

Platelets, Leukocyte Reduced (LR)

This component information addresses:

- CPD Platelets, Pooled, LR
- Platelets Apheresis, LR

Composition and properties

CPD Platelets, Pooled, LR, is a platelet concentrate prepared by separation of the buffy coat layer from approximately 480mL whole blood collected in 70mL of CPD anticoagulant. Four ABO matched platelet concentrates are pooled in the residual plasma from one of the four donations. The pool is leukocyte reduced by filtration. The pooled platelet product is labelled as Rh negative, only when all units contained in the pool are from Rh negative donors.

Platelets, Apheresis, LR, is a platelet concentrate collected into approximately 50mL of ACD-A anticoagulant using automated apheresis techniques, which includes leukoreduction.

Note:

CPD (citrate, phosphate, dextrose) anticoagulant contains citric acid 3.27g/L, sodium citrate 26.3g/L, sodium acid phosphate 2.51g/L, dextrose 25.5g/L.

ACD-A (adenine, citrate dextrose – formula A) anticoagulant contains sodium citrate 22.0g/L, citric acid 7.3g/L, dextrose 24.5g/L.

TABLE 1: Typical unit content is based on the number of units (n) tested from October 2007 to March 2008, inclusive.

Platelet Component	Volume (mL) Mean ± 2sd	Platelet Count (x10 ⁹) Mean ± 2sd	Residual Leukocytes (10 ⁶ /unit) Mean ± 2sd
CPD Platelets, Pooled, LR	342 ± 32 n = 198	326 ± 93 n = 195	0.008 ± 0.056 n = 195
Platelets Apheresis, LR	250 ± 62 n = 16,151	369 ± 102 n = 5467	0.020 ± 0.085 n = 235

Quality criteria that must be met:

CPD Platelets: Volume: ±10% labelled volume in all units tested; Platelet Count: ≥150 and ≤450x10⁹/unit in all units tested and >240x10⁹/unit in ≥75% of units tested; Residual Leukocytes: <5 x10⁶ in all units tested.

Apheresis Platelets: Platelet Count: ≥300x10⁹/unit in ≥75% of units tested; Residual Leukocytes: <5 x10⁶ in all units tested.

Trace amounts of red blood cells may be present in some units.

The donor sample is tested for ABO group, Rh type and unexpected antibodies against red cell antigens. ABO, Rh and, if present, antibody identity are indicated on the component label.

Prior to making blood components available for transfusion, a sample of each donor's blood must test negative for:

- antibodies against human immunodeficiency virus (HIV-1 and HIV-2), hepatitis C virus (HCV), human T-cell lymphotropic virus, type I and II (HTLV-I/II), hepatitis B core antigen (HBcore)
- hepatitis B surface antigen (HBsAg)
- presence of viral RNA [HIV-1, HCV and West Nile Virus (WNV)]
- syphilis

Platelets, LR components are cultured for bacteria 24 hours after collection and are issued to hospitals only if the culture is negative at the time of

issue. If the component culture becomes positive after issue, the hospital is notified.

In some cases, a donor sample is also tested for cytomegalovirus (CMV) antibody and/or the presence of IgA; if negative this is indicated on the label.

In some emergency situations, with the approval of both the Canadian Blood Services and attending physician, partially tested or untested blood may be released for transfusion.

Packaging

CPD Platelets, Pooled, LR and **Platelets Apheresis LR** are stored in gas-permeable bags. Platelet component storage bags do not contain di-ethyl hexyl phthalate (DEHP) plasticizer.

Platelets Apheresis LR may be supplied in a single container or, in some instances, in two connected containers. If supplied in two connected containers, instructions for pooling the two containers are included on the transfusion instruction label that is adhered to the secondary container.

Storage and handling

CPD Platelets, Pooled, LR and **Platelets Apheresis LR** must be stored at 20 - 24°C with continuous gentle agitation. During transport cessation of agitation for 24 hours is acceptable.¹ The shelf life is 5 days.

Visual inspection should occur. A platelet unit should be mixed thoroughly prior to transfusion.

Action

The primary role of transfused platelets is to participate in primary hemostasis through the provision of functionally normal platelets. The aim of transfusion is to reduce or stop bleeding and to increase platelet count.

Indications

Platelet transfusion is indicated for the treatment of patients with clinically significant bleeding and low platelet counts secondary to decreased production or dilutional thrombocytopenia.

On occasion, platelet transfusion may be indicated for the treatment of patients with platelet destructive conditions or functionally abnormal platelets in the setting of clinically significant bleeding or prior to an invasive procedure associated with high risk of bleeding.

Prophylactic platelet transfusions may be indicated for very low platelet counts (≤ 10 x 10⁹/L) secondary to decreased production. Prophylactic transfusions at higher platelet count thresholds may be indicated for invasive procedures and/or in the presence of additional risk factors for bleeding.

