

**Duke**Medicine

Division of Cellular Therapy

DOCUMENT NUMBER: ABMT-GEN-025 FRM2**DOCUMENT TITLE:**

Photopheresis Run Sheet FRM2

DOCUMENT NOTES:**Document Information****Revision:** 11**Vault:** ABMT-General-rel**Status:** Release**Document Type:** ABMT**Date Information****Creation Date:** 28 Feb 2020**Release Date:** 26 Feb 2022**Effective Date:** 26 Feb 2022**Expiration Date:****Control Information****Author:** MC363**Owner:** MC363**Previous Number:** ABMT-GEN-025 FRM2 Rev 1 **Change Number:** ABMT-CCR-304



DUKE UNIVERSITY HEALTH SYSTEM

Patient Label

Form
M0345**ABMT-GEN-025 FRM2 Photopheresis Run****Room Temp/Humidity:** _____°C _____%**Room Temp/Humidity Acceptable?** ☐ Yes ☐ No(Acceptable Ranges for Temperature: 15°C to 30°C **AND** Acceptable Ranges for Humidity 10%-75%)

Supplies Pass Visual Inspection: <input type="checkbox"/> Yes <input type="checkbox"/> No		CELLEX SN#:	DIAGNOSIS:
Lot # Cellex kit:	Exp:	<input type="checkbox"/> 40143 <input type="checkbox"/> 40524 <input type="checkbox"/> 40670 <input type="checkbox"/> 41127	<input type="checkbox"/> cGVHD <input type="checkbox"/> Organ rejection <input type="checkbox"/> CTCL <input type="checkbox"/> _____
Lot # Methoxsalen:	Exp:		
Lot # Normal Saline:	Exp:		
Lot # ACD-A:	Exp:	Pre-treatment Lamp Hours:	
Lot # 10 mL syringe:	Exp:	Treatment Number:	
Lot # 3mL syringe:	Exp:	Access Type: <input type="checkbox"/> PIV <input type="checkbox"/> CVC <input type="checkbox"/> PORT	
Lot # 20g needle:	Exp:		
18 g Autoguard:	Exp:		
16 g Autoguard:	Exp:		
IV Extension Set:	Exp:	<input type="checkbox"/> Single Needle Mode	
IV Start Kit:	Exp:	<input type="checkbox"/> Double Needle Mode	

☐ Current HCT%: _____ HgB: _____ WBC: _____ Plts: _____ Weight: _____(kg) Height: _____(cm)
Total Blood Volume (as calculated on CELLEX) _____ mL

CELLEX Predicted ECV: _____	Max Safe Extracorporeal Volume (10%)
	Max Safe Extracorporeal Volume (15%)

Pre-treatment	Temp.	HR	RR	B/P	O ₂	<input type="checkbox"/> In EMR (Electronic Medical Record)

Notify MD if vital signs, lab results, or % ECV are out of these parameters:

<input type="checkbox"/> Temperature: > 38C	<input type="checkbox"/> Heart Rate: < 50 or > 120	<input type="checkbox"/> %ECV: > 15%
<input type="checkbox"/> Systolic BP: < 80 or > 160	<input type="checkbox"/> Diastolic BP: < 50 or > 90	<input type="checkbox"/> Platelets: < 75,000
<input type="checkbox"/> Hemoglobin: < 8	<input type="checkbox"/> Hematocrit: < 27%	<input type="checkbox"/> WBC: <1,500 or > 15,000

Is the patient suitable for treatment, per MD?

<input type="checkbox"/> Yes	<input type="checkbox"/> No
------------------------------	-----------------------------

IF THE PATIENT IS RECEIVING IV CALCIUM, CALCIUM MUST BE DISCONTINUED PRIOR TO PHOTOACTIVATION RETURN PHASE. (Calcium and Methoxsalen are not compatible)

ABMT-GEN-025 FRM2 Photophoresis Run

[illegible]

Pre-Photoactivation	Temp.	HR	RR	B/P	O ₂	<div><input type="checkbox"/> In EMR</div> <div>(Electronic Medical Record)</div>
Treatment Volume (mLs):				Uvadex Dose (mcgs):		
Photoactivation Time:				Procedure Time:		
Post-treatment	Temp	HR	RR	B/P	O ₂	<div><input type="checkbox"/> In EMR</div> <div>(Electronic Medical Record)</div>
Fluid Balance:				Cleaned By:		

