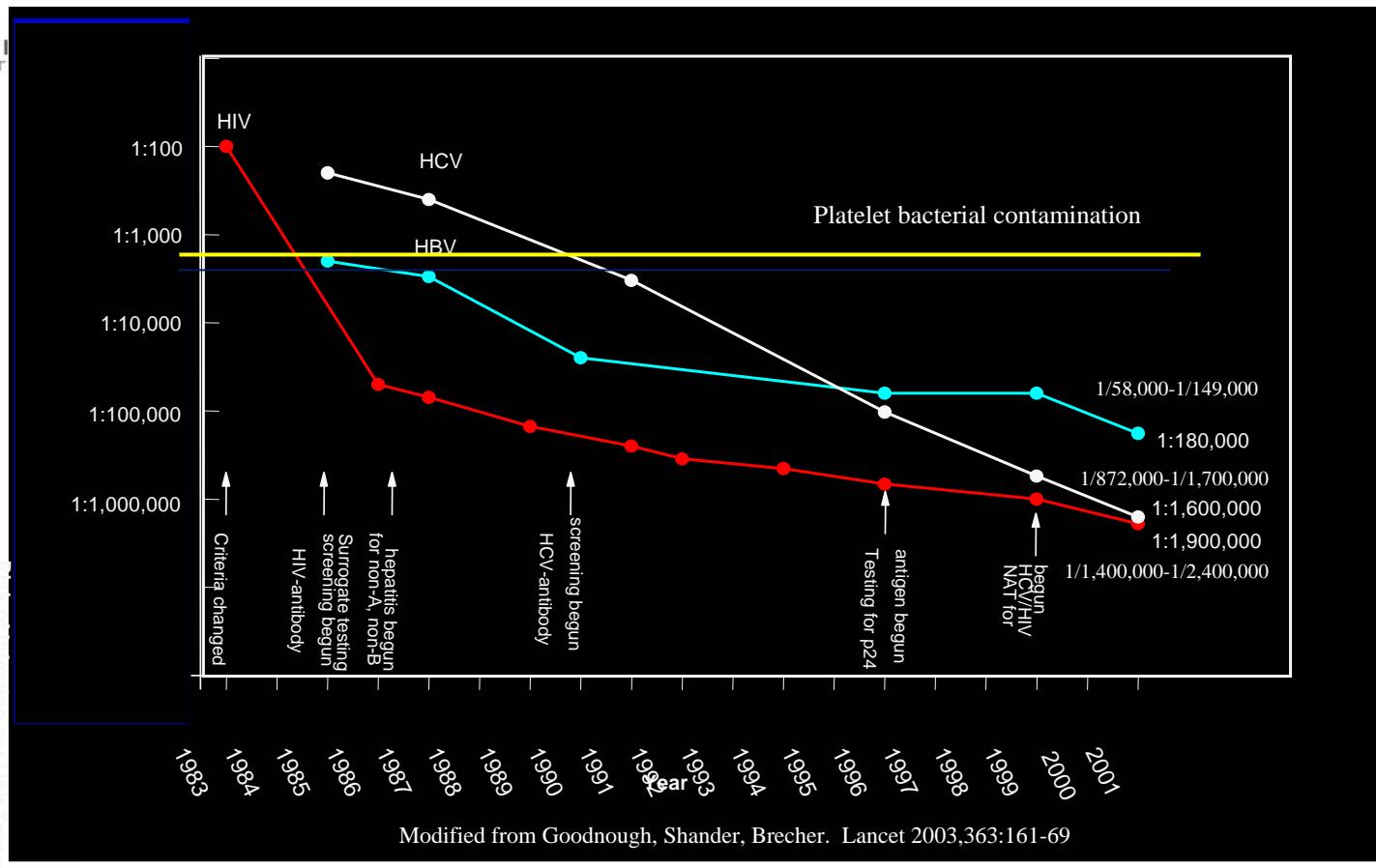




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# BacT/ALERT Microbial Detection System

A.C. Marchionne, BS, MS  
National Sales and Marketing Manager  
Blood Bank / Tissue Bank



## Platelet transfusions in the United States

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**4 million platelet bags transfused/year**

