

Guidelines for the Blood Transfusion Services

A3.2 Red Cells in Additive Solution, Leucocyte Depleted, Pathogen Reduced

<http://www.transfusionguidelines.org/red-book/annexe-3/a3-2>

Provisional Component

A3.2: Red Cells in Additive Solution, Leucocyte Depleted, Pathogen Reduced

A red cell component containing less than 1×10^6 leucocytes and suspended in an approved additive solution. Subsequently the component is subjected to treatment using a pathogen inactivation system prior to storage.

A3.2.1: Technical information

- The primary red cell component prior to pathogen-reduction must meet the specifications set by the manufacturer of the pathogen-reduction system.
- Provided the pathogen reduction system CE/UKCA/UKNI mark states that it may be used as an alternative to irradiation to prevent transfusion-associated graft versus host disease, irradiation of the component is not required.
- Provided the pathogen reduction system CE/UKCA/UKNI mark states that it may be used as an alternative to serological testing for the prevention of transfusion-associated CMV infection, CMV testing of the component is not required.
- The component is manufactured as a secondary component from red cells in additive solution, leucocyte depleted. The primary component (red cells in additive solution) must not have been previously remanufactured from red cells for exchange transfusion.
- Where the production process transfers 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 audit trail and the correct identification number is put on the final component pack.
- Red Cells in Additive Solution, Leucocyte Depleted, Pathogen Reduced should be administered through a CE/UKCA/UKNI marked transfusion set.

A3.2.2: 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, Pathogen Reduced* 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

A3.2.3: Storage

For general guidelines, see section 6.7.

- The component may be stored for a maximum of 35 days at a core temperature of $4 \pm 2^\circ\text{C}$.
- Variation from the core temperature of $4 \pm 2^\circ\text{C}$ must be kept to a minimum during storage 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, red cell components which have been prepared in a closed system and exposed to a core temperature not exceeding 10°C and not less than 1°C 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 to cover such eventualities
 - adequate records of the incident are compiled and retained.

A3.2.4: 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 A3.2 shall meet the specified values.

Table A3.2 Red Cells in Additive Solution, Leucocyte Depleted, Pathogen Reduced – additional tests

Parameter	Frequency of test	Specification
Volume	1% or as determined by statistical process control	190 – 330 mL
Haemoglobin content ¹	(if ≤ 10 components produced per month then test every available component)	≥ 40 g/unit
Haemolysis	As per section 7.1.3	$< 0.8\%$ of red cell mass
Leucocyte count ²	As per sections 6.3 and 7.1.1	$< 1 \times 10^6$ /unit
¹ Units measured and found to have < 30 g/unit should not be issued for transfusion		
² Methods validated for counting low numbers of leucocytes must be used		

A3.2.5: 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.