Signature: _____

Date: _____

ABMT-GEN-025 FRM2 Photopheresis Run Sheet

Instructions

Patient Label	Place a patient label with Name, MRN, DOB, and Date
Room Temp/Humidity	Record the room temperature and humidity at the time of CELLEX operation.
Room Temp/Humidity Acceptable	Check YES or NO based on the acceptable ranges listed (Temperature: 15°C to 30°C AND Humidity 10%-75%)
Supplies Pass Visual Inspection	Check YES or NO
CELLEX SN#	Check the correct CELLEX for the procedure.
Diagnosis	Check the correct diagnosis for the patient. (If not listed ADD to blank space provided)
Lot # and Expiration (Exp) date for ALL supplies	Record the lot numbers and expiration dates for all supplies used during the procedure (Supplies NOT used do NOT require a NA in Space)
Pre-treatment Lamp Hours	Record the lamp hours before the procedure
Treatment Number	Record the patient's treatment number.
Access Type	Check the correct patient access
Needle Mode	Check the correct needle mode (If double needle is checked, the return rate should be 5 higher than the collect rate)
Current HCT, HgB, WBC, Plts, Weight, and Height	Record the patient's current (< 48hrs.) hematocrit, hemoglobin, WBC count, platelets, weight, and height.
Total Blood Volume (as calculated on CELLEX)	Record the volume given on the CELLEX machine.
CELLEX Predicted ECV	Record the estimated extracorporeal volume based on the patient's HCT% and needle mode selected.
Max Safe Extracorporeal Volumes (10% and 15%)	Record the max safe ECV at the percentage listed.
Pre-treatment	Record the patient's vital signs prior to the procedure. (Check-In EMR if documentation is performed in the EMR)
Notification Results for Clearance of Procedure	Check any result, not within the selected parameters. (Notification of abnormal results requires documentation in EMR)
Is the patient suitable for treatment, per MD	Check YES or NO depending on MD's clearance.
Important Information when using IV Calcium	When using IV Calcium, the infusion must be discontinued before the photoactivation return phase of the procedure. (Calcium and Methoxsalen are not compatible)
Photopheresis monitoring	Every 15 minutes, record the time, collect pressures, return pressures, and interface # during the collect phase of the procedure. (Note any comments and/or alarms that occurred and what relevant actions were taken to eliminate the alarms)
Pre-Photoactivation	Record the vital signs before photoactivation. (Check In EMR if documentation is performed in the EMR)
Treatment Volume	Document the treatment volume collected in mLs.
Uvadex Dose in Micrograms	Calculate Uvadex dose by using: Treatment volume (mL) multiplied by 0.017= dose of Uvadex (mL), then multiple doses of Uvadex by 20 mcg to find the microgram dose.
Photoactivation Time	Record the time of photoactivation.
Procedure Time	Record the total time of the procedure.
Post-treatment	Record the vital signs at the end of the procedure. (Check In EMR if documentation is performed in the EMR)
Fluid Balance	Record the patient's fluid balance at the end of the procedure.
Cleaned by	Record the photopheresis nurse's initials for verification of clean machine at the start of the procedure and completed cleaning at the end of the procedure.
Signature and Date	Record the photopheresis nurse's signature completing the procedure and the date of the procedure.

Signature Manifest**Document Number:** ABMT-GEN-025 FRM2**Revision:** 11**Title:** Photopheresis Run Sheet FRM2**Effective Date:** 26 Feb 2022

All dates and times are in Eastern Time.

ABMT-GEN-025 FRM2 Photopheresis Run Sheet FRM2**Author**

Name/Signature	Title	Date	Meaning/Reason
Mary Beth Christen (MC363)		29 Oct 2021, 10:26:31 AM	Approved

Management

Name/Signature	Title	Date	Meaning/Reason
Jennifer Frith (JLF29)		10 Nov 2021, 08:10:15 AM	Approved

Medical Director

Name/Signature	Title	Date	Meaning/Reason
Nelson Chao (CHAO0002)		10 Nov 2021, 08:40:15 AM	Approved

Quality

Name/Signature	Title	Date	Meaning/Reason
Bing Shen (BS76)		07 Feb 2022, 09:54:16 AM	Approved

Document Release

Name/Signature	Title	Date	Meaning/Reason
Betsy Jordan (BJ42)		08 Feb 2022, 02:54:32 PM	Approved