Guidelines for the Blood Transfusion Services

7.4: Platelet Components

http://www.transfusionguidelines.org/red-book/chapter-7/7-4

7.4: Platelet Components

Platelet components are manufactured from pooling whole blood-derived buffy coats or directly from apheresis collections. They are suspended in plasma with or without a platelet additive solution.

Specifications

7.4.1: Platelets, Pooled, Buffy Coat Derived, Leucocyte Depleted

A pool of platelets, derived from buffy coats, which contains less than 1×10^6 leucocytes.

7.4.1.1: Technical information

- Donations of whole blood where the bleed time exceeded 15 minutes are not suitable for platelet production.
- The buffy coats must be prepared at ambient temperature from whole blood where the surface temperature of packs has not dropped below 18°C.
- Initial separation of buffy coat must occur within 24 hours of venepuncture (unless supported by additional validation), with a minimum buffy coat rest period of 2 hours before secondary pooling and processing of buffy coats to produce the final component, which is generally completed before the end of Day 1.
- The volume of suspension medium must be sufficient to maintain the pH at >=6.4 at the end of the shelf life of the component.
- The production process transfers the final component into a pack that was not part of the original pack assembly. Therefore a secure system must be in place to ensure a full audit trail and that the correct identification number is put on the final component pack.
- Where the production method requires the use of a single unit of plasma for resuspension, the plasma from group O donors should be tested for high-titre anti-A and anti-B and ‘high-titre negative’ units labelled. The testing method and acceptable limits should be defined (see also Chapter 9). Plasma should be selected from male donors as a TRALI risk reduction strategy.
- Platelets, Pooled, Buffy Coat Derived, Leucocyte Depleted, should be administered through a CE /UKCA/UKNI marked transfusion set.

7.4.1.2: Labelling

For general guidelines, see section 6.6.

The following shall be included on the label:

(* = in eye-readable and UKBTS approved barcode format)

- Platelets, Pooled, Buffy Coat Derived, Leucocyte Depleted* and volume
- the blood component producer's name*
- a unique pool or batch number or the donation number of all contributing platelet units*
- the ABO group*
- the RhD group stated as positive or negative*
- the expiry date*
- the temperature of storage and a comment that continuous gentle agitation throughout storage is recommended
- the blood pack lot number*
- the name, composition and volume of the anticoagulant or additive solution.

In addition, the following statements should be made:

INSTRUCTION
Always check patient/component compatibility/identity
Inspect pack and contents for signs of deterioration or damage
Risk of adverse reaction/infection, including vCJD

7.4.1.3: Storage

For general guidelines, see section 6.7.

- The storage period depends on a number of factors including the nature of the container, the concentration of platelets and on whether an open or closed system is used.

- Packs currently in use for this purpose allow for storage at a core temperature of 22 ±2°C with continuous gentle agitation for up to 5 days in a closed system. Appropriate pack and platelet concentration combinations may allow storage up to 7 days, but due to concerns over bacterial contamination requires either an assay to exclude bacterial contamination prior to transfusion or application of a licensed pathogen inactivation procedure.

- If any production stage involves an open system, after preparation the component should be used as soon as possible. If storage is unavoidable, the component should be stored at a core temperature of 22 ±2°C with continuous agitation and used within 6 hours.

- Platelets should be gently agitated during storage. If agitation is interrupted, for example due to equipment failure or prolonged transportation, the components are suitable for use, retaining the same shelf life, provided that no single interruption lasts for more than eight hours, and the total length of all interruptions is no longer than 24 hours.

7.4.1.4: Testing

In addition to the mandatory and other tests required for blood donations described in Chapter 9, and leucocyte counting (see sections 6.3 and 7.1.1), a minimum of 75% of those components tested for the parameters shown in Table 7.4.1 shall meet the specified values.

Table 7.4.1 Platelets, Pooled, Buffy Coat Derived, Leucocyte Depleted – additional tests

Parameter	Frequency of test	Specification
Volume [1]	1% or as determined by statistical process control (if <=10 components produced per month then test every available component)	Within locally defined nominal volume range
Platelet count [2]		>=240 × 10^9/pool
pH at end of shelf life [3]		>=6.4
Leucocyte count [4]	As per sections 6.3 and 7.1.1	<1 × 10^6/pool
[1] Units measured and found to be <150 mL or >380 mL should only be issued for transfusion under concessionary release		
[2] Units measured and found to have <160 × 10^9/pool, or more than the maximum recommended by the manufacturer of the storage pack where stated, should only be issued for transfusion under concessionary release		
[3] A minimum of 95% of those components tested shall meet the specified values		
[4] Methods validated for counting low numbers of leucocytes must be used		

Note: Visual inspection of platelet components for the swirling phenomenon, clumping, excessive red cell contamination and abnormal volume is a useful pre-issue check.

