BLOOD COMPONENT MONOGRAPH
RED CELLS RESUSPENDED LEUCOCYTE DEPLETED

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

Council of Europe Guide Monograph	Red Cells, Leucocyte Depleted in Additive Solution
eProgesa Component Names	Red Cells Resuspended Leucocyte Depleted
eProgesa Component Codes	04480, E9623V00, E9625V00, E9623200, E9625200

1. DEFINITION and PROPERTIES:

Red Cells Resuspended Leucocyte Depleted (LD) is a red cell component derived from a *Whole Blood* by removal of the plasma, either with or without removal of the buffy coat, resuspended in an additive solution and removal of the leucocytes to a maximum residual content.

Red Cells Resuspended LD contains a minimum haemoglobin content of 40 g. The haematocrit is 0.50 – 0.70.

Red Cells Resuspended LD contains less than 5 x 10^6 leucocytes.

2. PREPARATION:

A filtration technique is used to produce *Red Cells Resuspended LD.* Pre-storage leucocyte depletion should be performed prior to midnight on Day 2.

Red Cells Resuspended LD are produced by one of two methods; either:

- by leucocyte filtration of *Whole Blood*, with subsequent centrifugation, removal of the plasma and immediate addition of the additive solution, followed by careful mixing; or:
- by centrifugation of *Whole Blood,* removal of the plasma and buffy coat, addition of the additive solution, removal of leucocytes by filtration, followed by careful mixing.

3. RELEASE REQUIREMENTS and QUALITY CONTROL

The tables below list the requirements to comply with NZBS Manufacturing Standards 112P003 Standards for Infectious Marker Testing and 112P004 Standards for Blood Group Serology.

3.1 Release Requirements

Parameter	Requirements	Frequency of control
ABO, RhD	Grouping	All units
Anti-HIV 1 & 2	Negative by approved screening test	
HBsAg	Negative by approved screening test	
Anti-HCV	Negative by approved screening test	
Syphilis serology	Negative by approved screening test	
Anti-HTLV I / II [1]	Negative by approved screening test	
Nucleic Acid test for HIV RNA, HCV RNA and HBV DNA	Negative by approved screening test	

1. Donor is tested on the first occasion they donate. A negative result accredits the donor for future donations

3.2 Quality Monitoring Requirements

Parameter	Requirements	Frequency of control
Volume [2]	220 – 340 mL	As determined by SPC
Haematocrit [2]	0.50 – 0.70	
Haemoglobin [2]	≥ 40 g per unit	
Residual leucocyte content [3]	< 5 x 10^6 per unit	
Haemolysis at the end of storage [2]	<0.8% of red cell mass	All units

2. A minimum of 90% of units tested should meet the required value
3. This requirement is met when there is 95% confidence that 99% of units tested comply.

4. STORAGE and TRANSPORT:

4.1 Storage

Red Cells Resuspended LD must be kept at a controlled temperature between +2 °C and +6°C during storage. Depending on the anticoagulant / additive system, the storage time may be extended up to the approved limit of the additive solution system. *Red Cells Resuspended LD* may be stored for a maximum period of 35 days when CPD is used as the anticoagulant and SAGM as the preservative solution.

Variation from the core temperature of +2 °C to +6 °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, red cells 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 the duration of the temperature change is less than 5 hours.

4.2 Transport

Validated transport systems must ensure that at no time during a maximum transit time of 24 hours did the temperature exceed +10 °C.

In some instances it is necessary to issue red cell components that have not been cooled to their storage temperature prior to placement in the transit container. The transport temperature specified above is not applicable for such consignments.

5. LABELLING

The following information must be shown on the label or contained in this component monograph, as appropriate:

- name of the component – *Red Cells Resuspended LD*
- component code*
- volume
- name of the Processing centre
- donation number*
- ABO group*
- RhD group stated as positive or negative*
- blood group phenotypes other than ABO and RhD (optional)
- date of collection
- date of expiry*
- name of the approved anticoagulant solution
- name of the additive solution
- additional component information: irradiated, etc (if appropriate)
- storage temperature

  * 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 other damage
- use a standard transfusion set
- this product carries a risk of adverse reaction / infection
- contact your Blood Bank for further information

6. WARNINGS:

Compatibility of *Red Cells Resuspended LD* with the intended recipient must be verified by suitable pre-transfusion testing.

RhD negative female recipients of child-bearing age or younger should not be transfused with red cells from Rh D positive donors.

Red Cells Resuspended Leucocyte Depleted is not recommended in the case of:

- Plasma intolerance

Adverse reactions include:

- haemolytic transfusion reaction;
- non-haemolytic transfusion reaction (mainly chills, fever and urticaria);
- anaphylaxis and allergic reactions;
- alloimmunisation against red cell and HLA (very rarely) antigens;
- transfusion related acute lung injury (TRALI);
- post transfusion purpura;
- graft versus host disease (TA-GvHD);
- 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;
- citrate toxicity in neonates and in patients with impaired liver function;
- metabolic imbalance in massive transfusion (e.g. hyperkalaemia);
- transfusion-associated circulatory overload (TACO);
- iron overload