

Leukopak, Fresh/Whole Blood, Fresh				
Clinical Donor Eligibility		Clinical Capabilities		
Donor Characteristics	Healthy donors, age 18-65 years old  <i>Specific donor requirements available on request and subject to additional fee</i>	GMP compliant Collection Centers	Leukopak, Fresh	Whole Blood, Fresh
			Folsom, CA East Norriton, PA Boston, MA	Folsom, CA East Norriton, PA Boston, MA
FDA and CLIA registered	FDA and CLIA registered			
Location specific donor recruitment available and subject to additional fees	Location specific donor recruitment available and subject to additional fees			
Donor Consent	IRB-approved donor informed consent for further manufacture and commercialization  <i>Modifications subject to fee</i>			
Donor History	Donor History Questionnaire compliant with AABB DHQ for Hematopoietic Progenitor Cells (HPC-DHQ)	Catalogue Number	CG-LE010F	CG-PBCPD250F
Donor Physical Exam	Included		Includes Leukopak, standard donor screening and backup donor on-site	Includes Whole Blood collection, standard donor screening and backup donor on-site
Donor Eligibility Screening	Performed within 7 days of collection  FDA Licensed testing compliant with 21 CFR Part 1271 for donor eligibility and performed by CLIA licensed laboratory  Full Panel details:  ◦ <i>HIV I &amp; II Ab + Reflex</i> ◦ <i>HIV/HBV/HCV NAT</i> ◦ <i>HCV Ab</i> ◦ <i>HBV Ab Core + Reflex</i> ◦ <i>HBV Ab Surface Ag + Reflex</i> ◦ <i>HTLV I &amp; II Ab + Reflex</i> ◦ <i>Syphilis Ab</i> ◦ <i>West Nile Virus NAT</i> ◦ <i>T. Cruzi (Chagas) Ab</i> ◦ <i>CMV Total</i> ◦ <i>CMV Total with Reflex to IgM (Only performed if CMV total test result is positive)</i> ◦ <i>CMV Total with Reflex to IgM and IgG/IgM (Only performed if CMV total test result is positive)</i> ◦ <i>Zika NAT* inquire</i>		<i>Additional products and services quoted separately</i>	<i>Additional products and services quoted separately</i>
		Description	Leukopak, Full collection, Fresh Clinical (GMP compliant)	Whole Blood, Fresh <i>Clinical (GMP compliant)</i>
		Anticoagulent	ACD-A	CPD available
		Cell Count/ Volume/ Viability	Target 10 Billion WBC	250mL (CPD)
			<i>Actual donor collection yield may vary</i>  ≥ 90% viability	
		Quality & Regulatory	QC and QA review and release of Summary of Record and Certificate of Analysis	QC and QA review and release of Summary of Record and Certificate of Analysis
			Performed under QMS controlled batch record and GMP compliant  <i>Inquire for addtl regulatory support</i>	Performed under QMS controlled batch record and GMP compliant  <i>Inquire for addtl regulatory support</i>
Shipping	Validated shipping containers available	Validated shipping containers available		
Additional Infectious Disease Testing	<i>Available upon request and subject to additional fees</i>	Price	Custom  <i>Inquire for full project questionnaire</i>	Custom  <i>Inquire for full project questionnaire</i>
HLA Testing, KIR Typing & other characterization	<i>Available upon request and subject to additional fees</i>			