Guidelines for the Blood Transfusion Services

9.5: Recommended standards for the reduction of bacterial contamination of blood components


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Update notice: Section 9.5.3.1 - Single-test system has been updated following the the issue of Change Notification 16 - 2013.

In recent years bacterial contamination of blood has been significantly reduced by the introduction of improved donor arm cleansing using 70% isopropyl alcohol/2% chlorhexidine gluconate applied as a single-step procedure, and diversion of the first 20–30 mL of the blood donation. The risk of bacterial contamination can be further reduced, but not eliminated, by screening of blood components.

9.5.1: Arm cleansing

There should be an effective, specified and validated method of arm cleansing, using an approved skin-cleansing system. 70% isopropyl alcohol/2% chlorhexidine gluconate is recommended by the National Evidence-Based Guidelines for Preventing Healthcare-Associated Infections in NHS Hospitals in England. Adherence to the principles, protocols and practices relating to the correct use of the specified skin-cleansing system shall be regularly audited by periodic bacterial sampling and observation, and corrected if found to be lacking.

Periodic bacterial sampling of the skin of donors' arms may be carried out as an audit of correct use of the specified skin-cleansing system. If such sampling is performed, it will give an indication of how well staff are complying with the use of the system. In practice, it should be expected that bacterial sampling after skin cleansing with 70% isopropyl alcohol/2% chlorhexidine gluconate will reveal bacteria at a rate of no greater than 2 cfu per standard contact plate. Such levels may be difficult to achieve with other cleansing systems. Consistent finding of higher levels may require a review of compliance/re-education of relevant staff and further observational audits.

Periodic bacterial sampling may also take the form of anonymous sampling of staff fingertips after hand hygiene and after dealing with donors to assess levels of hand contamination and effectiveness of hand washing and decontamination in practice. Findings can then be fed back to staff as an educational tool.

9.5.2: Diversion of donation

A minimum of 20 mL of the first part of every blood donation should be diverted into a side-arm pouch, in order to minimise the level of bacterial skin contaminants in the collection bag. This diverted volume can be used as a source of blood samples for mandatory and other testing of the donation.

9.5.3: Screening of platelet components
There should be a means of detecting bacterial contamination of platelet components, using validated methods. The key requirements of a detection system are (i) effective sample size, (ii) a rapid test result or automated 24-hour readout with alarm notification and (iii) reliable detection of bacteria at a level indicating emerging risk to recipient.

Bacterial culture using an automated microbial detection system represents the most widely used and efficient method for screening of components. Its key feature is the continuous monitoring of incubation to allow immediate withdrawal of contaminated units.

The following protocols are considered to be optimal for single and two-test systems for the screening of platelets using an automated microbial detection system. Both require the use of a minimum 16 mL sample for aerobic and anaerobic culture and allow a 7-day shelf life. A two-test protocol is the ideal method for optimal performance, but this has significant operational issues. A single-test protocol with a minimum hold period of 36 hours before sampling will allow extension of shelf life of the product to 7 days providing incubation and monitoring is continued for the duration. Services may choose to initiate testing earlier than the 36-hour holding period (e.g. 18 hours), but these platelets will not qualify for a 7-day shelf life unless a second test is performed.

9.5.3.1: Single-test system

1. Platelet components are held for at least 36 hours after collection

2. Minimum 8-mL samples are inoculated into each aerobic and anaerobic bottle.

3. If samples are negative after a minimum of 6 hours of incubation, release product on a negative-to-date basis with 7-day shelf life and continue incubation and monitoring for the shelf life of the product.

4. A suitable protocol must be in place for confirmation of the presence of contamination.

5. Discard unused platelets on Day 8. (Time-expired units may be referred to the relevant bacteriology laboratory for surveillance testing.)

9.5.3.2: Two-test system

1. Platelet components are held for at least 18 hours after collection.

2. Minimum 8-mL samples are inoculated into each aerobic and anaerobic bottle.

3. If samples are negative after 24 hours of incubation, release product on a negative-to-date basis with 5-day shelf life and continue incubation and monitoring for the shelf life of the product.

4. A suitable protocol must be in place for confirmation of the presence of contamination.

5. Re-sample and test remaining stock at 4 days after collection and if negative at 24 hours release for use with a 7-day shelf life.

6. Discard unused platelets on Day 8. (Time-expired units may be referred to the relevant bacteriology laboratory for surveillance testing.)
* Release of red cells requires a negative result from both the index culture bottles and testing of the platelet component.

† AMDS: Automated microbial detection system, re-test aerobic and anaerobic culture in duplicate.

* Figure 9.7 Platelet components testing algorithm. If the index pooled platelet component is not available to re-test, the associated red cell unit should be tested.

The following definitions of screening test results are recommended.

**Initial reactive:** Positive bottle or bottles from which bacteria are isolated on initial screen.

**Repeat reactive:** Positive bottle or bottles from repeat testing of the index unit from which bacteria are isolated.

**Confirmed positive:** Bacteria detected from the initial and repeat tests which are of the same species.

**Indeterminate:** Bacteria detected in only the initial or repeat test, but not both, or bacteria detected in the initial or repeat reactives which cannot be matched at species level.

**False positive:** A positive signal is obtained for a culture bottle but no bacteria are detected on subculture.
**Confirmed positive** = a match at species level on the initial RBC test and re-test.

**Non-confirmed positive** = negative repeat test and no match at species level with the PC confirmed positive result.

† AMDS: Automated microbial detection system, re-test aerobic and anaerobic culture in duplicate.

**False negative**: Initial test negative but component associated with a post-transfusion reaction is subsequently positive on re-testing.

If the initial test is positive any components (plasma, red cells etc.) from the same donation must be quarantined pending the result of the repeat test and a recall procedure should be initiated for any platelet units or other components already issued.

The algorithms shown in Figures 9.7 and 9.8 are recommended for the confirmation of bacterial contamination of platelet components or red blood cells using an automated microbial detection system.