

Guidelines for the Blood Transfusion Services

A5.1 Red Cells in Additive Solution, Leucocyte Depleted, Extended Shelf Life

<http://aws-lon-jpac.targetservers.uk/red-book/annexe-5/a5-1>

Blood Components for Contingency Use

A5.1: Red Cells in Additive Solution, Leucocyte Depleted, Extended Shelf Life

A red cell component containing less than 1×10^6 leucocytes and suspended in an approved additive solution.

A5.1.1: Technical information

- A red cell component prepared by removing a proportion of the plasma from leucocyte-depleted whole blood and suspending in an approved additive solution. Leucodepletion may be carried out on either the whole blood starting material or on the final component.
- Red Cells in Additive Solution, Leucocyte Depleted, Extended Shelf Life should be administered through a CE/UKCA/UKNI marked transfusion set.
- May be produced by remanufacture of Red Cells for Exchange Transfusion, Leucocyte Depleted (section 7.7.3) up to 6 days after donation.

A5.1.2: 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 in Additive Solution, 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 additive 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, including vCJD

A5.1.3: Storage

For general guidelines, see section 6.7.

- The component may be stored for a maximum of 42 days at a core temperature of $4 \pm 2^{\circ}\text{C}$.
- Variation from the core temperature of $4 \pm 2^{\circ}\text{C}$ of the finished component must be kept to a minimum during storage at all stages of the blood supply chain and restricted to any short period necessary for examining, labelling or issuing the component.
- Exceptionally, i.e. due to equipment failure at a Blood Centre or hospital, for temperature excursions where the core temperature has not exceeded 10°C or fallen below 1°C , components may be released for transfusion provided that:
 - the component has been exposed to such a temperature change on one occasion only
 - the duration of the temperature excursion has not exceeded 5 hours
 - a documented system is available in each Blood Centre or hospital to cover such eventualities
 - adequate records of the incident are compiled and retained.

A5.1.4: 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 A5.1 shall meet the specified values.

Table A5.1 Red Cells in Additive Solution, Leucocyte Depleted, Extended Shelf Life – additional tests

Parameter	Frequency of test	Specification
Volume ¹	1% or as determined by statistical process control (if ≤ 10 components produced per month then test every available component)	280 ± 60 mL
Haemoglobin content ²		≥ 40 g/unit
Haemolysis	As per section 7.1.3	$< 0.8\%$ of red cell mass
Leucocyte count ³	As per sections 6.3 and 7.1.1	$< 1 \times 10^6$ /unit
¹ Units measured and found to be > 375 mL should not be issued for transfusion		
² Units measured and found to have < 30 g/unit should not be issued for transfusion		
³ Methods validated for counting low numbers of leucocytes must be used		

A5.1.5: 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
- for transportation between blood supplier and hospital an upper limit of 10°C surface temperature is acceptable but should be limited to one occasion, not exceeding 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.

A5.1.6: Removal from and return to 2-6°C controlled storage within hospitals

For occasions when red cells are removed from 2-6°C controlled storage (e.g. when issued to a clinical area immediately prior to transfusion) and returned then:

- If possible, time out of a controlled temperature environment should be restricted to under 30 minutes
- if 30 minutes is exceeded the unit should not be returned to the issue location in the refrigerator, but returned to the transfusion laboratory or quarantined remotely using electronic blood tracking
- up to 60 minutes out of controlled temperature is acceptable, provided the unit is then quarantined by placing in a secure refrigerator for at least 6 hours prior to reissue, to allow the unit to return to 2-6°C
- Hospitals will need to identify such units so that they are not subject to being out of controlled temperature storage for between 30 and 60 minutes on more than three occasions.

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