

**BacT/ALERT Culture Bottles**

**510(k) Summary**

- (a)(1) **The submitter's name, address, telephone number, a contact person, and the date the summary was prepared;**

**Submitter's Name: bioMérieux, Inc.**

**Submitter's Address: 100 Rodolphe Street  
Durham, North Carolina 27712**

**Submitter's Telephone: (919) 620-2000**

**Submitter's Contact: Thomas S. Clement**

**Date 510(k) Summary Prepared: 2/15/02**

- (a)(2) **The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known;**

**Trade or Proprietary Name: BacT/ALERT Culture Bottles**

**Common or Usual Name: BacT/ALERT Culture Bottles**

**Classification Name: SYSTEM, DETECTION, BACTERIAL, FOR PLATELET TRANSFUSION PRODUCTS**

- (a)(3) **An identification of the legally marketed device to which the submitter claims substantial equivalence;**

**Device Equivalent to: Pre-Amendment Thioglycollate Tubes**

- (a)(4) **A description of the device.**

**The BacT/ALERT Culture Bottles to include BacT/ALERT Aerobic Culture Bottle (SA), BacT/ALERT Anaerobic Culture Bottle (SN), BacT/ALERT FAN Aerobic Culture Bottle (FA), BacT/ALERT FAN Anaerobic Culture Bottle (FN) and BacT/ALERT Pedi-BacT Culture Bottle were developed to provide suitable nutritional and environmental conditions for organisms commonly encountered in blood infections, normally sterile body fluids and platelets. An inoculated bottle is placed into the BacT/ALERT Microbial Detection Instruments where it is incubated and continuously monitored for the presence of microorganisms that will grow in the BacT/ALERT Bottle.**

- (a)(5) **A statement of the intended use of the device.**

**Device Intended Use:**

**BacT/ALERT Aerobic and Anaerobic Culture Bottles are used with the BacT/ALERT Microbial Detection System in qualitative procedures for the recovery and detection of aerobic and anaerobic microorganisms (bacteria and fungi) from blood, other normally sterile body fluids. BacT/ALERT Culture Bottles**

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may also be used for quality control testing of leukocyte reduced apheresis platelet (LARP) units.

BacT/ALERT FAN Aerobic Culture Bottles are used with the BacT/ALERT Microbial Detection Systems in qualitative procedures for enhanced recovery and detection of aerobic and facultative anaerobic microorganisms (bacteria and fungi) from blood, other normally sterile body fluids. BacT/ALERT Culture Bottles may also be used for quality control testing of leukocyte reduced apheresis platelet (LARP) units.

BacT/ALERT FAN Anaerobic Culture Bottles are used with the BacT/ALERT Microbial Detection Systems in qualitative procedures for enhanced recovery and detection of anaerobic microorganisms from blood, other normally sterile body fluids. BacT/ALERT Culture Bottles may also be used for quality control testing of leukocyte reduced apheresis platelet (LARP) units.

BacT/ALERT Pedi-BacT Aerobic Culture Bottles are used with the BacT/ALERT Microbial Detection Systems in qualitative procedures for the recovery and detection of aerobic and facultative anaerobic microorganisms (bacteria and yeast) from blood. BacT/ALERT Culture Bottles may also be used for quality control testing of leukocyte reduced apheresis platelet (LARP) units..

**NOTE:** The BacT/ALERT System (3D and 240) and Culture Bottles may be used for quality control testing of LRAP. The laboratory should follow it's own quality control procedures for this use. The BacT/ALERT System, including the Culture Bottles, should not be used in determining suitability for release of LRAP for transfusion. Users considering such release testing should first consult CBER for the appropriate clinical studies.

The performance of the BacT/ALERT System to detect bacteria in whole blood derived platelets and non-leukocyte reduced platelet products is not known since studies were conducted utilizing LRAP products. The testing alone should not be used to extend the shelf life of platelets. Users considering such testing should first consult CBER for appropriate clinical studies.

- (a)6) The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performed as well or better than the legally marketed device identified in (a)(3).

Studies to determine the ability of the culture bottles to detect the presence of microorganisms in leukocyte reduced apheresis platelets were performed at two clinical sites. Various platelet bags were seeded with 15 individual microorganisms to include:

<i>Staphylococcus epidermidis</i>	<i>Staphylococcus aureus</i>	<i>Bacillus subtilis</i>
<i>Bacillus cereus</i>	<i>Echerichia coli</i>	<i>Klebsiella oxytoca</i>
<i>Serratia marcescens</i>	<i>Candida albicans</i>	<i>Clostridium perfringens</i>
<i>Streptococcus pyogenes</i>	<i>Streptococcus viridans</i>	<i>Pseudomonas aeruginosa</i>
<i>Enterobacter cloacae</i>	<i>Propionibacterium acnes</i>	<i>Corynebacterium sp.</i>

Twenty bottles of each type were seeded at each site for a total of 40 seeded bottles per organism and compared to the same organisms inoculated into Fluid Thioglycolate tubes. The initial concentration of organism seeded varied for each organism and ranged from 1 CFU/ml to 560 CFU/ml. An additional 20% of all bottle types served as negative controls (platelets with no seeded organisms added). No false positive were detected. However, of the total 600 negative control bottles evaluated, 2 were found to be positive as a result of

