ADSOL RED CELL PRESERVATION SOLUTION SYSTEM IN PLASTIC CONTAINER (PL 146 PLASTIC)- anticoagulant citrate phosphate dextrose (cpd) solution and adsol preservation solution
Fenwal, Inc.

Anticoagulant Citrate Phosphate Dextrose Solution, USP (CPD) BLOOD-PACK™ Unit; Satellite Container with ADSOL™ Red Cell Preservation Solution

Instructions for Blood Collection Using Anticoagulant Citrate Phosphate Dextrose Solution, USP (CPD) BLOOD-PACK™ Unit with an Integrally Attached Container of ADSOL™ Red Cell Preservation Solution

Rx only

Contains Sample Diversion System for the collection of whole blood samples for laboratory testing.

Also includes the DONORCARE™ Needle Guard.

Instructions for Use

Collection Procedure:

Use aseptic technique.

Notes:

If Sample Diversion System is not used, donor samples may be collected using an alternate method following standard procedures.
Nominal tubing dimensions of product are 0.118" inner diameter x 0.025" wall thickness.

Precautions:

Upon removal of BLOOD-PACK™ unit from the clear plastic overwrap, visually inspect the unit.
Do not use the product if the in-line cannula is broken and/or anticoagulant is present in the sample pouch or in the tubing from the in-line cannula to the sample pouch and donor needle (see Figure 1). Note that condensation in the empty tubing of the BLOOD-PACK unit is expected as a result of the sterilization process.
Do not use unless the solutions are clear.

1. Identify BLOOD-PACK unit using appropriate donor identification system.
2. Donor Scale

   Adjust donor scale to desired collection weight.
   Position primary container on the donor scale as far as possible below donor arm.

3. Clamp donor tubing between the needle and Y-junction with hemostat. (This step can be performed prior to step 1 or 2.)
4. Visually inspect the tubing from the in-line cannula to the sample pouch and donor needle, as well as the sample pouch to reconfirm that there is no anticoagulant present.
   Note: Ensure that the sample pouch remains below the donor's arm.
5. Following blood center procedures, apply pressure to donor's arm and disinfect site of venipuncture.

6. Remove needle cover per instructions below:

   Holding the hub and cover near the tamper-evident seal, twist cover 1/4 turn to break seal. Remove needle cover, being careful not to drag the cover across the needle point.

7. Following blood center procedures, perform venipuncture, appropriately secure donor needle and/or tubing and release hemostat.
8. When good blood flow is established, slide the DONORCARE™ needle guard over the needle hub into the engaged position. Leave the front third of the needle hub exposed for access. Stabilize the front of the needle guard to arm with tape. (see Figure 2)
   Note: In difficult collection conditions (e.g. slow blood flow), leave the needle guard disengaged behind the hub during collection. **Engage the needle guard at the end of blood collection. Appropriately secure needle and/or tubing.**
9. Allow the sample pouch to fill with blood according to center procedure. Monitor blood flow into sample pouch.

Notes:

The sample pouch contains an average fill volume of approximately 53 mL with a maximum fill volume of approximately 60 mL when filled to capacity.

If less blood sample volume is required, the flow to the sample pouch may be stopped prior to completely filling the pouch. For example, in order to target a fill volume of approximately 40 mL, fill to the level indicated by the arrows in Figure 1. Ensure the pouch is hanging vertically.

The tube leading from the Y-junction to the sample pouch contains an additional volume of approximately 2 mL.

Precautions:

Do not elevate or squeeze the sample pouch as this could cause blood to backflow from the sample pouch into the collection system.

Once the sample pouch is filled to desired volume, complete steps 10 – 18 within approximately 4 minutes to avoid possible clot formation in the tubing and/or sample pouch.

10. Close the blue clamp on tubing between the Y-junction and the sample pouch.
11. Break the in-line cannula below the Y-junction in the donor tubing to the primary container allowing blood collection to proceed. To completely break the in-line cannula, grasp with both hands. Snap it at a 90° angle in one direction, and then bend it at a 90° angle in the opposite direction. Ensure the in-line cannula is completely broken and that the blood flows freely to the primary container.

