Guidelines for the Blood Transfusion Services

7.7: Red Cells, Washed, Leucocyte Depleted

Update notice: Table 7.4 has been updated following the issue of Change Notification 30 - 2015.

A red cell component, containing less than $1 \times 10^6$ 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.

7.7.1: 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 washing procedures that incorporate chilled saline or other 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. Use of an automated, closed washing system would be preferable.

- 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 transfused through a 170–200 µm filter.

7.7.2: 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

7.7.3: Storage

For general guidelines, see section 6.7.

The 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.

7.7.4: 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), a minimum of 75% of those components tested for the parameters shown in Table 7.4 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.

7.7.5: 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.

### Table 7.4 Red Cells, Washed, Leucocyte Depleted – additional tests

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Frequency of test</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume</td>
<td>100% unless the process capability by SPC demonstrates otherwise</td>
<td>Within locally specified volume range</td>
</tr>
<tr>
<td>Haemoglobin content</td>
<td></td>
<td>&gt;=40 g/unit</td>
</tr>
<tr>
<td>Haematocrit</td>
<td></td>
<td>0.5 - 0.70</td>
</tr>
<tr>
<td>Residual protein**</td>
<td></td>
<td>&lt;0.5 g/unit</td>
</tr>
<tr>
<td>Leucocyte count* (pre-wash)</td>
<td>As per sections 6.3 and 7.1</td>
<td>&lt;1 x 10^6/unit</td>
</tr>
</tbody>
</table>

* Methods validated for counting low numbers of leucocytes must be used

** Units tested and found to have >0.5 g/unit should not be issued for transfusion