

Case Study

**Bone marrow aspirate concentrates produced with the EmCyte
GSBMA-544E system and the Harvest/Terumo BMAC2
system**

**Prepared for:
Patrick Pennie
Chairman & CEO
EmCyte Corporation**

**Sample analysis by:
Biosciences Research Associates
Cambridge, MA**

Prepared by: *R J Mandle*
Robert J. Mandle, PhD
Laboratory Director

Date: 10 June 2015

Case Study: Bone marrow aspirate concentrates produced with the EmCyte GSBMA-544E system and the Harvest/Terumo BMAC2 system

Date of processing: 14 May 2015 Date of Testing: 15 May 2015

Objective: to compare bone marrow concentrates produced with two commercial systems, the EmCyte GSBMA-544E and the Harvest/Terumo BMAC2.

Approximately 120mL of bone marrow aspirate was drawn from each of two donors prior to surgical procedure. For each donor, 50 mL of aspirate plus 5mL of Na Heparin (1000 U/mL) and 5mL of NaCitrate was processed with the EmCyte system according to manufacturer's instructions for use. For each donor, 60mL of aspirate was added to the Harvest MarrowPREP Filter Bag along with 8mL of Anticoagulant Citrate Dextrose formula A and processed with the Harvest/Terumo SmartPREP 2 system according to manufacturer's instructions for use.

One mL samples of bone marrow concentrates aspirates were sent to the Testing Laboratory for the following analysis:

Total Nucleated Cell Counts (TNC): determined with a Coulter AcT Diff2 hematology analyzer.

Platelet Counts (PLT): determined with the Coulter analyzer

CD34 Pos. Cells: CD34 Positive cells were measured using an Accuri C6 flow cytometer.

Results:

Donor 1: Hematology parameters for marrow concentrates

Platform	TNC x 10 ⁶ /mL	PLT x 10 ⁶ /mL	Htc %	CD34 Pos./mL	Volume(mL)
EmCyte	75	767	56	286,697	8
Harvest	60	576	47	209,871	7

Donor 2: Hematology parameters for marrow concentrates

Platform	TNC x 10 ⁶ /mL	PLT x 10 ⁶ /mL	Htc %	CD34 Pos./mL	Volume(mL)
EmCyte	125	548	36	956,597	8
Harvest	132	406	39	726,264	7

Number of cells delivered

Platform	Nucleated Cells	Platelets	CD34 Positive Cells
EmCyte Donor 1	599 x 10 ⁶	6,136 x 10 ⁶	2,293,576
Harvest Donor 1	423 x 10 ⁶	4,032 x 10 ⁶	1,469,097
EmCyte Donor 2	998 x 10 ⁶	4,384 x 10 ⁶	7,652,776
Harvest Donor 2	925 x 10 ⁶	2,842 x 10 ⁶	5,083,848