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| **Issued by JPAC:** 02 March 2022 | **Implementation:** To be determined by each Service |

## Change Notification UK National Blood Services No. 10 - 2022

# Convalescent Plasma (VCOV-19), FFP, leucocyte depleted

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

**The specification for COVID-19 Convalescent Plasma has changed.**

**Please move:**

**Provisional components**

- **A3.7 (Convalescent Plasma (COVID-19), FFP, leucocyte depleted) and**
- **A3.8 (Convalescent Plasma (COVID-19), FFP, for neonates and infants, leucocyte depleted)**

**to Annex 4, Redundant Components.**

**These will be replaced by this new specification. The trial in which this component will be used currently includes only adult participants.**

## New Specification

## A3.10 Convalescent Plasma (VCOV-19), FFP, Leucocyte Depleted

Plasma that has been obtained by apheresis from vaccinated donors who have very high titre antibodies (Roche Elisa of at least 20,000 units/ml or equivalent), for the treatment of patients with COVID-19. The plasma contains less than $1 \times 10^6$ leucocytes per component and has been rapidly frozen to a temperature that will maintain the activity of labile coagulation factors.

## *A3.10.1: Technical information*

- Plasma can be selected from male or female donors. Female donors must be screened and negative for HLA/HNA antibodies, as a TRALI risk reduction measure. Plasma should only be selected as CP for treatment of patients with COVID-19 if it is validated to contain a minimum

concentration of SARS-CoV-2 antibody levels according to national clinical guidelines.

- Greater FVIII yields will be obtained when the plasma is rapidly frozen to –25°C or below.
- The method of preparation should be validated to ensure there is no evidence of significant activation at 24 hours shelf life, with minimum cellular contamination. The production process should be validated to ensure that components meet the specified limits for FVIII concentration. If plasma collected for CP were to be re-manufactured for any other purpose these procedures must be fully validated and in accordance with the specification of the alternative component.
- 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.
- Convalescent Plasma (VCOV-19), FFP, Leucocyte Depleted should be administered through a CE/UKCA marked transfusion set.

## *A3.10.2: Labelling*

For general guidelines, see section 6.6.

The following shall be included on the label:

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

- Convalescent Plasma (VCOV-19), FFP, 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 of the frozen component*
- the temperature of storage

- the blood pack lot number*
- a warning that the component must be used within four hours of thawing if maintained at 22 ±2°C, 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

## *A3.10.3: 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 water bath 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, and at the time of administration, 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 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 Convalescent Plasma (VCOV-19), FFP, Leucocyte Depleted should be completed within 4 hours of issue out of a controlled temperature environment.

## *A3.10.4: 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 and Table A3.10), a minimum of 75% of those components tested for the parameters shown in Table A3.10 shall meet the specified values with the exception of FVIII:C.

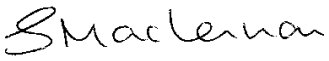
**Table A3.10 Convalescent Plasma (VCOV-19), FFP, Leucocyte Depleted – additional tests**

| 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 | | <30 × $10^9$/L***/****** |
| Red cell count | | <6 × $10^9$/L*** |
| FVIII****/***** | | Mean ≥0.70 IU/mL |
| Leucocyte count* | As per sections 6.3 and 7.1 (but see ** below for leucocyte count) | <1 × $10^6$/unit**/*** |
| * Methods validated for counting low numbers of leucocytes must be used | | |
| ** 90% units should have less than 1 × $10^6$ leucocytes and more than 99% of units should contain less than 5 × $10^6$ leucocytes, both with 95% confidence | | |
| *** Pre-freeze in starting component | | |
| **** Units tested and found to have < 0.3 IU/mL should not be issued for transfusion | | |
| ***** A minimum of 90% of those components tested should have ≥0.50 IU/mL | | |
| ****** Units tested and found to have a platelet count >100 × $10^9$/L should not be issued for transfusion | | |

## *A3.10.5: 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.



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