Guidelines for the Blood Transfusion Services

7.7: Components suitable for use in Intrauterine Transfusion, Neonates and Infants under 1 year

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

7.7: Components suitable for use in Intrauterine Transfusion, Neonates and Infants under 1 year

General requirements

- Unless they are subjected to a validated pathogen inactivation process, components for use in intrauterine transfusion, neonates and infants under 1 year must be prepared from previously tested donors who fulfil the following criteria:
    - have given at least one donation in the last 2 years, which was either negative for all mandatory markers, or if repeat reactive, has been confirmed to be non-specifically reactive and the donor reinstated in accordance with section 9.4, Reinstatement of blood donors
    - negative results were obtained for mandatory microbiology markers with the current donation.
- Red cell and platelet components should be negative for CMV antibodies although leucodepleted components may be used if CMV antibody negative components are not available.
- Components should be tested and shown to be free of clinically significant, irregular blood group antibodies including high-titre anti-A and anti-B.
- It is good practice to provide neonates, who are likely to be repeatedly transfused, with components in which the original donation has been split, thereby providing the potential to reduce donor exposures in this vulnerable group of recipients.
- When a component is to be split for neonatal use, the original pack must first be mixed thoroughly by a validated procedure to ensure that the contents are homogeneous.
- When a component is split for neonatal use, it is sufficient to undertake leucocyte counting on the parent pack or process.
- When a component is split for neonatal use, each ‘split’ must be identified by a unique number to ensure all splits can be accounted for.

Specifications

7.7.1: Red Cells for Intrauterine Transfusion, Leucocyte Depleted

A component for intrauterine transfusion (IUT), prepared by removing a proportion of the plasma from fresh whole blood. The component should be leucocyte depleted to less than 1×10^6 leucocytes per unit.

7.7.1.1: Technical information

- Section 7.7 provides general guidance on the requirements for components for intrauterine transfusion and use in neonates and infants under 1 year.
- The component must be prepared and used for IUT by the end of Day 5, should be free from clinically significant irregular blood group antibodies including high-titre anti-A and anti-B (see Chapter 12), and should be negative for antibodies to CMV.
- Whenever possible the component should be selected from male donors as a TRALI risk reduction measure.
- The component must be irradiated and should be transfused within 24 hours of irradiation. See the British Society for Haematology (BSH) ‘Guidelines on transfusion for fetuses, neonates and older children’.[6]
- Unless the Blood Centre recommends screening is unnecessary, the donor should be Haemoglobin S screen negative.
- Red Cells for Intrauterine Transfusion, Leucocyte Depleted should be administered through a CE /UKCA/UKNI marked transfusion set.

7.7.1.2: Labelling

For general guidelines, see section 6.6.

The following shall be included on the label:

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

- Red Cells for Intrauterine Transfusion, Leucocyte Depleted* and volume
- the blood component producer’s name*
- the donation number*
- the ABO group*
- the RhD group stated as positive or negative*
- the name, composition and volume of the anticoagulant solution
- the date of collection
- the expiry date*
- the temperature of storage
- 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

7.7.1.3: Storage

For general guidelines, see section 6.7.

- The component may be stored for a maximum of 5 days at a core temperature of 4 ±2°C.
- The component must be used within 24 hours of irradiation and within the overall maximum 5-day shelf life.
- Variation from the core temperature of 4 ±2°C of the finished component must be kept to a minimum during storage at all stages of the blood supply chain and restricted to any short period necessary for examining, labelling or issuing the component.
- Exceptionally, i.e. due to equipment failure at a Blood Centre or hospital, for temperature excursions where the core temperature has not exceeded 10°C or fallen below 1°C, components may be released for transfusion provided that:
  - the component has been exposed to such a temperature change on one occasion only
  - the duration of the temperature excursion has not exceeded 5 hours
  - a documented system is available in each Blood Centre or hospital to cover such eventualities
  - adequate records of the incident are compiled and retained.

7.7.1.4: 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), the component shall be free from clinically significant irregular blood group antibodies and high-titre anti-A and/or anti-B, and antibodies to CMV. Furthermore, a minimum of 75% of those components tested for the other parameters shown in Table 7.7.1 shall meet the specified values.

Table 7.7.1 Red Cells for Intrauterine Transfusion, 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
Haematocrit [2]		0.70 – 0.85
Haemoglobin content [3]		Locally defined
Leucocyte count [4]	As per sections 6.3 and 7.1.1	$<1 \times 10^6$/unit
[1] Units measured and found to be <150 mL or >350 mL should only be issued for transfusion under concessionary release		
[2] Units measured and found to be <0.70 or >0.85 should only be issued for transfusion under concessionary release		
[3] Units measured and found to have <40 g/unit should only be issued for transfusion under concessionary release		
[4] Methods validated for counting low numbers of leucocytes must be used		

7.7.1.5: Transportation

For general guidelines, see section 6.11.

For red cell components, transit containers, packing materials and procedures should have been validated to ensure the component surface temperature can be maintained between 2°C and 10°C during transportation. Additionally:

- the validation exercise should be repeated periodically
- if melting ice is used, it should not come into direct contact with the components
- dead air space in packaging containers should be minimised
- as far as is practicable, transit containers should be equilibrated to their storage temperature prior to filling with components
- for transportation between blood supplier and hospital an upper limit of 10°C surface temperature is acceptable but should be limited to one occasion, not exceeding 12 hours

In some instances, it is necessary to issue red cell components from the blood supplier to hospitals that have not been cooled to their storage temperature prior to placing in the transit container. The transport temperature specified above is not applicable for such consignments.

7.7.1.6: Removal from and return to 2-6°C controlled storage within hospitals

For occasions when red cells are removed from 2-6°C controlled storage (e.g. when issued to a clinical area immediately prior to transfusion) and returned then:

- If possible, time out of a controlled temperature environment should be restricted to under 30 minutes
- if 30 minutes is exceeded the unit should not be returned to the issue location in the refrigerator, but returned to the transfusion laboratory or quarantined remotely using electronic blood tracking
- up to 60 minutes out of controlled temperature is acceptable, provided the unit is then quarantined by placing in a secure refrigerator for at least 6 hours prior to reissue, to allow the unit to return to 2-6°C
- Hospitals will need to identify such units so that they are not subject to being out of controlled temperature storage for between 30 and 60 minutes on more than three occasions.

Transfusion should be completed within 4 hours of issue out of a controlled temperature environment.

7.7.2: Whole Blood for Exchange Transfusion, Leucocyte Depleted

A component for exchange or large-volume transfusion of neonates, containing less than 1×10^6 leucocytes per unit.

