

**RAPID DETECTION OF BACTERIAL  
CONTAMINANTS IN PLATELET COMPONENTS:  
COMPARISON OF TIME TO DETECTION  
BETWEEN THE BACT/ALERT® 3D AND THE  
BACT/ALERT® VIRTUO™ SYSTEMS.**

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PIONEERING DIAGNOSTICS

*Parampal Deol, Ph.D, MBA  
Senior Director, R&D Microbiology North America*



# Virtuo™

**The new generation of BacT/ALERT®  
for Platelet Bacterial Screening**



# Higher throughput, full automation, faster time to detection



- **Fully automated growth detection system**
- **Set & forget**
  - Place bottles on conveyor & walk away
  - Automatic loading & unloading of bottles from the racks
  - 3 times faster bottle loading
- **Better thermal stability**
  - No drawers to open when loading and unloading
  - Potential for reduced false positives
- **Modular and scalable**
  - 2/3 the floor space vs. BacT/ALERT® 3D
  - Increase testing capacity and optimize lab space
- **No change in consumables, inoculation or incubation protocols**

# Optimized footprint -30%

240 240 240 240 240



3m

**BacT/ALERT® 3D 1200**  
(5 x 240 configuration)

432 432 432



2.17m

**BacT/ALERT® VIRTUO™ 1296**  
(3 x 432 configuration)

## Improved hardware & software

Improved robustness

Improved optics

Improved sensitivity

Improved specificity



**Faster time to detection (TTD)**  
~15% shorter TTD\*  
➔ **Increased patient safety**

**Potential to minimize false positive**  
**Minimized temperature fluctuations**  
➔ **Increased efficiency**



## Purpose and Study Design

### ■ Goal:

- Validate the performance of VIRTUO™ for use with BPA and BPN bottles with pooled platelet preparations
- For optimal recovery and sensitivity use of paired Aerobic (BPA) and Anaerobic (BPN) bottles are recommended.

### ■ Study Design:

- Growth Performance Comparison testing: Two sites
  - NHS Blood and Transplant, London
  - bioMérieux (bMX), Durham, USA
- Leukocyte Reduced platelet concentrate: Buffy coats and LRAP
  - NHS Sites: Buffy coats
    - Whole Blood Derived with plasma only
    - Whole Blood Derived plasma + Platelet additive solution (SSP+-Safe Platelets through saved plasma-Macopharma)
  - bMX site: LRAP (American Red Cross)
    - LRAP from single donor without PAS were pooled from 4-6 donors

## ■ Testing Overview

### ■ Most prevalent contaminants were selected

- Aliquots of pooled platelet preparations were seeded with low levels (<1-31 CFU/ml) of organism with BioBall™ or ATCC
- NHS: 11 species of organisms tested
- bMX: 13 species of organisms tested

### ■ Volume and Bottles

- NHS: 8 ml volume per bottle was used for buffy coat testing (800 bottles)
- bMX: 4 ml volume per bottle was used for LRAP testing (192 bottles)
  - False positives: 144 additional bottles were tested with 10 ml of LRAP

### ■ BPA and BPN Bottles were loaded onto the VIRTUO and BTA 3D

## Organisms tested by NHS

| Microorganisms                            | ATCC/NCTC (bioBall™) Strain |
|---|-----------------------------|
| <i>Staphylococcus aureus</i>              | NCTC 10788                  |
| <i>Staphylococcus epidermidis</i>         | NCTC 6513                   |
| <i>Enterobacter cloacae</i>               | ATCC 29005                  |
| <i>Escherichia coli</i>                   | NCTC 12241                  |
| <i>Klebsiella pneumoniae</i>              | ATCC 8045                   |
| <i>Bacillus cereus</i>                    | NCTC 7464                   |
| <i>Salmonella choleraesuis</i>            | ATCC 8326                   |
| <i>Streptococcus agalactiae</i>           | ATCC 12927                  |
| <i>Pseudomonas aeruginosa</i> (BPA only)  | NCTC 12924                  |
| <i>Serratia marcescens</i>                | ATCC 43862                  |
| <i>Clostridium perfringens</i> (BPN only) | NCTC 8798                   |



