

# Bacterial Contamination Residual Risks and Mitigations at the Kuwait Central Blood Bank

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**Presented at the  
AABB Annual Meeting and TXPO 2008  
October 4-7, 2008  
Montréal, Québec, Canada**



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## Background

The Kuwait Central Blood Bank (KCBB) is the only collection facility in Kuwait where blood is collected, processed, tested and distributed to all hospitals in government, private and military sectors. The blood bank has been accredited by AABB since 1989. KCBB collects approximately 6800 adult doses of apheresis platelets per year and occasionally platelets are prepared by PRP from whole blood during long holiday seasons (100 units per year). KCBB utilizes numerous safety measures to limit bacterial contamination which include the following; component collection in a sterile closed system, a 2 step sterile method with alcohol and iodine is used at puncture site as well as directing the first 10 ml of collection into separate sample pouch. KCBB

implemented the Scansystem™ Platelet Kit in March of 2005 to detect bacterial contamination in leukocyte reduced platelet concentrates as a further safety measure to meet the AABB Standard 5.1.5.1. In June 2007, the Scansystem was replaced with Pall® eBDS, utilizing the Pall eBDS Oxygen Analyzer. Numerous drawbacks to the bacterial detection methods were discovered including platelet release delay as well as false positive and false negative results. This study analyzes the efficacy of bacterial detection for the purpose of identifying issues as part of the process to receive a variance to AABB Standard 5.1.5.1 (24th and 25th Ed.). The standard 5.1.5.1 states that the blood bank or transfusion service shall have methods to limit and detect bacterial

contamination in all platelet components. KCBB considered the use of pathogen inactivation by INTERCEPT as an alternative to bacterial detection. Based on the AABB variance and results of this study, KCBB replaced bacterial screening with the INTERCEPT Blood System™ to inactivate bacteria in platelets in 2008. The INTERCEPT Blood System for Platelets is an ex vivo photochemical process utilizing a combination of 150 µM amotosalen and a 3 J/cm<sup>2</sup> UVA treatment. This process has been shown to inactivate high levels of viruses, bacteria (Table 1), parasites, and leukocytes in platelet components while maintaining platelet function.

Table 1: INTERCEPT Blood System Extent of Bacterial Inactivation

Bacterial Species Tested Using the INTERCEPT Blood System for Platelets	Extent of Inactivation* (log <sup>10</sup> reduction)
<b>Gram-Negative Bacteria</b>	
<i>Escherichia coli</i>	>6.4
<i>Serratia marcescens</i>	>6.7
<i>Klebsiella pneumoniae</i>	>5.6
<i>Pseudomonas aeruginosa</i>	4.5
<i>Salmonella choleraesuis</i>	>6.2
<i>Yersinia enterocolitica</i>	>5.9
<i>Enterobacter cloacae</i>	5.9
<b>Gram-Positive Bacteria</b>	
<i>Staphylococcus epidermidis</i>	>6.6
<i>Staphylococcus aureus</i>	6.6
<i>Streptococcus pyogenes</i>	>6.8
<i>Listeria monocytogenes</i>	>6.3
<i>Corynebacterium minutissimum</i>	>6.3
<i>Bacillus cereus</i> (includes spores)	3.6
<i>Bacillus cereus</i> (vegetative)	>6.0
<i>Bifidobacterium adolescentis</i>	>6.5
<i>Propionibacterium acnes</i>	>6.7
<i>Lactobacillus species</i>	>6.9
<i>Clostridium perfringens</i> (vegetative form)	>7.0
<b>Spirochete Bacteria</b>	
<i>Treponema pallidum</i>	>6.8 to <7.0
<i>Borrelia burgdorferi</i>	>6.8

\* ">" refers to inactivation below the limit of detection of the assay

## Aims

- Analyze the efficacy of bacterial detection in regards to prevention of septic transfusion reactions, platelet shelf life as well as false negative and false positive results.
- Identify AABB Standard 5.1.5.1 compliance issues for limiting and detecting bacterial contamination.
- Evaluate options to assure compliance to the AABB 5.1.5.1 Standard including a variance for adopting pathogen inactivation.

## Methods

Bacterial detection data was retrospectively analyzed prior to the implementation of pathogen inactivation. Apheresis platelets were collected and screened for bacterial contamination with the Scansystem and the Pall eBDS System. These systems detect aerobic and facultative anaerobic bacterial contamination in platelet concentrates. Individual samples were taken from the platelet bag and results received within 48 hours. Components that screened positive for bacteria were cultured and discarded. In addition, components that screened negative are randomly cultured as part of routine QC. Data was collected for suspected cases of septicemia.