7.7.2.1: Technical information

- Section 7.7 provides general guidance on the requirements for components for use in neonates and infants under 1 year.

- The component must be prepared and used for exchange transfusion by the end of Day 5, should be free from clinically significant irregular blood group antibodies including high-titre anti-A and anti-B (see Chapter 12) and should be negative for antibodies to CMV.

- Whenever possible the component should be selected from male donors as a TRALI risk reduction measure.

- The component should be irradiated and transfused within 24 hours of irradiation. See the BSH 'Guidelines on transfusion for fetuses, neonates and older children'.[6]

- Unless the Blood Centre recommends screening is unnecessary, the donor should be Haemoglobin S screen negative.

- Whole Blood for Exchange Transfusion, Leucocyte Depleted should be administered through a CE /UKCA/UKNI marked transfusion set.

- If not required for exchange transfusion, the component may be remanufactured into Red Cells in Additive Solution, Leucocyte Depleted (see section 7.3.2), up to 6 days after donation, with a shelf life of up to 35 days in total.

7.7.2.2: Labelling

For general guidelines, see section 6.6.

The following shall be included on the label:

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

- Whole Blood for Exchange Transfusion, Leucocyte Depleted* and volume
- the blood component producer's name*
- the donation number*
- the ABO group*
- the RhD group stated as positive or negative*
- the name, composition and volume of the anticoagulant solution
- the date of collection
- the expiry date*
- the temperature of storage
- 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

7.7.2.3: Storage

For general guidelines, see section 6.7.

- The component may be stored for a maximum of 5 days at a core temperature of 4 ±2°C.
- The component should be used within 24 hours of irradiation and within the overall maximum 5-day shelf life.
- Variation from the core temperature of 4 ±2°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 at a Blood Centre, red cell components 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 that:
    - the component has been exposed to such a temperature change on one occasion only
    - the duration of the temperature excursion has not exceeded 5 hours
    - a documented system is available in each Blood Centre to cover such eventualities
    - adequate records of the incident are compiled and retained.
- If Whole Blood for Exchange Transfusion, Leucocyte Depleted is unused within its specified shelf life, the Blood Centre may return the component to stock provided that:
    - the component was stored within specification
    - the component is appropriately relabelled as Whole Blood Leucocyte Depleted and, if necessary, ‘irradiated’
    - the storage restrictions of irradiated red cells are observed, i.e. use within 14 days of irradiation.

7.7.2.4: 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), the component shall be free from clinically significant irregular blood group antibodies and high-titre anti-A and/or anti-B, and antibodies to CMV. Furthermore, a minimum of 75% of those components tested for the other parameters shown in Table 7.7.2 shall meet the specified values.

Table 7.7.2 Whole Blood for Exchange Transfusion, 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
Haematocrit		0.4 – 0.5
Haemoglobin content		>=40 g/unit
Leucocyte count [1]	As per sections 6.3 and 7.1.1	$<1 \times 10^6$/unit
[1] Methods validated for counting low numbers of leucocytes must be used		

7.7.2.5: Transportation

For general guidelines, see section 6.11.

For red cell components, transit containers, packing materials and procedures should have been validated to ensure the component surface temperature can be maintained between 2°C and 10°C during transportation. Additionally:

- the validation exercise should be repeated periodically
- if melting ice is used, it should not come into direct contact with the components
- dead air space in packaging containers should be minimised
- as far as is practicable, transit containers should be equilibrated to their storage temperature prior to filling with components
- for transportation between blood supplier and hospital an upper limit of 10°C surface temperature is acceptable but should be limited to one occasion, not exceeding 12 hours

In some instances, it is necessary to issue red cell components from the blood supplier to hospitals that have not been cooled to their storage temperature prior to placing in the transit container. The transport temperature specified above is not applicable for such consignments.

7.7.2.6: Removal from and return to 2-6°C controlled storage within hospitals

For occasions when red cells are removed from 2-6°C controlled storage (e.g. when issued to a clinical area immediately prior to transfusion) and returned then:

- If possible, time out of a controlled temperature environment should be restricted to under 30 minutes
- if 30 minutes is exceeded the unit should not be returned to the issue location in the refrigerator, but returned to the transfusion laboratory or quarantined remotely using electronic blood tracking
- up to 60 minutes out of controlled temperature is acceptable, provided the unit is then quarantined by placing in a secure refrigerator for at least 6 hours prior to reissue, to allow the unit to return to 2-6°C
- Hospitals will need to identify such units so that they are not subject to being out of controlled temperature storage for between 30 and 60 minutes on more than three occasions.

Transfusion should be completed within four hours of issue out of a controlled temperature environment.

7.7.3: Red Cells for Exchange Transfusion, Leucocyte Depleted

A component for exchange or large-volume transfusion of neonates prepared by leucodepleting fresh whole blood to less than 1×10^6 leucocytes per component and removing a proportion of the plasma.

7.7.3.1: Technical information

- Section 7.7 provides general guidance on the requirements for components for use in neonates and infants under 1 year.

- The component must be prepared and used by the end of Day 5, should be free from clinically significant irregular blood group antibodies including high-titre anti-A and anti-B (see Chapter 12), and should be negative for antibodies to CMV.

- Whenever possible, the component should be selected from male donors as a TRALI risk reduction measure.

- The component should be irradiated and transfused within 24 hours of irradiation. See the BSH 'Guidelines on transfusion for fetuses, neonates and older children'.[6]

- Unless the Blood Centre recommends screening is unnecessary, the donor should be Haemoglobin S screen negative.

- Red Cells for Exchange Transfusion, Leucocyte Depleted should be administered through a CE /UKCA/UKNI marked transfusion set.

- If not required for exchange transfusion, the component may be remanufactured into Red Cells in Additive Solution, Leucocyte Depleted (see section 7.3.2), up to 7 days after donation, with a shelf life of up to 35 days in total.

7.7.3.2: Labelling

For general guidelines, see section 6.6.

The following shall be included on the label:

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

- Red Cells for Exchange Transfusion, Leucocyte Depleted* and volume
- the blood component producer's name*
- the donation number*
- the ABO group*
- the RhD group stated as positive or negative*
- the name, composition and volume of the anticoagulant solution
- the date of collection
- the expiry date*
- the temperature of storage
- 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

7.7.3.3: Storage

For general guidelines, see section 6.7.

- The component may be stored for a maximum of 5 days at a core temperature of 4 ±2°C.

- Transfusion of this component should commence within 24 hours of irradiation and within the overall maximum 5day shelf life.

- Variation from the core temperature of 4 ±2°C of the finished component must be kept to a minimum during storage at all stages of the blood supply chain and restricted to any short period necessary for examining, labelling or issuing the component.

