BLOOD COMPONENTS

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Leukocyte-depleted whole blood

1. Definition and properties

Leukocyte-depleted whole blood is a component obtained from whole blood by removing almost all leukocytes. A unit contains at least 43 g hemoglobin.
Under normal conditions, leukocyte-depleted whole blood contains less than 1.0×10^6 leukocytes. It should not be used routinely.

2. Preparation

In general, the leukocyte-depleted whole blood is obtained by filtration. Leukocyte depletion is usually performed prior to storage, within 48 hours of donation.

3. Quality control

Parameter to test	Specifications	Frequency of testing[1]
Volume	450 ± 50 mL Volume excluding the anticoagulant. Non-standard donations must be labeled accordingly	1 % of the total units with a minimum of 4 units per month
Hemoglobin	At least 43 g/unit	1 % of the total units with a minimum of 4 units per month
Residual leukocytes[2]	< 1×10^6 per unit per count	1 % of the total units with a minimum of 10 units per month
End of storage hemolysis	< 0,8 % of red cell mass	4 units per month

1 When the frequency of testing is different from «all the units», this is an indication for the minimum frequency: we will use statistical process control to minimize the risk of deviation.

2 These specifications are considered met if 90% of the tested units are within the defined ranges.

4. Storage and transportation

Leukocyte-depleted whole blood must be stored under controlled temperature conditions, between +2 °C and +6 °C. The shelf life depends on the anticoagulant/storage solution used (e.g., 35 days for CPDA-1).
Validated transport systems must ensure that the temperature does not exceed +10 °C at any time during a maximum transport period of 24 hours.

5. Labelling

The label or notice attached to the blood component must include the following information:

- The producer name;
- A unique identification number;
- The blood component type;
- The ABO and RhD groups;
- The phenotypes of blood groups other than ABO and RhD (optional);
- The date of collection;
- The expiry date;

- The type of the anticoagulant solution ;
- Other blood component information: irradiated… (if applicable);
- The blood component volume or weight;
- The storage temperature ;
- Contraindication to transfusion if abnormal hemolysis or other deteriorations are present ;
- The need to administer the blood component through a 150-200 µm filter.

6. Cautions

The compatibility between the leukocyte-depleted whole blood and the recipient must be checked by appropriate testing prior to transfusion.

It is preferable not to transfuse RhD + red blood cells derived from male donors to RhD - females of childbearing age or younger.

The transfusion of leukocyte-depleted whole blood is not recommended in the following cases:

- Anemia without hypovolemia;
- Plasma proteins intolerance.

The transfusion of leukocyte-depleted whole blood should be reserved for exceptional situations such as natural or national disasters.

Leukocyte-depleted red blood cell concentrate

1. Definition and properties

The leukocyte-depleted red blood cell concentrate is a component obtained by removing almost all leukocytes from a whole blood donation, a red blood cell concentrate or a leukocyte-poor red blood cell concentrate.
The hemoglobin content is at least 40g/unit. The hematocrit is between 0.50 and 0.70. It contains less than 1.0×10^6 leucocytes.

2. Preparation

In general, the leukocyte-depleted red blood cell concentrate is obtained by filtration. Leukocyte depletion is usually performed within 48 hours of collection.
Leukocyte-depleted packed red blood cell concentrate can be produced by:

- Filtering whole blood, followed by centrifugation and plasma removal;
- Filtering a red blood cell concentrate.

3. Quality control

Parameter to test	Specifications	**Frequency of testing**[#]
Volume	To be defined for the used system	1 % of the total units
Hematocrit	0.50 – 0.70	4 units per month
Hemoglobin	At least 43 g/unit	1 % of the total units with a minimum of 4 units per month
Residual leukocytes*	< 1×10^6 per unit per count	1 % of the total units with a minimum of 10 units per month
End of storage hemolysis	< 0,8 % of the red cell mass	4 units per month

[#] When the frequency of testing is different from « all the units », this is an indication for the minimum frequency: we will use statistical process control to minimize the risk of deviation.
* These specifications are considered met if 90% of the tested units are within the defined ranges.

4. Storage and transportation

Leukocyte-depleted red blood cell concentrate must be stored under controlled temperature conditions, between +2 °C and +6 °C. The shelf life depends on the anticoagulant/additive solution used.

Validated transport systems must ensure that the temperature does not exceed +10 °C at any time during a maximum transport period of 24 hours.