## Results

Using bacterial detection methods, platelet release was delayed for approximately two days. Seven false positive tests (.19%) were proven by negative culture (Table 2). In addition, 1,241 routine QC done for platelet concentrates passed the bacterial detection as negative but showed two positive cultures (.16%) (*E. coli* and *Staph. aureus*). There have been eight transfusion reactions reported as suspected contamination. One was confirmed to be positive for *Staph. aureus*. AABB granted a variance to Standard 5.1.5.1 based on these results and the alternative use of INTERCEPT to replace



bacterial detection. In October 2007, the government of Kuwait approved the INTERCEPT Blood System for pathogen inactivation as a safety measure for platelet components.

Table 2: Summary Results of Bacterial Detection of Platelet Apheresis Components

Detection System	Tested Components	Initial Positive	False Positive	False Negative
Scansystem	2475	5 (0.20%)	5 (0.20%)	1 (0.04%)
eBDS	1292	2 (0.15%)	2 (0.15%)	1 (0.07%)
<b>TOTAL</b>	<b>3767</b>	<b>7 (0.19%)</b>	<b>7 (0.19%)</b>	<b>2 (0.05%)</b>

## Conclusions

- Implementation of bacterial detection at KCBB did not prevent all septic transfusion reactions. Moreover, two days of platelet shelf life are lost and the bacterial detection screening gave both false negative and false positive results.
- Based on results of this study, the AABB granted a variance for KCBB to replace bacterial detection screening by INTERCEPT Blood System to ensure compliance with STD 5.1.5.1. The variance stated that INTERCEPT meets the intent of the standard for limiting and detecting bacteria in platelet components.
- In May 2008, KCBB replaced bacterial detection with pathogen inactivation by using INTERCEPT.

Figure 1: Production Scheme and Schedule for Platelets

Implementation of bacterial cultures requires an initial delay in release date (to allow growth prior to sampling), followed by extended monitoring of cultures, which may exceed the unit's maximum shelf life. Even after the unit has left the blood bank, the center has the obligation to continue monitoring the status of culture results, and to transmit subsequent positive results to the institution receiving the platelet unit. The INTERCEPT Blood System can be performed concurrently with conventional serology and NAT testing, without any additional monitoring or delay in platelet release time.

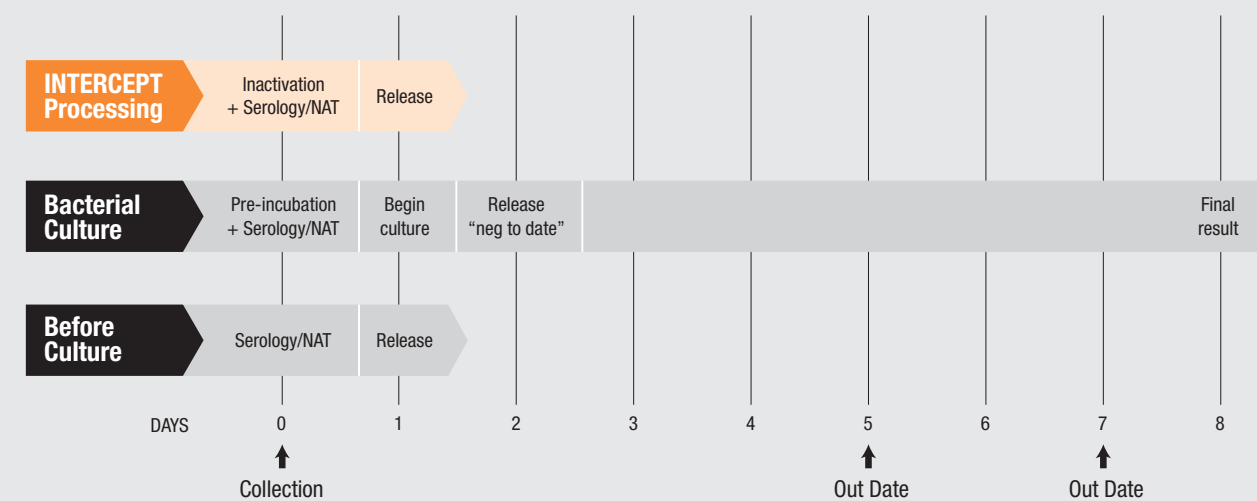


Figure 2: The INTERCEPT Blood System for Platelets

Using a sterile connecting device (SCD), the platelet container is sterilely connected to the INTERCEPT kit. Amotosalen (1) is added by gravity flow and the platelet mixture is illuminated with UVA light (2). Residual amotosalen and its photoproducts in the platelet mixture are reduced to low levels using a compound adsorption device (CAD) (3) before the platelets are transferred to the storage container (4).

