

PrepaCyte®-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 Cryo-Cell International's patented PrepaCyte technology platform.

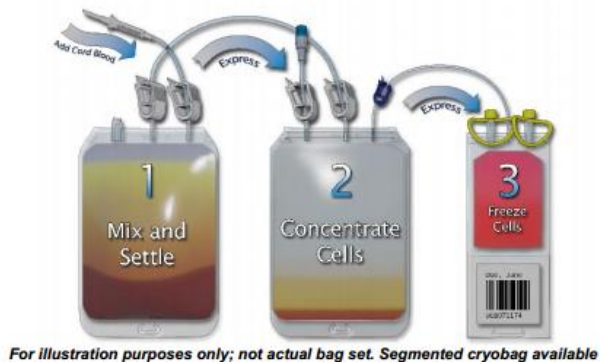
Equipment and Reagents (not included): Plasma Extractor, Centrifuge, Controlled Rate Freezer, Liquid Nitrogen Freezer, Dielectric Sealer, Freezing Cassette, 5% Human Serum Albumin (USP), DMSO/Dextran 40

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 Cryo-Cell International at 813-749-2103

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.
- Re-suspend the pelleted cells. A reagent (Cryo-Cell International 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.***