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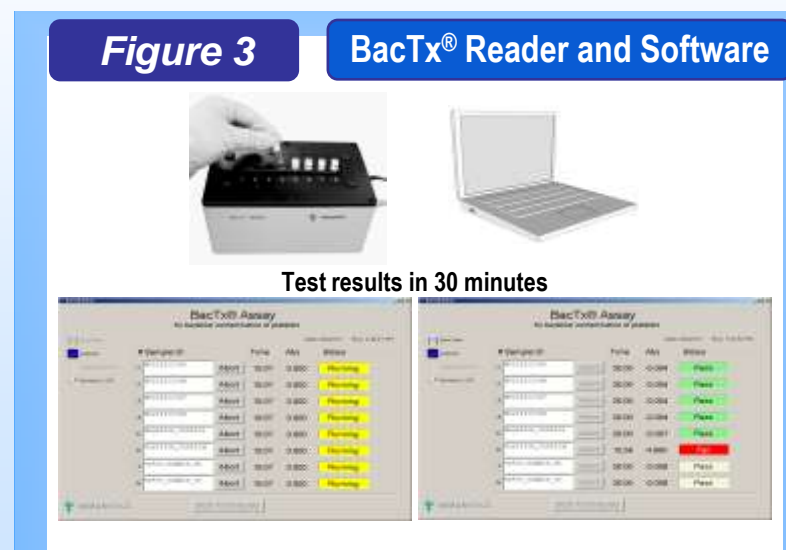
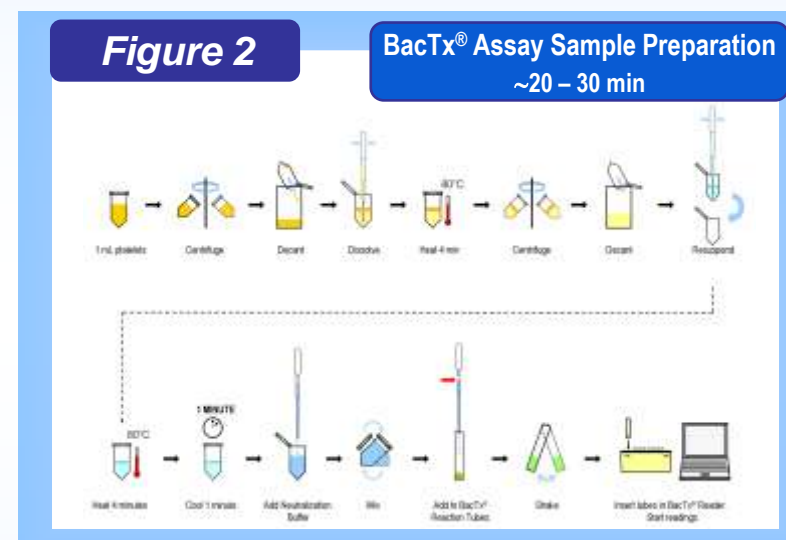
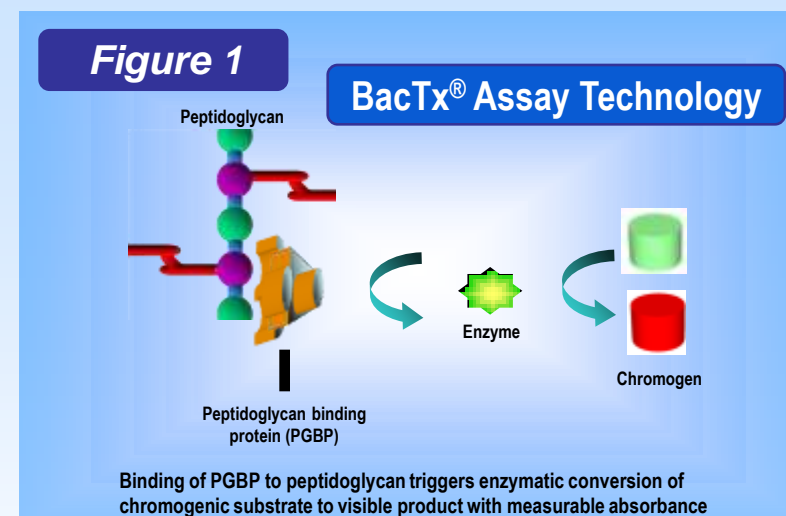
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Introduction

Bacterial contamination of platelets continues to be a hazard despite the implementation of early culture. Immunetics' BacTx[®] Test for bacterial contamination of platelets is based on a direct assay for peptidoglycan, a universal component of both Gram-positive and Gram-negative bacteria. The assay relies on the binding of peptidoglycan by specific proteins, with enzymatic amplification of the resulting signal, detected as a soluble, colored reaction product by a photometer within 30 min (Fig. 1). The test requires 1 ml platelet samples; turnaround time is less than one hour.

Methods

Aliquots of two random platelet units were inoculated with bacteria at 3 concentrations, ranging from 2×10^2 to 5×10^4 cfu/ml. Inocula included an initial inoculum of 5×10^3 to 5×10^4 cfu/ml, and 1:5 and 1:10 dilutions of these inocula. Nine bacterial strains (ATCC no.) were tested: *Staphylococcus aureus* (27853), *Staphylococcus epidermidis* (49134), *Bacillus cereus* (11778), *Streptococcus pyogenes* (19615), *Serratia marcescens* (43862), *Escherichia coli* (25922), *Klebsiella oxytoca* (13882), *Clostridium perfringens* (3629) and *Propionibacterium acnes* (11827). Bacterial inocula were prepared based on optical density, and quantitated by plate culture. BacTx[®] testing was immediately performed in duplicate on inoculated and uninoculated samples for each bacterial strain and platelet unit according to the manufacturer's directions (Figs. 2 and 3).



Results

All 3 bacterial loads were detected by BacTx[®] assay in both replicates from both units for all organisms except *S. marcescens*, where bacteria were detected at 5×10^3 but not at 3.3×10^3 (Table 1).

Table 1 Detection by BacTx[®] at various inocula (CFU/mL)

Organism	Original inoculum	1:5 dilution	1:10 dilution	Control
<i>Bacillus cereus</i>	3.50E+04	5.00E+03	2.80E+03	0
<i>Clostridium perfringens</i>	5.20E+03	1.00E+03	5.50E+02	0
<i>Escherichia coli</i>	5.43E+04	1.10E+04	4.70E+03	0
<i>Klebsiella oxytoca</i>	4.60E+04	1.10E+04	4.70E+03	0
<i>Propionibacterium acnes</i>	1.00E+04	2.00E+03	4.00E+02	0
<i>Serratia marcescens</i>	2.60E+04	5.00E+03	3.30E+03	0
<i>Staphylococcus aureus</i>	7.80E+03	1.30E+03	7.30E+02	0
<i>Staphylococcus epidermidis</i>	1.80E+04	3.60E+03	2.30E+03	0
<i>Streptococcus pyogenes</i>	5.00E+03	1.00E+03	2.00E+02	0

Negative result in both replicates from both platelet units
Positive result in both replicates from both platelet units

Discussion

Bacterial contamination with a battery of 9 clinically important platelet bacterial contaminants was detected by the BacTx[®] assay, with the lower detection limits ranging from 4×10^2 to 5×10^3 . These findings suggest that this assay is a suitable method for use near the time of issue of platelet units. Additional studies are in progress to determine the limit of bacterial detection with low inocula of bacteria inoculated into platelet units.