

Date of publication: 06 April 2017

Implementation: To be determined by each Service

Change Notification UK National Blood Services No. 10 - 2017

Chapter 7 – Sections 7.3, 7.15, 7.17 and 7.18

Applies to the Guidelines for the Blood Transfusion Services in the United Kingdom – 8th Edition 2013

Following a review of current data on residual viral risk from new and repeat blood donors in the UK, the requirement to only produce plasma components from repeat donors has been removed. Therefore the following changes have been made to section 7.3, 7.15, 7.17 and 7.18.

Section 7.3 Production advice

Replace

Unless a validated pathogen inactivation process is used, blood components for use in intrauterine transfusion, neonates and infants (see also section 7.21), and plasma components for direct clinical use must be derived from selected 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 (on reinstatement of blood donors).

Negative results were obtained for mandatory microbiology markers with the current donation.

With

Unless a validated pathogen inactivation process is used, blood components for use in intrauterine transfusion and neonates and infants (see also section 7.21), ~~and plasma components for direct clinical use~~ must be derived from selected 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 (on reinstatement of blood donors).

Negative results were obtained for mandatory microbiology markers with the current donation.

\Continued

Section 7.15 Fresh Frozen Plasma leucocyte depleted

Change

'Plasma that has been obtained from whole blood or by apheresis from a previously tested donor'

To

'Plasma that has been obtained from whole blood or by apheresis.'

Section 7.17 Cryoprecipitate, leucocyte depleted

Change

The component represents a source of concentrated FVIII:C, 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 and is derived from a previously tested donor (as defined in section 7.3).

To

The component represents a source of concentrated FVIII:C, 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.

7.18: Cryoprecipitate Pooled, Leucocyte Depleted

Change

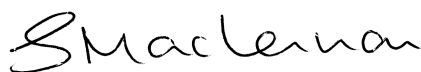
The pooled component represents a source of concentrated FVIII:C, von Willebrand factor, fibrinogen, FXIII and fibronectin from primary cryoprecipitate components derived from units of fresh frozen plasma. The plasma from which the cryoprecipitate was produced was derived from a previously tested donor (as defined in section 7.3) and contains less than 1×10^6 leucocytes per primary component.

To

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.

Further information

The supporting paper, JPAC 17-10 Amended – Use of plasma from first time donors, leading to this Change Notification can be found in the Document Library/Supporting Papers of the JPAC website: <http://www.transfusionguidelines.org.uk/Index.aspx?Publication=DL&Section=12&pageid=7528>



Dr Sheila MacLennan
Professional Director - Joint UKBTS Professional Advisory Committee
 Direct Dial: (0113) 820 8638  sheila.maclennan@nhsbt.nhs.uk