5. Labelling

The label or notice attached to the blood component must include the following information:

- The producer name;
- A unique identification number;
- The blood component type;

- The ABO and RhD groups ;
- The phenotypes of blood groups other than ABO and RhD (optional);
- The date of collection;
- The expiry date ;
- The type of the anticoagulant solution ;
- The type and the volume of the additive solution (if applicable) ;
- Other blood component information: irradiated… (if applicable);
- The blood component volume or weight;
- The storage temperature ;
- Contraindication to transfusion if abnormal hemolysis or other deteriorations are present ;
- The need to administer the blood component through a 150-200 µm filter.

6. Cautions

The compatibility between the leukocyte-depleted red blood cell concentrate and the recipient must be checked by appropriate testing prior to transfusion.

It is preferable not to transfuse RhD + red blood cells derived from male donors to RhD - females of childbearing age or younger.

The transfusion of leukocyte-depleted red blood cell concentrate is not recommended in the following cases:

- Plasma proteins intolerance

Leukocyte-depleted red blood cell concentrate with additive solution

1. Definitionand properties

The leukocyte-depleted red blood cell concentrate with additive solution is a component obtained by removing almost all leukocytes from a whole blood donation, a red blood cell concentrate with additive solution or a leukocyte-poor red blood cell concentrate.

The hemoglobin content is at least 40g/unit. The hematocrit is between 0.50 and 0.70. It contains less than 1.0×10^6 leucocytes.

2. Preparation

In general, the leukocyte-depleted red blood cell concentrate with additive solution is obtained by filtration. Leukocyte depletion is usually performed within 48 hours of collection.

Leukocyte-depleted red blood cell concentrate with additive solution can be produced by:

- Filtering whole blood to remove the leukocytes, then centrifugation and plasma removal, followed immediately by the addition of an additive solution and careful mixing;
- Filtering a red blood cell concentrate with additive solution or a leukocyte-poor red blood cell concentrate with additive solution.

3. Quality control

Parameter to test	Specifications	Frequency of testing#
Volume	To be defined for the used system	1 % of the total units
Hematocrit	0.50 – 0.70	4 units per month
Residual leukocytes*	$< 1 \times 10^6$ per unit per count	1 % of the total units with a minimum of 10 units per month
Hemoglobin	At least 43 g/unit	1 % of the total units with a minimum of 4 units per month
End of storage hemolysis	< 0,8 % of the red cell mass	4 units per month

When the frequency of testing is different from « all the units », this is an indication for the minimum frequency: we will use statistical process control to minimize the risk of deviation.

*These specifications are considered met if 90% of the tested units are within the defined ranges.

4. Storage and transportation

Leukocyte-depleted red blood cell concentrate with additive solution must be stored under controlled temperature conditions, between +2 °C and +6 °C.

The shelf-life can be extended to the validated limits of the additive solution depending on the type of the anticoagulant/additive used.

Validated transport systems must ensure that the temperature does not exceed +10 °C at any time during a maximum transport period of 24 hours.

5. Labelling

The label or notice attached to the blood component must include the following information:

- The producer name;
- A unique identification number;
- The blood component type;
- The ABO and RhD groups ;
- The phenotypes of blood groups other than ABO and RhD (optional);
- The date of collection;
- The expiry date ;
- The type of the anticoagulant solution ;
- The type and the volume of the additive solution ;
- Other blood component information: irradiated… (if applicable);
- The blood component volume or weight;
- The storage temperature ;
- Contraindication to transfusion if abnormal hemolysis or other deteriorations are present ;
- The need to administer the blood component through a 150-200 µm filter.

6. Cautions

The compatibility between the leukocyte-depleted red blood cell concentrate with additive solution and the recipient must be checked by appropriate testing prior to transfusion.

It is preferable not to transfuse RhD + red blood cells derived from male donors to RhD - females of childbearing age or younger.

The transfusion of leukocyte-depleted red blood cell concentrate is not recommended in the following cases:

- Plasma proteins intolerance (this might not apply to the units having a poor plasma content)

Washed red blood cell concentrate

1. Definition and properties

A washed red cell blood concentrate is obtained by secondary processing of a red blood cell concentrate or a whole blood unit with successive washings and re-suspension of the red blood cells in an additive solution.

Most of the plasma, leukocytes and platelets are removed. The amount of residual plasma depends on the washing protocol. The hematocrit can be adjusted according to the clinical needs.