- Exceptionally, i.e. due to equipment failure at a Blood Centre or hospital, for temperature excursions where the core temperature has not exceeded 10°C or fallen below 1°C, components may be released for transfusion provided that:
    - the component has been exposed to such a temperature change on one occasion only
    - the duration of the temperature excursion has not exceeded 5 hours
    - a documented system is available in each Blood Centre or hospital to cover such eventualities
    - adequate records of the incident are compiled and retained.

- If Red Cells for Exchange Transfusion, Leucocyte Depleted are unused within their specified shelf life, the Blood Centre may return them to stock provided that:
    - the component was stored within specification
    - the component is appropriately relabelled as Red Cells, Leucocyte Depleted and, if necessary, 'irradiated'
    - the storage restrictions of irradiated red cells are observed, i.e. use within 14 days of irradiation.

7.7.3.4: 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), the component shall be free from clinically significant irregular blood group antibodies and high-titre anti-A and/or anti-B, and antibodies to CMV. Furthermore, a minimum of 75% of those components tested for the other parameters shown in Table 7.7.3 shall meet the specified values.

Table 7.7.3 Red Cells for Exchange Transfusion, 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
Haematocrit [2]		0.50 – 0.60
Haemoglobin content [3]		>=40 g/unit
Leucocyte count [4]	As per sections 6.3 and 7.1.1	$<1 \times 10^6$/unit
[1] Units measured and found to be <220 mL or >420 mL should only be issued for transfusion under concessionary release		
[2] Units measured and found to be <0.50 or >0.60 should only be issued for transfusion under concessionary release		
[3] Units measured and found to have <40 g/unit should only be issued for transfusion under concessionary release		
[4] Methods validated for counting low numbers of leucocytes must be used		

7.7.3.5: Transportation

For general guidelines, see section 6.11.

For red cell components, transit containers, packing materials and procedures should have been validated to ensure the component surface temperature can be maintained between 2°C and 10°C during transportation. Additionally:

- the validation exercise should be repeated periodically
- if melting ice is used, it should not come into direct contact with the components
- dead air space in packaging containers should be minimised
- as far as is practicable, transit containers should be equilibrated to their storage temperature prior to filling with components
- for transportation between blood supplier and hospital an upper limit of 10°C surface temperature is acceptable but should be limited to one occasion, not exceeding 12 hours

In some instances, it is necessary to issue red cell components from the blood supplier to hospitals that have not been cooled to their storage temperature prior to placing in the transit container. The transport temperature specified above is not applicable for such consignments.

7.7.3.6: Removal from and return to 2-6°C controlled storage within hospitals

For occasions when red cells are removed from 2-6°C controlled storage (e.g. when issued to a clinical area immediately prior to transfusion) and returned then:

- If possible, time out of a controlled temperature environment should be restricted to under 30 minutes
- if 30 minutes is exceeded the unit should not be returned to the issue location in the refrigerator, but returned to the transfusion laboratory or quarantined remotely using electronic blood tracking
- up to 60 minutes out of controlled temperature is acceptable, provided the unit is then quarantined by placing in a secure refrigerator for at least 6 hours prior to reissue, to allow the unit to return to 2-6°C
- Hospitals will need to identify such units so that they are not subject to being out of controlled temperature storage for between 30 and 60 minutes on more than three occasions.

Transfusion should be completed within 4 hours of issue out of a controlled temperature environment.

7.7.4: Red Cells for Neonates and Infants, Leucocyte Depleted

A red cell component suitable for neonates and infants under 1 year that contains less than 1×10^6 leucocytes (per starting component). The Red Cells for Neonates and Infants, Leucocyte Depleted may be divided into approximately equal volumes using a closed system.

7.7.4.1: Technical information

- Section 7.7 provides guidance on the requirements for components for use in neonates and infants under 1 year.

- The component should be free from clinically significant irregular blood group antibodies including high-titre anti-A and anti-B and should be negative for antibodies to CMV.

- Red Cells for Neonates and Infants, Leucocyte Depleted should be administered through a CE/UKCA /UKNI marked transfusion set.

- Unless the Blood Centre recommends screening is unnecessary, the donor should be Haemoglobin S screen negative.

7.7.4.2: Labelling

For general guidelines, see section 6.6.

The following shall be included on the label:

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

- Red Cells for Neonates and Infants, 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 name, composition and volume of the anticoagulant solution
- the date of collection
- the expiry date*
- the temperature of storage
- 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

7.7.4.3: Storage

For general guidelines, see section 6.7.

- For top-up transfusions of neonates and infants under 1 year, this component may be stored for a maximum of 35 days at a core temperature of 4 ±2°C if an adenine-supplemented anticoagulant is used, otherwise (e.g. with CPD anticoagulant) the maximum period of storage is 28 days at a core temperature of 4 ±2°C.

- Variation from the core temperature of 4 ±2°C of the finished component must be kept to a minimum during storage at all stages of the blood supply chain and restricted to any short period necessary for examining, labelling or issuing the component.

- For large-volume transfusion of neonates, this component should be used within 24 hours of irradiation and before the end of Day 5.
- Exceptionally, i.e. due to equipment failure at a Blood Centre or hospital, for temperature excursions where the core temperature has not exceeded 10°C or fallen below 1°C, components may be released for transfusion provided that:
  - the component has been exposed to such a temperature change on one occasion only
  - the duration of the temperature excursion has not exceeded 5 hours
  - a documented system is available in each Blood Centre or hospital to cover such eventualities
  - adequate records of the incident are compiled and retained.

7.7.4.4: 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), the component shall be free from clinically significant irregular blood group antibodies and high-titre anti-A and/or anti-B, and antibodies to CMV. Furthermore, a minimum of 75% of those components tested for the other parameters shown in Table 7.7.4 shall meet the specified values.

Table 7.7.4 Red Cells for Neonates and Infants, 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
Haemoglobin content		Locally defined
Haemolysis (only required if produced as part of primary component	As per section 7.1.3	<0.8% of red cell mass
Leucocyte count [1]	As per sections 6.3 and 7.1.1	$<1 \times 10^6$/starting component
[1] Methods validated for counting low numbers of leucocytes must be used		

7.7.4.5: Transportation

For general guidelines, see section 6.11.

For red cell components, transit containers, packing materials and procedures should have been validated to ensure the component surface temperature can be maintained between 2°C and 10°C during transportation. Additionally:

- the validation exercise should be repeated periodically
- if melting ice is used, it should not come into direct contact with the components
- dead air space in packaging containers should be minimised
- as far as is practicable, transit containers should be equilibrated to their storage temperature prior to filling with components

- for transportation between blood supplier and hospital an upper limit of 10°C surface temperature is acceptable but should be limited to one occasion, not exceeding 12 hours

In some instances, it is necessary to issue red cell components from the blood supplier to hospitals that have not been cooled to their storage temperature prior to placing in the transit container. The transport temperature specified above is not applicable for such consignments.

