LEUKOTRAP RC SYSTEM- cp2d/as-3 triple blood bag unit with in-line rc2d filter and sampling system solution
GVS TM INC

CP2D/AS-3- 129-63

For collection of 500ml of whole blood and preapration of red blood cells and plasma or red blood cells, plasma and platelets with pre-storage leukocyte reduction of red blood cells.

Leukotrap RC System CP2D/AS-3 - Triple blood bag unit with In-Line RC2D filter and sampling system

Sterile, Non-pyrogenic fluid pathway. Sterilized by Steam

Store at room temperature. Unused bags in opened pouches may be kept 30 days by folding and securing open end of pouch to prevent possible loss of moisture.

PLACE DONATION
IDENTIFICATION NUMBER HERE

DO NOT TRANSFUSE UNLESS ABO
LABEL APPLIED HERE

Nutricel®
ADDITIVE
SOLUTION
(AS-3)

VOLUNTEER DONOR

110 ml of preservative AS-3 solution contains 1.21 g dextrose (monohydrate), USP; 0.647 g sodium citrate (dihydrate), USP; 0.451 g sodium chloride, USP; 0.304 g monobasic sodium phosphate (monohydrate), USP; 0.046 g citric acid (monohydrate), USP; and 0.033 g adenine, USP.

The protective packaging outside is not a part of the sterile barrier system.

GVS TM Inc.
1630 W Industrial Park St
Covina, CA 91722, USA

131192G-00 REV.0

Bag Intended For

RED BLOOD CELLS

Store at 1—6 °C.

REF **129–63**

LOT

5GV0012963

PLACE DONATION
IDENTIFICATION NUMBER HERE

DO NOT TRANSFUSE UNLESS ABO
LABEL APPLIED HERE

VOLUNTEER DONOR

CLX®

Container

The protective packaging outside is not a part of the sterile barrier system

GVS TM Inc.
1630 W Industrial Park St
Covina, CA 91722, USA

STERILE

US: Rx Only

2 STERILIZE

131191G-00 REV.0

Bag Intended For

PLATELETS OR PLASMA

REF **129–63**

LOT

6GV0012963

PLACE DONATION
IDENTIFICATION NUMBER HERE

DO NOT TRANSFUSE UNLESS ABO
LABEL APPLIED HERE

ANTICOAGULANT
CITRATE
PHOSPHATE
DOUBLE DEXTROSE
SOLUTION

70 ml Anticoagulant Citrate Phosphate Double Dextrose Solution for collection of 500 ml of blood. Each 70 ml of CP2D solution contains 3.57 g dextrose (monohydrate), USP; 1.84 g sodium citrate (dihydrate), USP; 0.229 g citric acid (monohydrate), USP; and 0.155 g monobasic sodium phosphate (monohydrate), USP.

VOLUNTEER DONOR

The protective packaging outside is not a part of the sterile barrier system

Bag Intended For

WHOLE BLOOD

Store at 1—6 °C.

GVS TM Inc.
1630 W Industrial Park St
Covina, CA 91722, USA

CP2D 500

STERILE

US: Rx Only

131190G-00 REV.0

REF 129–63

LOT

1GV0012963

GVS

US: Rx Only

GVS TM Inc.
1630 W Industrial Park St
Covina, CA 91722, USA

STERILE

RC2D Triple

500 ml CP2D/AS-3

LEUKOTRAP® RC SYSTEM

CP2D/AS-3 Triple Blood Bag Unit with In-Line RC2D Filter and Sampling System

For collection of 500 ml of whole blood and preparation of red blood cells and plasma or red blood cells, plasma, and platelets with pre-storage leukocyte reduction of red blood cells

Each unit consists of a collection bag with 70 ml of CP2D solution, an additive bag with 110 ml of AS-3 solution, and two empty CLX® satellite bags. Each 70 ml of CP2D solution contains 3.57 g dextrose (monohydrate), USP; 1.84 g sodium citrate (dihydrate), USP; 0.229 g citric acid (monohydrate), USP; and 0.155 g monobasic sodium phosphate (monohydrate), USP. Each 110 ml of AS-3 solution contains 1.21 g dextrose (monohydrate), USP; 0.647 g sodium citrate (dihydrate), USP; 0.451 g sodium chloride, USP, 0.304 g monobasic sodium phosphate (monohydrate), USP; 0.046 g citric acid (monohydrate), USP; and 0.033 g adenine USP.

