GMPrime™ Bone Marrow Aspirate

Key Advantages

Quality. Collected within HemaCare's FDA-registered, GMP-compliant donor center.

Standardized. Streamlined processes to ensure a seamless transition from RUO to GMP materials.

Donor Pool. Access to a robust recallable donor pool.

Customizable. Collection, packaging, and shipping following your protocol.

Trusted Supplier. Expertise in collection, handling, and shipping.

Overview

Bone marrow is a rich source of stem and progenitor cells. Because hematopoietic stem cells (HSC) and mesenchymal stem cells (MSC) are capable of regenerating and differentiating into many different cell types, they offer a great deal of promise for future therapeutic development and are a major area of investigation.

Seamlessly Transition Your Discovery From Research to Commercialization

GMP-compliance adds an extensive level of quality review and documentation that serves to standardize raw materials and processes, eliminating most external sources of variability with the exception of those associated with the donor. The transition to GMP-compliant materials is a necessary step in the development of cell therapies to satisfy regulatory guidelines and ensure the safety of recipients of these therapies. The success of cellular therapeutics will greatly benefit from the early adoption of stringent quality management systems and consistent, high-quality materials.

Our GMPrime bone marrow aspirate, and it's research use only (RUO) counterpart HemaPrime™ bone marrow aspirate, are collected following consistent collection procedures and processes. Thus, partnering with HemaCare for RUO and GMP-compliant raw materials during the early stages of development can simplify and streamline your journey to commercialization.

High-Quality, Consistent Starting Material

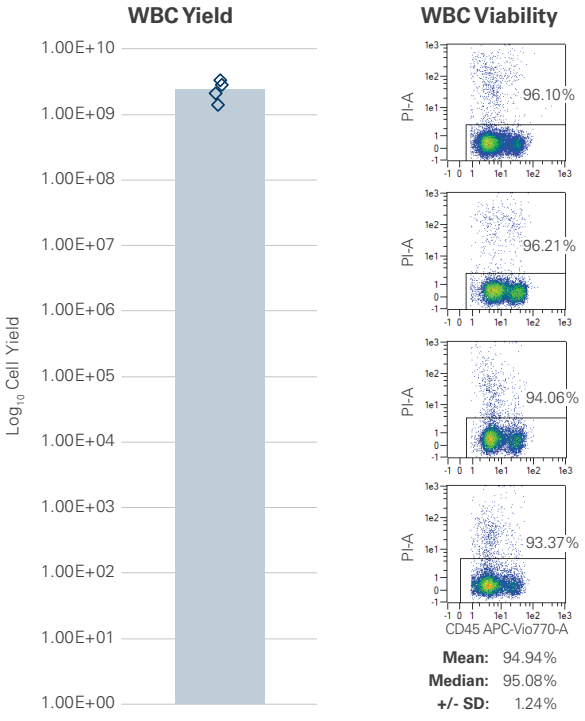

Figure 1. Representative bone marrow aspirate samples were assessed for white blood cell (WBC) yield and viability. As with other raw materials, yield was variable and within this sampling ranged from a max of 3.29E+09 to a min of 1.38E+09 (blue diamonds) with an average WBC yield of 2.39E+09 (light blue bar). High viability was observed with all samples averaging 94.94%.

