

## 510(k) Summary

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

#### **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

Date of Preparation : September 27, 2017

#### **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 (BK170142)  
BACT/ALERT® BPN Culture Bottle (BK170142)

### 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 aerobic microbial growth. The BACT/ALERT® BPA culture bottle does not require venting. Bottles are prepared with an atmosphere of CO<sub>2</sub> in oxygen under vacuum.

**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 anaerobic and facultative anaerobic microbial growth. Bottles are prepared with an atmosphere of CO<sub>2</sub> in nitrogen under vacuum.

### 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 the BACT/ALERT® Microbial Detection Systems for quality control testing of platelets. BACT/ALERT® BPA culture bottles support the growth of aerobic microorganisms (bacteria and fungi).

- For the BACT/ALERT® 3D Systems, the following platelet preparation methods have been validated: leukocyte reduced apheresis platelet (LRAP) units, and both leukocyte reduced single and a pool of up to six (6) units of leukocyte reduced whole blood platelet concentrates (LRWBPC).
- For the BACT/ALERT® VIRTUO® System, the following platelet preparation methods have been validated: leukocyte-reduced apheresis platelet (LRAP) units.

**Note:** The performance characteristics of BACT/ALERT® BPA bottle on BACT/ALERT® VIRTUO® Microbial Detection System testing of leukocyte-reduced whole blood platelet concentrates (LRWBPC) have not been established.

**BACT/ALERT® BPN** culture bottles are used with the BACT/ALERT® Microbial Detection Systems for quality control testing of platelets. BACT/ALERT® BPN culture bottles support the growth of anaerobic and facultative anaerobic microorganisms (bacteria).

- For the BACT/ALERT® 3D Systems, the following platelet preparation methods have been validated: leukocyte reduced apheresis platelet (LRAP) units, and both leukocyte reduced single and a pool of up to six (6) units of leukocyte reduced whole blood platelet concentrates (LRWBPC).

- For the BACT/ALERT® VIRTUO® System, the following platelet preparation methods have been validated: leukocyte-reduced apheresis platelet (LRAP) units.

**Note:** The performance characteristics of BACT/ALERT® BPA bottle on BACT/ALERT® VIRTUO® Microbial Detection System testing of leukocyte-reduced whole blood platelet concentrates (LRWBPC) have not been established.

### Summary and Explanation

BACT/ALERT® Microbial Detection Systems (BACT/ALERT® 3D and BACT/ALERT® VIRTUO®) and culture bottles provide both a microbial detection system and 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 BACT/ALERT® BPN culture bottles.

BACT/ALERT® Microbial Detection Systems and culture bottles may be used for quality control testing of platelets and as a secondary safety measure test. 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 LRAP and leukocyte reduced WBPC products.

**NOTE:** The information provided applies to all configurations of BACT/ALERT® Microbial Detection Systems, unless otherwise noted.

### Substantial Equivalence

The BACT/ALERT® BPA and BPN culture bottles (last cleared under 510(k) BK170142) demonstrated substantial equivalent performance testing for LRAP on the BACT/ALERT® VIRTUO® Microbial Detection when compared with testing the BPA and BPN culture bottles on the BACT/ALERT® 3D Microbial Detection System. This 510(k) Premarket Notification presents data in support of the use of the BACT/ALERT® BPA and BPN bottles for testing on BACT/ALERT® VIRTUO®.

### Performance Characteristics

External (i.e. clinical) and internal studies were conducted to validate the performance of the BACT/ALERT® BPA and BACT/ALERT® BPN bottles tested on the BACT/ALERT® VIRTUO® for quality control testing and as a secondary safety measure test for LRAP.

The following tables show the results of the BACT/ALERT® BPA and BACT/ALERT® BPN culture bottles tested on the BACT/ALERT® VIRTUO® and BACT/ALERT® 3D.

Reproducibility of Detection Rates of Microorganisms in LRAP with BACT/ALERT® VIRTUO®

% Recovery [95% Confidence Interval]			
Site 1	Site 2	Site 3	Overall
100%	100%	100%	100%
[96.0-100]%	[96.0-100]%	[96.0-100]%	[98.6-100]%
(90/90)	(90/90)	(90/90)	(270/270)

- Six microorganisms tested in the reproducibility set
- With time to detection (TTD) ranges between 6.6 to 16.9 hours.
- Inoculum ranges for the BPA and BPN culture bottles were between 1 – 20 CFU/ml
- The negative agreement rate for this testing was 100%. All negative controls (54/54) were declared negative by the VIRTUO®.