7.7.4.6: Removal from and return to 2-6°C controlled storage within hospitals

For occasions when red cells are removed from 2-6°C controlled storage (e.g. when issued to a clinical area immediately prior to transfusion) and returned then:

- If possible, time out of a controlled temperature environment should be restricted to under 30 minutes
- if 30 minutes is exceeded the unit should not be returned to the issue location in the refrigerator, but returned to the transfusion laboratory or quarantined remotely using electronic blood tracking
- up to 60 minutes out of controlled temperature is acceptable, provided the unit is then quarantined by placing in a secure refrigerator for at least 6 hours prior to reissue, to allow the unit to return to 2-6°C
- Hospitals will need to identify such units so that they are not subject to being out of controlled temperature storage for between 30 and 60 minutes on more than three occasions.

Transfusion should be completed within 4 hours of issue out of a controlled temperature environment.

7.7.5: Red Cells in Additive Solution for Neonates and Infants, Leucocyte Depleted

A red cell component suitable for top-up or large-volume transfusion of neonates and infants under 1 year containing less than 1×10^6 leucocytes (per starting component). The red cells are suspended in an additive solution and may be divided into approximately equal volumes using a closed system.

7.7.5.1: Technical information

- Section 7.7 provides general guidance on the requirements for components for use in neonates and infants under 1 year.
- The component should be free from clinically significant irregular blood group antibodies including high-titre anti-A and anti-B and should be negative for antibodies to CMV.
- Red Cells in Additive Solution for Neonates and Infants, Leucocyte Depleted should be administered through a CE/UKCA/UKNI marked transfusion set.
- Unless the Blood Centre recommends screening is unnecessary, the donor should be Haemoglobin S screen negative.

7.7.5.2: Labelling

For general guidelines, see section 6.6.

The following shall be included on the label:

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

- Red Cells in Additive Solution for Neonates and Infants, 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 name, composition and volume of the additive solution
- the date of collection
- the expiry date*
- the temperature of storage
- 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

7.7.5.3: Storage

For general guidelines, see section 6.7.

- Red Cells in Additive Solution for Neonates and Infants, Leucocyte Depleted for top-up transfusion of neonates and infants under 1 year may be stored for a maximum of 35 days at a core temperature of 4 ±2°C.

- Variation from the core temperature of 4 ±2°C of the finished component must be kept to a minimum during storage at all stages of the blood supply chain and restricted to any short period necessary for examining, labelling or issuing the component.

- For large-volume transfusion of neonates and infants under 1 year, this component should be transfused within 24 hours of irradiation and before the end of Day 5.

- Exceptionally, i.e. due to equipment failure at a Blood Centre or hospital, for temperature excursions where the core temperature has not exceeded 10°C or fallen below 1°C, components may be released for transfusion provided that:
    - the component has been exposed to such a temperature change on one occasion only
    - the duration of the temperature excursion has not exceeded 5 hours
    - a documented system is available in each Blood Centre or hospital to cover such eventualities
    - adequate records of the incident are compiled and retained.

7.7.5.4: 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), the component shall be free from clinically significant irregular blood group antibodies and high-titre anti-A and/or anti-B, and antibodies to CMV. Furthermore, a minimum of 75% of those components tested for the other parameters shown in Table 7.7.5 shall meet the specified values.

Table 7.7.5 Red Cells in Additive Solution for Neonates and Infants, 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)	280 ±60 mL
Haemoglobin content [1]		>=40 g/unit
Haematocrit [2]		0.50 – 0.70
Haemolysis (only required if produced as a primary component)	As per section 7.1.3	<0.8% of red cell mass
Leucocyte count [3]	As per sections 6.3 and 7.1.1	$<1 \times 10^6$/starting component
[1] Units measured and found to have <30 g/unit prior to splitting (or 30 g/no. of units for split units) should only be issued for transfusion under concessionary release		
[2] Units measured and found to have haematocrit <0.40 or >0.70 should only be issued for transfusion under concessionary release		
[3] Methods validated for counting low numbers of leucocytes must be used		

7.7.5.5: Transportation

For general guidelines, see section 6.11.

For red cell components, transit containers, packing materials and procedures should have been validated to ensure the component surface temperature can be maintained between 2°C and 10°C during transportation. Additionally:

- the validation exercise should be repeated periodically
- if melting ice is used, it should not come into direct contact with the components
- dead air space in packaging containers should be minimised
- as far as is practicable, transit containers should be equilibrated to their storage temperature prior to filling with components
- for transportation between blood supplier and hospital an upper limit of 10°C surface temperature is acceptable but should be limited to one occasion, not exceeding 12 hours

In some instances, it is necessary to issue red cell components from the blood supplier to hospitals that have not been cooled to their storage temperature prior to placing in the transit container. The transport temperature specified above is not applicable for such consignments.

7.7.5.6: Removal from and return to 2-6°C controlled storage within hospitals

For occasions when red cells are removed from 2-6°C controlled storage (e.g. when issued to a clinical area immediately prior to transfusion) and returned then:

- If possible, time out of a controlled temperature environment should be restricted to under 30 minutes
- if 30 minutes is exceeded the unit should not be returned to the issue location in the refrigerator, but returned to the transfusion laboratory or quarantined remotely using electronic blood tracking
- up to 60 minutes out of controlled temperature is acceptable, provided the unit is then quarantined by placing in a secure refrigerator for at least 6 hours prior to reissue, to allow the unit to return to 2-6°C
- Hospitals will need to identify such units so that they are not subject to being out of controlled temperature storage for between 30 and 60 minutes on more than three occasions.

Transfusion should be completed within 4 hours of issue out of a controlled temperature environment.

7.7.6: Platelets for Intrauterine Transfusion, Leucocyte Depleted

A hyperconcentrated platelet component for intrauterine transfusion, prepared by apheresis, that contains less than 1×10^6 leucocytes per donation.