Sterile, nonpyrogenic fluid path. Sterilized by steam. See accompanying directions for use. Store at room temperature. Unused bags in opened pouches may be kept 30 days by folding and SECURING open end of pouch to prevent possible loss of moisture.

REF 129-63

LOT 0000000

QTY 3 Units

0000-00 #

Made in Mexico

131187G-00 Rev.0

(01)10810197810651(17)000000(10)0000000

GVS

GVS TM Inc.
1630 W Industrial Park St
Covina, CA 91722, USA

REF 129-63

RC2D 500 ml
Triple CP2D/AS-3

LEUKOTRAP® RC SYSTEM

CP2D/AS-3 Triple Blood Bag Unit with In-Line RC2D Filter and Sampling System. For collection of 500 ml of whole blood. Sterile, nonpyrogenic fluid path. Sterilized by steam. Store at room temperature. Avoid excessive heat. Protect from freezing.

(01) 20387069129632
(17) 000000
(10) 0000000

QTY 18 Units

LOT 0000000

0000-00 #

Made in Mexico

(01)20810197810658(17)000000(10)0000000

US: Rx Only

STERILE

131188G-00 Rev.0

GVS TM Inc.
1630 W Industrial Park St
Covina, CA 91722, USA

Leukotrap® RC System

CP2D/AS-3 Blood Bag Unit with In-Line RC2D Filter and Sampling System

Intended for the collection of whole blood and preparation of red blood cells and plasma or red blood cells, plasma, and platelets with pre-storage leukocyte reduction of red blood cells.

Instructions for Use for Systems Containing a Sample Diversion Pouch (SDP) with a pre-attached Vacuum Tube Holder - See unit foil envelope for specific product code/description being used.

Sterile, nonpyrogenic fluid path. Sterilized by steam.

Precautions:

- Use aseptic technique.
- Use only if solutions are clear.
- Before use, visually inspect the sterile barrier system for any breaches of integrity, including tears, punctures, or seal damage.
- Do not use if the sterile barrier system is compromised.
- If moisture is observed on the outside of the collection system when removed from the cellophane pouch, subsequent handling and storage of an unused set within the foil pouch could encourage the growth of mold on the base label. Do not remove bag(s) from the foil pouch until ready to use. Unused bags in opened foil pouches may be kept 30 days by folding and SECURING open end of pouch to prevent possible loss of moisture.

Warning:

- Failure to achieve and maintain a closed system during processing will result in a product that must be transfused within 24 hours.

Notes:

- Filter and process whole blood within 72 hours of collection.
- When whole blood is at room temperature, filter within 8 hours of collection.
- When whole blood is at 1 – 6 °C, filter within 72 hours of collection.
- Follow AABB recommended centrifugation guidelines for component preparation.
- Do not exceed maximum head heights as indicated within the processing instructions.
- For systems with in-line snap-open closure(s), use oval style centrifuge buckets.
- This product is not made with natural rubber latex.
- During processing, always observe the following precautions:
  1. Sealing should be done in a manner that avoids fluid splatter.
  2. Always dispose of blood-contaminated products in a manner consistent with established BIOHAZARD safety procedures.

Tubing specifications:	**Fill line only:**
OD = 0.163"	OD = 0.160"
ID = 0.114"	ID = 0.114"
Wall = 0.0245"	Wall = 0.0245"