## Organisms Tested by bMX Site

| Microorganism                             | ATCC/NCTC (bioBall™) Strain |
|---|-----------------------------|
| <i>Bacillus cereus</i>                    | NCTC 7464                   |
| <i>Enterobacter cloacae</i>               | ATCC 33549                  |
| <i>Esherichia coli</i>                    | NCTC 12241                  |
| <i>Klebsiella pneumoniae</i>              | ATCC 35657                  |
| <i>Pseudomonas aeruginosa</i> (BPA only)  | NCTC 12924                  |
| <i>Proteus mirabilis</i>                  | ATCC 7002                   |
| <i>Salmonella enterica</i>                | NCTC 12023                  |
| <i>Salmonella choleraesuis</i>            | ATCC 10729                  |
| <i>Serratia marcescens</i>                | ATCC 43862                  |
| <i>Staphylococcus aureus</i>              | NCTC 10788                  |
| <i>Staphylococcus epidermidis</i>         | NCTC 6513                   |
| <i>Streptococcus sanguinis</i>            | ATCC 10556                  |
| <i>Clostridium perfringens</i> (BPN only) | NCTC 8798                   |

## ■ Summary of Results:

### ■ NHS site with buffy coat

- Both systems (VIRTUO and 3D) detected 800/800 (100%) of bottles seeded with organism regardless of platelet preparation type
- VIRTUO average time to detection 2.1 hours faster than BTA 3D

### ■ bioMérieux, Durham, USA with LRAP

- VIRTUO detected 144/144 (100%) of bottles seeded with organism
- BTA 3D detected 48/48 (100%) of bottles seeded with organism
- VIRTUO average time to detection 2.8 hours faster than BTA 3D

### ■ Negative Controls

- No false positives in LRAP testing (0%)
- 1/800 BacT/ALERT BPN on BTA 3D was declared positive with buffy coat (0.13%).

*Data from these studies were presented as a poster at 34<sup>th</sup> ISBT , Dubai*

- *Poster # 589/ P-300, DOI: 10.13140/RG.2.2.23879.50084*

# Results with Buffy Coat in Plasma

| Microorganism                              | Bottle type | Inoculum (CFU/mL) | cultures    |             | Time to detection (hours) |           |             |           |
|--|-------------|-------------------|-------------|-------------|---------------------------|-----------|-------------|-----------|
|  |             |                   | BTA 3D      | BTA VIRTUO  | BTA 3D                    |           | BTA VIRTUO  |           |
|  |             |                   | n=10        | n=10        | mean                      | range     | mean        | range     |
| <i>Bacillus cereus</i> NCTC7464            | BPA         | 4                 | 10          | 10          | 10.1                      | 9.9-10.3  | 8.1         | 7.9-8.3   |
|  | BPN         | 2                 | 10          | 10          | 10.7                      | 10.1-11.6 | 8.5         | 7.9-9.0   |
| <i>Clostridium perfringens</i> NCTC8798    | BPN         | 2                 | 10          | 10          | 11.4                      | 10.4-13.9 | 8.9         | 8.0-10.6  |
| <i>Enterobacter cloacae</i> ATCC29005      | BPA         | 23                | 10          | 10          | 14.8                      | 14.4-15.2 | 12.6        | 12.2-13.3 |
|  | BPN         | 23                | 10          | 10          | 11.4                      | 11.2-11.4 | 8.9         | 8.6-9.1   |
| <i>Escherichia coli</i> NCTC12241          | BPA         | 4                 | 10          | 10          | 12.7                      | 12.4-13.1 | 10.3        | 10.1-10.5 |
|  | BPN         | 3                 | 10          | 10          | 11.6                      | 11.4-11.7 | 9.9         | 9.5-10.1  |
| <i>Klebsiella pneumoniae</i> ATCC8045      | BPA         | 10                | 10          | 10          | 15.3                      | 15.0-16.2 | 13.7        | 12.9-15.2 |
|  | BPN         | 8                 | 10          | 10          | 12.9                      | 12.5-13.0 | 11.1        | 10.9-11.4 |
| <i>Pseudomonas aeruginosa</i> ATCC27853    | BPA         | 14                | 10          | 10          | 16.7                      | 16.3-16.9 | 13.8        | 13.6-14.0 |
| <i>Salmonella choleraesuis</i> ATCC8326    | BPA         | 14                | 10          | 10          | 15.6                      | 14.9-16.1 | 12.6        | 12.3-13.4 |
|  | BPN         | 13                | 10          | 10          | 10.9                      | 10.8-11.3 | 8.7         | 8.6-8.9   |
| <i>Serratia liquefaciens</i> ATCC35551     | BPA         | 1                 | 10          | 10          | 16.1                      | 16.0-16.3 | 14          | 13.6-14.4 |
|  | BPN         | 2                 | 10          | 10          | 14.6                      | 14.3-15.2 | 13.4        | 12.5-14.3 |
| <i>Staphylococcus aureus</i> NCTC10788     | BPA         | 2                 | 10          | 10          | 18                        | 17.7-18.4 | 15.2        | 15.0-16.0 |
|  | BPN         | 4                 | 10          | 10          | 15.7                      | 15.0-16.5 | 13.9        | 12.9-14.6 |
| <i>Staphylococcus epidermidis</i> NCTC6513 | BPA         | 3                 | 10          | 10          | 17.5                      | 17.2-17.7 | 15.3        | 15.0-15.5 |
|  | BPN         | 3                 | 10          | 10          | 18.9                      | 16.4-20.9 | 16.1        | 15.0-17.8 |
| <i>Streptococcus agalactiae</i> ATCC 12927 | BPA         | 20                | 10          | 10          | 10.9                      | 10.7-11.1 | 8.3         | 8.0-8.5   |
|  | BPN         | 21                | 10          | 10          | 10.2                      | 10.1-10.4 | 7.9         | 7.8-8.2   |
| <b>Positive</b>                            |             |                   | <b>200</b>  | <b>200</b>  | <b>13.8</b>               |           | <b>11.6</b> |           |
| <b>Total % Recovery</b>                    |             |                   | <b>100%</b> | <b>100%</b> |                           |           |             |           |

