ARCBS Bacterial Contamination Screening of Platelets
Frequently Asked Questions (FAQs)

Doesn't the Australian Red Cross Blood Service (ARCBS) already do bacterial testing of platelets?
In accordance with regulatory requirements, ARCBS does already test 5% of its platelets for bacterial contamination as part of routine quality control. From April 2008, however, all platelet components will have a sample taken 24 hours after collection for bacterial contamination screening.

Why change now?
This change is occurring because ARCBS has now received funding from Government through the National Blood Authority (NBA). This represents an opportunity to reduce the risk of bacterial contamination of platelet components, and is in line with international best practice. Bacterial contamination events may have serious, even fatal, outcomes for patients.

How was the decision made?
ARCBS reviewed the benefits and costs of implementation of universal bacterial screening of platelets and submitted a business case to the National Blood Authority (NBA) for consideration by governments. The government has provided funding this year to allow ARCBS to commence 100% pre-release bacterial contamination screening of platelets from 28 April 2008.

Are all platelets to be tested?
All platelet components, both apheresis and pooled platelets, will be tested.

What if my patient needs a special phenotyped platelet component and can't wait 24 hours for the platelet to be sampled?
As samples for bacterial contamination screening will be taken 24 hours after collection, this should be taken into consideration when scheduling procedures for patients requiring special platelet components e.g. phenotyped or HLA-compatible platelets. Early release of platelet components without all ARCBS required release criteria being met may be considered in clinically urgent circumstances and following discussion with an ARCBS Transfusion Medicine Specialist. A disclaimer accepting clinical responsibility for the decision to transfuse will be required from the treating clinician. Prior to their release from ARCBS, all such platelet components will still be sampled for bacterial contamination screening and the samples will still be incubated over the full shelf life of the component.

Will red cells be tested?
It should be noted that the incidence of bacterial contamination in red cells is much lower than in platelet components (largely due to refrigerated storage conditions) and the types of bacteria implicated are often different. ARCBS routinely tests a small percentage of red cells for bacterial contamination at expiry for quality control purposes. Red cells will not be specifically tested during their available shelf life, except indirectly if a platelet component is made from that donation. In the case where red cells have been issued from the same donations that make up an implicated platelet pool, ARCBS will also recall those red cells.

What system is ARCBS using?
ARCBS will be using the bioMerieux® BacT/ALERT® Automated Microbial Detection System.

Does the BacT/ALERT® system detect both aerobic and anaerobic bacteria?
The BacT/ALERT® system is specifically designed to detect both aerobic and anaerobic bacteria and there are separate aerobic and anaerobic culture bottles for this purpose. ARCBS will inoculate both the aerobic and anaerobic bottles for every platelet component.

Why will ARCBS wait 24 hours before inoculating?
It takes time for any contaminating bacteria to proliferate to a concentration that will give a positive result when sampled and cultured. If sampling is undertaken too early there is a greater chance of false negative results occurring.

Why will you release the platelet immediately after taking the sample without waiting for the results of the culture?
There is currently no standard hold time that is advocated internationally. During the first 6 months after implementation of routine screening, ARCBS will be monitoring results to assess the optimal additional hold time that will balance bacterial detection with adequate platelet supply.

How will I know if my patient receives a potentially 'contaminated' product?
ARCBS will instigate a recall as soon as the culture system flags a positive result, an Initial Machine Positive (IMP).

What is an IMP?
An IMP is an Initial Machine Positive. This occurs when the culture system registers the possible presence of bacterial growth in the system.

What is the significance of an IMP?
An IMP indicates that bacteria may be growing in the culture system and hence that there may be bacterial contamination in the platelet component from which the original sample was taken. A proportion of the IMPs may ultimately be found to be 'false positives', occurring in the absence of true bacterial contamination.

Why are there so many false positives?
The system is designed to detect as many truly contaminated platelet components as possible. To achieve this, the system must be very sensitive even if it means that a proportion of the initial positive results turn out to be false alarms.