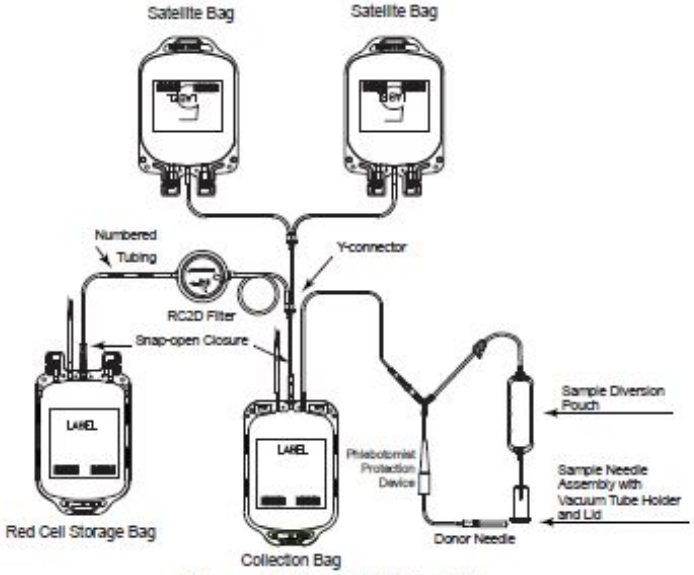


Diagram of the Complete Product Set

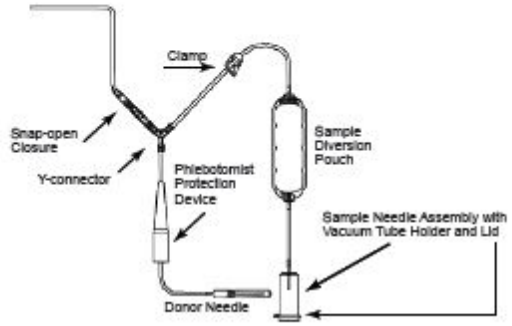


Figure 1: Donor Line with Sample Diversion Pouch and Pre-attached Vacuum Tube Holder with Lid

Blood Collection Instructions:

I. Systems Containing a Sample Diversion Pouch with a Pre-attached Vacuum Tube Holder – See Figure 1.

A. Accomplishing Phlebotomy:

1. Load blood collection mixer or suspend blood bag on donor scale. Adjust to desired collection volume or weight as per operating instructions for whichever equipment is being used. Place collection bag on blood collection mixer or donor scale as far below donor arm as possible.
2. If not previously performed, place a temporary clamp on the donor tubing between the donor needle and Y-connector, if required.
3. Disinfect site of phlebotomy and apply pressure to donor arm. If using a blood pressure cuff, inflate to not more than 60 mm Hg. If desired, secure the tubing to the donor's arm with tape below Phlebotomist Protection Device (PPD).

   Note:
   - Steps 1 through 3 can be performed in any order.

4. Remove donor needle cover by first twisting the cover at the base to break the seal, and then remove cover carefully.
5. Perform phlebotomy. Remove the temporary clamp, if used, and ensure there is blood flow. The donor's blood will automatically flow into the sample diversion pouch.
6. Stabilize the donor needle with tape.

   Warnings:
   - To avoid risk of air embolism to donor, do not squeeze sample diversion pouch while tubing to the pouch is open.
   - Ensure sample diversion pouch remains below the donor arm while tubing to the pouch is open.

   Note:
   - Do not reduce pressure on donor's arm until the snap-open closure has been opened (see Step 10).

7. If not previously performed, further stabilize the donor needle by taping the tubing below the PPD, if desired.
8. Once the sample diversion pouch is filled with the desired amount of blood, close clamp immediately on tubing between the sample diversion pouch and Y-connector.
9. Seal tubing between the sample diversion pouch and Y-connector to maintain sterility of the system prior to sample collection.
10. Open snap-open closure on the Y-connector to initiate blood flow into the collection bag. Reduce pressure on donor's arm as needed.

B. Collecting Samples from Sample Diversion Pouch:

1. Position the sample diversion pouch so that the air rises to the top of the pouch (away from the vacuum tube holder).
2. Open lid of the vacuum tube holder and collect samples.

   Precautions:
   - During sample collection ensure the vacuum tubes are centered within the vacuum tube holder and maintain forward pressure on the vacuum tube.
   - Collect blood samples from the sample diversion pouch into vacuum tube(s) within approximately four minutes to avoid possible clot formation.
   - Drawing air into a vacuum tube may cause hemolysis.

3. After the final sample collection, close the lid on the vacuum tube holder.

C. Collecting Blood:

1. Collect appropriate volume of blood into collection bag as indicated on packaging.

   Notes:
   - If blood collection mixer is used, follow manufacturer's operating instructions.
   - Mix blood and anticoagulant frequently during collection; for example, once every 45 seconds and immediately after collection.

