2015 EDITION

Selection of Publications

BACT/ALERT™

FAN® Plus Media

BIOMÉRIEUX

PIONEERING DIAGNOSTICS

INTRODUCTION

bioMérieux solutions for diagnosing bloodstream infections and sepsis.

Sepsis, a systemic inflammation due to infection, can lead to severe sepsis and septic shock. These serious conditions incur long hospital stays, and high morbidity and mortality. The Surviving Sepsis Campaign's guidelines offer clear strategies for better patient outcomes. When time is critical, you need accurate information – and you need it fast.

bioMérieux is your partner along the sepsis management pathway, bringing you rapid and reliable results to support clinical decisions for better patient care.

bioMérieux, a world leader in the field of in vitro diagnostics for over 50 years, has extensive experience in microbial detection and the **rapid diagnosis of bacterial infections**. Our products include automated blood culture systems, culture media, immunoassays and systems for organism identification and antimicrobial susceptibility testing.

bioMérieux has recently introduced **three new blood culture bottles** which have been designed to provide broad antimicrobial neutralization, organism recovery and optimized time to detection. These new bottles are compatible with all instruments in the BacT/ALERT® range including the 3D Compact 60, 3D Combo 120, 3D 240 and VIRTUO™.

This selection of publications contains the most current list of peer reviewed journal articles related to the FAN® Plus media.

New FAN® Plus media: optimized time to detection and recovery

Our **next generation Fastidious Antimicrobial Neutralization Plus media** (FAN® Plus) offers **optimized time to detection** and recovery. FAN® Plus bottles provide even clearer Gram stains and new Adsorbent Polymeric Beads offer antimicrobial neutralization.

Microorganism recovery

- **Reformulated media** provides a robust growth environment to encourage growth of bacteria and yeasts
- FDA cleared for **blood and sterile body fluid specimens**
- Colorimetric technology and instrument algorithms **minimize false negatives** due to samples delayed in entry

Time To Detection

- **Effective antimicrobial neutralization** provides improved environment for organism growth and detection
- New bottle algorithms promote **overall faster time to detection**

Additional benefits

- Clear, **easy to read** Gram stains
- Shatter-resistant polycarbonate bottles for **increased safety and reduced costs** related to shipping and disposal

CONTENTS

JOURNAL OF CLINICAL MICROBIOLOGY
2013; 51(12): 4150-4155
http://jcm.asm.org/content/51/12/4150

Clinical Evaluation of BacT/ALERT FA Plus and FN Plus Bottles Compared with Standard Bottles

Lee DH., Kim S.C., Bae IG., Koh EH., Kim S.

This study compared the BacT/ALERT FA Plus and FN Plus to the standard aerobic (SA) and standard anaerobic (SN) bottles. 20 ml of blood was drawn from each adult patient enrolled in the study and was divided equally between the four bottle types. Organism recovery and Time To Detection (TTD) were determined for clinically significant pathogens. Blood volume was measured by weight and any blood culture set which contained bottles with fill volumes less than 4 ml was excluded from the study to limit bias. During the six month study period there were 3,103 sets of blood cultures drawn throughout the institution, of which 1,481 met the inclusion criteria.

Overall, the performance of the FA Plus and FN Plus media was superior to that of the standard media. The FA Plus media had two hour faster TTD (11.1) compared to the SA bottle (13.1). The FA Plus isolated significantly more pathogens than the SA bottles. The FN Plus media had a 0.8 hour faster TTD (12.0) compared to the SN bottle (12.8). The FN Plus isolated significantly more pathogens than the SN bottle, especially with Gram negative organisms (22 vs 6, respectively).

In conclusion, the authors found that the FAN Plus media isolated more clinically significant bacteria and had a faster TTD than the standard media.

"This study showed that clinically significant bacteria were isolated more frequently from the resin bottles than from the standard bottles, both overall and in the subgroup of patients who had received antibiotics prior to specimen collection. […] Clinically significant bacteria were detected faster using the aerobic resin bottles than using the standard aerobic bottles."

KEY POINTS

- ➔ FA Plus had a 2 hr faster TTD vs. the SA bottle and the FN Plus had a 0.8 hr faster TTD vs. the SN bottle.
- ➔ The FA Plus bottle isolated more organisms than the SA bottle (38 vs. 14; P=0.001).
- ➔ The FN Plus bottle isolated more organisms than the SN bottle (27 vs. 10; P=0.008).

EUROPEAN JOURNAL OF CLINICAL MICROBIOLOGY & INFECTIOUS DISEASE
2015 Feb; DOI 10.1007/s10096-015-2319-8
http://link.springer.com/article/10.1007/s10096-015-2319-8

High medical impact of implementing the new polymeric bead-based BacT/ALERT® FA Plus and FN Plus blood culture bottles in standard care

Amarsy-Guerle R., Mougari F., Jacquier H., Oliary J., Benmansour H., Riahi J., Berçot B., Raskine L., Cambau E

In this study, the positivity rates and Time To Detection (TTD) differences of two periods were examined after implementation of the FAN Plus media. The FAN Plus media contains a polymeric bead designed to adsorb antimicrobials. During the first ten-month period the BacT/ALERT standard aerobic (SA) and standard anaerobic (SN) media were used, whereas during the second ten-month period the BacT/ALERT FA Plus and FN Plus media were used. Each period had the same number of enrolled patients.

