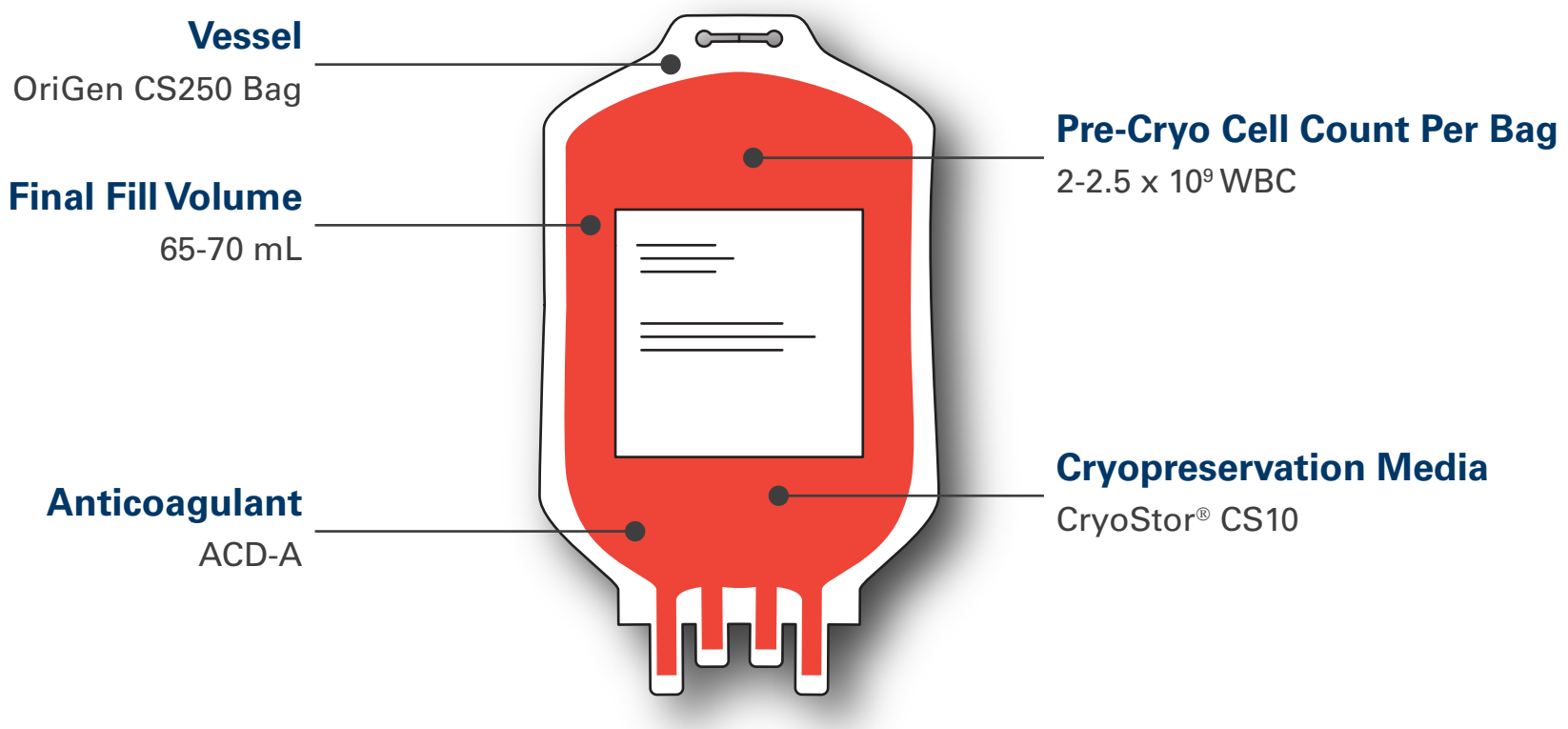
WHICH CRYOPRESERVED LEUKOPAK HEMAPRIME™ vs. GMPRIME™ IS RIGHT FOR YOU?

HemaCare's cryopreserved leukopak is collected and processed following standardized procedures. The difference between HemaPrime (research use) and GMPrime (GMP compliant) is the level of quality management systems oversight and the extensive documentation that accompany the GMPrime leukopak. With streamlined processes, development of cell-based therapies can be expedited as you transition from preclinical to clinical development, while ensuring a consistent, high-quality product throughout the development process.



HemaPrime

Donor Eligibility Assessment (1)
Healthy donors are assessed in accordance with current FDA requirements for allogeneic blood donation. Donors are screened with current FDA-approved Donor History Questionnaire (DHQ).

Donor Testing (2)
Full infectious disease panel

GMPrime

1 Donor Eligibility Assessment
Healthy donors are assessed in accordance with current FDA requirements for allogeneic cell and tissue donation. Donors meet all 21 CFR Part 1271 requirements and are screened with current AABB and FDA-approved HCT/P-DHQ.

2 Donor Testing
Full infectious disease panel, in addition to Zika and CMV screening

HemaPrime		GMPrime
Meets applicable requirements for collection of research use products	Regulatory Compliance	Compliant with 21 CFR Part 1271, AABB standards, and international regulatory requirements, as applicable
Contains identifying information and meets some aspects of the ISBT 128 standards	Labels	Meets ISBT 128 standards; managed by a controlled, validated labeling system
Processed in a classified non-controlled (CNC) laboratory	Manufacturing Location	Processed in Class A and Class B controlled environments
Mycoplasma testing on cryopreserved products performed at random	Biosafety Testing	Mycoplasma, endotoxin, and sterility testing on every product
Manufactured using an SOP; MBR is not included	Master Batch Record (MBR)	Manufactured using a controlled MBR
Limited	Environmental Monitoring Program	Full
Limited	Equipment Validated/Qualified	Full
Full	Staff Training	Full
All vendors are qualified by QA	Raw Materials Approved	All vendors are qualified and materials are approved by QA
N/A	Facility and Process Qualification/Validation	Qualified/Validated
N/A	Batch Record Review and Release	Reviewed and released by QA
Yes	SOP for Donor Eligibility Assessment and Product Collection	Yes
N/A	SOP for Processing, Storage, and Shipping	Yes

Learn more at www.hemacare.com

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