Will there be any false negatives?
Although the great majority of bacterially contaminated components will be detected, a negative result will not absolutely exclude the possibility of contamination. In addition, a positive result may be flagged by the system after the component has been issued by ARCBS. ***Any transfused patient who exhibits signs and symptoms consistent with receiving a bacterially contaminated component should still be investigated and treated appropriately and bacterial contamination considered as a potential diagnosis. This should include culture of the transfused component where possible as well as notification to ARCBS.***

How many IMPs will there be?
It is currently estimated that approximately 0.5% of platelet components may have an IMP result.

Who will contact me?
The ARCBS National Recall Office will notify the relevant transfusion laboratory of IMPs by fax and accompanying telephone call as per the current ARCBS recall process. This Office will operate 24 hours a day, 7 days a week.

It is important that ARCBS has an up-to-date record of your transfusion laboratory's contact details including:

- Daytime telephone number;
- Daytime fax number;
- Name and contact details of relevant senior staff member(s) (e.g. Scientist in Charge);
- After-hours telephone number, if different from the daytime number;
- After-hours fax number, if different from the daytime number; and
- Name and contact details of relevant after-hours senior staff member(s).

If you need to update your details, please contact the ARCBS National Recall Office by email AusRecall@arcbs.redcross.org.au or by telephone – 1300 664 260.

What do I need to do if I am notified of an IMP?
If the component has not been transfused, the transfusion laboratory will need to immediately withdraw it from their inventory and return it to ARCBS as part of the recall process.

If the component has been transfused, the transfusion laboratory will need to inform urgently the treating clinician of the patient who received the component. This will enable early clinical review and consideration of recipient blood cultures and antibiotic intervention as appropriate. If the patient has experienced any adverse reactions to the transfusion, it is important that these be reported to ARCBS as soon as possible.

Will ARCBS perform any additional testing on IMPs?
All IMPs will be sent by ARCBS to an external laboratory to have a Gram stain and culture performed for micro-organism identification and, where relevant, antibiotic sensitivity testing.

Will a Gram stain be done on IMPs?
ARCBS will have a Gram stain performed on all IMPs. Any organisms seen at microscopy in the Gram stain will be notified to the transfusion laboratory as a progress report.

What is the significance of no organism being seen on Gram stain?
Unfortunately, absence of organisms on Gram stain in the setting of a positive flag from the machine is not a good predictor of the absence of bacteria. For this reason, a negative Gram stain result will not be routinely communicated to transfusion laboratories.

Is there any relationship between the time to detection of an IMP (i.e. time between platelet sampling and the culture system flagging an IMP) and the likely type of contaminating micro-organism?
The average time to detection of an IMP varies with the type of organism and level of contamination. Machine false positives tend to flag earlier, however, so do some Gram negative organisms e.g. Klebsiella. Therefore, it is important that the potential clinical implications of all IMPs are carefully considered.

The following table shows the average time to detection for a number of bacterial species that are most commonly implicated in contaminated platelet components, as well as the average time to detection of machine false positives.

Table 1: ARCBS quality control data 06/07

Organism	% of QC detections 06/07	Average detection time after inoculation (hrs)
Proprionibacterium sp	44%	78
Bacillus sp	14%	17.5
Staphylococcus sp	24%	14
Other e.g. *Corynebacterium sp*, *Citrobacter sp.* etc	18%	43
Machine false positive (expect about 50% or less to be true positives)		12.5

What follow-up information will I be sent?
ARCBS will send progress reports as relevant additional information becomes available on implicated transfused components. This will include available Gram stain result, micro-organism identification and antibiotic sensitivities where relevant.

Will I find out the exact type of bacteria involved?
ARCBS will send progress reports, as well as a final report that will include the results of all testing, including the identity of any bacterial species detected.

Will I get a final report?
Yes. ARCBS will send a final report containing the results of the investigations performed to the transfusion laboratory at the conclusion of the investigation of the implicated component.