Precaution: Failure to break the in-line cannula completely may result in restricted blood flow.

12. Following blood center procedures, mix blood and anticoagulant in the primary container immediately and at several intervals during collection.
13. Following blood center procedures, hermetically seal the tubing between the sampling site and the Y-junction to maintain sterility of the blood collection system prior to removing blood samples.

Warning:

Do not proceed with the remaining steps until the tubing leading to the sample pouch is

hermetically sealed between the sampling site and the Y-junction. To maintain the whole blood collection container as a closed system, the tubing between the sample pouch and Y-junction must be hermetically sealed prior to inserting the access device into the sampling site. Failure to do so may lead to contamination of the whole blood collection.

14. Insert the access device by pushing firmly into the sampling site until the membrane seal is penetrated.

Note: If the access device is assembled such that the outer barrel is screwed onto the Luer, make sure to rotate clockwise upon insertion to avoid barrel detaching from Luer.

15. Open the cap on the access device (if applicable). Hold access device so that the sample pouch hangs down.
16. Directly align the vacuum sample tube with the internal needle in the access device. Insert vacuum sample tube into device.
17. Allow vacuum sample tube to fill with blood then remove from the access device.
18. Repeat steps 16 and 17 until the desired number of vacuum sample tubes have been filled.

Notes:

If the access device needs to be replaced, use a hemostat to clamp the tubing between the sampling site and the sample pouch. Then, grasp base of sampling site with one hand and pull the access device out with the other hand. Firmly insert the new access device. Remove hemostat and continue sampling.

If the access device is assembled such that the outer barrel is screwed onto the Luer, make sure to rotate clockwise upon removal to avoid barrel detaching from Luer.

The access device can only be replaced one time.

Precaution: When replacing access device, be careful to avoid contact with any blood droplets on the Luer or sampling site. Discard used access device appropriately.

19. Collect the appropriate volume based on BLOOD-PACK unit used.
Note: The volume of anticoagulant is sufficient for the blood collection indicated on BLOOD-PACK unit ± 10%.

Precaution: Once the desired blood volume is collected, complete steps 20-23 within approximately 4 minutes to avoid possible clot formation in the tubing.

20. Release pressure on the donor's arm. If appropriate, apply hemostat to donor tubing between the needle and the Y-junction.
21. Hermetically seal donor tubing near in-line cannula on side leading to the primary container.
22. **Withdrawal of Needle** (see Figure 3)

Precaution: The needle guard must be held stationary while the needle is withdrawn into it.

a) Place folded sterile gauze over puncture site and hold in place with finger tip without exerting pressure.
b) Hold sides of needle guard near the front, between the index finger and thumb. Pull the tubing smoothly until the needle is locked into the needle guard.
c) Confirm the needle lock by:

Listen for the 2nd “click” as the needle is drawn into the needle guard.
Ensure the tubing cannot be pulled through the needle guard.

23. Strip blood from donor tubing into primary container, mix and allow the tubing to refill; repeat once.
24. Seal at X marks on donor tubing to provide numbered aliquots of anticoagulated blood for typing or crossmatching.

Note: Step 25 may be performed prior to step 23 or 24 if desired.

25. Remove and discard the Sample Diversion System and needle guard into an appropriate biohazardous waste container following established procedures.

Component Preparation:

Notes:

If a platelet concentrate is to be prepared, it should be separated from the red blood cells within 8 hours after blood collection.

Fresh frozen 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.

ADSOL™ red cell preservation solution should be added to the red blood cells immediately after the removal of plasma. Preparation of AS-1 red blood cells may vary depending on processing option selected:

a) Within 8 hours of blood collection if whole blood is held at ambient temperature.
b) Within 3 days of blood collection if whole blood is refrigerated.

