

 CONTROLLED AND CONFIDENTIAL	Category: Operations (OPS) Standard Operating Procedures, 700 – Apheresis Operations Title: GEN117-01– Apheresis Certification of Analysis, Fresh		
	Sanguine Document Number: GEN117-01	Version Number: 01	Zen Document Number: 959976

Product Description

Mononuclear cells are collected and concentrated from peripheral blood of a healthy consented donor according to IRB approved protocols using an automated leukapheresis system. During the procedure an anticoagulant is added to venous blood to prevent blood from clotting as it passes through the apheresis device. The enriched cell fraction consisting of pan T, NK, B cells, hematopoietic stem cells (CD34+), monocytes, dendritic and other white blood cell types is collected and shipped in a blood bag.

Product Description: Human Peripheral Blood CD34+ Cells, Fresh

Lot Number: (Add)

Subject ID: (Add)

Storage Temperature: 2-8°C

Manufacture Date: (Add MM/DD/YYYY)

Intended Use Statement: For Research Use Only. Not for Use in Diagnostic or Therapeutic Procedures.

Other Donor Supplied Information: (Add current medications, etc., if available)

PARAMETER	SPECIFICATION	RESULT
Total Nucleated Cells	≥ 10.0 x 10e5 cells/mL	(Add) cells/mL
Viable Cell Count Per Product: Total viable cells based on assessment	≥ 2.0 x 10e5 viable cells/mL	(Add) viable cells/mL
Cell Viability: Viability based on assessment	≥ 80%	(Add) %
Cell Purity: Purity by Flow Cytometry CD34+ as a percentage of CD45+ cells	≥ 90%	(Add) %
Donor Age	18-89 years	(Add) years
Donor Height	Inches	(Add) in
Donor Weight	Pounds	(Add) lb
Donor Gender	Male/Female	(Add)
Donor Ethnicity	Any	(Add)
Donor Smoking Status	Yes/No/Unknown	(Add)
Anticoagulant	ACD or Na-Hep	(Add)
HIV-1	Negative	(Add)
HIV-2	Negative	(Add)
HBV	Negative	(Add)
HCV	Negative	(Add)



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CBC Results:

WBC	
RBC	
HGB	
HCT	
PLT	

Flow Cytometry Analysis: <Remove if not tested>

The post thaw purity of CD34+ positive selected cells as assessed by flow cytometry is shown below. CD34+ cells were analyzed by gating on CD45+ cells.

(Insert Plot)

Caution: Use Universal Precautions for handling human specimens. Do not pipette by mouth. Avoid direct inhalation of the solution and use with adequate ventilation. Do not smoke, eat, or drink, in areas where specimens are being handled. Dispose of this product as appropriate for biohazardous material.

Prepared by: _____

Date: _____

QA Review by: _____

Date: _____