

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 a bag of 500 ml +/- 15 ml PrepaCyte CB reagent which can be added directly to the Cord Blood Collection bag then attached to a transfer/ freeze set (not included) to process and store.

Product Description

The PrepaCyte CB Processing System consists of a bag with an attached sterile port. It is a sterile, non-pyrogenic device, sterilized by gamma irradiation, prior to aseptic filling. One bag can be used to process up to eight cord blood units using 60mls of the media per cord blood unit. This media can be accessed by syringe through the syringe port, or a spike adapter can be added to the bag to supply the desired port.

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 813-749-2189



Procedure Summary

- Aseptically transfer 60 ml of PrepaCyte-CB Solution into the Cord Blood Collection Bag utilizing a sterile 60mL or equivalent syringe.
- Mix the Cord Blood Collection Bag for a minimum of one minute. Mixing can be extended up to 20 minutes for batch processing if desired.
- Hang bag for 30 ± 5 minutes at room temperature for aggregations and sedimentation to occur.
- Red blood cells will sediment to bottom of bag resulting in two distinct layers. The top layer (supernatant) contains the desired white blood cells, including CD34+ hematopoietic stem / progenitor cells.
- Using aseptic technique, insert a transfer bag spike into the cord blood collection bag port. Alternatively, sterile docking equipment can be used to connect the cord blood collection unit to the primary transfer bag of transfer set.
- Using the plasma extractor, express the supernatant into the Primary Transfer Bag.
- Centrifuge at 400 to 450 x g for 10 minutes to pellet cells.
- Express the centrifuged supernatant waste until desired final volume is achieved.
- Mix cell suspension.
- Add cryopreservative and perform a controlled rate freeze. Transfer cryobag to vapor phase or liquid nitrogen for storage.

*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.***