7.7.6.1: Technical information

- Section 7.7 provides general guidance on the requirements for components for intrauterine transfusion and use in neonates and infants under 1 year.
- The component should be free from clinically significant irregular blood group antibodies including high-titre anti-A and anti-B and should be negative for antibodies to CMV.
- The component must be used by the end of Day 1.
- The component must be irradiated. See the BSH ‘Guidelines on transfusion for fetuses, neonates and older children’.[6]
- The component should contain a concentration of platelets between 2 and 4×10^{12}/L in a collected volume generally in the range of 50-100 mL. 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.
- All components should be quality monitored and achieve the specified requirements. The testing need not necessarily be performed before component release.
- Screening of female donors for HLA/HNA antibodies should be considered as a TRALI risk reduction strategy. If platelets are to be issued as HPA-matched (e.g. HPA-1a or HPA-5b negative) then donors should be screened and found negative for all clinically significant HLA and HPA antibodies (as defined in Chapters 16 and 18). This screening can be done on an initial sample and does not need repeating at each donation unless the donor has been transfused or pregnant since the last antibody screen.
- A record which demonstrates that the donor has not been transfused since the initial negative screen for antibodies and in case of female donors that the donor has not been pregnant since the initial negative screen for antibodies needs to be maintained.

- Platelets for Intrauterine Transfusion, Leucocyte Depleted should administered through a CE/UKCA /UKNI marked transfusion set.

7.7.6.2: 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 for Intrauterine Transfusion, Leucocyte Depleted* and volume
- the blood component producer's name*
- the donation number*
- the ABO group*
- the RhD group stated as positive or negative*
- the relevant HPA and HLA type, if necessary
- the date of collection
- the expiry date and time*
- the temperature of storage and a comment that continuous gentle agitation during storage is recommended
- the blood pack lot number*
- the name, composition and volume of the anticoagulant.

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

7.7.6.3: Storage

For general guidelines, see section 6.7.

- The component should be stored at a core temperature of 22 ±2°C for use up to the end of Day 1.
- The component should be gently and continuously agitated during storage.

7.7.6.4: 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 7.7.1), the component shall be free from clinically significant irregular blood group antibodies and high-titre anti-A and/or anti-B and antibodies to CMV. Furthermore, all components tested for the other parameters shown in Table 7.7.6 shall meet the specified values.

Table 7.7.6 Platelets for Intrauterine Transfusion, Leucocyte Depleted – additional tests

Parameter	Frequency of test	Specification
Volume [1]	Every component	Within locally defined range
Platelet concentration		$2 – 4 \times 10^{12}$/L

pH at end of shelf life [2]		>=6.4
Leucocyte count [3,4]	As per sections 6.3 and 7.1.1	$<1 \times 10^6$/unit
[1] Units measured and found to be <50 mL or >120 mL should only be issued for transfusion under concessionary release		
[2] The shelf life of this hyperconcentrated platelet component has been set to reflect validation data. Therefore, once this has been validated locally, there is no need to measure pH at expiry on a routine basis		
[3] Methods validated for counting low numbers of leucocytes must be used		
[4] Units measured and found to have $>=2.5 \times 10^6$/unit should only be issued for transfusion under concessionary release		

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

7.7.6.5: 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°C with continuous gentle agitation.
- Plastic overwraps should be removed prior to storage.

7.7.7: Platelets for Neonatal Use, Leucocyte Depleted

An apheresis platelet component for neonatal use that contains less than 1×10^6 leucocytes per starting component.

7.7.7.1: Technical information

- Section 7.7 provides general guidance on the requirements for components for use in neonates and infants under 1 year.
- The component should be free from clinically significant irregular blood group antibodies including high-titre anti-A and anti-B and should be negative for antibodies to CMV.
- The component may be prepared by splitting Platelets, Apheresis, Leucocyte Depleted (see section 7.4.2) using a closed system.
- The component should contain $>40 \times 10^9$ platelets in sufficient plasma to maintain the pH at >=6.4 at the end of the shelf life of the component.

- The component may be leucodepleted as part of an apheresis process or by subsequent filtration of the platelet component.

- Screening of female donors for HLA/HNA antibodies should be considered as a TRALI risk reduction strategy. If platelets are to be issued as HPA-matched (e.g. HPA-1a or HPA-5b negative) then donors should be screened and found negative for all clinically significant HLA and HPA antibodies (as defined in Chapters 16 and 18). This screening can be done on an initial sample and does not need repeating at each donation unless the donor has been transfused or pregnant since the last antibody screen.

- A record which demonstrates that the donor has not been transfused since the initial negative screen for antibodies and in the case of female donors that the donor has not been pregnant since the initial negative screen for antibodies needs to be maintained.

- Platelets for Neonatal Use, Leucocyte Depleted should administered through a CE/UKCA/UKNI marked transfusion set.

7.7.7.2: 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 for Neonatal Use, 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 date of collection
- 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

7.7.7.3: Storage

For general guidelines, see section 6.7.

- The component should be stored at a core temperature of 22 ±2°C for up to 5 days. 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 inactivation procedure.

- Platelets should be 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 the interruption is for no longer than a total of 24 hours.

7.7.7.4: 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), the component shall be free from clinically significant irregular blood group antibodies and high-titre anti-A and/or anti-B, and antibodies to CMV. Furthermore, a minimum of 75% of those components tested for the other parameters shown in Table 7.7.7 shall meet the specified values.

Table 7.7.7 Platelets for Neonatal Use, 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 range
Platelet count [2]		>=40 × 10^9/unit
pH at end of shelf life [3,4]		>=6.4
Leucocyte count [5]	As per sections 6.3 and 7.1.1	<1 × 10^6/starting component
[1] Units measured and found to be <30 mL or >95 mL should only be issued for transfusion under concessionary release		
[2] Units measured and found to have <40 × 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] If producing low numbers, use of most units is likely to make testing of outdated units impossible. In this situation periodic checks to ensure end-of-shelf-life quality should be undertaken with the combination of blood pack platelet concentration and storage conditions in routine use.		
[4] A minimum of 90% of components tested shall meet the specified value		
[5] 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.

7.7.7.5: 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°C with continuous gentle agitation.

- Plastic overwraps should be removed prior to storage.

7.7.8: Platelets in Plasma and Additive Solution for Neonatal Use, Leucocyte Depleted

An apheresis platelet component for neonatal use which contains less than 1×10^6 leucocytes per starting component and where the suspending medium comprises approximately 80% plasma and 20% additive solution.