The FAN Plus media period had a higher number of positive bottles compared to the standard media period (7.0% vs 5.8%, P<0.0001) and also had more positive Blood Culture sets (9.6% vs. 7.8% with 995 and 832 positive BC sets respectively, P<0.0001).

The FAN Plus media period isolated more cases of staphylococci (P<0.0001) and Gram-negative bacilli (P<0.005). The contamination rate was similar during both periods (2.4% with FAN Plus vs. 2.3% with standard media).

The FAN Plus media showed an overall 2.5 hour faster TTD (15.5 h vs. 18.0 h, P<0.01).

"In conclusion, the new BacT/ALERT® FA Plus/ FN Plus BC bottles improved the diagnosis of BSI in our hospital, with an increased recovery rate and a decreased time to detection, particularly in patients at a high risk of concomitant administration of antimicrobials, such as ICU patients"

KEY POINTS

- ➔ FAN Plus media outperformed Standard media in both recovery and time to detection.
- ➔ FAN Plus bottle set positivity rate was 9.6% versus 7.8% for the Standard media.
- ➔ FAN Plus bottle positivity rate was 7.0% versus 5.8%.
- ➔ FAN Plus media had a 2.5 hour faster Time To Detection than Standard media (18.2 versus 21.4).

JOURNAL OF CLINICAL MICROBIOLOGY
2014; 52(3): 839-843
http://jcm.asm.org/content/52/3/839

Controlled Clinical Comparison of BacT/ALERT FA Plus and FN Plus Blood Culture Media with BacT/ALERT FA and FN Blood Culture Media

Kirn T.J., Mirrett S., Reller L.B., Weinstein M.P.

This clinical study compares the new BacT/ALERT (bioMérieux, Durham NC) blood culture media which contains antibiotic-binding polymeric beads to the existing FAN media which containing a charcoal based antibiotic-binding media. Performance was assessed between the two bottle types by inoculation with 6 to 10 ml of blood from adults. Only compliant sets with comparable fill volumes were used (6 to 10 ml of blood and bottle with smallest volume was within 30% of bottle with highest volume). There were 1,507 study pairs, of which 170 were clinically significant isolates causing true blood stream infections (BSIs).

The FA Plus bottle isolated more *Staphylococcus aureus* (P<0.001) and total microorganisms (P<0.1). The FA Plus had fewer coagulase negative staphylococcus (CoNS) than the FA bottle (10 versus 22; P<0.05). The FA Plus media had a two hour faster Time To Detection (TTD) for all microorganisms (14.4 versus 16.4; P<0.001).

The FN Plus bottle isolated more *S. aureus* (P<0.001), CoNS (P<0.005), and total microorganisms (P<0.001). The FN Plus media had faster TTD for *S. aureus*, CoNS, Streptococcus and 2.4 hours for all microorganisms combined (15.1 versus 17.5; P<0.005).

"… our study demonstrated improved performance characteristics of the BacT/ALERT FA Plus and FN Plus media with blood specimens collected from all patients, regardless of whether or not they were receiving antimicrobial therapy."

KEY POINTS

- ➔ FAN Plus media outperformed FAN media in both recovery and time to detection.
- ➔ FA Plus bottles had a 2 hour faster TTD than FA bottles (14.4 versus 16.4) and isolated more organisms (45 vs. 23).
- ➔ FN Plus bottles had a 2.4 hour faster TTD than FN bottles (15.1 versus 17.5) and isolated more organisms (63 versus 13).

JOURNAL OF CLINICAL MICROBIOLOGY
2014; 52(6): 1898-1900
http://jcm.asm.org/content/52/6/1898

Controlled Clinical Comparison of New Pediatric Medium with Adsorbent Polymeric Beads (PF Plus) versus Charcoal-Containing PF Medium in the BacT/ALERT Blood Culture System.

Doern C., Mirrett S., Halstead D., Abid J., Okada P., Reller L.B.

A controlled clinical comparison of the new PF Plus pediatric blood culture medium versus the currently available charcoal-containing PF medium used in the BacT/ALERT blood culture system was performed. The newly formulated media containing adsorbent polymeric beads was designed to maximize recovery of microorganisms from pediatric patients in the presence of antimicrobials.

