Guidelines for the Blood Transfusion Services

7.1.4: Production advice

http://aws-lon-jpac.targetservers.uk/red-book/chapter-7/7-1/7-1-4

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The timing and method of separation depends on the components to be prepared from a given donation.

If the production, washing or splitting 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 correct identification number is put on the final component pack.

Where a production process amends the expiry date of the component, there are different consequences, dependent on the process.

Further processing or irradiation may reduce the expiry date of the component. Here the expiry date of the new component must not exceed that of the primary component or the expiry date limitations conferred by the process.

Components produced by pooling primary components must have an expiry date of the shortest dated component used.

When remanufacturing neonatal or paediatric red cell components into adult components, to avoid unnecessary wastage, the expiry date may be extended.

Processing of a red cell component to allow frozen storage will result in a lengthened expiry date.

The method of preparation should ensure that plasma components have the maximum level of labile coagulation factors with minimum cellular contamination.

Donations from donors with clinically significant human platelet antigen (HPA) and/or human leucocyte antigen (HLA) antibodies should not be used for the production of plasma-rich blood products (e.g. fresh frozen plasma, platelet concentrate, whole blood, cryoprecipitate). Red cells suspended in additive solution can be produced from such donations.

Platelet and plasma components should not be produced from lipaemic or icteric donations or be contaminated with red cells. Procedures should exist for assessing these findings.

An upper platelet concentration should be assigned for each platelet component type based on pack validation data or the pack manufacturer’s recommendations.

pH measurements on platelet components should be made between 20°C and 24°C or the measurements corrected to 22°C.

Unless a validated pathogen inactivation process is used, blood components for use in intrauterine transfusion and for neonates and infants (see also section 7.7) must be derived from selected donors who fulfil the following criteria:

- Have given at least one donation in the last 2 years, which was either negative for all mandatory markers, or if repeat reactive, has been confirmed to be non-specifically reactive and the donor reinstated in accordance with section 9.4 (on reinstatement of blood donors).

- Negative results were obtained for mandatory microbiology markers with the current donation.

Each component should be visually inspected at each stage of processing and immediately prior to issue. The component must be withdrawn if there is evidence of leakage, damage to or fault in the container, excessive air, suspicion of microbial contamination or any other contraindications such as platelet clumping, unusual turbidity, haemolysis or other abnormal colour change.