7.4.1.5: Transportation

For general guidelines, see section 6.11.

- Containers for transporting platelets should be equilibrated at room temperature before use. During transportation the temperature of platelets must be kept as close as possible to the recommended storage temperature and, on receipt, unless intended for immediate therapeutic use, the component should be transferred to storage at a core temperature of 22 ±2°C with continuous gentle agitation.
- Plastic overwraps should be removed prior to storage.

7.4.2: Platelets, Apheresis, Leucocyte Depleted

A single-donor platelet component containing less than 1 × 10^6 leucocytes.

7.4.2.1: Technical information

- Platelets, Apheresis, Leucocyte Depleted may be collected by a variety of apheresis systems using different protocols. Since platelet yields may vary, each procedural protocol must be fully validated, documented and specifications set accordingly.
- If a double or triple dose is collected the platelet concentrate must be temporarily split, as a continuous part of the collection process, into the storage packs integral to the collection set so that the capacity of an individual pack is not exceeded.
- If filtration is used the recommended capacity of the filter should not be exceeded.

- The volume of suspension medium must be sufficient to maintain the pH at >=6.4 at the end of the shelf life of the component.

- If the leucodepletion process transfers the final component into a pack that was not part of the original pack assembly, a secure system must be in place to ensure the correct identification number is put on the final component pack.

- The plasma from group O donors should be tested for high-titre anti-A and anti-B, and ‘high-titre negative’ units labelled. The testing method and acceptable limits should be defined (see also Chapter 9). Screening of female donors for HLA/HNA antibodies should be considered as a TRALI risk reduction strategy.

- Platelets, Apheresis, Leucocyte Depleted should be administered through a CE/UKCA/UKNI marked transfusion set.

7.4.2.2: Labelling

For general guidelines, see section 6.6.

The following shall be included on the label:

(* = in eye-readable and UKBTS approved barcode format)

- Platelets, Apheresis, Leucocyte Depleted* and volume
- the blood component producer’s name*
- the donation number and, if divided, sub-batch number*
- the ABO group*
- the RhD group stated as positive or negative*
- the expiry date*
- the temperature of storage and a comment that continuous gentle agitation throughout storage is recommended
- the blood pack lot number*
- the name, composition and volume of the anticoagulant or additive solution.

In addition, the following statements should be made:

INSTRUCTION
Always check patient/component compatibility/identity
Inspect pack and contents for signs of deterioration or damage
Risk of adverse reaction/infection, including vCJD

7.4.2.3: Storage

For general guidelines, see section 6.7.

- The storage period depends on a number of factors including the nature of the container, the concentration of platelets and whether an open or closed system is used.

- Packs currently in use for this purpose allow for storage at a core temperature of 22 ±2°C with continuous gentle agitation for up to 5 days in a closed system. Appropriate pack and platelet concentration combinations may allow storage up to 7 days, but due to concerns over bacterial contamination requires either an assay to exclude bacterial contamination prior to transfusion or application of a licensed pathogen inactivation procedure.

- Where any manufacturing step involves an open system the platelets should be used as soon as possible after collection. If storage is unavoidable, the component should be stored at a core temperature of 22 ±2°C with continuous agitation and used within 6 hours.

- Platelets should be gently agitated during storage. If agitation is interrupted, for example due to equipment failure or prolonged transportation, the components are suitable for use, retaining the same shelf life, provided that no single interruption lasts for more than eight hours, and the total length of all interruptions is no longer than 24 hours.

7.4.2.4: Testing

In addition to the mandatory and other tests required for blood donations described in Chapter 9, and leucocyte counting (see sections 6.3 and 7.1.1), a minimum of 75% of those components tested for the parameters shown in Table 7.4.2 shall meet the specified values.

Table 7.4.2 Platelets, Apheresis, Leucocyte Depleted – additional tests

Parameter	Frequency of test	Specification
Volume [1]	1% or as determined by statistical process control (if <=10 components produced per month then test every available component)	Within locally defined nominal volume range
Platelet count [2]		>=240 × 10^9/unit
pH at end of shelf life [3]		>=6.4
Leucocyte count [4]	As per sections 6.3 and 7.1.1	<1 × 10^6/unit
[1] Units measured and found to be <150 mL or >380 mL should only be issued for transfusion under concessionary release		
[2] Units measured and found to have <160 × 10^9/unit, or more than the maximum recommended by the manufacturer of the storage pack where stated, should only be issued for transfusion under concessionary release		
[3] A minimum of 95% of those components tested shall meet the specified values		
[4] Methods validated for counting low numbers of leucocytes must be used		

Note: Visual inspection of platelet components for the swirling phenomenon, clumping, excessive red cell contamination and abnormal volume is a useful pre-issue check.

