stemexpress®

Clinical LEUKOPAKS

For use in GTP/GMP compliant cell-based therapies and allogeneic manufacturing

StemExpress Clinical Leukopaks

Clinical fresh Leukopak products contain a high concentration of all major cell populations (T Cells, B Cells, NK Cells, and monocytes) and are GTP/GMP compliant products for cell-based therapy. Clinical grade fresh Leukopaks can also be used as starting material for further manufacturing in allogeneic cell therapies.

- ✓ Donors follow FDA 21 CFR 1271 guidelines
- ✓ Collections occur under enhanced Quality oversight with defined protocols
- ✓ FDA-registered collection centers
- ✓ Customizable donor selection process and infectious disease screening time points
- ✓ International regulatory compliance

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Stratech

Fresh Clinical Leukopaks

stemexpress®

Clinical Donor Eligibility	
Donor Characteristics	Healthy donors, age 18-65 years old Backup donor included *Specific donor demographic requirements available on request and subject to additional fee*
Donor Consent	IRB-approved donor informed consent for further manufacture and commercialization *Modifications subject to fee*
Donor History	Donor History Questionnaire compliant with AABB DHQ for Hematopoietic Progenitor Cells (HPC-DHQ)
Donor Physical Exam	Included
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: ◦*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)*
Additional Viral Testing	*Available upon request and subject to additional fees*
HLA Testing, KIR Typing & other characterization	*Available upon request and subject to additional fees*

Clinical Capabilities	
GMP compliant Collection Centers	Folsom, CA San Diego, CA Raleigh, NC Rockville, MD East Norriton, PA Cambridge, MA *FDA and CLIA registered* *Location specific donor recruitment available and subject to additional fees*
Catalogue Number	CG-LE010F Includes Leukopak, standard donor screening and backup donor on-site *Additional products and services quoted separately*
Description	Leukopak, Full Collection, Fresh *Clinical (GMP-Compliant)*
Anticoagulent	ACD-A
Cell Count (Yield)	Target 10 Billion WBC *Actual donor collection yield may vary*
Viability	≥ 90% viability
Quality & Regulatory	QC and QA review and release of Summary of Record and Certificate of Analysis Performed under QMS controlled batch record and GMP compliant *Inquire for addtl regulatory support*
Shipping	Validated shipping containers available *Custom packaging and shipping arrangements upon request and subject to additional fee*
Price	Custom *Inquire for full project questionnaire*

ORDERING & SHIPPING
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