**1:1000 - 1:2000 bacterially contaminated  
(N = 2000 - 4000 bags)**

**1/10 to 2/5 result in clinical sepsis  
(N = 200 - 1600 cases)**

**Perhaps 1/5 to 1/3 result in fatalities  
(N = 40 - 533 deaths)**

**or**

**(1:7,500 to 1:100,000 fatalities/unit)**

BIOMÉRIEUX  
INDUSTRY



# BacT/ALERT 3D



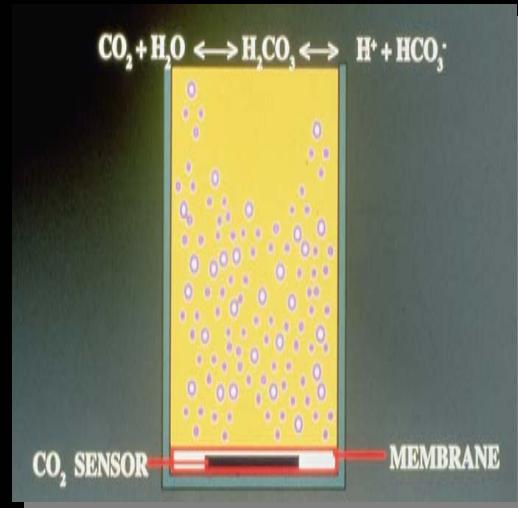
# Colorimetric Technology

## Growth chemistry

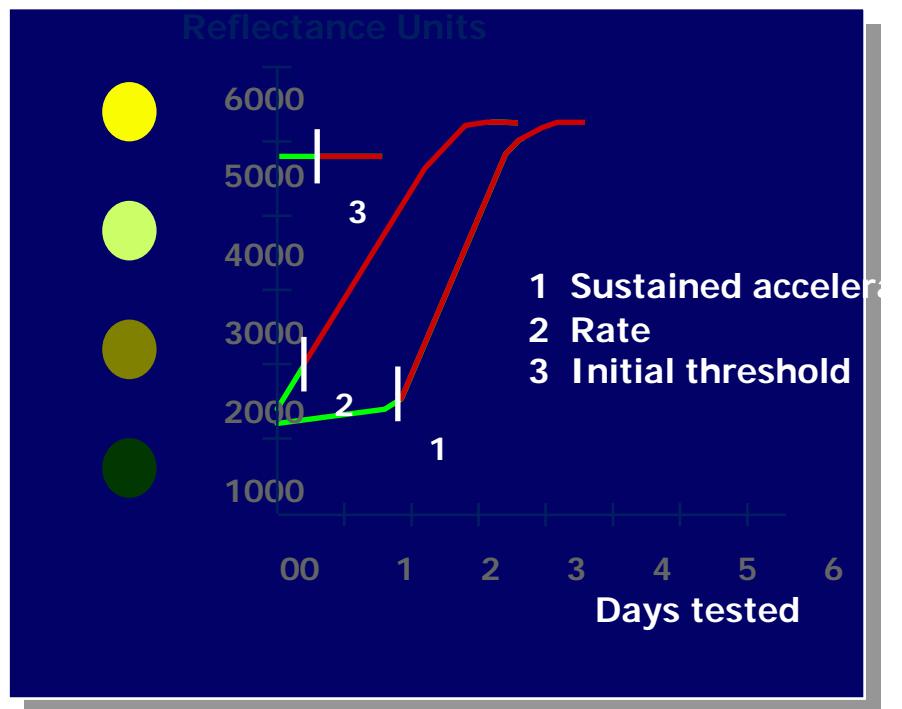
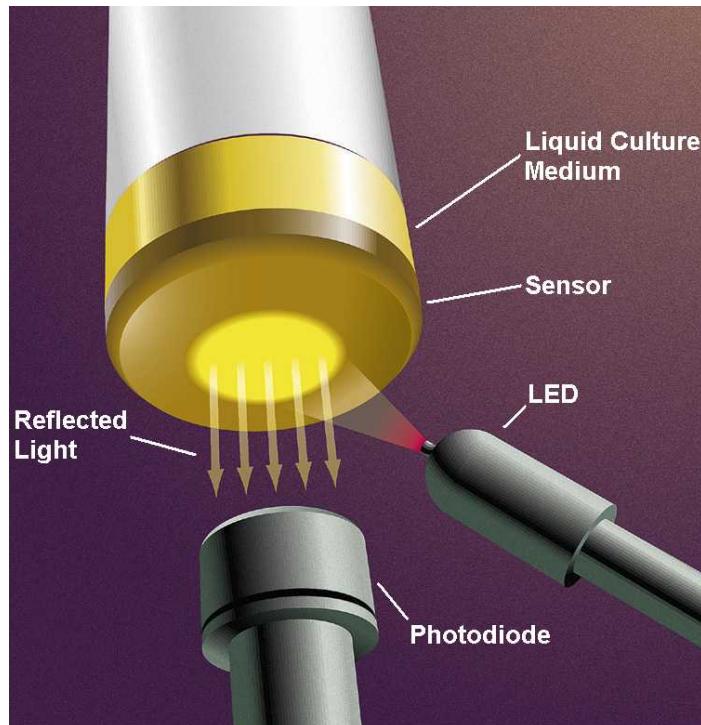
Organisms grow in media and produce CO<sub>2</sub>

