

510(k) Summary

BacT/ALERT® BPA and BPN Culture Bottles used with the BacT/ALERT® Microbial Detection Systems

510(k) Submission Information:

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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 (BK050037)
BacT/ALERT® BPN Culture Bottle (BK050043)

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 CO₂ 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 CO₂ 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 (CO₂) 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 CO₂, 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).

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).

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 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. The laboratory should follow its own quality control procedures for these uses. BacT/ALERT Microbial Detection Systems, including the culture bottles, were not cleared for use in determining suitability for release of platelets for transfusion. Users considering such release testing should first consult the national regulatory agency for requirements and studies necessary to support that release testing.

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. The testing of platelets and non-leukocyte reduced platelet products alone should not be used to extend the shelf life of platelets without consulting your national regulatory agency.

NOTE: The information provided applies to all configurations of BacT/ALERT Microbial Detection Systems, 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.

The Indications for Use described in the Summary and Explanation section of the Instructions for Use of the bottles has been expanded to include not only primary quality control testing but secondary safety measure testing of platelet products.

For the secondary safety measure claim for platelet testing on days 3 and ≥ 6 , the overall false positive (FP) rate 0.3% (with a range 0 – 1.1%). This is not significantly different than the FP rate on a day 2 test, which is 0.19% (with a range 0 – 0.49%).

Expanding the Indications for Use to include not only primary quality control testing of platelets but testing as a secondary safety measure later in the shelflife of the platelets, has no impact to the Intended Use. Additionally, using the BacT/ALERT Microbial Detection Systems for secondary safety measure 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.