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2. Preparation

After centrifuging the primary component and removing the plasma or the additive solution (and, if necessary, the buffy coat), the red blood cells are washed by successively adding and removing the additive solution. The centrifugation should be performed at a controlled temperature.

3. Quality control

Parameter to test	Specifications	Frequency of testing[#]
Volume	To be defined for the used system	All the units
Hematocrit	0.65 to 0.75	All the units
Hemoglobin	At least 43 g/unit	All the units
End of preparation hemolysis	< 0,8 % of the red cell mass	All the units
Residual protein	< 0,5 g/unit	All the units

4. Storage and transportation

The washed red cell concentrate should be stored at a controlled temperature between +2 °C and +6 °C.

The storage time should be as short as possible, preferably 6 hours, and should never exceed 24 hours if the component has been produced in an open system.

If a closed system and a suitable additive solution has been used, the shelf life can be extended after validation. Validated transport systems must ensure that at no time does the temperature exceed +10 °C.

5. Labelling

The label or notice attached to the blood component must include the following information:

- The producer name;
- A unique identification number;
- The blood component type;
- The ABO and RhD groups ;
- The phenotypes of blood groups other than ABO and RhD (optional);
- The date of collection;
- The expiry date and time;

- The type of the anticoagulant solution ;
- The type and the volume of the additive solution ;
- Other blood component information: irradiated… (if applicable);
- The blood component volume or weight;
- The storage temperature ;
- Contraindication to transfusion if abnormal hemolysis or other deteriorations are present ;
- The need to administer the blood component through a 150-200 µm filter.

6. Cautions

The compatibility between the washed red blood cell concentrate with additive solution and the recipient must be checked by appropriate testing prior to transfusion.

It is preferable not to transfuse RhD + red blood cells derived from male donors to RhD - females of childbearing age or younger.

Leukocyte-depleted apheresis platelet concentrate

1. Definition and properties

Leukocyte-depleted apheresis platelet concentrate is obtained by a single donor apheresis using an automatic cell separator. This component contains platelets that are suspended in plasma at a therapeutic dose.

The platelet count is at least 2×10^{11}.

The leukocyte count is usually $< 1.0 \times 10^{6}$.

2. Preparation

Leukocyte-depleted apheresis platelet concentrate is prepared from whole blood collected through the cell separator and anticoagulated using a citrate solution before removing the platelets. The process then involves centrifugation, filtration or other processing steps in order to reduce the number of contaminating leukocytes. The leukocyte-depletion process should be incorporated into the apheresis collection procedure.

For neonatal and pediatric use, a leukocyte-depleted apheresis platelet concentrate can be split into subunits under sterile conditions.

3. Quality control

Determining the degree of swirling, which is based on the light diffraction caused by the movement of morphologically normal platelets, can be conducted as a separate quality control procedure or as a routine one during the release and the transfusion of this component.

Parameter to test	Specifications	Frequency of testing#
Volume	> 40 mL for 60×10^{9} platelets	All the units
Platelet count	Standard unit : at least 2×10^{11} per unit For neonatal or pediatric use: at least $0,5 \times 10^{11}$ per unit	1 % of the total units with a minimum of 10 units per month
Residual leukocytes*	$< 1 \times 10^{6}$ per unit	1 % of the total units with a minimum of 10 units per month
pH (+22 °C) at end of shelf life**	> 6.4	1 % of the total units with a minimum of 4 units per month

When the frequency of testing is different from «all the units», this is an indication for the minimum frequency: we will use statistical process control to minimize the risk of deviation.

* These specifications are considered met if 90% of the tested units are within the defined ranges.

** It is preferable to measure the pH in a closed system to avoid any CO2 release. Measurements can be performed at a different temperature and then converted by calculation to a pH value of +22°C.

4. Storage and transportation

Leukocyte-depleted apheresis platelet concentrate must be stored under conditions that ensure an optimal preservation of viability and hemostatic activity.

The storage temperature should be between +20°C to +24°C with constant agitation.

Leukocyte-depleted apheresis platelet concentrate intended for storage beyond 6 hours should be collected and prepared in a closed system. The maximum shelf life is 5 days. Leukocyte-depleted

apheresis platelet concentrate should be transported at a temperature as close as possible to the recommended storage temperature and should be stored as recommended upon receipt, unless intended for immediate therapeutic use.

