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Guidelines for the Blood Transfusion Services in the United Kingdom – 8th Edition 2013

Errata

Amended pages

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Platelets, Pooled, Buffy Coat Derived, Leucocyte Depleted

7.9.1 Technical information

- Donations of whole blood where the bleed time exceeded 15 minutes are not suitable for platelet production.
- The buffy coats must be prepared at ambient temperature from whole blood where the surface temperature of packs has not dropped below 18°C.
- Initial separation of buffy coat must occur within 24 hours of venepuncture (unless supported by additional validation), with a minimum buffy coat rest period of 2 hours before secondary pooling and processing of buffy coats to produce the final component, which is generally completed before the end of Day 1.
- The volume of suspension medium must be sufficient to maintain the pH within the range 6.4–7.4 at the end of the shelf life of the component.
- The production process transfers the final component into a pack that was not part of the original pack assembly. Therefore a secure system must be in place to ensure a full audit trail and that the correct identification number is put on the final component pack.
- Where the production method requires the use of a single unit of plasma for resuspension, the plasma from group O donors should be tested for high-titre anti-A and anti-B and 'high-titre negative' units labelled. The testing method and acceptable limits should be defined (see also Chapter 9). Plasma should be selected from male donors as a TRALI risk reduction strategy.
- Platelets, Pooled, Buffy Coat Derived, Leucocyte Depleted, should be transfused through a 170–200 µm filter.

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Platelets in Additive Solution and Plasma, Leucocyte Depleted

7.11.1 Technical Information

- The component is manufactured as a primary component and not as a remanufactured secondary component.
- Donations of whole blood where the bleed time exceeded 15 minutes are not suitable for platelet production.
- Where prepared from buffy coats, the buffy coats must be prepared at ambient temperature from whole blood where the surface temperature of packs has not dropped below 18°C.
- Where prepared from buffy coats, initial separation of buffy coat must occur within 24 hours of venepuncture (unless supported by additional validation), with a minimum buffy coat rest period of 2 hours before secondary pooling and processing of buffy coats to produce the final component, which is generally completed before the end of Day 1.
- Screening of female apheresis donors for HLA/HNA antibodies should be considered as a TRALI risk reduction strategy.
- The volume of suspension medium must be sufficient to maintain the pH within the range 6.4–7.4 at the end of the shelf life of the component.
- Where the production process transfers the final component into a pack that was not part of the original pack assembly, a secure system must be in place to ensure the audit trail and the correct identification number is put on the final component pack.
- Platelets in Additive Solution and Plasma, Leucocyte Depleted, should be transfused through a 170–200 µm filter.

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Platelets in Additive Solution, Leucocyte Depleted

7.12.1 Technical information

- Donations of whole blood where the bleed time exceeded 15 minutes are not suitable for platelet production.
- Where prepared from buffy coats, the buffy coats must be prepared at ambient temperature from whole blood where the surface temperature of packs has not dropped below 18°C.

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- Where prepared from buffy coats, initial separation of buffy coat must occur within 24 hours of venepuncture (unless supported by additional validation), with a minimum buffy coat rest period of 2 hours before secondary pooling and processing of buffy coats to produce the final component, which is generally completed before the end of Day 1.
- The volume of suspension medium must be sufficient to maintain the pH within the range 6.4–7.4 at the end of the shelf life of the component.
- Where the production process transfers the final component into a pack that was not part of the original pack assembly, a secure system must be in place to ensure a full audit trail and that the correct identification number is put on the final component pack.
- Platelets in Additive Solution, Leucocyte Depleted, should be transfused through a 170–200 µm filter.

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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.)

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12.11.2 Blood and blood components from group O donors with high titres of anti-A, anti-B and/or anti-A,B

- Red cells, platelets and fresh frozen plasma from group O donors with high titres of anti-A, anti-B and/or anti-A,B can result in haemolytic transfusion reactions (HTRs) when given to non-group O patients. Such group O donors are generally termed ‘high-titre group O donors’.
- Reactions are more likely to occur when:
  - the serological titre of the anti-A, anti-B and/or anti-A,B in the component is high
  - the plasma volume of the transfused product is high

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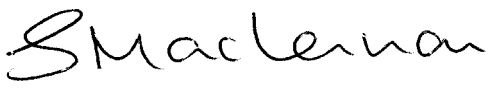
- the blood volume of the recipient is small.

- Each Blood Establishment should have a testing and issuing policy to avoid the use of high-titre anti-A and/or anti-B in instances where a significant adverse clinical reaction is likely. The policy should cover the following components:
  - whole blood and plasma reduced red cells (excluding red cells in additive solution)
  - fresh frozen plasma
  - apheresis platelet donations
  - pooled platelets containing plasma from a single 'high-titre' group O donor
  - blood/components for neonatal use, and infants under one year.
- Where high-titre anti-A/B testing is deemed necessary, a saline agglutination test (performed as detailed in Chapter 11) should give a negative result, at a dilution of 1/128, or an equivalent dilution by other techniques.
- There should be a procedure in place to collect and review testing and patient outcome data and to implement changes in policy in the light of continuing clinical experience with the plasma-containing blood products issued.
- Components from group O donors with 'low titres' of anti-A, anti-B and/or anti-A,B can cause intravascular haemolysis in non-group O recipients if given in sufficiently large volumes.
- It is important to recognise that, although testing for high-titre ABO antibodies in blood donors may reduce the risk of HTR in 'out of group transfusion', it cannot be entirely eliminated through this route. Group O platelets can cause HTR even when tested and labelled negative for high-titre haemolysins. They should only be used for non-group O patients (particularly paediatric patients) as a last resort.



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