- All bottles were positive
- Virtuo was on average 2.2 hours faster than BTA 3D

# Results with Buffy Coat in Plasma with SSP+(PAS)

| Microorganism                              | Bottle type | Inoculum (CFU/mL) | Number of positive cultures |             | Time to detection (hours) |           |             |           |
|--|-------------|-------------------|-----------------------------|-------------|---------------------------|-----------|-------------|-----------|
|  |             |                   | BTA 3D                      | BTA VIRTUO  | BTA 3D                    |           | BTA VIRTUO  |           |
|  |             |                   | n=10                        | n=10        | mean                      | range     | mean        | range     |
| <i>Bacillus cereus</i> NCTC7464            | BPA         | 3                 | 10                          | 10          | 9.8                       | 9.5-10.0  | 8           | 7.8-8.0   |
|  | BPN         | 2                 | 10                          | 10          | 11.7                      | 10.7-12.7 | 9.9         | 8.6-10.9  |
| <i>Clostridium perfringens</i> NCTC8798    | BPN         | 3                 | 10                          | 10          | 10.3                      | 9.7-11.2  | 8.4         | 8.3-8.8   |
| <i>Enterobacter cloacae</i> ATCC29005      | BPA         | 21                | 10                          | 10          | 12.3                      | 12.2-12.6 | 9.8         | 9.7-9.9   |
|  | BPN         | 16                | 10                          | 10          | 11.4                      | 11.2-11.6 | 9           | 8.8-9.2   |
| <i>Escherichia coli</i> NCTC12241          | BPA         | 2                 | 10                          | 10          | 12.1                      | 11.9-12.3 | 10.2        | 9.9-10.6  |
|  | BPN         | 3                 | 10                          | 10          | 11.1                      | 10.9-11.3 | 9.6         | 9.3-9.8   |
| <i>Klebsiella pneumoniae</i> ATCC8045      | BPA         | 9                 | 10                          | 10          | 13.5                      | 13.5-13.7 | 11.6        | 11.3-11.8 |
|  | BPN         | 9                 | 10                          | 10          | 13                        | 12.7-13.2 | 11.1        | 10.8-11.4 |
| <i>Pseudomonas aeruginosa</i> ATCC27853    | BPA         | 18                | 10                          | 10          | 16                        | 15.7-16.2 | 13.7        | 13.2-14.4 |
| <i>Salmonella choleraesuis</i> ATCC8326    | BPA         | 24                | 10                          | 10          | 12                        | 11.7-12.2 | 9.8         | 9.6-10.1  |
|  | BPN         | 19                | 10                          | 10          | 10.9                      | 10.7-11.0 | 9           | 8.7-9.2   |
| <i>Serratia liquefaciens</i> ATCC35551     | BPA         | 1                 | 10                          | 10          | 16.3                      | 16.1-16.6 | 14.2        | 13.8-14.7 |
|  | BPN         | 2                 | 10                          | 10          | 16.8                      | 16.0-17.3 | 15.1        | 14.5-15.5 |
| <i>Staphylococcus aureus</i> NCTC10788     | BPA         | 4                 | 10                          | 10          | 17.3                      | 17.1-17.4 | 14.8        | 14.5-15.5 |
|  | BPN         | 3                 | 10                          | 10          | 16.2                      | 15.6-16.7 | 14.2        | 13.6-15.1 |
| <i>Staphylococcus epidermidis</i> NCTC6513 | BPA         | 4                 | 10                          | 10          | 17.9                      | 17.6-18.1 | 16          | 15.7-16.5 |
|  | BPN         | 3                 | 10                          | 10          | 18.9                      | 17.8-19.8 | 18.8        | 14.7-19.7 |
| <i>Streptococcus agalactiae</i> ATCC12927  | BPA         | 19                | 10                          | 10          | 10.4                      | 10.3-10.4 | 8.6         | 8.5-8.7   |
|  | BPN         | 19                | 10                          | 10          | 10.2                      | 9.9-10.4  | 8.3         | 8.1-8.6   |
| <b>Positive</b>                            |             |                   | <b>200</b>                  | <b>200</b>  | <b>13.4</b>               |           | <b>11.5</b> |           |
| <b>Total % Recovery</b>                    |             |                   | <b>100%</b>                 | <b>100%</b> |                           |           |             |           |

