Guidelines for the Blood Transfusion Services

7.3.3: Red Cells, Washed, Leucocyte Depleted

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

7.3.3: Red Cells, Washed, Leucocyte Depleted

A red cell component, containing less than 1×10^6 leucocytes, which has been washed with 0.9% w/v sodium chloride for injection (BP) or other validated solution. The Red Cells, Washed, Leucocyte Depleted may then be suspended in an approved solution.

7.3.3.1: Technical information

- The amount of residual protein will depend on the washing protocol. Washing can be performed by interrupted or continuous flow centrifugation.
- The use of validated closed system washing procedures that incorporate chilled validated solution for suspension is recommended. This will minimise the risk of bacterial growth and help to produce a component that meets the transit temperature requirements.
- 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 component pack of Red Cells, Washed, Leucocyte Depleted.
- Red Cells, Washed, Leucocyte Depleted should be administered through a CE/UKCA/UKNI marked transfusion set.

7.3.3.2: 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, 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
Inspect pack and contents for signs of deterioration or damage
Risk of adverse reaction/infection, including vCJD

7.3.3.3: Storage

For general guidelines, see section 6.7.

- 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 up to 14 days if stored in SAGM. Where alternative additive solutions are used, storage will be defined through validation.

7.3.3.4: 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 7.3.3 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 7.3.3 Red Cells, Washed, Leucocyte Depleted – additional tests

Parameter	Frequency of test	Specification
Volume [1]	100% unless the process capability by SPC demonstrates otherwise	Within locally specified volume range
Haemoglobin content [2]		>=40 g/unit
Haematocrit [3]		0.50 – 0.70
Residual protein [4]		<=0.5 g/unit
Leucocyte count [5] (pre-wash)	As per sections 6.3 and 7.1.1	$<1 \times 10^6$/unit
[1] Units measured and found to be <210 mL or >375 mL should only be issued for transfusion under concessionary release		
[2] Units measured and found to have <30 g/unit should only be issued for transfusion under concessionary release		
[3] Units measured and found to have haematocrit <0.40 or >0.70 should only be issued for transfusion under concessionary release		
[4] Units measured and found to have >0.5 g/unit should only be issued for transfusion under concessionary release		
[5] Methods validated for counting low numbers of leucocytes must be used		

7.3.3.5: 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.