7.7.8.1: Technical information

- Section 7.7 provides general guidance on the requirements for components for use in neonates and infants under 1 year.
- The component should be free from clinically significant irregular blood group antibodies including high-titre anti-A and anti-B and should be negative for antibodies to CMV.
- The component is manufactured as a secondary component by splitting Platelets, Apheresis, Leucocyte Depleted (see section 7.4.2) after the sterile addition of a controlled volume of an approved platelet additive solution. Splitting must be performed using a closed system.
- The volume of additive solution added 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 / PAS must be performed at least annually on a minimum of 25 units and after any changes to production method.
- The volume of additive solution should be sufficient to maintain the pH >=6.4 at the end of the shelf life of the component.
- The component should contain $>=40 \times 10^9$ platelets.
- The component may be leucodepleted as part of an apheresis process or by subsequent filtration of the platelet component.
- Screening of female donors for HLA/HNA antibodies should be considered as a TRALI risk reduction strategy. If platelets are to be issued as HPA-matched (e.g. HPA-1a or HPA-5b negative) then donors should be screened and found negative for all clinically significant HLA and HPA antibodies (as defined in Chapters 16 and 18). This screening can be done on an initial sample and does not need repeating at each donation unless the donor has been transfused or pregnant since the last antibody screen.
- A record which demonstrates that the donor has not been transfused since the initial negative screen for antibodies and in the case of female donors that the donor has not been pregnant since the initial negative screen for antibodies needs to be maintained.
- Platelets in Plasma and Additive Solution for Neonatal Use, Leucocyte Depleted should be administered through a CE/UKCA/UKNI marked transfusion set.

7.7.8.2: 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 Plasma and Additive Solution for Neonatal Use 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 date of collection
- 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 of the anticoagulant and 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

7.7.8.3: Storage

For general guidelines, see section 6.7.

- The component should be stored at a core temperature of 22 ±2°C for up to 5 days. 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 inactivation procedure.

- Platelets should be 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 the interruption is for no longer than a total of 24 hours and no single interruption lasts for more than eight hours.

7.7.8.4: 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), the component shall be free from clinically significant irregular blood group antibodies and high-titre anti-A and/or anti-B, and antibodies to CMV.

Furthermore, a minimum of 75% of those components tested for the other parameters shown in Table 7.7.8 shall meet the specified values.

Table 7.7.8 Platelets in Plasma and Additive Solution for Neonatal Use, 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	Within locally defined range

Platelet count [1]	available component)	>=40 × 10^9/unit
pH at end of shelf life [2,3]		>=6.4
Leucocyte count [4]	As per sections 6.3 and 7.1.1	<1 × 10^6/starting component
[1] Units measured and found to have <40 × 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		
[2] If producing low numbers, issue of most units is likely to make testing of outdated units impossible. In this situation periodic checks to ensure end-of-shelf-life quality should be undertaken with the combination of blood pack platelet concentration and storage conditions in routine use.		
[3] A minimum of 90% of components tested shall meet the specified value		
[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.

7.7.8.5: 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°C with continuous gentle agitation.
- Plastic overwraps should be removed prior to storage.

7.7.9: Fresh Frozen Plasma for Neonates and Infants, Leucocyte Depleted

Fresh Frozen Plasma for Neonates and Infants, Leucocyte Depleted is plasma that has been obtained from whole blood or by apheresis. The plasma contains less than 1 × 10^6 leucocytes per component.

Using a closed system the component may be subdivided into approximately equal volumes and rapidly frozen to a temperature that will maintain the activity of labile coagulation factors.

7.7.9.1: Technical information

- Section 7.7 provides general guidance on the requirements for components for use in neonates and infants under 1 year.
- Donations of whole blood where the bleed time exceeded 15 minutes are not suitable for the production of plasma components for direct clinical use.

- The component should be free from clinically significant irregular blood group antibodies including high-titre anti-A and anti-B. Testing for CMV antibodies is not required.

- Plasma should be selected from male donors or consideration should be given to screening female donors for HLA/HNA antibodies, as a TRALI risk reduction measure.

- The plasma should be separated before the red cell component is cooled to its storage temperature. Greater FVIII yields will be obtained when the plasma is separated as soon as possible after venepuncture and rapidly frozen to -25°C or below.

- The method of preparation should ensure the component has the maximum level of labile coagulation factors with minimum cellular contamination. The production process should be validated to ensure that components meet the specified limits for FVIII concentration.

- Component samples collected for the quality monitoring assessment of FVIII should be from an equal mix of group O and non-O donations due to the difference in FVIII levels between ABO blood groups.

- Fresh Frozen Plasma for Neonates and Infants, Leucocyte Depleted should be transfused through a CE/UKCA/UKNI marked transfusion set.

7.7.9.2: Labelling

For general guidelines, see section 6.6

The following shall be included on the label:

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

- Fresh Frozen Plasma for Neonates and Infants, Leucocyte Depleted* and volume
- the blood component producer’s name*
- the donation number*
- the ABO group*
- the RhD group stated as positive or negative*
- the date of collection
- the expiry date of the frozen component*
- the temperature of storage
- the blood pack lot number*
- a warning that the component should be used within 4 hours of thawing if maintained at 22 ±2oC or up to a maximum of 24 hours of thawing if stored at 4 ±2°C
- the name, composition and volume of the anticoagulant.

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

7.7.9.3: Storage

For general guidelines, see section 6.7.

- The component should be stored at a core temperature of –25°C or below for a maximum of 36 months.
- Although a storage temperature below –25°C improves the preservation of labile coagulation factors, lower temperatures increase the fragility of plastic. Particular care must be taken when handling such packs.
- The component should be thawed in a waterbath or other equipment designed for the purpose, within a vacuumsealed overwrap bag according to a validated procedure. The optimal temperature at which the component should be thawed is 37°C; temperatures between 33°C and 37°C are acceptable.
- Protocols must be in place to ensure that the equipment is regularly cleaned and maintained to minimise the risk of bacterial contamination. After thawing, and at the time of administration, the content should be inspected to ensure that no insoluble precipitate is visible and that the container is intact.
- Once thawed, the component must not be refrozen and should be transfused as soon as possible. If delay is unavoidable, the component may be stored and should be used within 4 hours if maintained at 22 ±2°C, or up to a maximum of 24 hours if stored at 4 ±2°C.
- Transfusion of FFP should be completed within 4 hours of issue out of a controlled temperature environment.

7.7.9.4: 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), the component shall be free from clinically significant irregular blood group antibodies and high-titre anti-A and/or anti-B. Furthermore, a minimum of 75% of those components tested for the other parameters shown in Table 7.7.9 shall meet the specified values with the exception of FVIII.

Table 7.7.9 Fresh Frozen Plasma for Neonates and Infants, 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)	Stated volume ±10%
Total protein		>=50 g/L
Platelet count [1,2]		<30 × 10^9/L
Red cell count [2]		<6 × 10^9/L
FVIII [3,4]		Mean >=0.70 IU /mL
Leucocyte count [2,5]	As per sections 6.3 and 7.1.1	<1 × 10^6/unit
[1] Units with a residual platelet count >100 × 10^9/L should only be issued for transfusion under concessionary release		
[2] Pre-freeze in starting component		
[3] Units measured and found to have <0.30 IU/mL should only be issued for transfusion under concessionary		

release
[4] A minimum of 90% of those components tested should have >=0.50 IU/mL
[5] Methods validated for counting low numbers of leucocytes must be used

7.7.9.5: Transportation

For general guidelines, see section 6.11.

