Issued by JPAC: 24 February 2022	**Implementation:** To be determined by each Service

Change Notification UK National Blood Services No. 12 - 2022

Provisional Component: Cryoprecipitate Pooled, Leucocyte Depleted, Extended Shelf-Life Post-thaw

This change applies to the Guidelines for the Blood Transfusion Services in the United Kingdom 8th Edition 2013

New Specification

A3.9: Cryoprecipitate Pooled, Leucocyte Depleted, Extended Shelf-life Post-thaw

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

A3.9.1: Technical information

- 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 Pooled, Leucocyte Depleted, Extended Shelf-life Post-thaw is the cryoglobulin fraction of plasma obtained by thawing and pooling five single cryoprecipitate components or pooling five single cryoprecipitate components immediately after production from thawed fresh frozen plasma.
- 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 Pooled, Leucocyte Depleted, Extended Shelf-life Post-thaw 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:C should be from an equal mix of group O and non-O donations due to the difference in FVIII levels between ABO blood groups.
- Initial process validation must ensure that for a minimum of 20 tested Cryoprecipitate Pooled, Leucocyte Depleted, Extended Shelf-life Post-thaw components a minimum of 75% of those components tested for the parameters shown in Table A3.9 shall meet the specified values.

\Continued

Joint UKBTS Professional Advisory Committee (JPAC)
JPAC Office
Email: caroline.smith@nhsbt.nhs.uk
Mobile: +44 (0) 771 144 7302

- Annual process validation is acceptable for quality monitoring purposes, provided that the primary components, Fresh Frozen Plasma, Leucocyte Depleted and/or Cryoprecipitate, Leucocyte Depleted, Extended Shelf-life Post-thaw are separately monitored as part of monthly testing. If this is not the case, test monthly 1% or as determined by statistical process control (if ≤10 components produced per month then test every available component), of Cryoprecipitate Pooled, Leucocyte Depleted, Extended Shelf-life Post-thaw components. A minimum of 75% of those components tested for the parameters shown in Table 7.15 shall meet the specified values.

- 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.

- Cryoprecipitate Pooled, Leucocyte Depleted, Extended Shelf-life Post-thaw should be transfused through a CE/UKCA marked transfusion set.

A3.9.2: 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 Pooled, Leucocyte Depleted, Extended Shelf-life Post-thaw* and volume
- the blood component producer's name*
- a unique pool or batch number or the donation number of all contributing units*
- 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 if maintained at 22 ±2°C, or up to a maximum of 120 hours of thawing if stored at 4 ±2°C
- the name, composition and volume of 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

\Continued

A3.9.3: 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 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 cleaned daily and maintained to minimise the risk of bacterial contamination. After thawing, the content should be inspected to ensure that no insoluble cryoprecipitate 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 should either be used or returned to 4 ± 2°C within a maximum of 4 hours if maintained below 24°C. Extended Shelf-life Post-thaw cryoprecipitate may be stored up to 120 hours at 4 ± 2°C following thawing. Following storage at 4 ± 2°C, Extended Shelf-life Post-thaw cryoprecipitate must be briefly warmed using a plasma thawing device at 33-37°C until any precipitate has gone back into solution (through visual inspection). This should occur in the majority of units within 5 minutes, and should not exceed 20 minutes. Once re-warmed, Extended Shelf-life Post-thaw cryoprecipitate should not be placed back in the refrigerator.
- Transfusion of Extended Shelf-life Post-thaw cryoprecipitate should be completed within 4 hours of issue out of a controlled temperature environment unless it fulfils the criteria to be returned to storage at 4 ± 2°C and if this occurs on one occasion only.

A3.9.4: Testing

In addition to the mandatory and other tests required for blood donations described in Chapter 4, and leucocyte counting (see sections 6.3 and 7.1), a minimum of 75% of those components tested for the parameters shown at Table A3.9 shall meet the specified values.

\Continued

Table A3.9 Cryoprecipitate Pooled, Leucocyte Depleted, Extended Shelf-life Post-thaw – 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)	100–250 mL
Fibrinogen	Refer to Technical information (section 17.18.1) above	≥700 mg/unit
FVIII:C		≥350 IU/unit
Leucocyte count	As per sections 6.3 and 7.1	<1 × 10^6/unit* in the starting component
* Pre-freeze methods validated for counting low numbers of leucocytes must be used		

A3.9.5: 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.

Dr Sheila MacLennan
Professional Director - Joint UKBTS Professional Advisory Committee
✉ sheila.maclennan@nhsbt.nhs.uk