5. Labelling

The label or notice attached to the blood component must include the following information:

- The producer name;
- A unique identification number; If two or more units were collected from the same donor in one session, each component must have a unique identification number;
- The blood component type;
- The ABO and RhD groups ;
- The date of collection ;
- The expiry date ;
- The type of the anticoagulant solution ;
- Other blood component information: irradiated… (if applicable);
- The blood component volume ;
- The platelet count (average or actual, as appropriate) ;
- The storage temperature ;
- HLA and/or HPA phenotypes, if determined ;
- The need to administer the blood component through a 150-200 µm filter.

6. Cautions

The transfusion of leukocyte-depleted apheresis platelet concentrate is not recommended in the following cases:

- Plasma proteins intolerance;
- It is preferable not to transfuse RhD + red blood cells derived from male donors to RhD - females of childbearing age or younger.

Fresh Frozen Plasma (FFP)

1. Definition and properties

Fresh frozen plasma is a component intended for transfusion and is prepared from whole blood or by apheresis. It is kept frozen for a period of time at an appropriate temperature to maintain the activity of labile coagulation factors.

FFP intended for clinical transfusion must meet the specifications listed below. It must have on average at least 70 IU/100 ml of Factor VIII in addition to similar amounts of the other labile coagulation factors and natural inhibitors.

Clinically significant irregular antibodies should not be present.

If leukodepleted, the component must contain less than 1 x 10^6 leukocytes.

2. Preparation

a. From whole blood

The plasma is separated from the whole blood, which is collected in a blood bag system equipped with transfer bags, by high speed centrifugation preferably within 6 hours. Plasma can also be obtained from platelet-rich plasma. Freezing must be performed in a system that allows a thorough freezing at a temperature below -30°C within a period of 1 h.

Plasma may be also obtained from a whole blood donation that has been rapidly refrigerated after collection by a special apparatus validated to maintain the temperature between +20°C and +24°C, and stored at this level for up to 24 hours.

b. By apheresis

Plasma can be collected by manual or automated apheresis. The freezing process should begin within 6 h of collection, in a system that achieves a thorough freezing at a temperature below -30°C within a period of 1 h. If a special apparatus is used, that has been validated to rapidly refrigerate and maintain the plasma at a temperature between +20°C and +24°C, then the plasma may be stored at this temperature for up to 24 h before freezing..

3. Quality control

Parameter to test	Specifications	Frequency of testing#
Volume	Stated volume ±10 %	All the units
Factor VIII	Mean (after freezing/thawing) : at least 70 IU/100 ml of factor VIII mL	Every 3 months 10 units during the first month of storage*
Residual cells**	RBC : < 6.0 x 10^9/L ; leukocytes : <0.1 x 10^9/L Platelets : < 50 x 10^9/L	1 % of the total units with a minimum of 4 units per month
	If leukocyte-depleted: < 1 x 10^6	1 % of the total units with a minimum of 10 units per month ***
Leak	Verify the absence of leakage in the pack, e.g. by visual inspection after applying pressure in a plasma extractor, before freezing and after thawing	All the units
Macroscopic modifications	Abnormal color ; absence of clot	All the units

* The exact number of units that should be tested is determined by statistical process control
** Count performed before freezing.

4. Storage and transportation

The validated shelf lives and temperatures are as follows:

- 12 months at -25°C or below;
- 3 months at -18ºC to -25ºC.

The storage temperature must be maintained during transportation. The units, unless intended for immediate therapeutic use, should be transferred promptly to storage at the recommended temperature. After thawing, FFP should be transfused as soon as possible in order to preserve the labile factors. FFP must not be refrozen.

5. Labelling

The label or notice attached to the blood component must include the following information:

- The producer name;
- A unique identification number; If two or more units were collected from the same donor in one session, each component must have a unique identification number;
- The blood component type;
- The ABO and RhD (only when intended for clinical use) groups ;
- The date of collection ;
- The expiry date ;
- The type of the anticoagulant solution ;
- Other blood component information: leukocyte-depleted, irradiated, quarantined… (if applicable);
- The blood component volume or weight;
- The storage temperature ;
- The need to administer the blood component through a 150-200 µm filter.
  After thawing, the expiry date should be changed to the appropriate expiry date (and time). The storage temperature should be changed accordingly.

6. Cautions

ABO plasma transfusion may cause hemolytic transfusion reactions.

Fresh frozen plasma should not be administered to a patient who has intolerance to plasma proteins.

