Guidelines for the Blood Transfusion Services

A3.4 Red Cells, Rejuvenated and Washed, Leucocyte Depleted

http://www.transfusionguidelines.org/red-book/annexe-3/a3-4

Provisional Component

A3.4: Red Cells, Rejuvenated and Washed, Leucocyte Depleted

A red cell component, containing less than 1×10^6 leucocytes, which has been rejuvenated, washed, and resuspended in a validated additive solution (SAGM). The component is intended to be used as part of the REDJUVENATE clinical study only, with a maximum of 6 units to be transfused in any 24 hours.

A3.4.1: Technical information

- The starting material is Red Cells in Additive Solution, Leucocyte Depleted, on or after Day 7 and no later than Day 32.
- To reduce the risk of bacterial growth, periods where Red Cells in Additive Solution, Leucocyte Depleted for the trial are removed from controlled storage must not exceed 30 min on each occasion prior to receipt in NHSBT.
- Rejuvenation of red cells occurs via the addition of 50 mL rejuvesol® Red Blood Cell Processing Solution (rejuvesol Solution) and incubation at 37 ±2°C for 60 mins ±5 mins.
- The time that red cells are removed from controlled temperature storage for rejuvenation prior to placement in transport containers and cooling towards 10°C must be kept to a minimum and should not exceed 4 hours.
- Each 50 mL of rejuvesol Solution contains sodium pyruvate 0.550 g, inosine 1.34 g, adenine 0.034 g, dibasic sodium phosphate (heptahydrate) 0.730 g, and monobasic sodium phosphate (monohydrate) 0.311 g, in water for injection, pH 6.7-7.4.
- A validated closed manual washing procedure should be used following rejuvenation. The washing protocol used must be validated to ensure effective removal of the rejuvenating solution.
- Monitoring of component volumes and temperatures must be used to assure that the washing process has taken place on every unit rejuvenated.
- 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, Rejuvenated and Washed, Leucocyte Depleted.
- Red Cells, Rejuvenated, Washed, Leucocyte Depleted should be administered through a CE/UKCA /UKNI marked transfusion set.

A3.4.2: Labelling

For general guidelines, see section 6.6.

The following shall be included on the label:

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

- REDJUVENATE trial Red Cells, Leucocyte Depleted* and volume (note the trial is blinded and therefore control and treatment arms are labelled the same but that they can be differentiated through PULSE).
- 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

A3.4.3: Storage

The component should be used as soon as possible. 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 72 hours of rejuvenation if suspended in SAGM.

A3.4.4: Testing

In addition to the mandatory and other tests required for blood donations described in Chapter 9 of the Red Book, 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 A3.4 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 A3.4 Red Cells, Rejuvenated and Washed, Leucocyte Depleted – additional tests

Parameter	Frequency of test	Specification
Volume	100% (all tests are on the day after manufacture and are retrospective quality monitoring, not pre-release criteria)	Within locally specified volume range
Haemoglobin content		>=40 g/unit
Haematocrit		0.50 – 0.70
Haemolysis [1]		<0.3%
ATP and/or 2,3-DPG		ATP: >6 mol/g Hb 2,3-DPG: >9 mol/g Hb
Supernatant potassium (as a marker of washing efficiency)		<3.5 mmol/L
Leucocyte count [2] (pre-wash)	As per sections 6.3 and 7.1.1	<1 × 10^6/unit
[1] Note: this measurement is not at end of shelf-life as for standard red cell components		
[2] Methods validated for counting low numbers of leucocytes must be used. Since the starting material Red Cells in Additive Solution are monitored and controlled for LD performance, the final component does not require a leucocyte count.		

A3.4.5: Transportation

For general guidelines, see section 6.11.

- For red cell components, transit containers, packing materials and procedures must have been validated to ensure the component core temperature can be maintained between 2°C and 6°C during transportation between trial sites, and NHSBT prior to rejuvenation.
- Following rejuvenation and washing, red cells must be placed in transport containers with packing materials and procedures that are validated to reduce the core temperature of red cells to below 10° C within 3 hours and maintain a temperature below 10°C for at least 10 hours. Red Cells, Rejuvenated and Washed, Leucocyte Depleted should be returned to controlled storage at 2-6°C as soon as possible thereafter, and no later than 10 hours from being placed in the transport container to ensure that the core temperature does not exceed 10°C.

A3.4.6: Removal from and return to 2-6°C controlled storage within hospitals

For occasions when Red Cells, Rejuvenated and Washed, Leucocyte Depleted are removed from 2-6 °C controlled storage (e.g., when issued to a clinical area immediately prior to transfusion) then:

- The unit should not be returned to the issue location refrigerator for re-issue.

Transfusion should be completed within 4 hours of issue out of a controlled temperature environment.