COMPONENT STANDARD

THERAPEUTIC CELLS APHERESIS

REASON FOR ISSUE: New specification

1. Component Name

Therapeutic Cells - Apheresis

2. Component Description

A suspension of leucocytes, red cells and platelets in plasma, prepared by apheresis using a suitable apheresis machine with retention of a defined set of Therapeutic Cells as the major cellular component. These cells will not be subjected to modifications other than normal processing and cryopreservation. Therapeutic Cells Apheresis will normally be collected from designated donors. The cellular content of the product will be defined in advance of the procedure based on anticipated patient requirements.

3. Quality Specifications

Volume:	As locally defined
Cell count	Count based on patient requirement
CMV Status:	On demand
Irradiation	Not to be irradiated

4. Donor Specifications

Meets the requirements of the current edition of the Collection Standards.

5. Testing

100 % of all components tested must meet the criteria for volume and Therapeutic Cell count.

Tests	**Frequency**
Volume	All units
Mononuclear Cells	All units
Cell type (phenotype)	When required clinically

6. Storage and Expiry

Therapeutic Cells Apheresis should be used as soon as possible after their preparation. Normally If storage is unavoidable it should be stored at a temperature of 22°C ± 2°C irrespective of the method of preparation. The storage period must not exceed 24 hours. Do not agitate during storage.

Therapeutic Cells Apheresis may be stored in a frozen state using DMSO as a cryoprotectant. The product will be stored at or below -150 degrees Celsius.

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7. Transport

Transport temperature of this component must be kept as close as possible to the recommended storage temperature and the system must be validated to ensure the transport temperature does not vary significantly from the recommended temperatures.

8. Labelling

The label should include:

- Name of the component
- Volume
- Name of the collection centre*
- Donation number*
- ABO group*
- Rh(D) group stated as positive or negative*
- Date of collection
- Date of expiry*
- The storage temperature
- A statement – “Do not agitate during storage”
- Blood pack lot number*

(* eye readable and barcode format)

In addition the following instructions are included:

- Check the identity of the recipient and the component
- Inspect the pack for deterioration or damage
- Risk of adverse reaction/infection