Guidelines for the Blood Transfusion Services

7.2: Whole Blood Components

http://transfusionguidelines.org/red-book/chapter-7/7-2

7.2: Whole Blood Components

Whole blood components are collected from UK donors as described in Chapter 5. These components undergo primary processing to separate the blood constituents into red cell, platelet, granulocyte and plasma components.

Currently in the UK whole blood components are not routinely used for transfusion, although provisional component specifications for use in clinical trials are described in Annexe 3.

Specifications

7.2.1: Whole Blood, Leucocyte Depleted

A unit of blood collected into an anticoagulant, containing less than 1×10^6 leucocytes.

7.2.1.1: Technical information

- A unit of whole blood is collected in the UK from a suitable donor (see Chapters 3 and 5). The International Blood Pack specification contains 66.5 mL of anticoagulant and is suitable for the collection of 475 mL ±10%.
- Whole Blood, Leucocyte Depleted should be administered through a CE/UKCA/UKNI marked transfusion set.

7.2.1.2: Labelling

For general guidelines, see section 6.6.

The following shall be included on the label:

(* = in eye-readable and UKBTS approved barcode format)

- Whole Blood, Leucocyte Depleted* and volume
- the blood component producer’s name*
- the donation number*
- the ABO group*
- the RhD group stated as positive or negative*
- the name, composition and volume of the anticoagulant solution
- the date of collection
- the expiry date*
- the temperature of storage

- the blood pack lot number.*

In addition, the following statements should be made:

INSTRUCTION
Always check patient/component compatibility/identity
Inspect pack and contents for signs of deterioration or damage
Risk of adverse reaction/infection, including vCJD

7.2.1.3: Storage

For general guidelines, see section 6.7.

- The component may be stored for a maximum of 35 days at a core temperature of 4 ±2°C if an adeninesupplemented anticoagulant is used, otherwise the maximum period of storage is 28 days at a core temperature of 4 ±2°C.

- Variation from the core temperature of 4 ±2°C must be kept to a minimum during storage and restricted to any short period necessary for examining, labelling or issuing the component.

- Exceptionally, i.e. due to equipment failure at a Blood Centre, red cell components which have been exposed to a core temperature not exceeding 10°C and not less than 1°C may be released for transfusion provided that:
  - the component has been exposed to such a temperature change on one occasion only
  - the duration of the temperature excursion has not exceeded 5 hours
  - a documented system is available in each Blood Centre to cover such eventualities
  - adequate records of the incident are compiled and retained.

7.2.1.4: Testing

In addition to the mandatory and other tests required for blood donations described in Chapter 9, and leucocyte counting (see sections 6.3 and 7.1.1), a minimum of 75% of those components tested for the parameters shown in Table 7.2.1 shall meet the specified values.

Table 7.2.1 Whole Blood, Leucocyte Depleted – additional tests

Parameter	Frequency of test	Specification
Volume [1]	1% or as determined by statistical process control (if <=10 components produced per month then test every available component)	475 mL ±10%
Haemolysis	As per section 7.1.3	<0.8% of red cell mass
Haemoglobin content	1% or as determined by statistical process control (if <=10 components produced per month then test every available component)	>=40 g/unit
Leucocyte count [2]	As per sections 6.3 and 7.1.1	$<1 \times 10^6$/unit
[1] After volume losses resulting from leucodepletion		
[2] Methods validated for counting low numbers of leucocytes must be used		

7.2.1.5: Transportation

For general guidelines, see section 6.11.

For red cell components, transit containers, packing materials and procedures should have been validated to ensure the component surface temperature can be maintained between 2°C and 10°C during transportation. Additionally:

- the validation exercise should be repeated periodically
- if melting ice is used, it should not come into direct contact with the components
- dead air space in packaging containers should be minimised
- as far as is practicable, transit containers should be equilibrated to their storage temperature prior to filling with components
- transport time normally should not exceed 12 hours.

In some instances, it is necessary to issue red cell components that have not been cooled to their storage temperature prior to placing in the transit container. The transport temperature specified above is not applicable for such consignments.