Guidelines for the Blood Transfusion Services

7.3.4: Red Cells, Thawed and Washed, Leucocyte Depleted

http://www.transfusionguidelines.org/red-book/chapter-7/7-3/7-3-4

7.3.4: Red Cells, Thawed and Washed, Leucocyte Depleted

A red cell component that contains less than 1×10^6 leucocytes, frozen in the presence of a cryoprotectant (preferably within 5 days of collection), and washed before use. Red Cells, Thawed and Washed, Leucocyte Depleted may then be suspended in an approved additive solution.

7.3.4.1: Technical information

- The concentration and nature of the cryoprotectant must provide appropriate protection of the red cells at the intended storage temperature. The entire process of freezing, thawing and washing must be validated and documented.
- The use of validated washing procedures that incorporate chilled saline or other validated solution for suspension is recommended. This will minimise the risk of bacterial contamination and helps to produce a component that meets the transit temperature requirements. Use of an automated, closed washing system would be preferable.
- The target minimum haemoglobin content is 36 g.
- If the washing process results in the transfer of 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 donation identification number is put on the pack in which the component is frozen and the pack in which the final component is presented.
- Red Cells, Thawed and Washed, Leucocyte Depleted should be administered through a CE/UKCA /UKNI marked transfusion set.

7.3.4.2: Labelling

For general guidelines, see section 6.6.

The following shall be included on the label:

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

- Red Cells, Thawed and Washed, 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 suspending solution
- the date and time of preparation

- the expiry date and time*
- the temperature of storage
- the blood pack lot number.*

In addition, the following statements should be made:

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

7.3.4.3: Storage

For general guidelines, see section 6.7.

- Maintenance of a constant storage temperature is important, particularly if a low-glycerol cryoprotectant system is used. Storage should be controlled to ensure the temperature is:
  - –60°C to –80°C if stored in an electrical freezer, when a high-glycerol method is used
  - –140°C to –150°C if stored in vapour phase liquid nitrogen, when a low-glycerol method is used.

- Storage may be extended to 30 years if the correct storage temperature is guaranteed.

- The thawed component should be used as soon as possible if produced in an open system. Where the component has been produced in a closed system and storage is required the component should be stored at a core temperature of 4 ±2°C and used within 24 hours of production if suspended in saline or a defined validated period if suspended in an approved additive solution.

7.3.4.4: 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 7.3.4 shall meet the specified values. Provided the component is prepared from a process that is validated for leucocyte removal, testing of washed red cells for residual leucocytes is not required.

Table 7.3.4 Red Cells, Thawed and Washed, Leucocyte Depleted – additional tests

Parameter	Frequency of test	Specification
Volume	All	Within locally defined nominal volume range
Supernatant haemoglobin [1]	1% or as determined by statistical process control (if <=10 components produced per month then test every available component)	<0.2 g/unit
Red cell haemoglobin		>=36 g/unit
Leucocyte count [2]	As per sections 6.3 and 7.1.1	<1 × 10^6/unit
[1] Testing to be carried out prior to issue on all units as a product release criterion. Units measured and found to have >=0.5 g/unit should not be issued for transfusion except under clinical concession on a named patient basis. This may apply to some units of rare red cell phenotype associated with a known red cell membrane defect causing increased fragility (such as Rh_{null} and K_o).		
[2] Methods validated for counting low numbers of leucocytes must be used. Pre-freeze testing.		

7.3.4.5: Transportation

For general guidelines, see section 6.11.

- The transport requirements for red cells in the frozen state will be influenced by the nature and concentration of cryoprotectant used: e.g. a component containing <20% glycerol requires a refrigerant colder than dry ice, such as the vapour phase of liquid nitrogen.

- For thawed 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.