Clinical Study – Recovery of Microorganisms in LRAP with BACT/ALERT® BPA and BACT/ALERT® BPN Culture Bottles

Microorganism	BACT/ALERT® Culture Bottle	Number of Positive Cultures	
		BACT/ALERT® 3D	BACT/ALERT® VIRTUO®
Positive	BPA	200	199
	BPN	200	199
Total % Recovery	BPA	100%	99.5%
	BPN	100%	99.5%
95% Confidence Interval	BPA	98.2%-100%	97.2%-99.9%
	BPN	98.2%-100%	97.2%-99.9%

- Eleven microorganisms tested in the clinical study
- With time to detection (TTD) ranges for the BACT/ALERT® 3D between 9.8 to 39.6 hours.
- With time to detection (TTD) ranges for the BACT/ALERT® VIRTUO® between 7.1 to 34.3 hours.
- Inoculum ranges for both the BPA and BPN culture bottles were between 1 – 20 CFU/ml
- The negative agreement rate for this testing was 100% for the VIRTUO®, all negative controls (211/211) were declared negative by the VIRTUO®, and 99.5% (207/208) for the BACT/ALERT® 3D where 1 false positive bottle was observed.

Analytical Sensitivity: Growth Performance of Microorganisms in LRAP with BACT/ALERT® BPA and BACT/ALERT® BPN Culture Bottles

The data demonstrate that 100% of the thirteen microorganisms tested for growth performance at an inoculum range of 1 – 7 CFU/ml in LRAP were recovered and detected in the BACT/ALERT® BPA and BACT/ALERT® BPN bottles tested on the BACT/ALERT® VIRTUO® Microbial Detection System and on the BACT/ALERT® 3D Microbial Detection System. The TTD range for the BACT/ALERT® 3D was 10.1 to 23.3 hours, and the TTD range for the VIRTUO® was 7.0 to 21.6 hours. The negative agreement rate for this testing was 100%. All negative controls were declared negative by the VIRTUO® (20/20) and the BACT/ALERT 3D (4/4).

Within-Laboratory Precision (Repeatability) of BACT/ALERT® BPA and BACT/ALERT® BPN Culture Bottles Tested Over 10 Days

The data demonstrate 100% recovery with five of six microorganisms at an inoculum level of  $\leq 3$  CFU/ml, and tested over 10 days, with the exception of *Pseudomonas aeruginosa* at 98.3% (which had an inoculum with  $< 1$  CFU/ml). The TTD range for the VIRTUO® was 6.8 to 15.5 hours (with the exception of *Clostridium perfringens*, with a TTD range of 6.8 to 62.4 hours). The negative agreement rate for this testing was 100%. All negative controls were declared negative by the VIRTUO® (188/188).

Analysis of BACT/ALERT® BPA and BACT/ALERT® BPN Culture Bottles Time to Detection to Examine the Effects of Platelet Age

To establish the equivalency of the BACT/ALERT® BPA and BACT/ALERT® BPN bottles tested on BACT/ALERT® VIRTUO® to the BACT/ALERT® BPA and BACT/ALERT® BPN bottles tested on BACT/ALERT® 3D as a safety measure for secondary testing of previously tested platelet products, an internal bioMerieux, Inc. analytical study was performed to examine the effects of platelet age on the time to detection of microorganisms. In this study, aliquots of LRAP, 3 to 5 days post collection, were seeded with low levels ( $\leq 3$  CFU/mL) of 6 organisms. An analysis of variance was performed to determine whether the TTD was significantly different depending on the age of the platelets. P-values greater than 0.05 indicate that there is no statistically significant evidence indicating that platelet age effects TTD. All p-values for the BACT/ALERT® VIRTUO® were greater than 0.05 providing confirmation that platelet age does not affect TTD. A total of 96 BPA and 92 BPN negative control bottles were tested on the BACT/ALERT® VIRTUO®. No false positive detections were observed (0/188).

Specificity & Sensitivity

BACT/ALERT® VIRTUO® Instrument False Positive (FP) Results Observed When Testing LRAP

Study Data Source <sup>1</sup>	Quantity Tested Per Bottle	#FP / Bottles Tested	%FP
Reproducibility	10 mL	0 / 54	0.00%
Recovery	10 mL	0 / 211	0.00%
Analytical Sensitivity	10 mL	0 / 20	0.00%
Within-Laboratory Precision	4 – 10 mL	0 / 188	0.00%
Overall Specificity	-	0 / 463	0.00%

<sup>1</sup>Refer to tables above for the source of these data.

Sensitivity of the BACT/ALERT® VIRTUO® instrument was determined during performance validation testing for LRAP. All negative control bottles and any seeded bottles that were determined negative by the instrument were confirmed to be true negatives through subculture to plated media. There were no false negative bottles observed.

**IMPORTANT:** BACT/ALERT® BPA and BACT/ALERT® BPN tested on the BACT/ALERT® VIRTUO® have only been validated for use with LRAP.