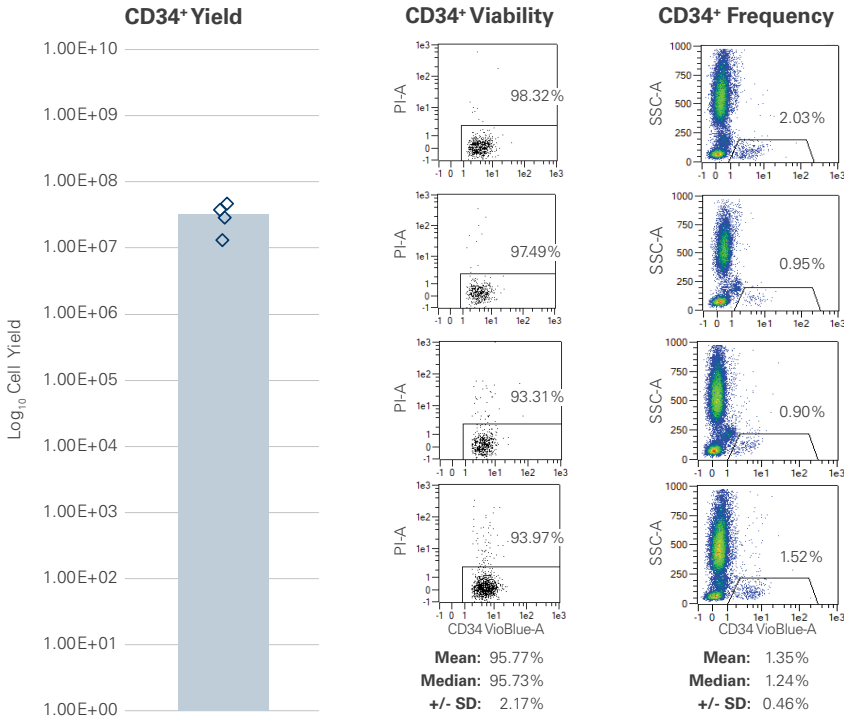

Figure 2. Representative bone marrow aspirate samples were assessed for CD34+ hematopoietic stem cells (HSC) yield and viability. The percentage of CD34+ cells was variable within this sampling and ranged from a max of 2.03% to a min of .90%. Average yield was 3.15E+07 (teal bar). As with WBCs, CD34+ HSC viability was high and averaged greater than 95.77%.

Bone marrow aspiration is performed at HemaCare's FDA-registered collection center by our qualified clinicians from IRB-consented healthy human donors. The aspirate is drawn from the posterior iliac crest (top ridge of the back of a hipbone). Aspiration requires a sharp eye and strong technical expertise. With over 20 years of aspiration experience, our staff know how to skillfully perform the procedure to maximize collection of desired cellular components.

Description	Catalog Number	Size	Format	Price
Aspirate	BM008F-1-GMP	100 mL	Fresh	Inquire

Donor Specifications

Specification	Description	Included
Donor	Normal random healthy with back-up (18-65 years old)	✓
History Assessment	Donor history assessed using the current AABB Donor History Questionnaire for HPC, Apheresis which ensures compliance with FDA current Good Tissue Practices (cGTP) regulations under 21 CFR 1271 for assessing donor eligibility. Includes physical exam.	✓
Testing Timelines	Pre-screen performed 30 days before collection and also on day of collection	✓
Standard Testing Panel	• CBC • ABO/Rh • Treponema pallidum antibody (Syphilis) • Red Blood Cell Antibody Screen • CMV Antibody (Anti-CMV IgG and IgM) – if donor must be CMV negative • Hepatitis B Core Antibody (Anti-HBc EIA) • Hepatitis B Surface Antigen (HBsAg EIA) • Hepatitis C Virus Antibody (Anti-HCV EIA) • Human Immunodeficiency Virus Antibody (HIV 1/2 plus O) • Human T-Lymphotropic Virus Antibody (HTLV-I/II) • HIV-1/HCV/HBV Nucleic Acid Testing • West Nile Virus Nucleic Acid Testing • Trypanosoma cruzi Antibody (Chagas Disease) • Zika Virus Nucleic Acid Testing	✓
Additional Testing	Dependent on testing	✓

Product Specifications

Specification	Description
Anticoagulant Offered	Heparin, ACD-A (EDTA currently not available)
Vessel	Bag (splitting not currently available)
Final Fill Volume	100 mL
Capacity	5 collections daily on agreed upon dates set by HemaCare

Shipping Specifications

Specification	Description	Included
Packed and Shipped by Courier	GMP-compliant shipping container and trained personnel must be provided by the customer or customer-contracted provider (i.e. Biocair, World Courier, or QuickStat)	Additional Fee
Packed by HemaCare	Customer provided instructions *Must be included in MBR*	Additional Fee
Packed by HemaCare	Currently not available	N/A

Quality Specifications

Specification	Description	Included
Release Department	HemaCare Operations, HemaCare Quality Assurance	✓
Regulation Compliance	Compliant with 21 CFR 1271	✓
Master Batch Record (MBR)	Includes Name, Address, Shipping Arrangement ***3-4 week lead time***	✓
MBR with Minor Modifications	Example: customer provided shipping instructions ***4-6 week lead time***	Additional Fee
MBR with Major Modifications	Example: Additional donor recruitment/testing ***8-12 week lead time***	Additional Fee

For more information on HemaCare's GMP-compliant human cells, visit www.hemacare.com or contact us at NRG-sales@crl.com.

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