

# HemaPrime™ Bone Marrow Aspirate

## GMPrime™ Bone Marrow Aspirate

### Product Description

Bone marrow aspirate is collected at HemaCare's FDA-registered collection center from healthy human donors who have consented under an IRB-approved protocol. The donor is required to review and sign an approved procedure-specific consent form prior to the collection.

Donors are pre-screened for HBV, HCV, HIV, HTLV, WNV, Trypanosoma cruzi, and Syphilis 30 days prior to the collection as well as on the day of collection.

### Sample Collection and Processing

Bone marrow aspirate is drawn from the posterior iliac crest using a syringe containing either anticoagulant citrate dextrose solution A (ACD-A) or heparin. The volume of ACD-A used is 20 mL per 100 mL of bone marrow collection, and the volume of heparin used is 3 mL per 100 mL of bone marrow collection.

Approximately 100 mL of fresh bone marrow with ACD-A or heparin is shipped in a 300 mL sterile gas-permeable transfer pack with coupler (Fresenius-Kabi, catalog # 4R2004)\*. The tail from the transfer pack is heat-sealed and not long enough for downstream sterile welding. A fluid transfer set, 2" tubing with piercing pin and syringe adapter (female luer) (Charter Medical Limited, catalog # 03-220-92), is inserted into one of the ports on the transfer pack.

\*The final volume of bone marrow aspirate is subject to variability depending on the donor and efficiency of the extraction procedure.

### Appearance and Composition

The bone marrow is noticeably oily, as it contains lipids that are found in the marrow. The collected bone marrow sample may contain some bone particles which can be typically removed using a cellular strainer (40-100 µm pore size).

The concentration of white blood cells (WBC) and CD34<sup>+</sup> hematopoietic stem cells that are present in the bone marrow aspirate is subject to variability and is donor dependent. The WBC concentration may range between  $10 \times 10^6$  to  $40 \times 10^6$  WBC/mL, and the concentration of CD34<sup>+</sup> cells in the bone marrow aspirate may range between 1 and 4 percent. Representative sampling data highlighting the yields of WBC and CD34<sup>+</sup> cells in bone marrow aspirate can be found in our [product note](http://www.hemacare.com/resources/) ([www.hemacare.com/resources/](http://www.hemacare.com/resources/)).

### Storage and Handling

Upon receipt, the fresh bone marrow sample should be used or processed as soon as possible. With longer storage periods, the contaminating platelets and granulocytes can increasingly interfere with the effectiveness of further downstream isolations.

The bone marrow aspirate is a human-derived biological material. Although the donor has been screened against and found to be negative for HBV, HCV, HIV, HTLV, WNV, Trypanosoma cruzi, and Syphilis, all materials which have come in contact with this product must be treated as infectious materials. Therefore, regulations for the treatment of infectious materials must be observed when handling this product.

Universal laboratory precautions must be utilized when working with the bone marrow aspirate, and trained personnel observing good laboratory practice should handle the product. Always wear protective gloves, eye protection, and a lab coat when handling this product. Avoid skin contact or swallowing.

### Shipping Condition

As defined by industry standard, the fresh bone marrow aspirate is shipped at controlled ambient temperature, unless requested otherwise.

### Downstream Applications

- Isolation of stem cells via the CD34 or CD133 antigen.
- Isolation of mononuclear cells via density gradient\*.
- General characterization of cellular subtypes via FACS.
- Culture and expansion of mesenchymal stem cells (MSCs). The identity of these cells can be confirmed using surface antigens like CD73, CD90, and CD105. In addition, the MSCs can be morphologically identified using an appropriate staining procedure, such as oil red O to visualize adipogenic MSCs and alizarin red to identify osteogenic MSCs.

\*Granulocyte populations within the bone marrow can be different enough from periphery populations (whole blood/apheresis), leading to possible problems when applying density gradient techniques to further isolate mononuclear cells.

Therefore, additional steps may be required to remove this population if desired. Immunomagnetic separation is a good option to remove the granulocytes. An alternate option would be to use reagents which can facilitate binding of granulocytes to red blood cells, making them functionally dense enough to be treated by a density gradient step.

## Hazard Identification

Emergency Overview	Mild irritation might result with eye contact and/or ingestion.  Although the donor has been screened against and found to be negative for HBV, HCV, HIV, HTLV, WNV, Trypanosoma cruzi, and Syphilis, the sample should still be treated as potentially infectious. Usage of gloves, eye protection, and laboratory coat is highly recommended when handling this product.
OSHA Hazards	This substance contains no ingredients at concentrations to be considered hazardous as defined by OSHA 29CFR 1910.1200.
Target Organs	Eyes, skin
Primary Route(s) of Entry	Skin, eye contact, inhalation, and ingestion
Symptoms of Exposure	Mild irritation.
Inhalation	May cause irritation to mucous membranes and upper respiratory tract.
Eye Contact	May cause mild irritation.
Skin Contact	May cause mild irritation.
Ingestion	May cause irritation to gastrointestinal tract and adverse health effects.

## Leak and Spill Procedures

1. Wear chemical-resistant gloves.
2. Absorb spill and place in a closed container for disposal.
3. Wash area thoroughly after clean-up is complete.

## First Aid Measures

*Report to your Safety Office and seek medical attention as soon as possible.*

Skin Contact	Wash thoroughly with copious amounts of water. If skin is broken, seek medical advice.
Eye Contact	Hold eye open. Flush with copious amounts of water for at least 15 minutes.
Inhalation	If person is unconscious, seek emergency medical attention. If person is conscious, move to fresh air and call a physician if respiratory complications arise.
Ingestion	If person is unconscious, seek emergency medical attention; never give anything by mouth to an unconscious person. If the person is conscious, wash mouth out with copious amounts of water and call a physician. Do not induce vomiting unless directed to do so by a physician.