CO<sub>2</sub> traverses semi-permeable membrane

Sensor changes from  
green to yellow



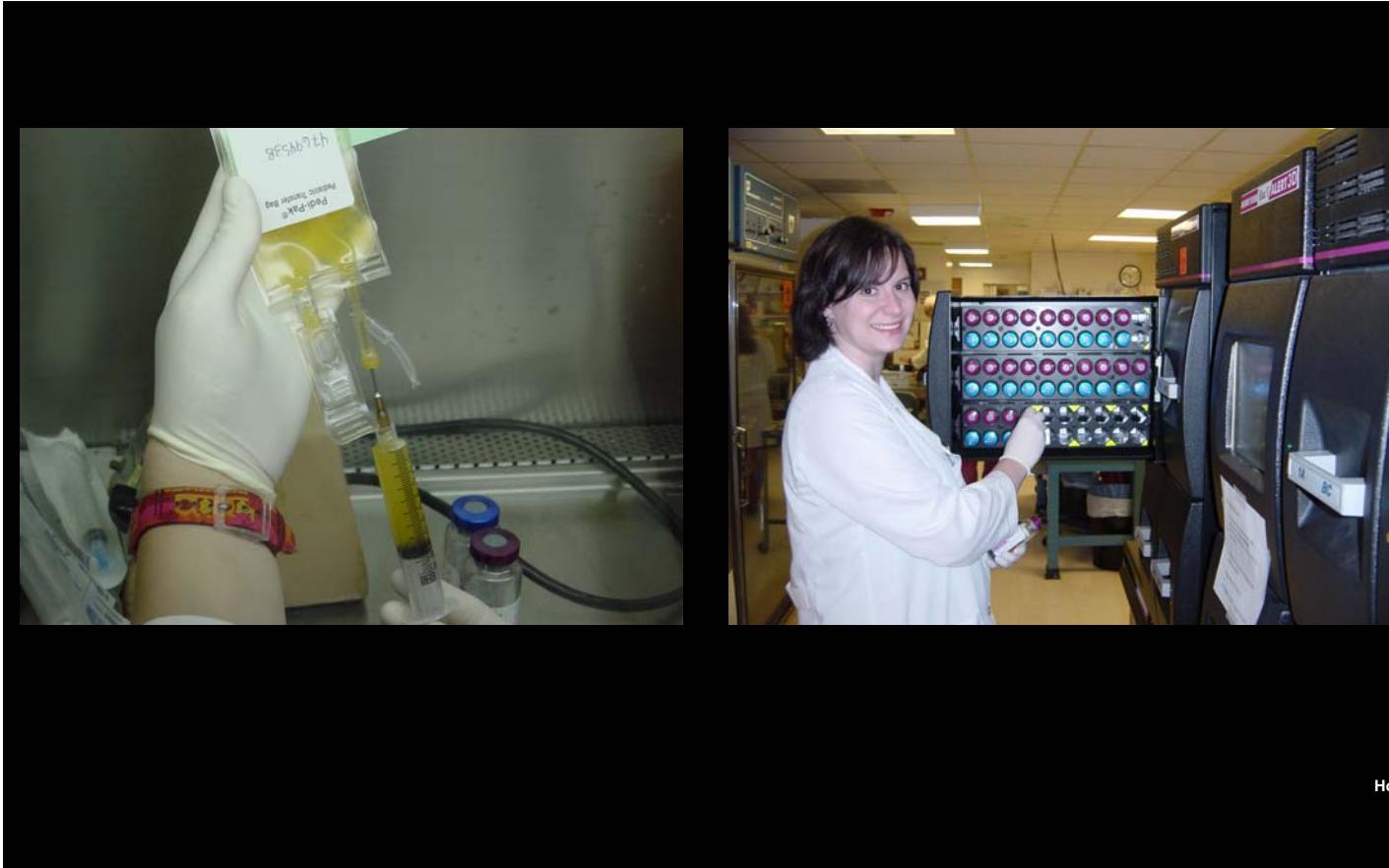
# Schematic View of Detection



# Sampling Devices

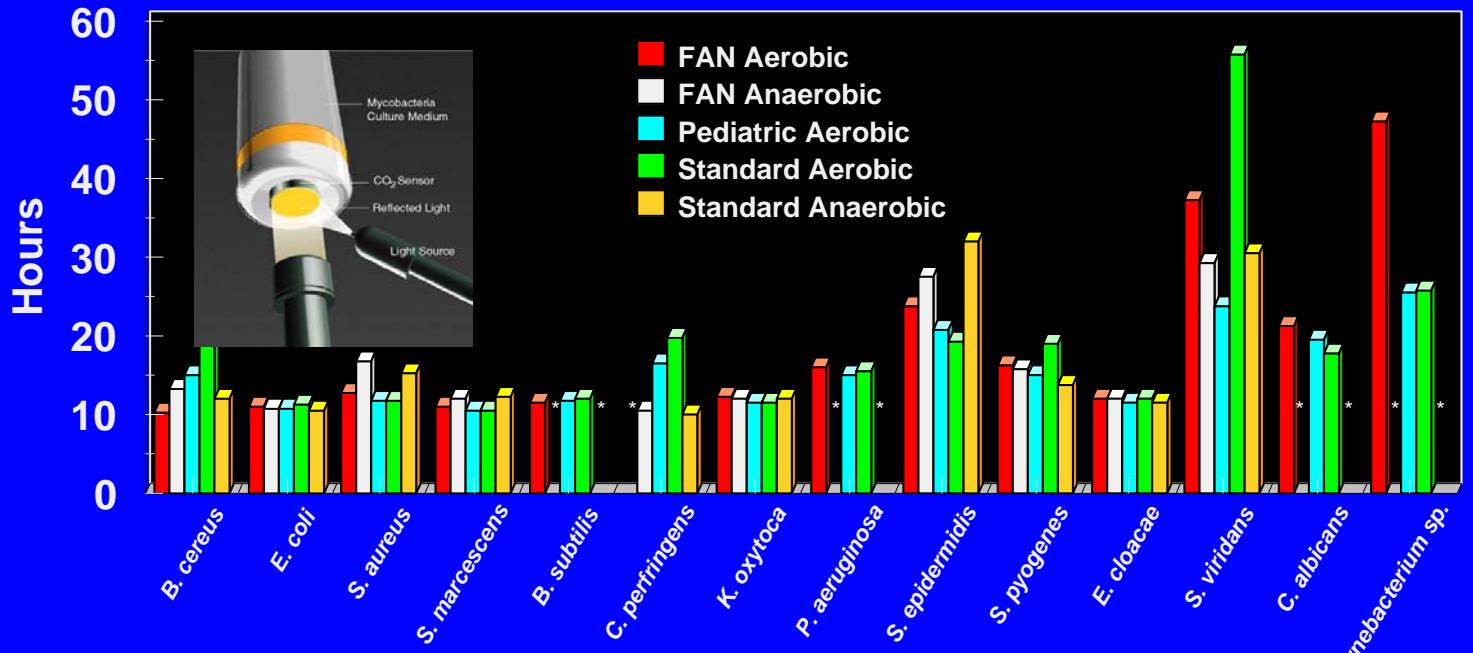


# Sampling & Loading



Hos

## Automated Culture (BacT/ 3D Alert)



Target = 10 CFU/mL inoculum, Actual mean = 10.9 CFU/mL

\* No growth

*C. albicans*  
*Corynebacterium sp.*

Brecher ME, Means N, Jere CS, Heath D, Rothenberg S, Stutzman LC. Evaluation of the BacT/ALERT 3D® Microbial Detection System for platelet bacterial contamination: An analysis of 15 contaminating organisms. Transfusion 2001;41:477-482.



**ORIGINAL PAPER**

**Evaluation of the Bact/Alert automated blood culture system for detecting bacteria and measuring their growth kinetics in leucodepleted and non-leucodepleted platelet concentrates**

C. F. WILKINSON,<sup>1</sup> J. M. P. LANE,<sup>2</sup> S. RODRIGUEZ,<sup>3</sup> R. HUMPHREY,<sup>1</sup> E. L. LEONARD<sup>1</sup>  
<sup>1</sup> Biomerieux, Marlow, Buckinghamshire, UK; <sup>2</sup> Biomerieux, North London, Colindale, London, UK

**Vox Sanguinis**

**Background and Objectives** To evaluate the Bact/Alert automated blood culture system for the detection of bacteria in platelet concentrates, and to determine the specific growth kinetics in leucodepleted and non-leucodepleted platelets.

**Materials and Methods** A Bact/Alert® Automated Blood Culture System (Becton Dickinson) was used to monitor the growth of *Escherichia coli*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Corynebacterium parvum*, *Bacillus cereus*, Group B streptococci, *Enterococcus faecalis*, *Enterococcus faecium* and *Enterococcus* spp. at different initial inoculae (CFU/ml), dilutions 0.2 and 5, in 20 mL standard media and controls for the non-inoculated and 0.2 and 5 dilution and background concentrations.

**Results** The Bact/Alert system detected all 10 bacterial species at all dilutions and concentrations, with all positive detections with an average detection time of 16 h. Growth curves, as the inoculum concentration increased, reflected the increase in the rate of growth, with a corresponding increase in the detection time, which took place in a non-linear fashion and reached a plateau at approximately 10<sup>3</sup> CFU/ml and did not change from 10<sup>3</sup> to 10<sup>4</sup> CFU/ml. No growth was not detected by the Bact/Alert system.