D. Discontinuing Phlebotomy:

1. After required amount of blood has been collected, seal donor tubing between snap-open closure and collection bag.

   Note:
   - If pre-filtration quality control (QC) is to be performed, use the QC tubing attached to the collection bag. If additional tubing is needed, leave the desired amount of tubing containing anticoagulated blood attached to the collection bag.

2. Release any remaining pressure from donor's arm.
3. Remove the tape stabilizing the donor needle and tubing.
4. Advance PPD over the donor needle hub. If desired, clamp tubing behind the PPD.

   Note:
   - Steps 1 through 4 can be performed in any order.

5. While holding the top of the PPD, grasp the tubing below the PPD and pull the donor needle into the PPD with a continuous motion until the needle is completely withdrawn and secured into place.
6. If desired, insert the PPD into the vacuum tube holder.
7. Detach and discard the donor/needle assembly (e.g. needle, PPD, sample diversion pouch, and tubing) in the usual manner.
8. Strip the tubing between seal and collection bag, gently mix the whole blood and allow the tubing to refill OR seal off the tubing, detach and discard in the usual manner.

Blood Processing Instructions:

A. Centrifugation:

1. Load unit into centrifuge bucket, ensuring that the tubing stays in the top half of the bucket. Position the red blood cell filter in a horizontal position on top of the entire assembly and secure with tape or a rubber band.
2. Centrifuge at appropriate conditions to produce desired components.

B. Preparing Set:

Note:
- Prior to expression, ensure tubing between the Y-connector and the red blood cell filter (non-numbered tubing) is clamped. For efficient processing, the tubing may be clamped prior to removing the unit from the centrifuge bucket.

Automated Method

1. Refer to Manufacturer's Operating Instructions for loading centrifuged unit into automated blood separator and for device parameters.

Manual Method

1. Carefully remove the unit from the centrifuge and place the bag containing red blood cells in the plasma expressor.
2. Gently apply expressor pressure.
3. If not previously clamped, clamp the non-numbered tubing between the Y-connector and the red blood cell filter.
4. Clamp tubing to extra satellite bag(s), if present.

C. Expressing Plasma:

Automated and Manual Methods

1. Open snap-open closure of the collection bag and express plasma or platelet-rich plasma into a satellite bag.

   Note:
   - If performing Manual Method, do not apply extra pressure to increase flow rate.

2. Stop expression by clamping or sealing the tubing leading to the satellite bag(s) and release expressor pressure.
3. If not already sealed, seal tubing below the Y-connector leading to the satellite bag(s). Detach and set aside the plasma or platelet-rich plasma for further processing.

   Notes:
   - If preparing a platelet concentrate, the platelet-rich plasma should be separated from the red blood cells within 8 hours after collection.
   - If preparing Fresh Frozen Plasma (FFP), the plasma should be separated from the red blood cells and placed in the freezer at –18 °C or colder within 8 hours after blood collection.
   - If preparing Plasma Frozen Within 24 Hours After Phlebotomy (PF24), the plasma should be separated from the red blood cells and placed in the freezer at –18 °C or colder within 24 hours after blood collection.

D. Transferring Additive:

Automated Method

1. Refer to Manufacturer's Operating Instructions for transfer of additive solution.

Manual Method

Note:
- The snap-open closure may be opened prior to hanging the bag containing the AS-3 additive solution for additive transfer, providing the non-numbered tubing between the bag containing the red blood cells and the red blood cell filter is clamped.

1. Hang the bag containing the AS-3 additive solution so that the numbered tubing is fully extended and ensure the red blood cell filter is in a vertical position and above the bag containing red blood cells (i.e. collection bag).
2. Open clamp or snap-open closure of the bag containing the AS-3 additive solution, and transfer additive solution to the bag containing red blood cells.

   Note:
   - AS-3 additive solution should be added to the bag containing the red blood cells immediately after plasma or platelet-rich plasma removal.

3. Transfer AS-3 additive solution under one of the following conditions:
   a. Within 8 hours of collection if blood is held at room temperature.
   b. Within 72 hours of collection if blood is refrigerated after collection.

