

Poietics™ Human Bone Marrow Technical Sheet

Introduction

Lonza Walkersville, Inc. operates a Research Bone Marrow Donor Program to recruit, screen, test, evaluate and select donors for collection of bone marrow samples **for research use**. Donors participate in a two stage process: 1) evaluation at a screening appointment 2) marrow collection.

Donation informed consent to participate in the bone marrow donor program includes:

- Program explanation with questions and answers about the process
- Health assessment through medical and behavioral questionnaire
- Permission for blood sample collection and testing by certain infectious disease tests
- Confidentiality of identity and protection of health information
- Risks and discomfort of participation
- Benefits of participation do not include any direct benefits or ownership
- Donor may stop participation in the program at any time
- Donor's options for continued program participation
- Reasonable compensation for participation
- Bone marrow will be sold to laboratories performing research

This Donor Program is currently approved, has been approved for over 10 years, and is submitted for annual approval by a commercial institutional review board.

Lonza Walkersville, Inc. 8830 Biggs Ford Road, Walkersville, MD 21793 is licensed as a tissue bank to conduct this donor program in the states of Maryland and New York, USA.

Please address questions/comments about this information to Lonza Scientific Support.

Bone Marrow Source

Human bone marrow is withdrawn from bilateral punctures of the posterior iliac crests of normal volunteers.

Normal Donor Eligibility Criteria

- Healthy males and non-pregnant females between the ages of 18 and 45 years old
- Signed and witnessed informed consent forms
- Acceptable vital signs and hematology values
- All donors are screened for general health and negative medical history for heart disease, kidney disease, liver disease, cancer, epilepsy and blood or bleeding disorders
- Negative clinical laboratory tests for HIV-1, HIV-2, hepatitis B and hepatitis C

Bone Marrow Sample Collection

Every 100 ml of bone marrow is collected into syringes containing 10 ml of heparin (Porcine Intestinal Mucosa) Sodium Injection (~100 units heparin per ml bone marrow).

Scheduling

Fresh cells and unprocessed marrow need to be ordered two to four weeks in advance depending on donor and volume requirements.

Products

Available as unprocessed marrow, mononuclear cells, isolated hematopoietic progenitor cells (CD34⁺), mesenchymal stem cells, and stromal cells.

Product Uses

Researchers may use these for:

- Hematopoietic growth factor studies
- Clonogenic assays
- Long-term culture initiating-cell assays (LTC-IC)
- Progenitor cell proliferation
- Progenitor cell differentiation
- Stem cell expansion
- Hematopoietic microenvironment studies
- Gene therapy research
- Drug screening
- Lead optimization
- High-throughput screening
- Toxicology

Product Preparation/Description

Fresh, Unprocessed Human Bone Marrow (Single Donor):

Human Unprocessed Bone Marrow is supplied in tubes and shipped fresh overnight. It is also available in gas permeable bags, upon request.

Cat. No.	Product	Description
1M-105	Human Bone Marrow, 10 ml	Fresh, Unprocessed Human Bone Marrow, 10 ml
1M-125	Human Bone Marrow, 25 ml	Fresh, Unprocessed Human Bone Marrow, 25 ml

Up to 100 ml of bone marrow can be obtained from a single donor upon request.

Fresh Bone Marrow Mononuclear Cells (Single Donor):

Bone marrow is diluted to 5-10 million cells per ml in HBSS. Cells are layered over Ficoll-Paque[®] and centrifuged. The mononuclear cell layer is removed and washed in HBSS. Cells are

resuspended in HBSS containing 0.5% Bovine Serum Albumin (BSA) and 5 mM EDTA, and shipped at 4°-8°C the same day the marrow is collected for next day delivery.

Cat. No.	Product	Description
1M-125C	Fresh MNC ≥25 million	Fresh Bone Marrow Mononuclear Cells, ≥25 million cells
1M-125D	Fresh MNC ≥100 million	Fresh Bone Marrow Mononuclear Cells, ≥100 million cells
1M-125A	Fresh MNC ≥200 million	Fresh Bone Marrow Mononuclear Cells, ≥200 million cells
1M-125E	Fresh MNC ≥300 million	Fresh Bone Marrow Mononuclear Cells, ≥300 million cells

Cryopreserved Bone Marrow Mononuclear Cells (Single Donor):

Cat. No.	Product	Description
2S-101D	MNC ≥5 million	Bone Marrow Mononuclear Cells, ≥5 million cells
2M-125C	MNC ≥25 million	Bone Marrow Mononuclear Cells, ≥25 million cells
2M-125B	MNC Cell Panel	Bone Marrow Mononuclear Cells, 5 Different Donors, 5 x ≥25 million cells
2M-125E	MNC ≥100 million	Bone Marrow Mononuclear Cells, ≥100 million cells

Cryopreserved Mesenchymal Stem Cells (Single Donor):

Bone marrow contains a population of rare progenitor cells known as Mesenchymal Stem Cells (MSC) capable of replication as undifferentiated cells or differentiating into bone, cartilage, fat, muscle, tendon and marrow stroma.

