

Fresh Clinical Leukopaks

Clinical Donor Eligibility		Clinical Capabilities	
Donor Characteristics	<p>Healthy donors, age 18-65 years old</p> <p>Backup donor included</p> <p><i>Specific donor demographic requirements available on request and subject to additional fee</i></p>	GMP compliant Collection Centers	<p>Folsom, CA San Diego, CA Raleigh, NC Rockville, MD East Norriton, PA Cambridge, MA</p> <p><i>FDA and CLIA registered</i></p> <p><i>Location specific donor recruitment available and subject to additional fees</i></p>
Donor Consent	<p>IRB-approved donor informed consent for further manufacture and commercialization</p> <p><i>Modifications subject to fee</i></p>		
Donor History	<p>Donor History Questionnaire compliant with AABB DHQ for Hematopoietic Progenitor Cells (HPC-DHQ)</p>	Catalogue Number	<p>CG-LE010F</p> <p>Includes Leukopak, standard donor screening and backup donor on-site</p> <p><i>Additional products and services quoted separately</i></p>
Donor Physical Exam	<p>Included</p>		
Donor Eligibility Screening	<p>Performed within 7 days of collection</p> <p>FDA Licensed testing compliant with 21 CFR Part 1271 for donor eligibility and performed by CLIA licensed laboratory</p> <p>Full Panel details:</p> <ul style="list-style-type: none"> ◦ HIV I & II Ab + Reflex ◦ HIV/HBV/HCV NAT ◦ HCV Ab ◦ HBV Ab Core + Reflex ◦ HBV Ab Surface Ag + Reflex ◦ HTLV I & II Ab + Reflex ◦ Syphilis Ab ◦ West Nile Virus NAT ◦ T. Cruzi (Chagas) Ab ◦ CMV Total ◦ CMV Total with Reflex to IgM (Only performed if CMV total test result is positive) ◦ CMV Total with Reflex to IgM and IgG/IgM (Only performed if CMV total test result is positive) 	Description	<p>Leukopak, Full Collection, Fresh</p> <p><i>Clinical (GMP-Compliant)</i></p>
	Anticoagulant	ACD-A	
	Cell Count (Yield)	Target 10 Billion WBC	<i>Actual donor collection yield may vary</i>
	Viability	≥ 90% viability	
	Quality & Regulatory	<p>QC and QA review and release of Summary of Record and Certificate of Analysis</p> <p>Performed under QMS controlled batch record and GMP compliant</p> <p><i>Inquire for addtl regulatory support</i></p>	
Shipping	<p>Validated shipping containers available</p> <p><i>Custom packaging and shipping arrangements upon request and subject to additional fee</i></p>		
Additional Viral Testing	<p><i>Available upon request and subject to additional fees</i></p>	Price	<p>Custom</p> <p><i>Inquire for full project questionnaire</i></p>
HLA Testing, KIR Typing & other characterization	<p><i>Available upon request and subject to additional fees</i></p>		

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Questions? Contact us!
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