26. Centrifuge primary and secondary containers to prepare CPD red blood cells.
27. Place primary container in plasma extractor and express plasma into empty TRANSFER PACK™ container by releasing pressure plate and opening closure in tubing of primary container.
28. When desired amount of plasma has been removed, clamp tubing between Y and plasma container.
29. Suspend ADSOL red cell preservation solution container, open closure in tubing and drain contents into primary container of CPD red blood cells. Clamp tubing.
30. Seal transfer tubing in three places between the Y-connector and primary container. Cut middle seal being careful to avoid fluid splatter. **For Double BLOOD-PACK unit codes, discard ADSOL solution container. For other ADSOL codes,** the empty solution container may be used as a TRANSFER PACK™ container for further component preparation.
31. Mix ADSOL red cell preservation solution and red cells thoroughly.
32. Store suspended AS-1 red blood cells between 1 and 6°C.
33. Infuse AS-1 red blood cells within 42 days of collection.
Warning: Failure to achieve closed system processing conditions negates the extended storage claim and the red blood cell product must be transfused within 24 hours.

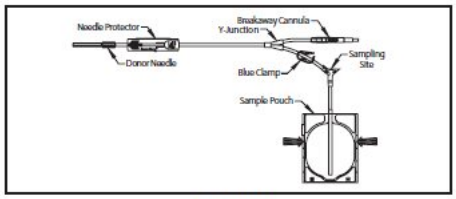


Figure 1

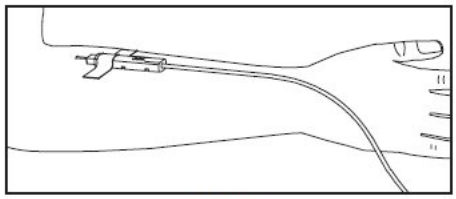


Figure 2

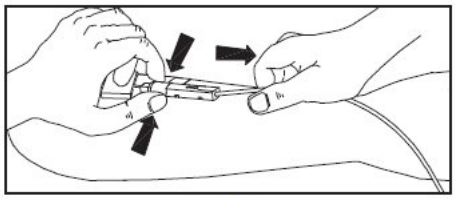
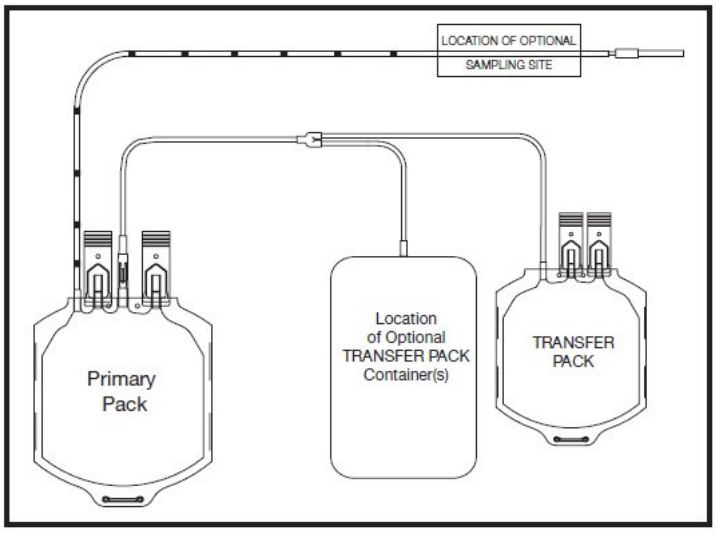


Figure 3



Representative Product Drawing

Store at Controlled Room Temperature.
USP Definition of “Controlled Room Temperature”
United States Pharmacopeia, General Notices.
United States Pharmacopeial Convention, Inc.
12601 Twinbrook Parkway, Rockville, MD

– Manufacturer

Fenwal, Inc
Lake Zurich, IL 60047 USA

Made in USA

1-800-933-6925

07-19-04-636 REV: A 03/2010

PACKAGE/LABEL DISPLAY PANEL

Code 4R3468

15 Units

Fenwal™

Anticoagulant Citrate Phosphate Dextrose Solution, USP (CPD) BLOOD-PACK™ Unit; Satellite Container with ADSOL™ Red Cell Preservation Solution