- All bottles were positive
- Virtuo was on average 1.9 hours faster than BTA 3D

# Results Testing with LRAP

| Microorganism                              | Bottle Type | Inoculum CFU/ml | Number of positive cultures |             | Time to detection (hours) |           |             |           |
|--|-------------|-----------------|-----------------------------|-------------|---------------------------|-----------|-------------|-----------|
|  |             |                 | BTA 3D                      | BTA VIRTUO  | BTA 3D                    |           | BTA VIRTUO  |           |
|  |             |                 | n=2                         | n=6         | mean                      | range     | mean        | range     |
| <i>Bacillus cereus</i> NCTC7464            | BPA         | 1               | 2                           | 6           | 10.4                      | 10.3-10.6 | 7.5         | 7.2-7.9   |
|  | BPN         |                 | 2                           | 6           | 13.8                      | 13.7-13.9 | 11.5        | 9.5-12.7  |
| <i>Clostridium perfringens</i> NCTC8798    | BPN         | 1               | 2                           | 6           | 10.2                      | 10.1-10.3 | 7.5         | 7.0-7.8   |
| <i>Escherichia coli</i> NCTC12241          | BPA         | 1               | 2                           | 6           | 13                        | 12.7-13.2 | 9.8         | 9.7-10.0  |
|  | BPN         |                 | 2                           | 6           | 11.6                      | 11.5-11.8 | 9           | 8.9-9.2   |
| <i>Pseudomonas aeruginosa</i> NCTC12924    | BPA         | 1               | 2                           | 6           | 17                        | 16.6-17.5 | 13.8        | 13.2-14.6 |
| <i>Salmonella typhimurium</i> NCTC12023    | BPA         | 1               | 2                           | 6           | 13.9                      | 13.9*     | 10.8        | 10.5-11.3 |
|  | BPN         |                 | 2                           | 6           | 12.1                      | 12.0-12.2 | 9.6         | 9.0-10.1  |
| <i>Staphylococcus aureus</i> NCTC10788     | BPA         | 1               | 2                           | 6           | 16.8                      | 16.6-17.0 | 14.1        | 13.3-15.1 |
|  | BPN         |                 | 2                           | 6           | 18.1                      | 17.8-18.5 | 14.3        | 13.9-14.9 |
| <i>Staphylococcus epidermidis</i> NCTC6513 | BPA         | 1               | 2                           | 6           | 18.7                      | 18.5-19.0 | 14.9        | 14.2-15.3 |
|  | BPN         |                 | 2                           | 6           | 22.2                      | 21.8-22.6 | 18          | 17.4-18.7 |
| <i>Enterobacter cloacae</i> ATCC33549      | BPA         | 1               | 2                           | 6           | 22.7                      | 22.1-23.3 | 22.5        | 18.3-26.6 |
|  | BPN         |                 | 2                           | 6           | 13.2                      | 13.2*     | 10          | 9.8-10.1  |
| <i>Klebsiella pneumoniae</i> ATCC35657     | BPA         | 1               | 2                           | 6           | 12                        | 12.0*     | 9.4         | 9.1-9.7   |
