



# PrepaCyte<sup>®</sup>-CB Cord Blood Processing System Procedure Summary

## Intended Use

The PrepaCyte-CB (Cord Blood) Processing System is intended for use in cell processing laboratories to process and store total nucleated cells (TNC) from human umbilical cord blood, prior to banking. The device is composed of three integrally-attached processing and storage containers (or a single processing container) with separation media.

## Product Description

The Processing System contains PrepaCyte-CB solution, designed to facilitate rapid 1 x g sedimentation of red blood cells. With PrepaCyte-CB, the desired white blood cells, including CD34+ hematopoietic stem / progenitor cells, are recovered in the supernatant. The bag set is then centrifuged to pellet the desired cells prior to cryopreservation. PrepaCyte-CB is based on BioE's patented PrepaCyte technology platform.

**Equipment and Reagents (not included):** Plasma Extractor, Centrifuge, Controlled Rate Freezer, Liquid Nitrogen Freezer, Dielectric Sealer, Freezing Cassette, 5% Human Serum Albumin (USP), DMSO/Dextran 40

## Product Features

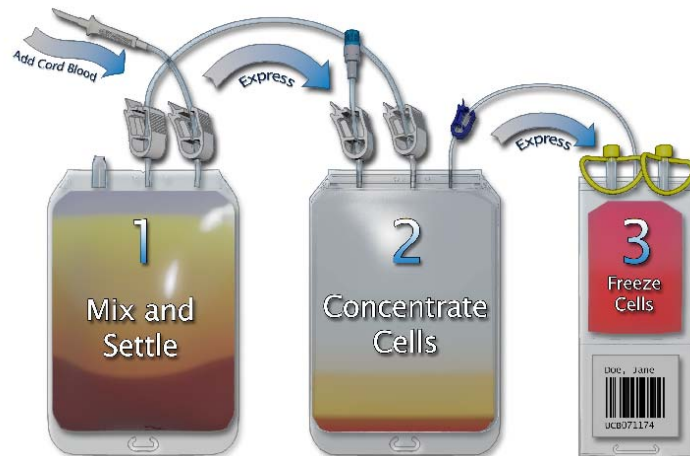
FDA 510(k) Cleared  
Manufactured under cGMP  
Simple and Cost Effective  
Intuitive and Easy to Use  
No additional Capital Equipment

## Processing Features

Process up to 200 mL of cord blood  
Needle-free ports on each bag  
Hands-on Time: 20 minutes  
Total processing time: approx. 1 hour

## Ordering Information

Contact BioE at 800-350-6466



*For illustration purposes only; not actual bag set. Segmented cryobag available*

## Procedure Summary

### Bag 1 (separation; bag pre-filled with PrepaCyte-CB reagent)

- Transfer cord blood into bag set using spike on bag 1.
- Mix bag for one minute. Mixing can be extended up to 20 minutes for batch processing if desired.
- Hang bag from a plasma extractor for 30 minutes. During this time, a red cell layer forms on bottom and a supernatant layer forms on top. The supernatant contains the nucleated cells and stem cells.
- Express supernatant into bag 2.

### Bag 2 (centrifugation)

- Centrifuge bag set at 400 x g for 10 minutes to pellet cells.
- Express centrifuge waste (top layer in bag 2) back into bag 1.
- Resuspend the pelleted cells. A reagent (BioE recommends 5% HSA) is added to bring to desired volume.

### Bag 3 (cryopreservation)

- Transfer cell suspension to bag 3 for cryopreservation.
- Add cryopreservative and perform a controlled rate freeze.
- Transfer cryobag to vapor phase or liquid nitrogen.

*This document is a summary of the PrepaCyte-CB Processing System procedure and is not intended to take the place of the Instructions for Use (product insert). Refer to the Instructions for Use for full processing procedure. **Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner.***