Guidelines for the Blood Transfusion Services

6.3: Component and process monitoring tests

http://www.transfusionguidelines.org/red-book/chapter-6/6-3

6.3: Component and process monitoring tests

These guidelines also indicate the minimum level of other process monitoring tests necessary to ensure components are prepared to specification.

Any assay used for blood component quality monitoring should be validated and documented before introduction and before any changes to methodology or manufacture are brought into use. Blood Establishments should ensure that they participate in the National External Quality Assessment Scheme (NEQAS) or other available external quality assurance schemes for the assays used to assess component quality.

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 The component must be withdrawn if there is evidence of leakage, damage to or fault in the container, excessive air, suspicion of microbial contamination or any other contraindications such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.

6.3.1: Sampling procedures

Sampling procedures should be designed and validated, prior to acceptance as standard practice, to ensure the sample truly reflects the contents of the component pack.

Validation of sampling procedures should be repeated before application to new components, relevant changes to blood pack design or different quality parameters, or before the introduction of new sampling equipment. Also there should be a procedure for continuous assessment of staff competence/sampling techniques.

Where test samples are removed from a component to be issued for transfusion, the sampling procedure should be designed and validated to ensure that the sterility and essential properties of the component are not adversely affected.

Samples for leucocyte counting must be taken and tested within 48 hours of donation, unless the sampling and testing times used have been validated to yield equivalent results.

6.3.2: Frequency of tests

The regularity with which components are made and the extent of their compliance with specification influences the frequency with which component and process monitoring tests are required.

If there is a trend towards the minimum requirements specified in Chapter 7, the frequency of quality monitoring tests should be increased according to defined procedures and/or in consequence of corrective actions until the relevant component attributes have been brought under control.

The testing protocol should take into account all major production variables and ensure samples are representative of these.

6.3.3: Component weight:volume

To provide information that is useful for clinicians, the component specifications given in Chapter 7 generally require the component label to indicate a volume. This may be either the calculated volume or nominal volume, and the nominal volume may be based on a national or locally established volume specification.

Since volume generally is calculated by dividing the component weight by its specific gravity, the following conventions should apply in order to ensure some element of standardisation:

- Whole blood volume is most appropriately calculated by deducting the weight of the pack assembly and dividing the resulting weight by the nominal specific gravity of 1.06.
- To provide quality monitoring data that demonstrate the capability of the blood collection process, deduct the weight of the anticoagulant before converting to volume.
- To provide quality monitoring data that reflect the provision of whole blood as a component, the volume given on the component label should include whole blood and anticoagulant.
- For red cell components, volume is calculated by weighing the pack, deducting the weight of the pack assembly only, and dividing the resultant weight by the nominal specific gravity 1.06. The weight of anticoagulant and, if relevant, additive solution are not deducted when calculating the volume of red cell components.
- For platelets suspended in plasma and plasma components, volume is calculated by weighing the pack, deducting the weight of the pack assembly and dividing the resulting weight by the nominal specific gravity of 1.03.
- For platelets suspended in platelet additive solution and plasma, volume is calculated by weighing the pack, deducting the weight of the pack assembly and dividing the resulting weight by the nominal specific gravity of 1.02.
- For platelets suspended in platelet additive solution, volume is calculated by weighing the pack, deducting the weight of the pack assembly and dividing the resulting weight by the nominal specific gravity of 1.01.