7.4.2.5: Transportation

For general guidelines, see section 6.11.

- Containers for transporting platelets should be equilibrated at room temperature before use. During transportation the temperature of platelets must be kept as close as possible to the recommended storage temperature and, on receipt, unless intended for immediate therapeutic use, the component should be transferred to storage at a core temperature of 22 ±2°C with continuous gentle agitation.

- Plastic overwraps should be removed prior to storage.

7.4.3: Platelets, Pooled, Buffy Coat Derived, in Additive Solution and Plasma, Leucocyte Depleted

A platelet concentrate, derived from buffy coats, which contains less than 1×10^6 leucocytes and where the suspending medium comprises approximately 30% plasma and 70% additive solution.

7.4.3.1: Technical Information

- The component is manufactured as a primary component and not as a remanufactured secondary component.
- Donations of whole blood where the bleed time exceeded 15 minutes are not suitable for platelet production.
- The buffy coats must be prepared at ambient temperature from whole blood where the surface temperature of packs has not dropped below 18°C.
- Initial separation of buffy coat must occur within 24 hours of venepuncture (unless supported by additional validation), with a minimum buffy coat rest period of 2 hours before secondary pooling and processing of buffy coats to produce the final component, which is generally completed before the end of Day 1.
- The proportion of plasma carried over into the final component should be determined by validation and will depend upon the type of additive solution and platelet storage pack. Re-validation of the proportion of plasma carried over must be performed at least annually on a minimum of 25 units and after any changes to production method.
- The volume of suspension medium must be sufficient to maintain the pH at >=6.4 at the end of the shelf life of the component.
- Where the production process transfers the final component into a pack that was not part of the original pack assembly, a secure system must be in place to ensure the audit trail and the correct identification number is put on the final component pack.
- Platelets, Pooled, Buffy Coat Derived, in Additive Solution and Plasma, Leucocyte Depleted, should be administered through a CE/UKCA/UKNI marked transfusion set.

7.4.3.2: Labelling

For general guidelines, see section 6.6.

The following shall be included on the label:

(* = in eye-readable and UKBTS approved barcode format)

- Platelets in Additive Solution and Plasma, Leucocyte Depleted * and volume
- the blood component producer’s name*
- a unique pool or batch number or the donation number of all contributing platelet units*
- the RhD group stated as positive or negative*
- the expiry date*
- the temperature of storage and a comment that continuous gentle agitation throughout storage is recommended

- the blood pack lot number*

In addition, the following statements should be made:

INSTRUCTION
Always check patient/component compatibility/identity
Inspect pack and contents for signs of deterioration or damage
Risk of adverse reaction/infection, including vCJD

7.4.3.4: Storage

For general guidelines, see section 6.7.

- The storage period depends on a number of factors including the nature of the container, the concentration of platelets and on whether an open or closed system is used.

- Packs currently in use for this purpose allow for storage at a core temperature of 22 ±2°C with continuous gentle agitation for up to 5 days in a closed system. Appropriate pack and platelet concentration combinations may allow storage up to 7 days, but due to concerns over bacterial contamination would require either an assay to exclude bacterial contamination prior to transfusion or application of a licensed pathogen reduction procedure.

- If any production stage involves an open system, after preparation the component should be used as soon as possible. If storage is unavoidable, the component should be stored at a core temperature of 22 ±2°C with continuous agitation and used within 6 hours. If platelet agitation is interrupted due to equipment breakdown or prolonged transportation, platelets are suitable for use provided that no single interruption lasts for more than eight hours, and the total length of all interruptions is no longer than 24 hours.

7.4.3.4: Testing

In addition to the mandatory and other tests required for blood donations described in Chapter 9 and leucocyte counting (see section 6.3 and 7.1.1), a minimum of 75% of those components tested for the parameters shown at Table 7.4.3 shall meet the specified values.

Table 7.4.3 Platelets, Pooled, Buffy Coat Derived, in Additive Solution and Plasma, Leucocyte Depleted – additional tests

Parameter	Frequency of test	Specification
Volume [1]	1% or as determined by statistical process control (if <=10 components produced per month then test every available component)	Within locally defined nominal volume range
Platelet count [2]		>=240 × 10^9/pool
pH at end of shelf life [3]	If less than 10 per month, every available component	>=6.4
Leucocyte count [4]	As per sections 6.3 and 7.1.1	<1 × 10^6/pool
[1] Units measured and found to be <150 mL or >380 mL should only be issued for transfusion under concessionary release		
[2] Units measured and found to have <160 × 10^9/pool, or more than the maximum recommended by the manufacturer of the storage pack where stated, should only be issued for transfusion under concessionary release		
[3] A minimum of 95% of those components tested shall meet the specified values		
[4] Methods validated for counting low numbers of leucocytes must be used		

Note: Visual inspection of platelet components for the swirling phenomenon, clumping, excessive red cell contamination and abnormal volume is a useful pre-issue check.