**Conclusion** The evidence demonstrates that the Bact/Alert automated blood culture system is capable of substantial growth kinetics with all organisms tested. Leucodepletion does not appear to enhance bacterial detection. The Bact/Alert automated blood culture system is a reliable and rapid method for monitoring platelets, making an automated blood culture system is therefore a potential option.

**Key words:** automated, bacteria, culture, platelets, platelet, platelet

Received 17 January 2002; accepted 27 May 2002.  
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**Introduction**

Platelet transfusion remains the major component of availability and mortality associated with haemostatic intervention.

**Assessments.** C. F. Wilkinson, Biomerieux, Marlow, Buckinghamshire, UK; Tel.: +44 1494 820000; fax: +44 1494 820270; E-mail: cfw@biomerieux.com

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In the United States during the 1990s, 10–15% of transfused platelets were found to contain bacteria [1]. In the United Kingdom, 11 deaths from sepsis in 1997 in hospital patients were attributed to infection with bacteria [2]. Several mechanisms have been proposed to explain the increased incidence of bacterial contamination, the most frequently identified cause of about 5% of total transfused platelets [3]. The introduction of automated blood culture systems has greatly reduced the incidence of bacterial contamination of platelets [4], although it is still present in all blood components used for transfusion. Platelet concentrates (PCs) are the most common cause of bacterial

**Transfusion Medicine**, 2003, 13, 151–160**ORIGINAL ARTICLE****Operational feasibility of routine bacterial monitoring of platelets**

A. MACAULEY,<sup>1</sup> A. CHANDRAPAL,<sup>2</sup> G. GEDDIS,<sup>1</sup> K. G. MORRIS<sup>1</sup> AND W. M. McCLELLAND<sup>1</sup> *Northern Ireland Blood Transfusion Service, Belfast, Northern Ireland, UK*

Received 9 December 2002; accepted 26 February 2003; accepted 30 April 2003

**Abstract.** Bacterial contamination of platelets poses the greatest risk of mortality and morbidity to platelet transfusion recipients. Some European countries have adopted the use of leukoreduced platelets to reduce the risk of transmission of bacteria. A pilot study was carried out at the Northern Ireland Blood Transfusion Service (NIBTS) to evaluate the use of the Bact/ALERT 3D automated culture system, to assess the operational feasibility of routine bacterial monitoring of platelets. About 1000 units of platelets were monitored over a 1-year period. Of the 28 of 5756 initial positive cultures, 13 (46%) were reproducible on repeat sampling. The remaining 15 cultures were due to contamination either in aseptic or both aseptic and secondary culture bottles. A sample of time-expired units (429) that had initial negative culture results

continued negative when retested on day 8. About 213 time-expired units were subjected to routine quality assessment and more than 85% were found to contain no bacteria. The Bact/ALERT 3D culture media for platelets reduced the number of false positives and provided clear growth patterns and positive or negative cultures from the instrument.

**Keywords:** bacteria, culture, platelets, screening

Bacterial contamination of blood components, particularly platelets, is a significant problem because of mortality and morbidity because of transfusion-transmitted infections (TTIs). (Prest et al., 1999) The incidence of TTIs has increased to 22% of transfusions to the general public and has reported to the French Haemovigilance network between 1993 and 2000. The incidence of TTIs in the UK, between 1999 and 2001, the Scottish Hemocyte Transfusion (SHT) surveillance system reported 35 transfusion-associated infections (TAIs) per 1000 units of bacteria (Aher et al., 2002). Bacterial contamination of platelets accounted for 17 of 21 cases resulting in TAIs. Strategies to reduce bacterial transmission are mainly implemented via cleaning methods

infection prevention, by donation of the initial unit of blood, by leukoreduction, plasma and bacterial removal of blood components.

Evaluation studies of the automated Bact/ALERT 3D system have shown a 95% detection rate of 22% of non-leukoreduced platelet units reported to the French Haemovigilance network between 1993 and 2000. The Bact/ALERT 3D culture media system is able to detect a wide range of bacteria at various dilutions of up to 10<sup>4</sup> CFU/ml. Based on this model, we carried out a pilot study to evaluate the feasibility of using the Bact/ALERT 3D culture media system to detect bacteria in platelet units. During this study between June 2001 and May 2002, pre-donation sampling was in routine use at the Northern Ireland Blood Transfusion Centre.

