EXACTECH | **BIOLOGICS**

PreparationTechnique

Accelerate®

CONCENTRATING SYSTEM

Bone Marrow

Exactech® BIOLOGICS

PREPARATION TECHNIQUE

1 CLOTTING PREVENTION

Step 1: Rinse the 60mL VacLok™ syringe with 10mL of heparin (1000 units per mL). Be sure to aspirate all the way back to the 60mL mark and completely empty syringe into medicine cup.

Step 2: Flush the Bone Marrow Aspirate (BMA) needle and Accelerate® tube with heparin.

Step 3: Fill the syringe with exactly 8mL of Anticoagulant Citrate Dextrose Solution (ACD-A).

Note: *Heparin must be transferred aseptically to the sterile field.*

2 BONE MARROW ASPIRATION

Step 1: Position the BMA needle at the harvest site *(Figure A)*.

Step 2: Advance the needle 4 to 6cm into the harvest site. Tap the needle into the bone while rotating in an alternating clockwise/counterclockwise motion *(Figure B)*.

Note: *You may need to use a hammer when inserting the needle into the bone.*

Step 3: Once the needle is in place, remove the stylet and attach the VacLok syringe to the needle *(Figure C)*.

Step 4: Aspirate 8-10mL of bone marrow. Withdraw the needle 1cm while rotating, then aspirate another 8-10mL. Continue this step until 52mL of bone marrow is obtained *(Figure D)*.

Note: *BMA + ACDA= 60mL*

Step 5: Gently mix the BMA and ACD-A by rotating back and forth 5 times.

3 BMA FILTRATION

Step 1: It is recommended to filter the bone marrow, because it may contain solid debris and fat.

Step 2: Attach the VacLok syringe to the sterile filter provided *(Figure E)*.

Step 3: Run the bone marrow through the filter and collect it in the empty 60mL syringe *(Figure F)*.

Step 4: Un-cap the line to aspirate the remaining bone marrow in the filter.

Note: *It may be necessary to bleed off air from the collection syringe.*

4 BMA SEPARATION/CONCENTRATION

Step 1: Fill the Accelerate tube with the filtered bone marrow *(Figure G)*, and counterbalance with an equivalent volume of water or saline. Place in the centrifuge at opposite ends *(Figures H, I)*.

Step 2a (Drucker Centrifuge): Centrifuge at 2400rpm for 12 minutes, 0 brake *(Figure H)*.

Step 2b (Eppendorf Centrifuge): Centrifuge at 3600rpm for 10 minutes, 0 brake *(Figure I)*.

Step 3: Remove the Accelerate tube and mount it on an IV pole with the clamp provided *(Figure J)*.

Figure A

Figure B

Figure C

Figure D

Figure E

Figure F

Figure G

Figure H

Figure I

Figure J

Continued on back side.

5 BMC EXTRACTION IN THE STERILE FIELD

Remove the Accelerate tube and harvest the buffycoat (2mL above the interface and 4mL below the interface) as follows:

Step 1: Connect one end of the transfer line to the three-way stopcock valve assembly that is attached to a 60mL syringe and a 12mL syringe.

Step 2: Connect the other end of the extension line from the sterile field to the bone marrow separator tube.

Step 3: With the stopcock valve closed to the 12mL syringe, SLOWLY draw plasma into the 60mL syringe. This will draw down the aspiration disc inside the blood tube *(Figure K)*.

Step 4: Stop when the buffycoat (red tint) reaches the blue marker *(Figure L)*.

Step 5: With the stopcock valve closed to the 60mL syringe, SLOWLY draw 6mL of the buffycoat (2mL above the interface and 4mL below the interface) into the 12mL syringe *(Figure M)*.

Figure K

Figure L

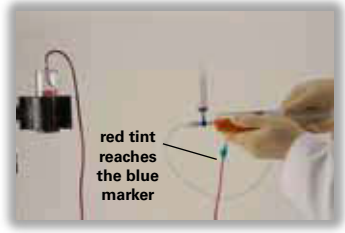

Figure M

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The Accelerate® Concentrating System is manufactured by Emcyte Corporation and distributed by Exactech. Accelerate Concentrating System has not been evaluated by the FDA for specific therapeutic indications or treatments.

The Accelerate Concentrating System is intended to be used in a clinical laboratory or intra-operatively at the point of care for the safe and rapid preparation of platelet poor plasma and platelet concentrate from a small sample of blood and for a preparation of a cell concentrate from bone marrow. The safety and effectiveness of this device for in vivo indications for use has not been established.

Some of the information concerning indications or applications applies only to locations outside the United States; these indications or applications may not have been evaluated by the USFDA.

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713-07-00 Rev. C
Accelerate BMC Prep. Tech. 1012

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