For patients with alloimmune refractoriness, HLA and/or HPA matched **Platelets Apheresis LR** may be indicated. For platelet refractoriness due to disseminated intravascular coagulation, idiopathic thrombocytopenic purpura, hypersplenism, certain drugs, fever and sepsis, HLA and/or HPA matched **Platelets Apheresis LR** are no more effective than unmatched **Platelets Apheresis LR** or **CPD Platelets, Pooled, LR**.

Contraindications

Do not use platelet components if bleeding is unrelated to decreased numbers of, or abnormally functioning, platelets.

Platelet components are not recommended for use in patients with destruction of endogenous and exogenous platelets, such as in thrombotic thrombocytopenic purpura, idiopathic thrombocytopenic purpura or heparin induced thrombocytopenia (HIT) unless the patient has a life-threatening hemorrhage.

Since platelet components contain donor plasma, recipients with known anti-IgA should receive IgA deficient platelets. Patients with known anaphylaxis to plasma should only receive platelet components under appropriate medical supervision.

Warnings and Precautions

The donor plasma in platelets should be ABO compatible with the recipient's red cells. Canadian Standards Association standards require that a policy be in place concerning group substitution when platelets with compatible plasma are not available.² Hemolysis has been reported as an uncommon complication of plasma ABO incompatibility with platelet transfusions.

The intended recipient must be properly identified before the transfusion is started.

Rh positive platelets given to an Rh negative recipient may cause sensitization. If Rh positive platelets are transfused to an Rh negative child or female especially of child-bearing potential, RhIgG should be considered.

Alloimmunisation of the recipient may be a consequence of transfusion.

Careful donor selection and available laboratory tests do not eliminate the hazard of transmitting infectious disease agents for which testing is performed (see Table 2)³ or for pathogens that are either not recognized or for which there is no donor screening test.

TABLE 2: Estimated residual risks of transfusion-transmitted viral infections in Canada with incidence rates from observed donor seroconversions, 2001 to 2005.⁴

Virus	Residual risk	
	Per million donations (95% CI)	Per number of donations
HIV	0.13 (0.05-0.28)	1 in 7.8 million
HCV	0.43 (0.27-0.66)	1 in 2.3 million
HBV	6.55 (3.90-10.29)	1 in 153,000
HTLV*	0.23 (0.04-0.83)	1 in 4.3 million‡

*95 percent CI is not available for HTLV window period, the listed numbers in brackets are the range.

‡This estimate represents potentially infectious units released into inventory. The risk to recipients would be much lower due to universal leukoreduction.

For some patients at particularly high risk of severe CMV disease (e.g., fetus requiring an intrauterine transfusion [IUT], or CMV-seronegative recipients of allogeneic, hematopoietic stem cell transplants from CMV-seronegative donors), clinicians may choose, in addition to the use of LR components, to transfuse components from CMV-seronegative donors.

Some collection needles are in contact with latex. Canadian Blood Services cannot guarantee that this component is latex free.

Adverse events

Potential adverse events related to a blood transfusion range in severity from minor with no sequelae to life-threatening. All adverse events occurring during a transfusion should be evaluated to determine whether or not the transfusion can be safely continued/restarted. All adverse events suspected to be related to a transfusion (whether during or after a transfusion) should be reported to your local transfusion service and when required (i.e. when the adverse event could be attributed to the quality of a blood component), to Canadian Blood Services and the hospital/regional hemovigilance network. Canadian Standards Association requires reporting of adverse events associated with blood component quality (e.g.: bacterial contamination) to Canadian Blood Services.^{2,5} For further information, refer to the Canadian Standards Association, *Blood and Blood Components*, Section 17.2.2. and Transfusion Transmitted Injuries Surveillance System.^{2,6}

