NZBS BLOOD COMPONENT MONOGRAPH
RED CELLS WASHED

REASON FOR ISSUE: Update to include ISBT128 component codes, and label changes.

Council of Europe Guide Monograph	Red Cells Washed
eProgesa Component Name	Red Cells Washed Leucocyte Depleted
eProgesa Component Code	04880, E8451V00, E8452V00

1. DEFINITION and PROPERTIES:

Red Cells Washed Leucocyte Depleted is derived from secondary processing of a red cell component or whole blood, involving sequential washing and re-suspension of red cells in an additive solution.

Red Cells Washed Leucocyte Depleted has most of the plasma, leucocytes and platelets removed.

Red Cells Washed Leucocyte Depleted contains less than 5.0 x 10^6 leucocytes per unit.

2. PREPARATION:

After centrifugation (controlled temperature) of the primary leucocyte depleted red cell component and removal of the plasma or additive solution (and, if applicable, the buffy coat layer) the red cells are washed with an approved wash and resuspended in an approved additive solution (SAG-M).

3. REQUIREMENTS and QUALITY CONTROL:

The table below lists the requirements. For details see *NZBS's Manufacturing Standards: Section 5 Standards for Infectious Serology Testing & Section 6 Standards for Blood Serology Group Serology*.

3.1 Release Requirements:

Parameter to be checked	Requirements	Frequency of control[1]
ABO, RhD	Grouping	All units
Anti-HIV 1 & 2	Negative by approved screening test	
Red cell alloantibodies	Negative Antibody screen	
HBsAg	Negative by approved screening test	
Anti-HCV	Negative by approved screening test	
Syphilis serology	Negative by approved screening test	
Anti-HTLV I/II[2]	Negative by approved screening test	
Nucleic acid test for HIV RNA, HCV RNA and HBV DNA	Negative by approved screening test	
Volume	220 – 340 mL	
Haematocrit	0.40-0.70 L/L	
Haemoglobin	≥ 36 g per unit	
Percentage Haemolysis	<0.8% of red cell mass	

1. Frequency of testing is determined by statistical process control methodology.
2. Donor is tested on first occasion they donate only. A negative result accredits the donor for future donations

3.2 Quality Monitoring Requirements:

Parameter to be checked	Requirements	Frequency of control[1]
Residual Protein	<0.5 g / unit	All units
Residual leucocyte content	<5 x10^6 per unit	
Bacterial Contamination	No growth	

1. Frequency of testing is determined by statistical process control methodology.

4. STORAGE and TRANSPORT:

Red Cells Washed Leucocyte Depleted must be kept at a controlled temperature between 2-6°C during storage.

Storage temperature for *Red Cells Washed Leucocyte Depleted* is 2-6ºC. Storage time will be 7 days. When an open system is used the storage time should be as short as possible after processing and must never exceed 24 hours.

During transportation the temperature of *Red Cells Washed Leucocyte Depleted* must be kept as close as possible to the recommended storage temperature and not exceed 10°C.

Transport time normally should not exceed 12 hours.

5. LABELLING:

The following information must be shown on the label

- Name of the Component; Red Cells Washed-Leucocyte Depleted
- Component Code*
- Volume
- Name of the processing centre
- Donation number*
- ABO group*
- Rh(D) group stated as positive or negative*
- Name of the approved additive solution used
- Date of collection
- Date of expiry*
- The storage temperature
- additional component information: irradiated, etc. (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.

6. WARNINGS:

Compatibility of *Red Cells Washed Leucocyte Depleted* 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.

Adverse reactions include:

- haemolytic transfusion reaction due to anti-A,-B in the case of incompatible transfusions;;
- non-haemolytic transfusion reaction (mainly chills, fever and urticaria);
- anaphylaxis and allergic reactions;

- allo-immunisation against red cell and HLA (very rarely) antigens;
- transfusion-related acute lung injury (TRALI);
- graft versus host disease (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;
- metabolic imbalance in massive transfusion (e.g. hyperkalaemia);
- transfusion-associated circulatory overload (TACO);
- iron overload