A total of 2,381 pediatric cultures were enrolled. Of those, 1,703 (71.5%) were considered compliant and acceptable for analysis. Seventy-two cultures (4.2%) were positive with 80 clinically significant microorganisms. Of the 80 isolates, 55 grew in both bottles, 18 grew in the PF Plus only and 7 grew in the PF bottle only ($p \leq 0.05$). The PF Plus bottle grew the same or more pathogens for all organism categories except yeast (2 isolates) and "other" Gram negative bacilli (1 isolate). The PF Plus bottle yielded more clinically significant microorganisms than the PF bottle ($p < 0.05$) including *Staphylococcus aureus* and Enterobacteriaceae. In addition, the PF Plus bottle yielded positive results an average of 5.0 hours faster than the PF bottle (18.3 h versus 23.2 h, $p=0.004$).

The PF Plus performed well in patients who were on antimicrobial therapy. The conclusion of this study is that the PF Plus medium is an improved medium for detecting microorganisms that cause pediatric bloodstream infections.

"Our data show that the new PF Plus bottle outperformed the present PF bottle in terms of microorganism yield from clinically significant cultures, cultures of uncertain significance, and cultures from patients on antimicrobial therapy... We conclude that the PF Plus bottle is superior to the PF bottle for the diagnosis of pediatric bloodstream infection."

KEY POINTS

- ➔ PF Plus media isolated 22.9% more microorganisms than the PF bottle.
- ➔ PF Plus media yielded positive results on average 5.0 h earlier than the PF bottle.

BacT/ALERT® FA Plus & FN Plus versus BACTEC™ Plus Aerobic/F and Anaerobic/F

JOURNAL OF CLINICAL MICROBIOLOGY
2014; 52(10): 3558-3567
http://jcm.asm.org/content/52/10/3558

Performance of Two Resin-Containing Blood Culture Media in Detection of Bloodstream Infections and in Direct Matrix-Assisted Laser Desorption Ionization–Time of Flight Mass Spectrometry (MALDI-TOF MS) Broth Assays for Isolate Identification: Clinical Comparison of the BacT/ALERT Plus and Bactec Plus Systems

Fiori B., D'Inzeo T., Di Florio V. , De Maio F., De Angelis G., Giaquinto A., Campana L., Tanzarella E., Tumbarello M., Antonelli M., Sanguinetti M., and Spanu T.

Clinical performance of the BacT/ALERT Plus (bioMérieux) and BACTEC Plus (Becton Dickinson) aerobic and anaerobic blood culture (BC) media was compared in this study. Patients in intensive care units and infectious disease wards with suspected bloodstream infections (BSIs) were enrolled. A 40 ml blood sample was collected from each patient and used to inoculate 10 ml of blood into one set of BacT/ALERT Plus bottles and one set of BACTEC Plus bottles, each set consisting of one aerobic and one anaerobic bottle. Cultures were incubated up to 5 days in the BacT/ALERT 3D and BACTEC FX instruments respectively.

A total of 128 unique BSI episodes were identified based on the recovery of clinically significant organisms in 212 aerobic cultures (106 BacT/ALERT; 106 BACTEC) and 151 anaerobic cultures (82 BacT/ALERT; 69 BACTEC). The BacT/ALERT aerobic medium had higher recovery rates for Gram positive cocci (P=0.024), whereas the BACTEC aerobic medium had higher recovery rates for Gram negative bacilli (P=0.006). BacT/ALERT anaerobic medium recovery rates exceeded those of the BACTEC anaerobic medium for total organisms (P=0.003), Gram-positive cocci (P=0.013), and *Escherichia coli* (P=0.030).

The BacT/ALERT and BACTEC blood culture sets were comparable in diagnosing the 128 septic episodes, although the BacT/ALERT diagnosed more BSIs caused by Gram positive cocci (P=0.008). The mean time for detection of the BSI episodes diagnosed by the BacT/ALERT (N=123) and BACTEC (N=118) sets were not significantly different (16.1 h vs. 16.9 h). In the 112 cases diagnosed by both sets, coagulase negative staphylococci were detected faster by the BacT/ALERT (mean 2.8 h; P=0.003). There were no significant differences between BacT/ALERT and BACTEC in time to detection when cultures were drawn after initiation of antimicrobial therapy, but the BacT/ALERT provided diagnoses 1.3 h earlier in treatment-negative cases (P<0.001).

"In our study, the performance displayed by BacT/ALERT Plus media was similar to that of resin-containing media in the BACTEC line. […] our experience indicates that the new BacT/ALERT FA Plus and FN Plus media are reliable, timesaving tools for routine identification of BSIs in patients in ICUs and infectious disease wards."

KEY POINTS

- ➔ The FN Plus outperformed the BACTEC anaerobic bottle in the recovery of total microorganisms.
- ➔ Diagnostic capability of the aerobic/anaerobic blood culture sets were comparable; 95.3% BacT/ALERT versus 91.4% for BACTEC.
- ➔ The mean TTD of BSI episodes by the BacT/ALERT (N=123) and BACTEC (N=118) were comparable (16.1 h vs. 16.9 h).

NOTES

Other "Selection of Publications" available

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