Double For the Collection and Processing of 500 mL Blood

Sample Diversion System, DONORCARE™ Needle Guard, 16 ga. Ultra Thin Wall Needle

Rx only

Each unit consists of a PL 146 Plastic primary container with 70 mL of CPD solution containing 1.84 g Sodium Citrate (dihydrate) USP, 1.78 g Dextrose (monohydrate) USP, 209 mg Citric Acid (anhydrous) USP, 155 mg Monobasic Sodium Phosphate (monohydrate) USP, pH may have been adjusted with sodium hydroxide; one PL 146 Plastic satellite container with 110 mL of ADSOL Red Cell Preservation Solution containing 2.42 g Dextrose (monohydrate) USP, 990 mg Sodium Chloride USP, 825 mg Mannitol USP, 30 mg Adenine USP; one empty 400 mL PL 146 Plastic TRANSFER-PACK™ container.

Sterile, non-pyrogenic fluid path
See instructions for use.

Store at Controlled Room Temperature (refer to direction insert).

Open pouch by tearing across at notch.

Direct handling of product surfaces prior to extended storage in the **foil** pouch, may result in mold growth.

Unused units in open **foil** pouch may be kept up to 60 days by folding and **securing** open end of **foil** pouch to prevent possible loss of moisture, provided:

I) Units are not removed from **foil** pouch, or

II) Unused units removed from **foil** pouch are returned to the **foil** pouch within 12 hours. Units may be removed from the pouch and returned only once.

Units removed from the **foil** pouch (that are not returned to the pouch within 12 hours) must be used within 4 days (96 hours). Units out of the **foil** pouch for longer than 96 hours must be discarded.

Fenwal, Inc.
Lake Zurich, IL 60047 USA

Made in USA

07-28-05-530 REV: A

Code 4R3468 15 Units

Fenwal

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Fenwal, Inc.
Lake Zurich, IL 60047 USA
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07-28-05-530 REV: A

ADSOL RED CELL PRESERVATION SOLUTION SYSTEM IN PLASTIC CONTAINER (PL 146 PLASTIC)

anticoagulant citrate phosphate dextrose (cpd) solution and adsol preservation solution kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0942-6461

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0942-6461-02	1 in 1 KIT		

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 BAG	70 mL
Part 2	1 BAG	110 mL

Part 1 of 2

CPD

citrate phosphate dextrose solution

Product Information	
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Trisodium Citrate Dihydrate (UNII: B22547B95K) (Anhydrous Citric Acid - UNII:XF417D3PSL)	Anhydrous Citric Acid	1.84 g in 70 mL
Dextrose Monohydrate (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	Dextrose Monohydrate	1.78 g in 70 mL
Anhydrous Citric Acid (UNII: XF417D3PSL) (Anhydrous Citric Acid - UNII:XF417D3PSL)	Anhydrous Citric Acid	209 mg in 70 mL
Sodium Phosphate, Monobasic, Monohydrate (UNII: 593YOG76RN) (PHOSPHATE ION - UNII:NK08V8K8HR)	Sodium Phosphate, Monobasic, Monohydrate	155 mg in 70 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Sodium Hydroxide (UNII: 55X04QC32I)	
Water (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
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	BN811104	03/01/2007	

Part 2 of 2

ADSOL RED CELL PRESERVATION SOLUTION SYSTEM

adsol red cell preservation solution solution

Product Information

Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Dextrose Monohydrate (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	Dextrose Monohydrate	2.42 g in 110 mL
Sodium Chloride (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37)	Sodium Chloride	990 mg in 110 mL
Mannitol (UNII: 3OWL53L36A) (Mannitol - UNII:3OWL53L36A)	Mannitol	825 mg in 110 mL
Adenine (UNII: JAC85A2161) (Adenine - UNII:JAC85A2161)	Adenine	30 mg in 110 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		110 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	BN811104	03/01/2007	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	BN811104	03/01/2007	

Labeler - Fenwal, Inc. (794519020)

Revised: 11/2019 Fenwal, Inc.