|  | BPN         |                 | 2                           | 6           | 12.1                      | 12.0-12.2 | 9.6         | 9.4-9.7   |
| <i>Proteus mirabilis</i> ATCC7002          | BPA         | 3               | 2                           | 6           | 13.1                      | 13.0-13.2 | 10.8        | 10.3-11.4 |
|  | BPN         |                 | 2                           | 6           | 11.6                      | 11.5-11.8 | 9.2         | 8.9-9.6   |
| <i>Salmonella choleraesuis</i> ATCC10729   | BPA         | 4               | 2                           | 6           | 12.8                      | 12.7-13.0 | 10.1        | 9.9-10.3  |
|  | BPN         |                 | 2                           | 6           | 11.6                      | 11.5-11.8 | 9.3         | 9.1-9.4   |
| <i>Serratia marcescens</i> ATCC43862       | BPA         | 3               | 2                           | 6           | 12.1                      | 12.0-12.2 | 9.7         | 9.6-9.9   |
|  | BPN         |                 | 2                           | 6           | 12.5                      | 12.5*     | 10.1        | 9.8-10.3  |
| <i>Streptococcus sanguinis</i> ATCC10556   | BPA         | 7               | 2                           | 6           | 19.3                      | 19.2-19.4 | 15.6        | 15.3-16.3 |
|  | BPN         |                 | 2                           | 6           | 21.8                      | 21.6-22.1 | 19          | 16.9-21.6 |
| <b>Positive</b>                            |             |                 | <b>48</b>                   | <b>144</b>  | <b>14.7</b>               |           | <b>11.9</b> |           |
| <b>Total % Recovery</b>                    |             |                 | <b>100%</b>                 | <b>100%</b> |                           |           |             |           |

\*The 2 BTA 3D replicates had the same time to detection

- All bottles were positive
- Virtuo was on average 2.8 hours faster than BTA 3D

## LRAP: Five day shelf life comparison

### ■ Repeatability study

- Aliquots of LRAP was used for consecutive days within shelf life
- Rest of the LRAP was resealed and stored at RT on a rocker for next use

### ■ Comparison analysis: day 3, 4 and 5 of LRAP Expiry

- Data collected for repeatability for LRAP without PAS were analyzed for TTD differences for both systems
- American Red Cross confirmed sterility testing was performed using the BacT/ALERT Detection System. Age of platelets did not impact results.
- A recent study with LRAP tested platelets on day 3 of shelf life. Preliminary results indicate similar results to previous testing. The age of platelets, throughout shelf life, did not impact results.

*Abstract on age of platelet data, was submitted to AABB, 2017*

## Summary and Conclusions

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### ■ Recovery of contaminants: Buffy coats and LRAP

- Both systems demonstrated equivalence in detecting low levels of contaminants

### ■ TTD comparison: Buffy coats and LRAP

- Virtuo performance demonstrated an average of 2.3 hours faster TTD than BTA 3D

### ■ Shelf Life comparison: LRAP

- Insignificant difference in TTD within 5 days of shelf life

### ■ For optimal recovery and sensitivity, a paired Aerobic (BPA) and Anaerobic (BPN) bottles are recommended.

*VIRTUO is not yet commercially available for Platelets testing*



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