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contamination. One contaminated negative control bottle had a *Bacillus* species and the other had mixed flora. Likely causes of contamination can be from inadequate aseptic technique or operator error (e.g. operator lab coat, aerosol, etc.), sampling or inoculation in an inadequate environment, or a spore sitting on top of the BacT bottle septum when introducing the specimen which was not removed with the 70% alcohol wipe. The following tables show the recovery of appropriate organisms in the BacT/ALERT Culture bottles:

TABLE 1 - Recovery of Organisms from Site A

Microorganism	SA	SN	FA	FN	Pedi-BacT	THIO
<i>Bacillus cereus</i>	20	20	20	20	20	20
<i>Bacillus subtilis</i> *	19	15	19	0	20	13
<i>Candida albicans</i> *	20	3	20	0	20	20
<i>Clostridium perfringens</i> **	1	20	0	20	5	20
<i>Corynebacterium sp.</i> *	20	0	20	0	20	12
<i>Enterobacter cloacae</i>	20	20	20	20	20	20
<i>Echerichia coli</i>	20	20	20	20	20	20
<i>Klebsiella oxytoca</i>	20	20	20	20	20	20
<i>Propionibacterium acnes</i> **	10	17	0	0	16	20
<i>Pseudomonas aeruginosa</i> *	20	1	20	0	20	20
<i>Staphylococcus aureus</i>	20	20	20	20	20	20
<i>Staphylococcus epidermidis</i>	20	20	20	20	20	20
<i>Serratia marcescens</i>	20	20	20	20	20	20
<i>Streptococcus pyogenes</i>	20	20	20	20	20	20
<i>Streptococcus viridans</i>	20	20	20	20	20	20
Positive	270	236	259	200	281	285
Total % Recovery	90.0%	78.7%	86.3%	66.7%	93.7%	95.0%
95% Confidence Interval (CI)	86.0-93.2	73.6-83.2	81.9-90.0	61.0-72.0	90.3-96.1	91.9-97.2
% recovery in Aerobic bottles of Facultative Organisms and Strict Anaerobes	99.6%		99.6%		100%	94.2%
95% CI	97.9-100.0		97.9-100.0		98.6-100.0	90.7-96.7
% recovery in Anaerobic bottles of Facultative Organisms and Strict Anaerobes		98.6%		90.9%		100%
95% CI		96.1-99.7		86.3-94.4		98.3-100

\* Strict Aerobes – not expected to recover in anaerobic culture bottles.

\*\*Strict Anaerobes - not expected to recover in aerobic culture bottles.

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**TABLE 2 - Recovery of Organisms from Site B**

<b>Microorganism</b>	<b>SA</b>	<b>SN</b>	<b>FA</b>	<b>FN</b>	<b>Pedi-BacT</b>	<b>THIO</b>
<i>Bacillus cereus</i>	20	20	20	20	20	20
<i>Bacillus subtilis</i> *	20	1	20	0	20	20
<i>Candida albicans</i> *	19	0	19	0	19	20
<i>Clostridium perfringens</i> **	20	20	1	20	20	20
<i>Corynebacterium sp.</i> *	18	0	19	0	18	18
<i>Enterobacter cloacae</i>	20	20	20	20	20	20
<i>Echerichia coli</i>	20	20	20	19	20	20
<i>Klebsiella oxytoca</i>	20	20	20	20	20	20
<i>Propionibacterium acnes</i> **	20	20	0	0	20	20
<i>Pseudomonas aeruginosa</i> *	20	0	20	0	20	20
<i>Staphylococcus aureus</i>	20	20	20	20	20	19
<i>Staphylococcus epidermidis</i>	20	18	20	20	20	20
<i>Serratia marcescens</i>	20	19	20	20	20	20
<i>Streptococcus pyogenes</i>	20	20	20	19	20	20
<i>Streptococcus viridans</i>	20	20	20	20	20	20
<b>Positive</b>	<b>297</b>	<b>218</b>	<b>259</b>	<b>198</b>	<b>297</b>	<b>297</b>
<b>Total % Recovery</b>	<b>99.0%</b>	<b>72.7%</b>	<b>86.3%</b>	<b>66.0%</b>	<b>99.0%</b>	<b>99.0%</b>
<b>95% Confidence Interval (CI)</b>	<b>97.1-99.8</b>	<b>67.2-77.6</b>	<b>81.9-90.0</b>	<b>60.3-71.3</b>	<b>97.1-99.8</b>	<b>97.1-99.8</b>
<b>% recovery in Aerobic bottles of Facultative Organisms and Strict Anaerobes</b>	<b>98.8%</b>		<b>99.2%</b>		<b>98.8%</b>	<b>98.8%</b>
<b>95% CI</b>	<b>96.7-99.8</b>		<b>97.2-99.9</b>		<b>96.7-99.8</b>	<b>96.7-99.8</b>
<b>% recovery in Anaerobic bottles of Facultative Organisms and Strict Anaerobes</b>		<b>98.6%</b>		<b>90.0%</b>	<b>N/A</b>	<b>99.5%</b>
<b>95% CI</b>		<b>96.1-99.7</b>		<b>85.3-93.6</b>		<b>97.5-100</b>

\* Strict Aerobes – not expected to recover in anaerobic culture bottles.

\*\*Strict Anaerobes - not expected to recover in aerobic culture bottles.