydrochloride (0.0008% w/v), pyruvic acid (sodium salt, 0.08% w/v), reducing agents, and other complex amino acid and carbohydrate substrates in purified water. Bottles are prepared with an atmosphere of CO<sub>2</sub> in nitrogen under vacuum. The composition of the media may be adjusted to meet specific performance requirements.

### **Principle of the Test**

The BacT/ALERT Microbial Detection System utilizes a colorimetric sensor and reflected light to monitor the presence and production of carbon dioxide (CO<sub>2</sub>) that is dissolved in the culture medium. If microorganisms are present in the test sample, carbon dioxide is produced as the organisms metabolize the substrates in the culture medium. When growth of the microorganisms produces CO<sub>2</sub>, the color of the gas-permeable sensor installed in the bottom of each culture bottle changes to yellow.

### **Intended Use:**

**BACT/ALERT® BPA** culture bottles are used with BACT/ALERT® Microbial Detection Systems (BACT/ALERT® 3D and BACT/ALERT® VIRTUO®) for quality control testing of leukocyte-reduced apheresis platelet (LRAP) units, and both single and pools of up to six (6) units of leukocyte-reduced whole blood platelet concentrates (LRWBPC). BACT/ALERT® BPA culture bottles support the growth of aerobic microorganisms (bacteria and fungi).

**BACT/ALERT® BPN** culture bottles are used with the BACT/ALERT® Microbial Detection Systems (BACT/ALERT® 3D and BACT/ALERT® VIRTUO®) for quality control testing of leukocyte-reduced apheresis platelet (LRAP) units, and both single and pools of up to six (6) units of leukocyte-reduced whole blood platelet concentrates (LRWBPC). BACT/ALERT® BPN culture bottles support the growth of anaerobic and facultative anaerobic microorganisms (bacteria).

BACT/ALERT® Microbial Detection Systems are used to detect bacteria in platelet components.

BACT/ALERT® Microbial Detection Systems are used as a safety measure, to extend dating beyond day 5 and up to day 7 for the following (Ref. FDA guidance):

- Large volume delayed sampling (LVDS) of platelets no sooner than 48 hours after collection; OR
- Secondary culture no sooner than day 4 after platelet collection

BACT/ALERT® Microbial Detection Systems are used to extend dating to five days for the following (Ref. FDA guidance):

- Large volume, delayed sampling of platelets no sooner than 36 hours after collection; OR
- Secondary culture no sooner than day 3 after platelet collection.

### **Summary and Explanation**

BACT/ALERT® Microbial Detection Systems and culture bottles provide both a microbial detection system and a culture media with suitable nutritional and environmental conditions for organisms which might be present in the test sample. Inoculated bottles are placed into the instrument where they are incubated and continuously monitored for the presence of microorganisms that will grow in the BACT/ALERT® BPA and BPN culture bottles.

BACT/ALERT® Microbial Detection Systems, and the BPA and BPN culture bottles in a blood bank application may be used for quality control testing of platelets using the single-step large volume delayed sampling test strategy or for a two-step testing strategy where primary quality control testing of platelets along with a secondary or safety measure test are used to extend platelet outdating to five days or seven days per FDA guidelines. Bacterial tests are labeled as a safety measure when they show benefit for detection of bacterial contamination not revealed by previous bacterial testing. The laboratory should follow its own quality control procedures for these uses.

The performance of BACT/ALERT Microbial Detection Systems for the detection of bacteria in non-leukocyte reduced platelet products is not known since studies were conducted utilizing leukocyte reduced apheresis platelets (LRAP) and leukocyte reduced whole blood platelet concentrates (LRWBPC).

**NOTE:** The information provided applies to all configurations of BACT/ALERT® Microbial Detection Systems (i.e. BACT/ALERT® 3D and BACT/ALERT® VIRTUO®, unless otherwise noted).

### **Substantial Equivalence**

The Intended Use of the BPA and BPN culture bottles remains unchanged. When used with the BACT/ALERT Microbial Detection Systems, the BPA and the BPN culture bottles are used for quality control testing of platelets. The bottles support the growth of aerobic bacteria and fungi or anaerobic bacteria, respectively.

BacT/ALERT® BPA and BPN Culture Bottles  
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The Indications for Use described in the Summary and Explanation section of the Instructions for Use of the bottles have been expanded to include not only the two-step testing strategy that consists of primary quality control testing of platelet products along with secondary or safety measure testing but the single-step large volume delayed sampling (LVDS) test strategy that are used to extend platelet outdating to five or seven days per FDA guidelines.

The overall false positive rate observed during LVDS testing of platelets performed at  $\geq 36$  hours or  $\geq 48$  hours after collection, was 0.29% (with a range of 0.17% - 0.34%). The overall false positive rate associated with the LVDS test falls within the false positive rate observed in controlled studies and reported in the BACT/ALERT BPA AND BACT/ALERT BPN culture bottles Instructions for Use (Overall 0.19%, range 0.00-0.49%).

Expanding the Indications for Use to include not only primary quality control testing of platelets along with secondary or safety measure testing but the single-step LVDS test strategy to extend platelet outdating per FDA guidelines has no impact to the Intended Use. Additionally, using the BACT/ALERT Microbial Detection Systems for LVDS testing can provide valuable information that could prevent the transfusion of a contaminated unit or to initiate patient follow-up that otherwise could be delayed.