Every effort should be made to maintain the core storage temperature during transportation. Unless the component is to be thawed and used straightaway it should be transferred immediately to storage at the recommended temperature.

7.7.10: Fresh Frozen Plasma for Neonates and Infants, Pathogen Reduced, Leucocyte Depleted

This component is plasma that has been obtained from whole blood or by apheresis, contains less than 1×10^6 leucocytes and has been treated with a pathogen inactivation (PI) system. The PI system must be approved (CE/UKCA/UKNI marked) for this use, and must have been validated by the Blood Service.

Following PI treatment, using a closed system the component may be subdivided into approximately equal volumes. The treated component is rapidly frozen to a temperature that will maintain the activity of labile coagulation factors.

7.7.10.1: Technical information

- Section 7.7 provides guidance on the requirements for components for use in neonates and infants under 1 year.
- Donations of whole blood where the bleed time exceeded 15 minutes are not suitable for the production of plasma components for direct clinical use.
- Fresh Frozen Plasma for Neonates and Infants, Pathogen Reduced, Leucocyte Depleted, may be prepared from small pools of up to 12 individual donations if validated and risk-assessed by the blood service and if in accordance with the specifications of the manufacturer of the PI system.
- The component should be free from clinically significant irregular blood group antibodies including high-titre anti-A and anti-B. Testing for CMV antibodies is not required.
- Plasma should be selected from male donors or consideration should be given to screening female donors for HLA/HNA antibodies, as a TRALI risk reduction measure.
- The plasma should be separated before the red cell component is cooled to its storage temperature. Greater FVIII yields will be obtained when the plasma is separated as soon as possible after venepuncture and rapidly frozen to –25°C or below.
- The method of preparation should ensure the component has the maximum level of labile coagulation factors with minimum cellular contamination. The production process should be validated

to ensure that components meet the specified limits for FVIII concentration.

- It contains, on average, greater than 60% of the labile coagulation factors and naturally occurring inhibitors present in standard fresh frozen plasma.
- The PI system typically reduces the risk of infection from enveloped viruses (e.g. HBV, HCV, HIV) by at least one thousand-fold.
- Component samples collected for the quality monitoring assessment of FVIII should be from an equal mix of group O and non-O donations due to the difference in FVIII levels between ABO blood groups.
- The level of removal of the photo-sensitising agent prior to final storage should be validated, if such a step is included in the PI system.
- Intact white blood cells in the plasma should be reduced to less than 1×10^6 per unit prior to the PI process.
- Fresh Frozen Plasma for Neonates and Infants, Pathogen Reduced, Leucocyte Depleted should be administered through a CE/UKCA/UKNI marked transfusion set.

7.7.10.2: Labelling

For general guidelines, see section 6.6.

The following shall be included on the label:

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

- Fresh Frozen Plasma for Neonates and Infants, Pathogen Reduced, Leucocyte Depleted * and volume
- the name of the PI system used
- the blood component producer’s name*
- the donation number*
- the ABO group*
- the RhD group stated as positive or negative*
- the date of collection
- the expiry date of the frozen component*
- the temperature of storage
- the blood pack lot number*
- a warning that the component should be used within 4 hours of thawing
- the name, composition and volume of the anticoagulant.

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 and allergy
to the compounds used for, or derived from, PI treatment

7.7.10.3: Storage

For general guidelines, see section 6.7.

- The component should be stored at a core temperature of –25°C or below for a maximum of 36 months.
- Although a storage temperature below –25°C improves the preservation of labile coagulation factors, lower temperatures increase the fragility of plastic. Particular care must be taken when handling such packs.
- The component should be thawed in a waterbath or other equipment designed for the purpose, within a vacuumsealed overwrap bag according to a validated procedure. The optimal temperature at which the component should be thawed is 37°C; temperatures between 33°C and 37°C are acceptable.
- Protocols must be in place to ensure that the equipment is regularly cleaned and maintained to minimise the risk of bacterial contamination. After thawing, the content should be inspected to ensure that no insoluble precipitate is visible and that the container is intact.
- Once thawed, the component must not be refrozen and should be transfused as soon as possible. If delay is unavoidable, the component may be stored and should be used within 4 hours if maintained at 22 ±2°C or 24 hours if stored at 4 ±2°C, but it should be borne in mind that extended post-thaw storage will result in a decline in the content of labile coagulation factors.

7.7.10.4: 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), the component shall be free from clinically significant irregular blood group antibodies and high-titre anti-A and/or anti-B. Furthermore, a minimum of 75% of those components tested for the other parameters shown in Table 7.7.10 shall meet the specified values.

Table 7.7.10 Fresh Frozen Plasma for Neonates and Infants, Pathogen Reduced, 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 and within any limits specified for the PI process used
Platelet count [1,2]		$<30 \times 10^9$/L
FVIII		>=0.50 IU/mL
Leucocyte count [2,3]	As per sections 6.3 and 7.1.1	$<1 \times 10^6$/unit
[1] Units with residual platelet count $>100 \times 10^9$/L should only be issued for transfusion under concessionary release		
[2] Pre-freeze in starting component		
[3] Methods validated for counting low numbers of leucocytes must be used		

7.7.10.5: Transportation

For general guidelines, see section 6.11.

Every effort should be made to maintain the core storage temperature during transportation. Unless the component is to be thawed and used straightaway it should be transferred immediately to storage at the recommended temperature.

7.7.11: Cryoprecipitate for Neonates and Infants, Leucocyte Depleted

The component represents a source of concentrated FVIII, and von Willebrand factor, fibrinogen, FXIII and fibronectin from a unit of fresh frozen plasma. The plasma from which the cryoprecipitate was produced contains less than 1×10^6 leucocytes per component.

7.7.11.1: Technical information

- Section 7.7 provides general guidance on the requirements for components for use in neonates and infants under 1 year.
- Donations of whole blood where the bleed time exceeded 15 minutes are not suitable for the production of plasma components for direct clinical use.
- Cryoprecipitate for Neonates and Infants, Leucocyte Depleted is the cryoglobulin fraction of plasma obtained by thawing a single donation of Fresh Frozen Plasma, Leucocyte Depleted (see section 7.5.1), fulfilling the requirements for neonates and infants, at 4 ±2°C.
- The component should be free from clinically significant irregular blood group antibodies including high-titre anti-A and anti-B. Testing for CMV antibodies is not required.
- Plasma should be selected from male donors or consideration should be given to screening female donors for HLA/HNA antibodies, as a TRALI risk reduction measure.
- For storage, Cryoprecipitate for Neonates and Infants, Leucocyte Depleted should be rapidly frozen to a core temperature of –25°C or below within 2 hours of preparation.
- Component samples collected for the quality monitoring assessment of FVIII should be from an equal mix of group O and non-O donations due to the difference in FVIII levels between ABO blood groups.
- Cryoprecipitate for Neonates and Infants, Leucocyte Depleted should be administered through a CE /UKCA/UKNI marked transfusion set.