**MATERIALS AND METHODS****Collection and processing**

Approximately 60% of the platelet inventory was prepared from pooling of fully units derived from whole blood donations and 40% from single-donor

*Transfusion Medicine*, 2003, 13, 151–160

**ORIGINAL ARTICLE****Evaluation of the 3D Bact/ALERT automated culture system for the detection of microbial contamination of platelet concentrates**

C. P. McDONALD,<sup>1</sup> A. ROZON,<sup>2</sup> M. COX,<sup>2</sup> R. SMITH,<sup>2</sup> A. REY,<sup>2</sup> S. ROBINSON,<sup>2</sup> S. HARVEY,<sup>2</sup> J. A. J. BURTON,<sup>2</sup> S. RODERICK,<sup>3</sup> T. L. SHARANTY<sup>4</sup> AND G. WHITFIELD<sup>5</sup>; *<sup>1</sup> School of Biological Sciences, <sup>2</sup> School of Veterinary Clinical Sciences, <sup>3</sup> School of Veterinary Dentistry, <sup>4</sup> School of Veterinary Nursing, <sup>5</sup> School of Veterinary Medicine, University of Liverpool, Liverpool, UK*

Received 20 September 2002; accepted 26 October 2002; accepted 22 April 2003

**Introduction.** Bacterial contamination remains the major component of mortality and morbidity associated with transfusion-transmitted infections. Platelets are the most common vehicle of bacterial transmission.

The Bact/ALERT 3D automated culture system was developed to detect bacterial contamination of platelet concentrates for the purpose of liaison. Evaluation of the system was performed using 4.5% gel agar plates in the presence of 100 µg/ml kanamycin and 100 µg/ml ampicillin. The Bact/ALERT 3D culture media system was evaluated using a panel of 10 different bacteria, including *Escherichia coli*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Corynebacterium parvum*, *Bacillus cereus*, Group B streptococci, *Enterococcus faecalis*, *Enterococcus faecium* and *Enterococcus* spp. at the most frequently identified concentrations of 10, 100 and 1000 colony-forming units (CFU).

**Methods.** The Bact/ALERT 3D culture media system was evaluated using a panel of 10 different bacteria, including *Escherichia coli*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Corynebacterium parvum*, *Bacillus cereus*, Group B streptococci, *Enterococcus faecalis*, *Enterococcus faecium* and *Enterococcus* spp. at the most frequently identified concentrations of 10, 100 and 1000 colony-forming units (CFU).

**Results.** Bacterial contamination results of the Bact/ALERT 3D culture media system were positive for all 10 organisms. *Escherichia coli* was the most frequently isolated bacterium. The Bact/ALERT 3D culture media system detected 100% of organisms at levels of 10, 100 and 1000 CFU/ml. The detection times ranged from 870 to 1754 h compared with 756–884 h for the Bact/ALERT 3D culture media system.

**Conclusion.** The Bact/ALERT 3D culture media system is able to detect bacterial contamination of platelet concentrates for the purpose of liaison.

**Keywords:** Bact/ALERT, bacteria, culture, platelets, screening, transmission

in the 2001 national surveillance survey has been addressed in relation to haemostatic agents, so that the Bact/ALERT 3D culture media system can provide clear growth patterns and positive or negative cultures from the instrument.

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**BacT/ALERT BPA** culture bottles are used with the BacT/ALERT Microbial Detection Systems for quality control testing of leukocyte reduced

apheresis platelet (LRAP) units

single units of whole blood platelet concentrates (WBPC).

