Change Notification for the UK Blood Transfusion Services

Date of Issue: 8 December 2025 **Implementation:** to be determined by each Service

No. 38 – 2025

Provisional component specification:

Red Cells for Neonates and Infants, Leucocyte Depleted, Washed

This notification includes the following changes:

	BM-DSG Bone Marrow & Peripheral Blood Stem Cell	CB-DSG Cord Blood	GDRI Geographical Disease Risk Index	TD-DSG Tissue – Deceased Donors	TL-DSG Tissue – Live Donors	WB-DSG Whole Blood & Components	Red Book Guidelines for the BTS in the UK
1. Red Cells for Neonates and Infants, LD, Washed	○	○	○	○	○	○	●

Ryan Evans
Chair, Standing Advisory Committee on Blood Components (SACBC)

Dr Stephen Thomas
Professional Director of JPAC

Changes are indicated using the key below. This formatting will not appear in the final entry.

original text	«inserted text»	~~deleted text~~

1. Changes apply to the **Red Book**

The following specification will be added to

Annex 3: Provisional Components

A3.5: Red Cells for Neonates and Infants, Leucocyte Depleted, Washed

A red cell component (≥250 mL) suitable for neonates and infants under 1 year that contains less than 1×10^6 leucocytes (per starting component), which has been washed with a validated solution. The Red Cells for Neonates and Infants, Leucocyte Depleted (LD), Washed will be divided into approximately equal volumes using a closed system.

A3.5.1: 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, LD.
- Section 7.7 provides general guidance on the requirements for components for use in neonates and infants under 1 year.
- The component should be free from clinically significant irregular blood group antibodies including high-titre anti-A and anti-B and should be negative for antibodies to CMV.
- Red Cells for Neonates and Infants, LD, Washed should be administered through a CE/UKCA/UKNI marked transfusion set.
- Unless the Blood Centre recommends screening is unnecessary, the donor should be Haemoglobin S screen negative.

A3.5.2: 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 for Neonates and Infants, Leucocyte Depleted, Washed* and volume

- the blood component producer's name*
- the donation number and, if divided, sub-batch 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

A3.5.3: Storage

For general guidelines, see section 6.7.

For top-up transfusions of neonates and infants under 1 year, 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.

A3.5.4: 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), the component shall be free from clinically significant irregular blood group antibodies and high-titre anti-A and/or anti-B, and antibodies to CMV.

Furthermore, a minimum of 75% of those components tested for the parameters shown in Table A3.5 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 A3.5: Red Cells for Neonates and Infants, LD, Washed – additional tests

Parameter	Frequency of test	Specification
Volume	100% unless the process capability by SPC demonstrates otherwise	Within locally specified volume range
Haemoglobin content		Locally defined
Haematocrit [1]		0.50–0.70
Haemolysis at end of storage		<0.8% of red cell mass
Residual protein [2]		<0.5 g/starting component
Leucocyte count (pre-wash) [3,4]	As per sections 6.3 and 7.1.1	$<1\times10^6$/starting component
1. Units tested and found to have haematocrit <0.40 or >0.70 should not be issued for transfusion		
2. Tested in the starting component (Red cells, Washed, LD)		
3. Tested in the pre-wash component		
4. Methods validated for counting low numbers of leucocytes must be used		

A3.5.5: 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 from the blood supplier to hospitals 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.