7.7.11.2: Labelling

For general guidelines, see section 6.6.

The following shall be included on the component label:

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

- Cryoprecipitate for Neonates and Infants, Leucocyte Depleted* and volume
- the blood component producer’s name*

- the donation number*
- the ABO group*
- the RhD group stated as positive or negative*
- the date of collection
- the expiry date of the frozen component*
- the temperature of storage
- the blood pack lot number*
- a warning that the component must be used within 4 hours of thawing
- the name, composition and volume of the anticoagulant.

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

7.7.11.3: Storage

For general guidelines, see section 6.7.

- The component should be stored at a core temperature of –25°C or below for a maximum of 36 months.

- Although a storage temperature below –25°C improves the preservation of labile coagulation factors, lower temperatures increase the fragility of plastic. Particular care must be taken when handling such packs.

- The component should be thawed in a waterbath or other equipment designed for the purpose, within a vacuum-sealed overwrap bag according to a validated procedure. The optimal temperature at which the component should be thawed is 37°C; temperatures between 33°C and 37°C are acceptable.

- Protocols must be in place to ensure that the equipment is regularly cleaned and maintained to minimise the risk of bacterial contamination. After thawing, the content should be inspected to ensure that no insoluble precipitate is visible and that the container is intact.

- Once thawed, the component must not be refrozen and should be used immediately. If delay is unavoidable, the component should be stored at ambient temperature and used within 4 hours.

7.7.11.4: 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 7.7.11 shall meet the specified values.

Table 7.7.11 Cryoprecipitate for Neonates and Infants, 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 range

Fibrinogen		>=140 mg/unit
FVIII		>=70 IU/unit
Leucocyte count [1,2]	As per sections 6.3 and 7.1.1	$<1 \times 10^6$/unit
[1] Methods validated for counting low numbers of leucocytes must be used		
[2] Pre-freeze in starting component		

7.7.11.5: Transportation

For general guidelines, see section 6.11.

Every effort should be made to maintain the core storage temperature during transportation. Unless the component is to be thawed and used straightaway it should be transferred immediately to storage at the recommended temperature.

7.7.12: Cryoprecipitate for Neonates and Infants, Pathogen Reduced, Leucocyte Depleted

The component provides a source of concentrated FVIII, and von Willebrand factor, fibrinogen, FXIII and fibronectin. It is derived from a unit of Fresh Frozen Plasma for Neonates and Infants, Pathogen Reduced, Leucocyte Depleted. The plasma from which this component is produced contains less than 1×10^6 leucocytes per component.

7.7.12.1: Technical information

- Section 7.7 provides general guidance on the requirements for components for use in neonates and infants under 1 year.
- Donations of whole blood where the bleed time exceeded 15 minutes are not suitable for the production of plasma components for direct clinical use.
- Cryoprecipitate for Neonates and Infants, Pathogen Reduced, Leucocyte Depleted is the cryoglobulin fraction of plasma obtained by thawing a single donation of Fresh Frozen Plasma, Neonatal Use, Methylene Blue Treated and Removed, Leucocyte Depleted (see section 7.7.10) at 4 ±2°C.
- The component should be free from clinically significant irregular blood group antibodies including high-titre antiA and anti-B. Testing for CMV antibodies is not required.
- Plasma should be selected from male donors or screening of female donors for HLA/HNA antibodies should be considered, as a TRALI risk reduction strategy.
- For storage, Cryoprecipitate for Neonates and Infants, Pathogen Reduced, Leucocyte Depleted should be rapidly frozen to a core temperature of –25°C or below within 2 hours of preparation.

- Component samples collected for the quality monitoring assessment of FVIII should be from an equal mix of group O and non-O donations due to the difference in FVIII levels between ABO blood groups.

- Cryoprecipitate for Neonates and Infants, Pathogen Reduced, Leucocyte Depleted should be administered through a CE/UKCA/UKNI marked transfusion set.

7.7.12.2: Labelling

For general guidelines, see section 6.6.

The following shall be included on the component label:

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

- Cryoprecipitate for Neonates and Infants, Pathogen Reduced, Leucocyte Depleted* and volume
- the name of the pathogen inactivation (PI) system used
- the blood component producer's name*
- the donation number*
- the ABO group*
- the RhD group stated as positive or negative*
- the date of collection
- the expiry date of the frozen component*
- the temperature of storage
- the blood pack lot number*
- a warning that the component must be used within 4 hours of thawing
- 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 and allergy
to the compounds used for, or derived from, PI treatment

7.7.12.3: Storage

For general guidelines, see section 6.7.

- The component should be stored at a core temperature of –25°C or below for a maximum of 36 months.

- Although a storage temperature below –25°C improves the preservation of labile coagulation factors, lower temperatures increase the fragility of plastic. Particular care must be taken when handling such packs.

- The component should be thawed in a waterbath or other equipment designed for the purpose, within a vacuumsealed overwrap bag according to a validated procedure. The optimal temperature at which the component should be thawed is 37°C; temperatures between 33°C and 37°C are acceptable.

- Protocols must be in place to ensure that the equipment is regularly cleaned and maintained to minimise the risk of bacterial contamination. After thawing, the content should be inspected to

ensure that no insoluble precipitate is visible and that the container is intact.

- Once thawed, the component must not be refrozen and should be used immediately. If delay is unavoidable, the component should be stored at ambient temperature and used within 4 hours.

7.7.12.4: 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 7.7.12 shall meet the specified values.

Table 7.7.12 Cryoprecipitate for Neonates and Infants, Pathogen Reduced, 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 range
Fibrinogen		>=140 mg/unit
FVIII		>=50 IU/unit
Leucocyte count [1,2]	As per sections 6.3 and 7.1.1	$<1 \times 10^6$/unit
[1] Methods validated for counting low numbers of leucocytes must be used		
[2] Pre-freeze in starting component		

7.7.12.5: Transportation

For general guidelines, see section 6.11.

Every effort should be made to maintain the core storage temperature during transportation. Unless the component is to be thawed and used straightaway it should be transferred immediately to storage at the recommended temperature.