NZBS BLOOD COMPONENT MONOGRAPH
WHOLE BLOOD, LEUCOCYTE-DEPLETED

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

Council of Europe Guide Monograph	Whole Blood, Leucocyte Depleted
eProgesa Component Names	Whole Blood Leucocyte Depleted
eProgesa Component Codes	01480, EA956V00, EA958V00

1. DEFINITION and PROPERTIES:

Whole Blood, Leucocyte Depleted (LD) is a component derived from *Whole Blood* by removing the leucocytes to a maximum residual content. Approved anticoagulants include CPD or CPDA1.

Whole Blood, LD contains a minimum haemoglobin content of 43 g per unit.

Whole Blood, LD normally contains less than 5 x 10^6 per unit leucocytes.

2. PREPARATION:

Generally, a filtration technique is used to produce *Whole Blood, LD.* Pre-storage leucocyte depletion should be performed prior to midnight on day two.

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
Red Cell Alloantibodies	Negative antibody screen	
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]	490 ± 50 mL	As determined by SPC
Haemoglobin [2]	≥ 43 g per unit	
Haematocrit [2]	0.30 – 0.50	
Residual leucocyte content [3]	< 5 x10^6 / 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 the units tested comply

4. STORAGE and TRANSPORT

4.1 Storage

Whole Blood, LD must be kept at a controlled temperature between +2 and +6°C during storage. The storage time depends on the anticoagulant / preservative solution used. *Whole Blood, LD may* be stored for a maximum period of 28 days when CPD is used as the anticoagulant or 35 days when CPDA-1 is used.

Variation from the core temperature of +2 and +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 component has been exposed to a temperature beyond +2 and +6°C on one occasion only following processing.
- The duration of 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.

NZBS BLOOD COMPONENT MONOGRAPH
WHOLE BLOOD, LEUCOCYTE-DEPLETED

5. LABELLING:

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

- name of the component: *Whole Blood, 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
- 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

NZBS BLOOD COMPONENT MONOGRAPH
WHOLE BLOOD, LEUCOCYTE-DEPLETED

6. WARNINGS:

Compatibility of *Whole Blood, 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 RhD-positive donors.

Whole Blood, LD is not recommended in cases of:

- anaemia without blood volume loss
- 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