7.4.3.5: Transportation

For general guidelines, see section 6.11.

- Containers for transporting platelets should be equilibrated at room temperature before use. During transportation the temperature of platelets must be kept as close as possible to the recommended storage temperature and, on receipt, unless intended for immediate therapeutic use, the component should be transferred to storage at a core temperature of 22 ±2°C with continuous gentle agitation.
- Plastic overwraps should be removed prior to storage.

7.4.4: Platelets in Additive Solution, Leucocyte Depleted

A platelet concentrate derived from buffy coats or apheresis, which contains less than 1 × 10^6 leucocytes and where the suspending medium is additive solution. This component is indicated for patients with reactions to plasma-containing components.

7.4.4.1: Technical information

- Donations of whole blood where the bleed time exceeded 15 minutes are not suitable for platelet production.
- Where prepared from buffy coats, the buffy coats must be prepared at ambient temperature from whole blood where the surface temperature of packs has not dropped below 18°C.
- Where prepared from buffy coats, initial separation of buffy coat must occur within 24 hours of venepuncture (unless supported by additional validation), with a minimum buffy coat rest period of 2

hours before secondary pooling and processing of buffy coats to produce the final component, which is generally completed before the end of Day 1.

- The volume of suspension medium must be sufficient to maintain the pH at >=6.4 at the end of the shelf life of the component.

- Where the production process transfers the final component into a pack that was not part of the original pack assembly, a secure system must be in place to ensure a full audit trail and that the correct identification number is put on the final component pack.

- Platelets in Additive Solution, Leucocyte Depleted, should be administered through a CE/UKCA /UKNI marked transfusion set.

7.4.4.2: Labelling

For general guidelines, see section 6.6.

The following shall be included on the label:

(* = in eye-readable and UKBTS approved barcode format)

- Platelets in Additive Solution, Leucocyte Depleted* and volume
- the blood component producer’s name*
- a unique pool or batch number or the donation number of all contributing platelet units*
- the ABO group*
- the RhD group stated as positive or negative*
- the expiry date and time*
- the temperature of storage and a comment that continuous gentle agitation throughout storage is recommended
- the blood pack lot number*
- the name, composition and volume of the additive solution.

In addition, the following statements should be made:

INSTRUCTION
Always check patient/component compatibility/identity
Inspect pack and contents for signs of deterioration or damage
Risk of adverse reaction/infection, including vCJD

7.4.4.3: Storage

For general guidelines, see section 6.7.

- The storage period depends on a number of factors including the nature of the container, the concentration of platelets, the additive solution used and whether an open or closed system is used.

- Platelets in Additive Solution, Leucocyte Depleted, should be used within 24 hours of production.

- If any production stage involves an open system, after preparation the component should be used as soon as possible. If storage is unavoidable, the component should be stored at a core temperature of 22 ±2°C with continuous agitation and used within 6 hours.

7.4.4.4: Testing

In addition to the mandatory and other tests required for blood donations described in Chapter 9, and leucocyte counting (see sections 6.3 and 7.1.1), a minimum of 75% of those components tested for the parameters shown in Table 7.4.4 shall meet the specified values.

Table 7.4.4 Platelets in Additive Solution, Leucocyte Depleted – additional tests

Parameter	Frequency of test	Specification
Volume	1% or as determined by statistical process control (if <=10 components produced per month then test every available component)	Within locally defined nominal volume range
Platelet count [1]		>=200 × 10^9/unit
pH at end of shelf life [2]		>=6.4
Leucocyte count [3]	As per sections 6.3 and 7.1.1	<1 × 10^6/unit
[1] Units measured and found to have <160 × 10^9/pool, or more than the maximum recommended by the manufacturer of the storage pack where stated, should only be issued for transfusion under concessionary release		
[2] A minimum of 95% of those components tested shall meet the specified values		
[3] Methods validated for counting low numbers of leucocytes must be used		

Note: Visual inspection of platelet components for the swirling phenomenon, clumping, excessive red cell contamination and abnormal volume is a useful pre-issue check.

7.4.4.5: Transportation

For general guidelines, see section 6.11.

- Containers for transporting platelets should be equilibrated at room temperature before use. During transportation the temperature of platelets must be kept as close as possible to the recommended storage temperature and, on receipt, unless intended for immediate therapeutic use, the component should be transferred to storage at a core temperature of 22 ±2°C with continuous gentle agitation.

- Plastic overwraps should be removed prior to storage.