Before use, the product should be thawed in controlled settings and the integrity of the bag should be checked to exclude any defects or leaks. No insoluble cryoprecipitate should be present at the end of the thawing process.

Cryoprecipitate

1. Definition and properties

Cryoprecipitate is a component that contains the cryoglobulin fraction of plasma, obtained by successively processing and concentrating FFP.
It contains most of the Factor VIII, Von Willebrand Factor, Fibrinogen, Factor XIII and Fibronectin that are present in whole blood derived plasma.

2. Preparation

Fresh frozen plasma is thawed, either overnight at +2ºC to +6ºC or by the rapid thawing technique. After thawing, the component is centrifuged again at high speed at the same temperature. The supernatant plasma (cryo-poor plasma), is partially removed, and the resulting cryoprecipitate is rapidly frozen.

The maximum volume of a cryoprecipitate is 40 ml when prepared from a whole blood donation.

Alternatively, cryoprecipitate may be obtained from apheresis plasma and is prepared using the same freeze/thaw/refreeze technique.

Leukocyte depletion of the raw material is mandatory.

3. Quality control

Parameter to test	Specifications	Frequency of testing[#]
Volume*	30 to 40 mL	All the units
Factor VIII	≥ 70 IU/unit	Every 2 months: 6 units of different blood groups during the first month of storage
Fibrinogen	≥ 140 mg/unit	1 % of the total units with a minimum of 4 units per month
Von Willebrand Factor	≥ 100 IU/unit	Every 2 months: 6 units of different blood groups during the first month of storage

*This table is intended for the quality control of cryoprecipitate derived from one whole blood unit. The volume may be different for apheresis derived plasma.

4. Storage and transportation

The stability depends on the storage temperature which is ideally below –25 ºC. The validated shelf lives are as follows:

- 12 months at -25°C or below;
- 3 months at -18ºC to -25ºC.

The storage temperature must be maintained during transportation. The receiving hospital's blood storage facility must ensure that the cryoprecipitate was kept frozen during transportation. The units, unless used immediately, should be transported promptly to a storage area at the recommended temperature.
Prior to use, cryoprecipitate should be thawed in controlled settings at +37°C immediately after removal from the storage area. Care should be taken during thawing to facilitate the dissolution process.

After thawing, cryoprecipitate should be transfused as soon as possible in order to preserve the labile factors. It must not be refrozen.

5. Labelling

The label or notice attached to the blood component must include the following information:

- The producer name;
- A unique identification number; If two or more units were collected from the same donor in one session, each component must have a unique identification number;
- The blood component type;
- The ABO group ;
- The preparation date ;
- The expiry date ;
- The type of the anticoagulant solution ;
- Other blood component information: leukocyte-depleted, irradiated, quarantined… (if applicable);
- The blood component volume or weight;
- The storage temperature;
- The need to administer the blood component through a 150-200 µm filter.

After thawing, the expiry date should be changed to the appropriate expiry date (and time). The storage temperature should be changed accordingly.

6. Cautions

Before use, the product should be thawed in controlled settings and the integrity of the bag should be checked to exclude any defects or leaks.

Cryoprecipitate should not be administered to a patient who has intolerance to plasma proteins.

Cryoprecipitate-depleted plasma

1. Definition and properties

Cryoprecipitate-depleted plasma is a component that is prepared from FFP after removing the cryoprecipitate.
Its albumin, immunoglobulin and coagulation factor content is identical to that of FFP, but the levels of labile factors V and VIII are significantly lower. The fibrinogen concentration is also lower compared to FFP.

2. Preparation

Cryoprecipitate-depleted plasma is the by-product obtained during the preparation of cryoprecipitate from FFP. Leukocyte depletion of the raw material is obligatory.

3. Quality control

Parameter to test	Specifications	Frequency of testing
Volume	Stated volume ±10 %	All the units

4. Storage and transportation

The stability depends on the storage temperature which is ideally below –25 ºC. The validated shelf lives are as follows:

- 12 months at -25°C or below;
- 3 months at -18ºC to -25ºC.

The storage temperature must be maintained during transportation. The receiving hospital's blood storage facility must ensure that the cryoprecipitate was kept frozen during transportation. The units, unless used immediately, should be transported promptly to a storage area at the recommended temperature.
Prior to use, cryoprecipitate should be thawed in controlled settings at +37°C immediately after removal from the storage area. Care should be taken during thawing to facilitate the dissolution process.
After thawing, cryoprecipitate should be transfused as soon as possible in order to preserve the labile factors. It must not be refrozen.