Event	Approximate Frequency	Symptoms and Signs	Notes
Mild allergy	1 in 100	Urticaria, pruritis and/or erythema.	Transfusion can be restarted after assessment and necessary intervention.
Febrile non-hemolytic transfusion reactions (FNHTR)	1 in 200	Fever, chills and/or rigor.	Diagnosis of exclusion. A patient with fever should be evaluated for other more serious transfusion reactions.
Transfusion associated circulatory overload (TACO)	1 in 700	Dyspnea, orthopnea, cyanosis, tachycardia, raised venous pressure and/or hypertension.	Due to excessive volume or excessively rapid transfusion rates. May be difficult to distinguish from TRALI.
Bacterial contamination	1 in 1,000 (see explanation in Notes)	Fever, chills, rigors, nausea, vomiting, diarrhea, abdominal and muscle pain, hypotension, hemoglobinemia, and disseminated intravascular coagulation and/or renal failure.	Approximate risks per platelet concentrate are: <ul style="list-style-type: none"> • bacterial contamination 1 in 1,000 to 1 in 3,000. • bacterial sepsis 1 in 10,000. • death from bacterial sepsis 1 in 40,000. For evaluation and treatment of a reaction due to suspected bacterial contamination, refer to reference #5.
Transfusion related acute lung injury (TRALI)	1 in 1,200-5,000	New onset of hypoxemia, new bilateral lung infiltrates on chest X-ray and no evidence of circulatory overload.	Occurs during or within 6 hours of transfusion. May be difficult to distinguish from TACO.
Post transfusion purpura (PTP)	Rare	Abrupt onset of severe thrombocytopenia 1 – 24 days post transfusion.	Most cases of PTP occur in recipients who are HPA-1b homozygous receiving HPA-1a positive blood components.
Transfusion-related alloimmune thrombocytopenia	Rare	Abrupt onset of potentially severe thrombocytopenia within hours of transfusion.	Passive transfer of platelet antibodies leading to thrombocytopenia.
Immediate hemolytic transfusion reactions (HTR)	Rare	Fever, chills, hemoglobinuria, dyspnea, shock, disseminated intravascular coagulation, chest pain and/or back pain.	May be associated with ABO plasma incompatibility.
Anaphylaxis	Rare	Hypotension, upper and/or lower respiratory obstruction, anxiety, nausea and vomiting.	Resuscitation according to institutional guidelines. IgA deficient patients who have formed anti- IgA antibodies may experience anaphylactic reactions. However, in most cases of anaphylactic reactions, no specific antibodies are found in the patient.
Graft-versus-host disease (GVHD)	Rare	Pancytopenia, rash, liver dysfunction, diarrhea.	Irradiated cellular blood components eliminate this risk.
Isolated hypotensive reaction	Unknown	Hypotension, occasionally accompanied by urticaria, dyspnea or nausea.	Diagnosis of exclusion. May occur more frequently in patients on angiotensin-converting enzyme (ACE) inhibitor.
Infectious disease	See Table 2, Residual risk of tested viruses	Variable according to infectious disease.	Blood components have been described to transmit viruses other than HIV, HBV, HCV, HTLV I/II and WNV as well as parasites, and prions.

Reporting of suspected cases of transfusion-related infections such as HIV, HCV, HTLV, HBV, WNV and other transfusion-related infections is described in the Clinical Guide to Transfusion, section 1: Vein to Vein: A Summary of Blood Collection and Transfusion in Canada.

Dose and administration

The number of units of Platelets, LR to be administered depends on the clinical situation of each patient. The response to platelet transfusions is best assessed by observing whether bleeding stops and by measuring post transfusion platelet counts. Standard doses are:

- a) **adults** - one unit of **Platelets Apheresis LR** or one unit of **CPD Platelets, Pooled, LR**.
- b) **children** - 25% of an adult standard dose per 10 kg body weight up to one standard adult dose.
- c) **neonates** - 10 mL/kg of Platelets, LR.

Each dose of platelets should increase the patient's platelet count by at least $15 \times 10^9/L$.⁹ In some instances more than one standard dose may be required.

A standard blood administration set containing a 170 – 260 micron filter or a filter of equivalent efficacy, approved by Health Canada, must be used for infusion. Transfusion may proceed as fast as tolerated but must be completed in less than four hours.

No medications or solutions, with the exception of 0.9% Sodium Chloride, may be added to or infused through the same tubing with the Platelets, LR components. In particular, the addition of commonly used solutions such as D5W (5% dextrose in water) or additives such as calcium (e.g. in Lactated Ringers), should never be added to, or administered concurrently through the same vascular access as blood or blood components. Co-administration of ABO-compatible plasma or 5% albumin could be performed at the discretion of the attending physician.

All transfusions should be complete within 4 hours of removal from storage. Patients should be under clinical observation, in accordance with institutional guidelines, during transfusion with close observation during the first 15 minutes.

Modifications and additional information

Modification	Description	Indication	Storage	Benefits	Adverse events
Irradiation ¹²	Cells are exposed to gamma irradiation.	Recipients who are immunocompromised or who receive cellular components from closely matched HLA or related/directed donor.	Unchanged.	Eliminates risk of GVHD.	As per Table 3.

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The Circular as a whole or in part cannot be considered or interpreted as an expressed or implied warranty of the safety or fitness of the described blood or blood components when used for their intended purpose. Attention to the specific indications for blood components is needed to prevent inappropriate transfusion.



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it's in you to give

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This *Circular* is an extension of the component label and conforms to the applicable Regulations issued by the Health Products and Food Branch, Health Canada.¹³