E. Blood Filtration Instructions:

1. Clamp the non-numbered tubing prior to raising the bag containing red blood cells and AS-3 additive solution for mixing in order to avoid the introduction of air into the red blood cell filter.
2. Mix red blood cells gently and thoroughly.
3. Hang the collection bag at one of the following heights:
   a. 60 ± 2 inches (1.52 ± 0.05 meters) for blood stored and filtered at room temperature.
   b. 60 to 72 inches (1.52 to 1.83 meters) for blood stored and filtered at 1—6 °C.
4. Ensure red blood cell filter is vertical and remove clamp to allow red blood cells to gravity flow through the red blood cell filter and into the red blood cell storage bag.

   Notes:
   - Do not apply mechanical or manual pressure to increase flow rate.
   - Filtration can begin at room temperature up to 8 hours or at 1—6 °C up to 72 hours post-collection.
   - If unit has not completely filtered by 8 hours post-collection at room temperature, filtration must be completed at 1—6 °C.
   - Filtration at maximum head height may shorten filtration times. "Head height" is the distance from the top of the bag containing the blood to be filtered to the horizontal plane where the filtered blood bag rests.
   - Filtration of red blood cells can be unattended.
   - Filtration times can be influenced by collection and processing conditions and biological variability of donors. Experimental data with some filter products indicate that a prolonged filtration can be an indication of sub-optimal leukocyte reduction.

5. Filtration is complete when the collection bag is empty. To maximize red blood cell recovery, allow the tubing above the red blood cell filter to empty.
6. Clamp and seal tubing below the red blood cell filter. The numbered tubing downstream of the red blood cell filter will not drain.

   Notes:
   - If the numbered tubing below the red blood cell filter has drained (emptied) after filtration, it is recommended to perform a residual white blood cell count on the unit.
   - Do not strip tubing prior to sealing the tubing below the red blood cell filter. If it is desired to strip blood from numbered tubing, do so only after tubing has been sealed close to the red blood cell filter and detached.
   - If it is necessary to strip blood from numbered tubing for re-suspension, care should be taken when stripping is performed. Increased (mechanical) hemolysis has been associated with stripping when blood is cold and has a higher hematocrit. Do not strip forcefully or frequently against a snap-open closure.

7. Detach and discard collection bag and red blood cell filter.
8. If desired, seal at or adjacent to "X" marks on tubing to provide numbered segments of anticoagulated blood for typing or crossmatching.

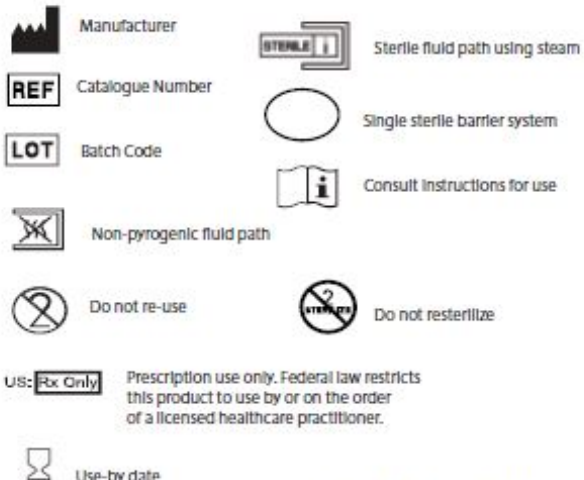
   Note:
   - If quality control is to be performed on post-filtration sample, use the attached QC line on the bag containing red blood cells.

9. Store CP2D/AS-3 preserved red blood cells at 1—6 °C for up to 42 days and use as indicated.

   Note:
   - If AS-3 additive solution is not used, whole blood or red blood cells in CP2D alone may be stored at 1—6 °C for up to 21 days.

F. Quality Control Testing:

Percent red blood cell recovery should be determined by following FDA Guidance entitled " Guidance for Industry - Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion", published in September 2012.



LEUKOTRAP RC SYSTEM

cp2d/as-3 triple blood bag unit with in-line rc2d filter and sampling system solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:87069-129
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	DEXTROSE, UNSPECIFIED FORM	3.57 g in 70 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:87069-129-63	18 in 1 CARTON		
1		3 in 1 POUCH		
1		70 mL in 1 BAG; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	BN820915	03/02/2026	

Labeler - GVS TM INC (119067149)

Registrant - GVS TM INC (119067149)

Establishment

Name	Address	ID/FEI	Business Operations
GVS TM INC		119067149	manufacture(87069-129)

Revised: 3/2026 GVS TM INC