What types of bacteria are most commonly involved?
The most common bacteria implicated in the contamination of platelet components are skin commensals, notably Staphylococcus epidermidis. In a UK study, the most common bacterial contaminants of platelet concentrates in order of frequency were Staphylococcus epidermidis (nearly 30% of cases) followed by Bacillus cereus, Group B Streptococcus, Staphylococcus aureus, Escherichia coli, Enterobacter aerogenes, Morganella morganii and Coagulase negative Staphylococcus.

Will antibiotic sensitivity be performed for any identified bacteria?
Antibiotic sensitivity will be performed in accordance with usual laboratory procedures.

Does contamination ever occur in 'epidemics' like the advent of HIV or bacteria in the population?
Bacterial contamination of blood is usually an isolated event specific to the individual blood component. Bacterial contamination has been reported very rarely in clusters related to blood bag contamination or due to processing failures.

If ARCBS uses skin decontamination and a diversion pouch system with a closed system where do the bacteria come from?
Bacteria contaminating blood donations may occur from the environment, particularly the donor's skin. The ARCBS skin decontamination procedures and diversion of the first 30mL of blood away from the collection bag greatly reduce the risk of bacterial contamination from this source. However, these measures do not completely eliminate this risk. Bacterial contamination can also occur when a donor has an asymptomatic bacteraemia at the time of donation.

Do any other countries do this?
Bacterial detection testing of platelets is being done in a number of other countries and this number is increasing as it becomes the internationally accepted standard.

Will the supply of platelets be affected?
International experience indicates that, with proper planning, the introduction of bacterial contamination screening of platelet components has minimal or no impact on the overall platelet supply. ARCBS will be increasing platelet production at the time of the change over and monitoring supply closely over the following weeks.

Will platelets, on average, be older when this screening is in use, than they are currently?
ARCBS modelling indicates that platelets will be older on average as a greater proportion will be issued on the second day after collection. The proportion of platelets that will be greater than 2 days old at the time of issue are most likely to remain the same.

Is ARCBS seeking to increase the shelf life of platelets from 5 to 7 days to improve stocks and supply?
No, not at this time.

Is there any difference in risk between apheresis platelets and pooled platelets?
The available literature indicates that the risk of contamination is probably slightly lower in apheresis products. This is due to the fact that most bacteria found to contaminate platelet units are skin commensals. For apheresis platelets, only one donor and one venepuncture (the source of the skin flora) is required to generate this product as opposed to 4 of each (donors and venepunctures) for a pooled platelet.

Does the risk increase with the age of the component?
Data from ARCBS quality control testing and the international literature indicate both likelihood and degree of bacterial contamination to be associated with the age of the platelet unit. For this reason, cultures will continue to be incubated over the full shelf life of the platelet, regardless of when it is issued from ARCBS, and notification of an IMP may occur at any time during this period.

Won't there be a mixed (tested and not tested platelet) inventory on 28 April?
All platelet components issued by ARCBS nationally from 28 April 2008 onwards will have been subject to bacterial detection screening.

Will ARCBS be following up any implicated donors?
ARCBS will follow up, and investigate as necessary, any donor of a component that is implicated in a case of bacterial contamination. Internal ARCBS investigations would require the review of donation, collection and processing information in any such incident.

My transfusion laboratory is not open 24 hours a day to receive notification of IMPs. What should I do?
If your transfusion laboratory is not open 24 hours a day, it is important that you provide ARCBS with the relevant after-hours contact details for your laboratory including:

- After-hours telephone number;
- After-hours fax number; and
- Name and contact details of relevant after-hours senior staff member(s).

If you need to update your details, please contact the ARCBS National Recall Office by email AusRecall@arcbs.redcross.org.au or by telephone – 1300 664 260.

What if I need additional information about a recalled component?
If you need additional information, please contact the ARCBS National Recall Office at any time on 1300 664 260.

What if I need clinical advice about what to do with the results ARCBS sends me, or to discuss a patient's situation?
If you require clinical advice regarding the results sent to you by ARCBS, please contact the ARCBS National Recall Office staff on 1300 664 260 who will be able to arrange contact with the local ARCBS Transfusion Medicine Specialist.