



DukeMedicine
Division of Cellular Therapy



ADULT AND PEDIATRIC BLOOD AND MARROW TRANSPLANT PROGRAM

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Assessment of Apheresis Collection Facility Parameters

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ASSESSMENT OF APHERESIS COLLECTION FACILITY PARAMETERS

Apheresis Collection Facility: _____

Date(s) Performed: _____

Following a review of the parameters for the area, the document should be signed by the area Medical/Program Director, Department Manager/Supervisor, and a member from Quality.

Parameter	Assessment
Contamination	<ul style="list-style-type: none"> • Closed system utilized for apheresis collection
Cross-contamination	<ul style="list-style-type: none"> • Closed system utilized for apheresis collection • Cleaning Apheresis Procedure <ul style="list-style-type: none"> ○ Hand Hygiene ○ Isolation Procedures ○ Waste management • Individual bays for apheresis collections • Fresh linens after each patient • Cleaning of all instruments after each patient
Temperature, humidity	<ul style="list-style-type: none"> • Controlled by the institutions building maintenance system throughout the hospital • Indicator is in place to display the temperature and humidity of room • Temperature and humidity is documented on day collection room is used by pediatric apheresis • Temperature and humidity is documented daily for the adult apheresis collection and storage room
Surface Contaminants	<ul style="list-style-type: none"> • Cleaning Apheresis procedure • Environmental Services staff clean the floors daily
Air Quality	<ul style="list-style-type: none"> • No laws or regulations require specific air quality classification when collections are performed using closed systems and therefore no particle counts or microbial colony counts are taken

These critical apheresis collection facility parameters, which could affect product viability, integrity, contamination, sterility, and cross-contamination during collection, have been assessed for risk to the cellular therapy product. It has been determined that the in place parameters are appropriate and adequate to ensure the product quality and prevent the contamination or cross-contamination of products being collected in the Apheresis area.

Reviewer Name	Job Title	Signature	Date

Signature Manifest**Document Number:** APBMT-GEN-003 JA1**Revision:** 01**Title:** Assessment of Apheresis Collection Facility Parameters

All dates and times are in Eastern Time.

APBMT-GEN-003 JA1 Assessment of Apheresis Collection Facility Parameters**Author**

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Document Release

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