**BPA culture bottles – aerobic bacteria**



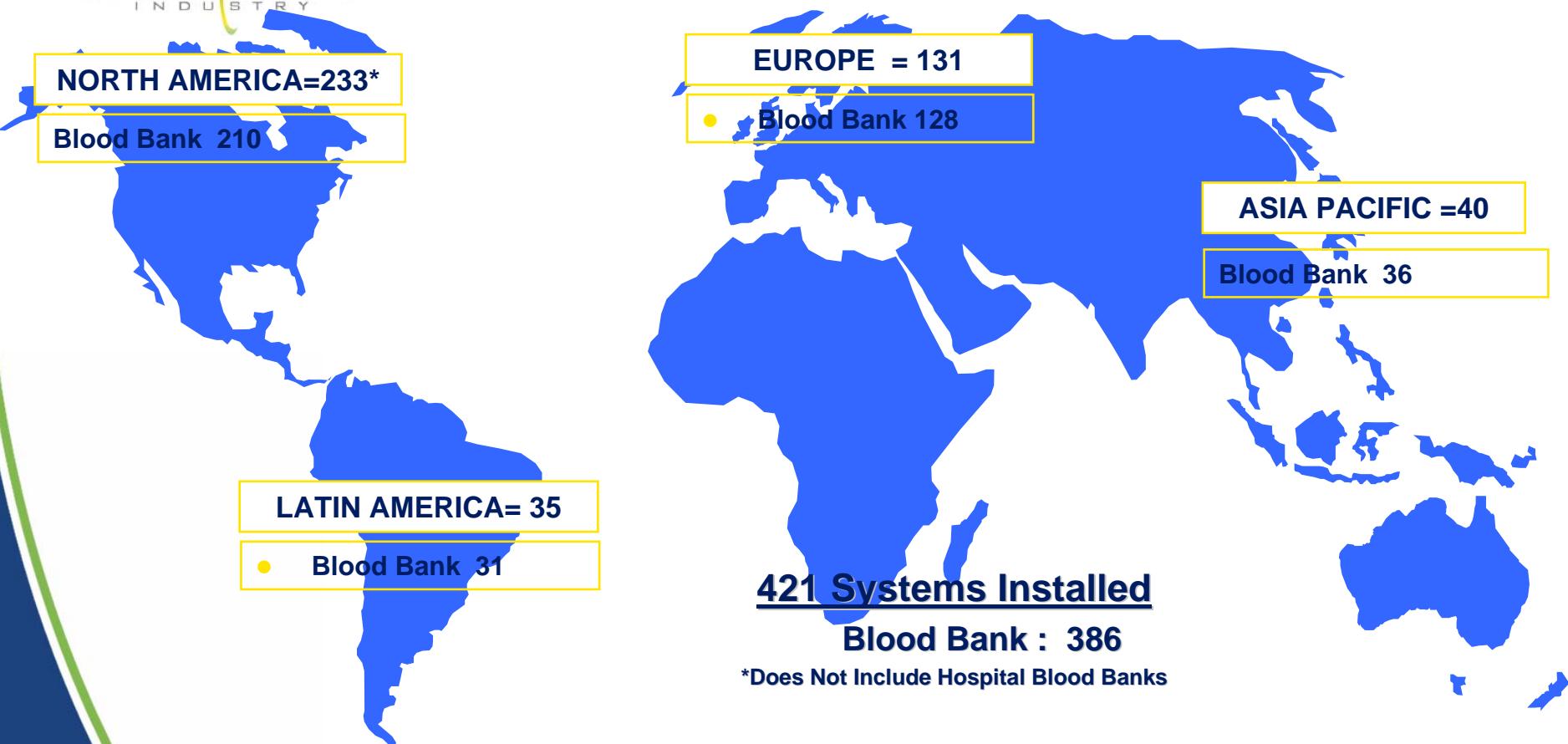
**BacT/ALERT BPN** culture bottles are used with the BacT/ALERT Microbial Detection Systems for quality control testing of leukocyte reduced

apheresis platelet (LRAP) units

single units of whole blood platelet concentrates (WBPC).

BPN culture bottles - anaerobic & facultative anaerobic bacteria.

# BacT/ALERT Worldwide Placements for Platelet Testing





## TRANSFUSION COMPLICATIONS

### Monitoring of apheresis platelet bacterial contamination with an automated liquid culture system: a university experience

M.C. Strain, S.H. Lee, and S.J. Rothberg

**BACKGROUND:** With 2 million platelet transfusions per year in the United States and with the current estimate of bacteria contamination in PLT units, it would be expected that 2000 to 4000 bacterially contaminated units are transfused and associated with 333 to 1000 cases of clinical infection.

**STUDY DESIGN:** In-hospital apheresis platelets were collected in Day 2 of storage (whole bag – Day 0) and assayed (or following outside Day 2–5) using a sternal connection device (SCD) to which a sampling bag (using weight, length, and a hammer) was tied. Both bags were inoculated and placed onto an automated liquid culture system (Bact/Alert 3D Microbial Detection System) for 7 days.

**RESULTS:** A total of 2397 apheresis PLT units were sampled. A triple apheresis collection was reached within 14 hours (1 hr Lay + Sampling (inoculated culture) and the bags were removed from inventory. A single aerobic organism was identified in all three contaminated bags. Two double apheresis collections were found to be contaminated with *Pseudomonas aeruginosa*, and one triple apheresis collection was found in four patients who developed clinical sequelae. There was one non-pathogenic aerobic culture and one non-pathogenic anaerobic result that is inadvertent contamination of a bottle. Thus, the overall true-positive rate was 7 of 2397 apheresis units (0.29%) with a false-positive rate for aerobic organisms (0.13%) and an anaerobic false-positive rate of 0.17%. The false-positive rate was 2 of 474 sampling (0.4%) or 2 out of 2397 bottles (0.02%).

**CONCLUSION:** The preliminary data suggests that the use of a SCD, aseptic technique, and a hammer to seal is associated with a low rate of contamination. In no case did an issue of contamination affect administration. The use of a SCD on the Day 1 collection. Additional surveillance is necessary before we can conclude that a Day 2 or Day 3 culture may provide an accurate (if slightly) sterile culture. Bacterial culture surveillance of PLTs would be expected to save time and may facilitate an extension in PLT storage.

