

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 Y-Sampling Site for the collection of unanticoagulated whole blood samples for laboratory testing and the DONORCARE™ Needle Guard

Use aseptic technique.

Note: Nominal tubing dimensions of product are 0.118" inner diameter x 0.025" wall thickness.

Note: If the Y-Sampling Site is not used, donor samples may be collected using an alternate method following standard procedures.

Precautions:

Do not use unless the solutions are clear.

Before beginning procedure, obtain one access device for each BLOOD-PACK™ unit with Y-Sampling Site to be processed.

1. Identify BLOOD-PACK unit using appropriate donor identification system.
2. Adjust donor scale to desired collection weight and position primary container on the donor scale as far as possible below donor arm.
3. Clamp donor tubing between needle and primary container. This step may be performed prior to step 1 or 2.
4. Apply pressure to donor's arm and disinfect site of venipuncture.
5. If blood pressure cuff is used, inflate to approximately 60 mmHg.
6. Remove needle cover per instructions below:
 - a) Holding the hub and cover near the tamper-evident seal, twist cover 1/4 turn to break seal.
 - b) Remove needle cover, being careful not to drag the cover across the needle point.
7. Perform venipuncture, appropriately secure donor needle and/or tubing and release clamp on donor tubing.
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 1)

Note: In difficult collection conditions (e.g. slow blood flow or fine veins), leave the needle guard disengaged behind the hub during collection. **Engage the needle guard at the end of blood collection.**

9. **Mix blood and anticoagulant in primary container at several intervals during collection and immediately after collection.**

10. 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 \pm 10%.
11. Release the pressure on the donor's arm as appropriate.

Precaution: Do not proceed with the remaining steps until the entire whole blood unit is collected.

12. To avoid possible contamination of the whole blood unit, before filling whole blood sample tubes, hermetically seal the donor tubing near the Y-Sampling Site on the side leading to the primary container using a metal clip or appropriate alternate method.

Precaution: Complete steps 13 - 21 within approximately 4 minutes after sealing the donor tubing to avoid possible clot formation in the tubing.

13. To collect samples, insert the access device by pushing firmly into the Y-Sampling Site until the membrane seal is penetrated (see Figure 2).

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.

14. Open the cap on the access device (if applicable).
15. Directly align the vacuum sample tube with the internal needle in the access device. Insert vacuum sample tube into device until the stopper is punctured.
16. Allow vacuum sample tube to fill with blood then remove from the access device.
17. Repeat steps 15 and 16 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 needle and the Y-Sampling Site. 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 the access device, be careful to avoid contact with any blood droplets on the Luer or Sampling Site. Discard used access device appropriately.

18. Release remaining pressure on donor's arm.
19. If desired, apply hemostat to donor tubing between needle and Y-Sampling Site.
20. **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.

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

Note: Step 23 may be performed prior to step 21 or 22 if desired.

23. Remove and discard the Y-Sampling Site and the DONORCARE Needle Guard into an appropriate biohazardous waste container following established procedures.

24. **Component Preparation:**

- 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.

25. Centrifuge primary and secondary containers to prepare CPD Red Blood Cells.
26. 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.
27. When desired amount of plasma has been removed, clamp tubing between Y and plasma container.
28. Suspend ADSOL Red Cell Preservation Solution Container, open closure in tubing and drain contents into primary container of CPD Red Blood Cells. Clamp tubing.
29. Hermetically seal and separate transfer tubing between the Y-connector and primary container. Be 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.**
30. Mix ADSOL Red Cell Preservation Solution and red cells thoroughly.
31. Store suspended AS-1 Red Blood Cells between 1 and 6° C.
32. Infuse AS-1 Red Blood Cells within 42 days of collection.

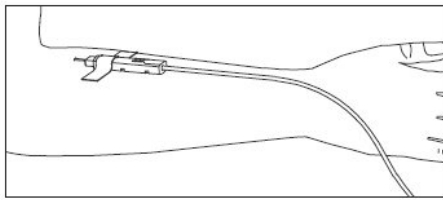


Figure 1

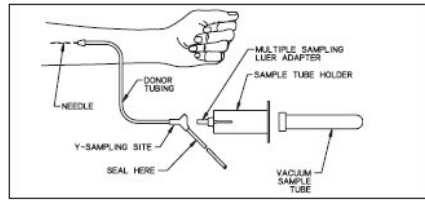


Figure 2

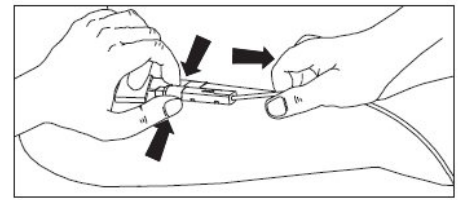
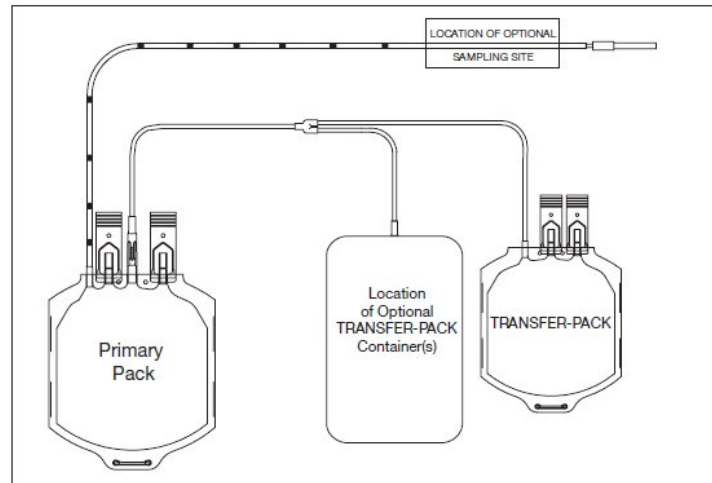


Figure 3



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



Fenwal, Inc.

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1-800-933-6925

Made in USA

07-19-07-484 REV: A

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DONORCARE is a trademark of ITL Corporation.



Manufacturer

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PACKAGE/LABEL DISPLAY PANEL

Code 4R3429

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

Y-Sampling Site, 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.

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DONORCARE is a trademark of ITL Corporation.



Fenwal, Inc.

Lake Zurich, IL 60047 USA

Made in USA

07-28-05-543 REV: A



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 Y-Sampling Site, DONORCARE™ Needle Guard, 16 ga. Ultra Thin Wall Needle

Rx only

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 - 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.

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Lake Zurich, IL 60047 USA

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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:0942-6431
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:0942-6431-02	1 in 1 KIT		
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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
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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:NK08 V8 K8 HR)	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	BN8 11104	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: 059QF0K00R)	

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	BN8 11104	03/01/2007	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	BN8 11104	03/01/2007	

Labeler - Fenwal, Inc. (794519020)