5. Labelling

The label or notice attached to the blood component must include the following information:

- The producer name;
- A unique identification number; If two or more units were collected from the same donor in one session, each component must have a unique identification number;
- The ABO group ;
- The preparation date;
- The type of the anticoagulant solution ;
- Other blood component information: leukocyte-depleted, irradiated, quarantined, treatment by pathogen reduction technique… (if applicable);
- The expiry date ;
- The blood component volume or weight;
- The storage temperature;
- The need to administer the blood component through a 150-200 µm filter.

After thawing, the expiry date should be changed to the appropriate expiry date (and time). The storage temperature should be changed accordingly.

6. Cautions

ABO plasma transfusion may cause hemolytic transfusion reactions.

Cryoprecipitate should not be administered to patients who has intolerance to plasma proteins.

Granulocytes apheresis concentrate

1. Definition and properties

Granulocytes apheresis concentrate is a suspension of granulocytes in plasma, obtained from a single donor apheresis using an automated cell separator.

An adult therapeutic dose contains between 1.5 x 10^8 and 3.0 x 10^8 granulocytes/kg body weight of the intended recipient.

Granulocyte apheresis concentrate contains significant amounts of red blood cells, lymphocytes and platelets.

It must be irradiated.

IMPORTANT NOTICE

The clinical efficacy, the indications and the dosage of granulocytes transfusion are not yet established. The potential donor must be premedicated prior to collection and receive sedimentation agents during the procedure. Both can cause serious side effects that are described below. Therefore, it is essential to obtain the donor informed consent. Other than the known complications of the regular apheresis procedure, the following side effects may occur:

- Hydroxyethyl starch (HES): acts as a volume expander, and may cause headache or peripheral edema in donors due to the expansion of the circulating volume; accumulation of HES may cause pruritus; allergic reactions are possible.
- Corticosteroids: may cause hypertension, diabetes, cataract, peptic ulcer, and other disorders.
- G-CSF (granulocyte colony growth factor): the most common direct complication of G-CSF administration to stem cell donors is bone pain; in very rare cases, it can cause splenic rupture or lung damage. Concerns about the development of acute myeloid leukemia (AML) or myelodysplasia (MDS) following G-CSF administration are based primarily on the reported increased incidence of AML/MDS in women with breast cancer who have undergone chemotherapy, or in patients with severe chronic neutropenia treated with G-CSF. To date, the data available from Europe and the United States (involving more than 100.000 healthy individuals who donated peripheral blood stem cells and were given G-CSF as premedication) do not indicate an increased risk of AML/MDS. However, the median duration of follow-up in these studies was less than 5 years.

2. Preparation

The donor is premedicated with corticosteroids and/or growth factors. Granulocytes apheresis concentrate is collected from a single donor via apheresis. A sedimentation agent (HES, low molecular weight dextran, modified fluid gelatin…) is given in order to achieve an optimal yield.

3. Quality control

Parameter to test	Specifications	Frequency of testing
Volume	< 500 mL	All the units
Granulocytes	Achieve the clinical dose, e.g. a 60 kg adult patient : 0.9-1,8 x 10^{10} granulocytes per unit	All the units

4. Storage and transportation

This component is not suitable for storage and should be transfused as soon as possible after collection. Storage, if unavoidable, should be limited to the shortest possible time period.

The unit should be transported to the recipient in a suitable container at +20 °C to +24 °C without agitation.

5. Labelling

The label or notice attached to the blood component must include the following information:

- The producer name;
- A unique identification number;
- The ABO and RhD groups ;
- The collection date;
- The type of the anticoagulant, additive or others solutions
- The blood component type;
- Other blood component information: irradiated ;
- The expiry date (and time if required) ;
- The leucocytes count
- The storage temperature;
- HLA phenotype if determined ;
- The need to administer the blood component through a 150-200 µm filter.

6. Cautions

Given the risk of serious adverse reactions associated with both the collection (effects on the donor) and the transfusion (effects on the recipient) of granulocytes, it is essential to clearly define the goals of granulocyte transfusion before initiating the therapy.
The compatibility between the donor's red blood cells and the recipient should be verified by appropriate pre-transfusion testing because the number of red blood cells is significant. Granulocytes concentrates derived from RhD-positive donors should not be transfused to RhD-negative female recipients of childbearing age; if their use is unavoidable, the use of anti-D immunoglobulin should be considered to prevent RhD alloimmunization.
HLA compatibility should be also considered if there is alloimmunization in the recipient. Apheresis granulocytes should be irradiated.
CMV-seronegative components should be considered for CMV-seronegative recipients.
Administration through a microaggregate filter or leukoreduction filter is contraindicated. The risk of an adverse reaction is increased with the concomitant administration of amphotericin B.

