

Kraft Family Blood Donor Center



Dana-Farber
Cancer Institute



Brigham and Women's Hospital
Founding Member, Mass General Brigham

Qualification Questionnaire Form

Authorized Treatment Center (ATC) Name and Address:	Kraft Family Blood Donor Center 35 Binney Street Boston, MA 02215
Contacts:	Suhayla Sarhan, Operations/Flow Manager ssarhan@partners.org ; 781-534-1244 Kate Hurley, Research RN, 617-939-1737 Eileen Green, Apheresis Quality Specialist, 617-992-6428 Vanessa Anjurthe, Research Coordinator, vanjurthe@bwh.harvard.edu
Operation Hours:	Monday through Friday 6:30am-5:00pm EST; ambulatory unit
Procedures:	HPC, MNC collections, plasma exchanges, red cell exchanges, ECP
Lead time to schedule apheresis	2-3 weeks
Number of beds/chairs in unit	5 chairs; 7 beds
Accreditations in good standing	FACT, CLIA, NMDP
Accreditation Agencies Inspection Dates	FDA: November 15, 2022 FACT: July 24, 2023 NMDP: February 8, 2023 (Audit only) CLIA: April 3, 2023
Accreditation Agencies Expiration Dates	FDA: July 14, 2024 FACT: January 3, 2027 CLIA: April 2, 2025
Infectious Disease Marker (IDM) Testing	IDM results turnaround time (for full panel): resulted in 24-48 hours Performed at: Rhode Island Blood Center 405 Promenade Street Providence, RI 02908 * can also be drawn day of collection if requested
Apheresis Instruments:	Spectra Optia (cMNC program) How many? 11 Back up device available: Yes Secondary power source? Yes
Anticoagulant used	ACD-A
Training	Documentation of HPC/MNC training Procedures for training client specific collections/labeling
Venous assessment	Week prior to collection- patient must visit Kraft Family Donor Center to determine if pt has adequate veins to collect peripherally or if a central line would be required—if a central line required, would need to be scheduled in Interventional Radiology

Nursing	12 core staff 3 per diem 1:1 nurse to patient ratio
Leukapheresis collections per year	~800+
Collection	Collection appt time: pts arrive at 7:30am Collection End time: end of rinseback is our standard
Plasma	Can be added to product per request
Temperature control continuous monitoring (Rees Scientific Monitoring System)	Apheresis collection area Storage room/area for collection materials supplies Biological Refrigerator
Routine calibration/preventative maintenance	Apheresis collection instruments Refrigerators Temperature chart recorders Temperature monitoring devices
Product labeling	ISBT 128 on-demand adhesive labeling size 4"x 4" (adhesive coating meets FDA; CFR21, Sec. 175.105 requirements)
Sponsor portals	Can be accommodated with sponsor training—request entire apheresis staff be granted access
Labs	Pre and post CBCs drawn day of collection; turn around time for Cell Product CD34+ test results: 1-2 hours ABO for products that will be re-infused HCG result within 7 days of collection Auto collections: Hct \geq 23; plt \geq 30; WBC \geq 65k/ul Allo collections healthy donor: hct \geq 30; plt \geq 120
Product samples	Apheresis Cell Products can be sampled on request using the pre-attached functionally closed sample bulb
Cell Product Transport	Apheresis Cell Product will be transported to CMCF via cooler by CMCF staff. Product packaged and shipped from CMCF. Time Proximity from ATC to CMCF <5 minutes
Leukapheresis product packing and shipping	Packed and shipped from Cell Therapy Lab
Material Storage	Supplies organized in a manner which facilitates first in first out (FIFO). Secured area.