

**BLOOD COMPONENT MONOGRAPH
RED CELLS CRYOPRESERVED, LEUCOCYTE-DEPLETED**

REASON FOR ISSUE: Update to include ISBT 128 component codes, and label changes.

Council of Europe Guide Monograph	Red Cells, Cryopreserved
eProgesa Component Names	Red Cells for Liquid Nitrogen Storage - Leucocyte Depleted Red Cells ex Liquid Nitrogen - Leucocyte Depleted
eProgesa Component Codes	06280, 06480
eProgesa Component Names	Red Cells for -80°C Storage - Leucodepleted Red Cells ex -80°C Storage - Leucodepleted
eProgesa Component Codes	06290, 06490, E8656100, E8656V00

1. DEFINITION and PROPERTIES:

Red Cells for Liquid Nitrogen Storage - Leucocyte Depleted and *Red Cells for -80°C Storage Leucodepleted* are red cell components derived by secondary processing of a red cell component or whole blood. The red cells are frozen preferably within seven days of collection using a cryoprotectant and stored at -60°C to -80°C or below, depending on the method of cryopreservation.

A reconstituted unit of *Red Cells ex Liquid Nitrogen – Leucocyte Depleted* or *Red Cells ex -80°C Storage - Leucodepleted* contains low amounts of protein, leucocytes and platelets. Each unit of *Red Cells ex Liquid Nitrogen – Leucocyte Depleted* and *Red Cells ex -80°C Storage - Leucodepleted* contains a minimum haemoglobin content of 36g / unit. The haematocrit is 0.35 – 0.70.

Red Cells ex Liquid Nitrogen – Leucocyte Depleted and *Red Cells ex -80°C Storage - Leucodepleted* contain less than 5.0×10^6 leucocytes / unit.

2. PREPARATION:

Two methods are generally used for the preparation of *Red Cells, Cryopreserved*. A red cell component which has been leucocyte depleted and frozen in cryoprotectant utilizing a method that is either high glycerol (used to freeze at -80°C) or low glycerol (used to freeze in Liquid Nitrogen, at or below -140°C). Both methods require a washing / de-glycerolisation procedure before use.

3. REQUIREMENTS and QUALITY CONTROL:

Release requirements are as indicated for the primary product with the following quality monitoring requirements:

Quality Monitoring Requirements:

Parameter	Requirements	Pre-Glyc	Post-Glyc	Post-Thaw	Frequency of control*
Volume	>185 mL	Required	Required	Required	All units
Supernatant Haemoglobin	< 0.2 g per unit			Required	
Haematocrit	0.35–0.70	Required	Required	Required	
Haemoglobin	≥36 g per unit	Required	Required	Required	
Supernatant Osmolarity*	<375 mOsm/L			Required	
Bacterial Contamination	No Growth		Required	Required	
Residual leucocyte content‡	< 5×10^6 / unit	Required			As determined by SPC

*Maximum 20 mOsm / L above osmolarity of resuspending fluid, osmolarity of SAG-M is 355 mOsm / L

‡Residual leucocyte content is not required to be measured on all units, as the primary product is sourced from a process stream that is monitored by statistical process control and complies with confidence limits.

Since cryopreservation allows prolonged storage, serum and / or plasma samples obtained at collection must also be stored to enable future testing for newly discovered markers of transmissible diseases when the components are thawed for use.

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4. STORAGE and TRANSPORT:

Red Cells for -80°C Storage Leucodepleted in the frozen state must be constantly maintained at -60°C to -80°C if stored in an electric freezer and when a high glycerol method is used.

Red Cells for Liquid Nitrogen Storage - Leucocyte Depleted in the frozen state must be constantly maintained at $\leq -140^{\circ}\text{C}$ if stored in vapour phase liquid nitrogen and when a low glycerol method is used.

The storage time may be extended to at least 10 years if the correct storage temperature can be guaranteed.

Thawed reconstituted red cells must be stored at 2-6°C. The storage time will not exceed 72 hours post wash. When an open system is used the storage time must be as short as possible after washing and must never exceed 24 hours.

If transport in the frozen state is unavoidable, storage conditions must be maintained. Transport of thawed, reconstituted red cells is limited by the short storage time. Storage conditions must be maintained during transport.

5. LABELLING:

- Name of the component: *Red Cells ex Liquid Nitrogen – Leucocyte Depleted* and *Red Cells ex -80°C Storage - Leucodepleted*
- Component code
- Volume mLs
- Name of the processing centre
- Donation number*
- ABO group*
- Rh(D) group stated as positive or negative*
- Date of collection
- Date of expiry*
- The storage temperature
- Name of the suspending solution
- the name and volume of the cryoprotective solution
- additional component information (if appropriate)

(* eye readable and barcode format)

In addition the following instructions are included:

- Always check that the recipient for this component is properly identified.
- Do not use if there are signs of deterioration or damage.
- Use a standard transfusion set.
- This product carries the risk of adverse reaction / infection.
- Contact your Blood Bank for further information.

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6. WARNINGS:

Compatibility of *Red Cells ex Liquid Nitrogen – Leucocyte Depleted* and *Red Cells ex -80°C Storage - Leucodepleted* with the intended recipient must be verified by suitable pre-transfusion testing.

Rh(D) Negative female recipients of child-bearing age or younger should preferably not be transfused with red cells from Rh(D) Positive donors.

When *Red Cells ex Liquid Nitrogen – Leucocyte Depleted* and *Red Cells ex -80°C Storage - Leucodepleted* are processed in an open system, the risk of bacterial contamination is increased and therefore extra vigilance is required during transfusion.

Adverse reactions include:

- transfusion-associated circulatory overload (TACO);
- haemolytic transfusion reaction; (mainly chills, fever and urticaria); the incidence is reduced by the use of pre-storage leucocyte depleted platelets;
- anaphylaxis and allergic reactions;
- alloimmunisation against red cell and HLA antigens (very rarely after pre-storage leucocyte - depletion)
- sepsis due to inadvertent bacterial contamination;
- viral transmission (hepatitis, HIV, etc.) is possible despite careful donor selection and screening procedures;
- syphilis can be transmitted if component is stored for less than 96 hours at + 4°C;
- protozoal transmission (e.g. malaria) may occur in rare instances;
- transmission of other pathogens that are not tested for or recognized;
- iron overload