Blood components for intrauterine, neonatal and pediatric use

Intrauterine, neonatal and pediatric transfusions require specifically prepared blood components. Since the recipients are particularly vulnerable to the complications of CMV infection, appropriate measures must be taken to minimize the risks.
Their methods of preparation, storage and administration must be validated to ensure that the delivered potassium load remains within the acceptable limits.
If these blood components were split for neonatal and pediatric transfusion, each unit should have a unique identification number to ensure its traceability to the collection.

Leukocyte-depleted RBC concentrate for intra-uterine transfusion (IUT)

1. Definition and properties

The leukocyte-depleted RBC concentrate for intra-uterine tranfusion, as the name implies, is a leukocyte-depleted RBC concentrate intended for intra-uterine transfusion.

The hematocrit range between 0.70 to 0.85 and contains less than 1.0×10^6 leucocytes per unit.

2. Preparation

The RBC concentrate for intra-uterine transfusion is prepared from the secondary processing of leukocyte-depleted whole blood, leukocyte-depleted RBC concentrate or leukocyte-depleted RBC concentrate with additive solution. To achieve the required hematocrit, the storage solution is partially removed and/or replaced with another appropriate one.

The component must be compatible with both the mother and the fetus. When the fetal blood group is not known, an O RhD-negative donation should be selected, unless the mother has antibodies to that blood group; in that case, another blood group should be used. The RBCs must not carry any antigens recognized by the mother's antibodies.

The component must not contain clinically significant irregular antibodies.

RBC concentrates for IUT must be used within 5 days of donation. They must be irradiated and used within 24 hours of irradiation.

3. Quality control

Parameter to test	Specifications	Frequency of testing
Hematocrit	0.70 – 0.85	All the units

4. Storage and transportation

The storage and transport conditions are the same as for the primary component.

The shelf life should not exceed 24 hours after concentration and irradiation, and 5 days after donation.

5. Labelling

The labelling requirements, whether additional and/or modified from those of the primary component, are as follows:

- Blood group phenotype for non anti-D maternal antibodies ;
- The preparation date and time ;
- The expiry date and time ;

- The type of the anticoagulant or additive solution ;
- Other blood component information: irradiated ;
- The blood component volume or weight ;

6. Cautions

The compatibility of this component with the maternal serum/plasma should be verified by appropriate pre-transfusion testing. The transfusion rate should be adjusted to avoid excessive fluctuations in blood volume.

Since the fetus is at high risk for graft-versus-host disease, this component should be irradiated.

Leukocyte-depleted platelet concentrate for intra-uterine transfusion

1. Definition and properties

Leukocyte-depleted platelet concentrate for IUT is obtained from a single donor, either by apheresis or from whole blood.
It must be leukodepleted and irradiated, and may be hyper concentrated.
This component has 45 to 85 x 10^9 platelets (on average 70 x 10^9) in 50 to 60 mL of suspension medium.

2. Preparation

Platelet concentrate for IUT is prepared either from leukocyte-depleted apheresis platelet concentrate or by leukodepletion of a regular platelet concentrate; if necessary, the collection is made from an HPA compatible donor.
This component can be further concentrated if necessary by centrifuging and removing a portion of the supernatant. This should be followed by a one-hour standby period.
Platelets collected from the mother, if needed, should be separated from the plasma and resuspended in an additive solution.

Platelet concentrate for IUT must be irradiated.

3. Quality control

Parameter to test	Specifications	Frequency of testing
HPA*	Phenotyping	If required
Volume	50-60 mL	All the units
Platelet count	45-85 x 10^9/unit	All the units

*HPA phenotyping is performed for the donor, and not for the component.

4. Storage and transportation

The storage and transportation conditions are similar to those for the primary component, but this component must be used within 6 h of any subsequent concentration process.