Cat. No.	Product	Description
PT-2501	hMSC	Human Mesenchymal Stem Cells, ≥750,000 cells

Fresh Bone Marrow CD34⁺ Progenitor Cells (Single Donor):

CD34⁺ progenitor cells are isolated from bone marrow mononuclear cells using positive immunomagnetic selection. Purity is ≥ 95%.

Cat. No.	Product	Description
1M-101	Fresh CD34+ Progenitors ≥100,000	Fresh Bone Marrow CD34+ Progenitor Cells, ≥100,000 cells
1M-101A	Fresh CD34+ Progenitors ≥300,000	Fresh Bone Marrow CD34+ Progenitor Cells, ≥300,000 cells
1M-101B	Fresh CD34+ Progenitors ≥500,000	Fresh Bone Marrow CD34+ Progenitor Cells, ≥500,000 cells
1M-101C	Fresh CD34+ Progenitors ≥1 million	Fresh Bone Marrow CD34+ Progenitor Cells, ≥1 million cells

Cryopreserved Bone Marrow CD34+ Progenitor Cells (Single Donor):

Cat. No.	Product	Description
2M-101	CD34+ Progenitors ≥100,000	Bone Marrow CD34+ Progenitor Cells, ≥100,000 cells
2M-101A	CD34+ Progenitors ≥300,000	Bone Marrow CD34+ Progenitor Cells, ≥300,000 cells
2M-101B	CD34+ Progenitors ≥500,000	Bone Marrow CD34+ Progenitor Cells, ≥500,000 cells
2M-101C	CD34+ Progenitors ≥1 million	Bone Marrow CD34+ Progenitor Cells, ≥1 million cells
2M-101D	CD34+ Progenitors ≥2 million	Bone Marrow CD34+ Progenitor Cells, ≥2 million cells

Cryopreserved Bone Marrow Stromal Cells (Single Donor):

Bone marrow stromal cells function as a feeder layer for hematopoietic progenitors allowing proliferation and differentiation of progenitors to continue for weeks without the addition of exogenous cytokines. Bone marrow stromal cells are isolated by culturing fresh mononuclear cells in liquid culture for 3 to 4 weeks using StemCell Technologies' MyeloCult® long term culture medium.

Cat. No.	Product	Description
2M-302	Bone Marrow Stromal Cells	Bone Marrow Stromal Cells, ≥5 million cells

Product Warranty

Cultures have a finite lifespan *in vitro*.

Lonza guarantees the performance of its cells only if Poietics™ Media and Reagents, where applicable, are used exclusively, and the recommend protocols are followed. The performance of cells is not guaranteed if any modifications are made to the complete cell system. Cryopreserved human bone marrow cells are assured to be viable and functional when thawed and maintained properly

When placing an order or for Scientific Support, please refer to the product numbers and descriptions listed above. For a complete listing of all Poietics™ Products, refer to the Lonza website or the current Lonza catalog. To obtain a catalog, additional information or want to speak with Scientific Support, you may contact Lonza by web, e-mail, telephone, fax or mail (See page 1 for details).

THESE PRODUCTS ARE FOR RESEARCH USE ONLY. Not approved for human or veterinary use, for application to humans or animals, or for use in clinical or *in vitro* procedures.

WARNING: CLONETICS™ AND POIETICS™ PRODUCTS CONTAIN HUMAN SOURCE MATERIAL, TREAT AS POTENTIALLY INFECTIOUS. Each donor is tested and found non-reactive by an FDA-approved method for the presence of HIV-1, hepatitis B virus and hepatitis C virus. Where donor testing is not possible, cell products are tested for the presence of viral nucleic acid from HIV, hepatitis B virus, and hepatitis C virus. Testing cannot offer complete assurance that HIV-1, hepatitis B virus, and hepatitis C virus are absent. All human-sourced products should be handled at the biological safety level 2 to minimize exposure of potentially infectious products, as recommended in the CDC-NIH manual, [Biosafety in Microbiological and Biomedical Laboratories](#), 5th ed. If you require further information, please contact your site safety officer or Scientific Support.

Ficol-Paque® is a registered trademark of GE Healthcare BIO-Sciences AB.

MyeloCult® is a registered trademark of StemCell Technologies.

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