Approximately 1 in 1000 to 1 in 200 PLT units are bacterially contaminated.<sup>1–3</sup> Deaths after PLT transfusion is the most common cause of death associated with transfusion-transmitted disease. With 1 million PLT units transfused annually in the United States at a cost of \$1000, it would be expected that 2000 to 4000 bacterially contaminated units would be transfused.<sup>4</sup> Of these contaminated units, perhaps 1 in 1000 to 1 in 2000 would be expected to result in clinical signs (333–1000 cases) and perhaps one-fifth to one-fifth could result in death (5–333 deaths/year).<sup>5–8</sup> This translates to a risk of death from bacterially contaminated PLT transfusions to 1 in 1000 and 1 in 60,000. The utility of these estimates has been confirmed from clinical observations from university hospitals. Ness et al.<sup>9</sup> from Johns Hopkins reported a mortality rate of 1 in 17,000 with pooled whole-blood-derived PLT and 1 in 1,000 with single-donor apheresis PLT. Similarly, the University Hospital of North Carolina has observed a mortality risk of approximately 1 in 39,000 aPLT units. At the University of South Carolina, an anonymous continual bactericidal test from a contaminated apheresis PLT in the last 10 years, resulted in approximately 20,000 aPLT units.

We have previously utilized an automated liquid culture system (Bact/Alert 3D, BioMérieux, Durham, NC, USA) with a wide range of organisms known to contaminate PLT units.

#### DEFINITION OF SCD = sterile connection device

From the University of North Carolina, Chapel Hill; and BioMérieux (formerly Organon Teknica), Durham, North Carolina.

Address reprint requests to Mark E. Rothberg, MD, Transfusion Medicine Service, CH750, University of North Carolina Hospitals, 311 Manning Drive, Chapel Hill, NC 27599-6608 (e-mail: Rothberg@email.unc.edu).

Funded by a grant from BioMérieux (formerly Organon Teknica).

Received for publication November 25, 2012; revision received February 25, 2013; and accepted March 10, 2013.

TRANSFUSION 2013;53:974–977.

The true positive rate for aerobic organisms was 3/2397 (0.13% or 1/799 units) and 4/2397 (0.17% or 1/599 units) for anaerobic organisms. No positives detected with late culture alone.

## Anaerobic Bacteria and Platelets

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1998;8:19-22

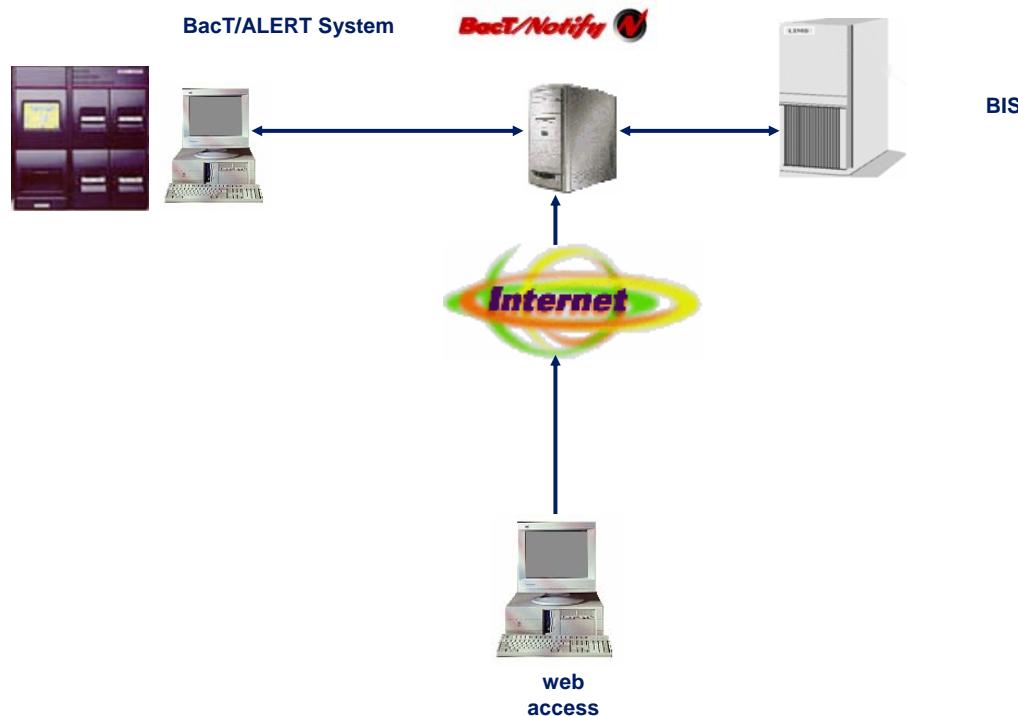


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INDUSTRY

BacT/Notify 

## View Latest Available Culture Status Just Before Transfusion!

Transfusion centers will be able to access specific culture results by accessing a webpage.





B I O M É R I E U X