5. Labelling

The labelling requirements, whether additional to and/or modified from those of the primary component, are as follows:

- If the components were split for neonatal and pediatric use, each split must have a unique identification number to ensure its traceability to the donation ;
- Other blood component information ;
- Irradiated, plasma- or supernatant-depleted… (if applicable) ;
- The blood component volume or weight ;
- The platelet count
- The expiry date and time ;

6. Cautions

Since the fetus is at high risk for graft-versus-host disease, this component should be irradiated.
The transfusion rate should be adjusted to avoid excessive fluctuations in blood volume.
It is important to check that there is no bleeding following the venipuncture.

Leukocyte-depleted red blood cells concentrate suspended in fresh frozen plasma for exchange transfusion

1. Definition and properties

The leukocyte-depleted RBC concentrate suspended in fresh frozen plasma for exchange transfusion is a reconstituted component prepared from a leukocyte-depleted RBC concentrate or a leukocyte-depleted RBC concentrate with additive solution, to which FFP is added..

2. Preparation

The leukocyte-depleted RBC concentrate or a leukocyte-depleted RBC concentrate with additive solution is selected within 5 days of collection and undergo secondary processing. The supernatant containing the additive solution and/or plasma is removed after centrifugation, and the FFP (thawed) is added to achieve the clinically required hematocrit.

If the mother has anti-D antibodies, the component is prepared from RhD-negative type O RBCs. If the mother has non-anti-D antibodies, red cells that do not carry antigens recognized by maternal antibodies will be selected.

This component must be irradiated:

- If there is a previous history of intrauterine transfusion;
- For all other patients, except in emergencies, where delay could compromise the clinical outcome

The leukocyte-depleted RBC concentrate suspended in fresh frozen plasma for exchange transfusion should be used within 24 hours of irradiation.

3. Quality control

Refer to the indications for the primary component (leukocyte-depleted RBC, leukocyte-depleted RBC with additive solution, and FFP), along with the additional modifications listed below.

Parameter to test	Specifications	Frequency of testing
Hematocrit	According to the clinical requirements or local recommendations	All the units

4. Storage and transportation

The storage and transportation conditions for leukocyte-depleted RBC concentrate suspended in FFP for exchange transfusion are identical to those for leukocyte-depleted RBC concentrate with or without additive solution.

The shelf life should not exceed 24 hours after reconstitution and irradiation, and 5 days after red cell donation.

5. Labelling

The labelling requirements, whether additional to and/or modified from those of the primary components, are as follows:

- The new unique identification number that allows its traceability to the donation ;
- The blood component type
- The RBC concentrate ABO and RhD group
- The blood group phenotype if non-anti-D antibodies
- The preparation date and time
- The new expiry date and time
- Other blood component information: Irradiated, hematocrit.

6. Cautions

The compatibility between the leukocyte-depleted RBC concentrate suspended in FFP for exchange transfusion and the recipient should be verified by appropriate pre-transfusion testing. The compatibility between the blood group and the maternal antibodies is essential.
The transfusion rate should be adjusted to avoid excessive fluctuations in blood volume.

Low volume RBC concentrate for neonatal and pediatric transfusion

1. Definition and properties

Low volume RBC concentrate for neonatal and pediatric transfusion is obtained by splitting a leukocyte-depleted RBC or a leukocyte-depleted RBC with additive solution into subunits.
The properties are those for the primary component.

2. Preparation

Low volume RBC concentrate for neonatal and pediatric transfusion is prepared by the secondary processing of leukocyte-depleted RBC or leukocyte-depleted RBC with additive solution. The selected component is divided into 3 to 8 satellite bags using a physically or functionally closed system.

If clinically indicated, this component may be irradiated.

3. Quality control

The quality control procedure for the primary component is described in the corresponding section. As for the final component, the additional requirements are given in the table below.

Parameter to test	Specifications	Frequency of testing
Volume	25 to 100 mL per unit	All the units

4. Storage and transportation

The storage and transportation conditions are identical to those for the primary RBC concentrate.

The shelf life should not exceed that of the primary component. If irradiated, it must be used within 48 hours.

5. Labelling

The labelling requirements, whether additional to and/or modified from those of the primary component, are as follows:

- If the components were split for neonatal and pediatric use, each split must have a unique identification number to ensure its traceability to the donation ;
- The blood component type;
- Other blood component information: irradiated… (if applicable) ;
- The blood component volume or weight ;
- The expiry date and time ;

6. Cautions

The transfusion rate should be carefully monitored.
This component is not intended for fast or high volume transfusion unless used within 5 days of the RBC donation.