

NUTRICEL ADDITIVE SOLUTION - CP2D- cp2d/as-3 anticoagulant and additive system solution

NUTRICEL ADDITIVE SOLUTION - AS-3- cp2d/as-3 anticoagulant and additive system solution

Haemonetics Manufacturing Inc.

CP2D/AS-3 Blood Collection and Sampling System

DESCRIPTION

CP2D/AS-3 Blood Collection and Sampling System – Nutricel Additive System

Instruction for Use for Systems Containing a Y Sampling Site (YSS) or Sample Diversion Pouch (with or without a pre-attached SampLok® Vacuum Tube Holder).

Refer to unit foil package label for specific product description being used.

Sterile, nonpyrogenic fluid path. Sterilized by steam.

Rx only

This product is free of natural rubber latex.

INDICATIONS AND USAGE

For collection of blood and preparation of red blood cells, plasma and platelets.

WARNINGS

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

GENERAL PRECAUTIONS

Use aseptic technique. Use only if solutions are clear. If preparing a platelet concentrate, the platelet-rich plasma should be separated from the red blood cells within 8 hours after blood collection. If preparing fresh frozen plasma, separate from the red blood cells and place in the freezer at -18 °C or colder within 8 hours after collection.

* 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.

STORAGE

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

I. BLOOD COLLECTION INSTRUCTIONS FOR SYSTEMS CONTAINING A Y SAMPLING SITE(YSS) ONLY

1. Load blood agitation device or suspend blood bag on donor scale and adjust donor scale to desired collection gross weight as per manufacturer's instructions.

2. Clamp donor tubing between DonorCare® Needle Guard (DCNG) and Y Sampling Site.
 3. Secure donor tubing above the Y connector and disinfect site of phlebotomy.
 4. If using blood pressure cuff, inflate to not more than 60 mm Hg.
 5. Remove donor needle cover and accomplish phlebotomy.
 6. Release clamp and ensure there is blood flow. Reduce pressure as required.
 7. Slide the DCNG midway over the needle hub and securely tape DCNG to the donor's arm as close to the top of the DCNG as possible. Note: If blood flow is slow, slide DCNG away from the needle hub, adjust and re-engage DCNG. If repeated needle adjustment is necessary, slide DCNG away from the needle hub and re-engage at the end of blood collection.
 8. Collect appropriate volume of blood into collection bag, as indicated on packaging.
- Note: Mix blood and anticoagulant frequently during collection, for example, once every 45 seconds, and immediately after collection. If blood agitation device is used, follow manufacturer's operating instructions.
9. After required amount of blood has been collected, seal donor tubing close to Y Sampling Site.*
 10. For blood sampling, remove the Y Sampling Site needle cover. Ensure the protective sheath is in place over the sampling needle.
 11. Fasten the vacuum tube holder on to the base of the sampling needle.
 12. Collect blood samples into vacuum tubes.
 13. Ensure the vacuum tubes are centered within the vacuum tube holder during sample collection.
 14. Maintain forward pressure on the vacuum tubes during sample collection. Note: After the last tube is collected, it is recommended that the vacuum tube holder be left in place.
 15. After blood samples are collected, clamp donor tubing between the Y Sampling Site and DCNG, and as close to the DCNG as possible.
 16. Release any remaining pressure from the donor's arm.
 17. DCNG must be held stationary while the needle is withdrawn into it. While holding sides of DCNG near the front, grasp the tubing below the clamp and pull the needle into the DCNG until it locks into place, and the needle hub engages the bottom of the DCNG.
 18. Insert the DCNG into the vacuum tube holder. Note: It is recommended that the DCNG be inserted securely into the vacuum tube holder, prior to discarding.
 19. Seal donor tubing adjacent to DCNG.* Detach and discard needle, DCNG, Y Sampling Site and tubing.*
 20. Strip tubing between seal and collection bag.
 21. Continue to "Processing Instructions", Section IV, Step 1.

II. BLOOD COLLECTION INSTRUCTION FOR SYSTEMS CONTAINING A SAMPLE DIVERSION POUCH WITH OR WITHOUT A PRE-ATTACHED SAMPLOK® VACUUM TUBE HOLDER

When using systems with a pre-attached SampLok vacuum tube holder, follow instructions as noted below, but refer to Section III when indicated to do so.

1. Load blood agitation device or suspend blood bag on donor scale and adjust donor scale to desired collection gross weight as per manufacturer's instructions.
2. Clamp donor tubing between DonorCare Needle Guard (DCNG) and Sampling Site.

3. Secure donor tubing above the Y connector and disinfect site of phlebotomy.
4. If using blood pressure cuff, inflate to not more than 60 mm Hg.
5. Remove donor needle cover and accomplish phlebotomy.
6. Release clamp and ensure there is blood flow.
7. Slide the DCNG midway over the needle hub and securely tape DCNG to the donor's arm as close to the top of the DCNG as possible. Note: If blood flow is slow, slide DCNG away from the needle hub, adjust and re-engage DCNG. If repeated needle adjustment is necessary, slide DCNG away from the needle hub and re-engage at the end of blood collection.
8. The donor blood will be automatically diverted to the sample diversion pouch. Once the sample diversion pouch is filled, close clamp immediately on tubing between the sample diversion pouch and Y connector. Warning: To avoid risk of air embolism to donor, do not squeeze sample diversion pouch while tubing is open.
9. Open snap-open closure between the Y connector and the collection bag to initiate blood collection. Reduce pressure as needed.
10. Permanently seal tubing between the sample diversion pouch and the Y connector to maintain sterility of the system prior to collecting blood samples.* Note: When using systems with a pre-attached SampLok vacuum tube holder, go to Section III.
11. For blood sampling, remove the Sampling Site needle cover. Ensure the protective sheath is in place over the sampling needle.
12. Fasten the vacuum tube holder on to the base of the sampling needle.
13. Position the sample diversion pouch downwards so that the air rises to the top of the pouch and away from the vacuum tube holder. Note: Drawing air into the vacuum tube may cause hemolysis.
14. Collect blood samples from the sample diversion pouch into vacuum tubes within approximately four minutes to avoid possible clot formation.
15. Ensure the vacuum tubes are centered within the vacuum tube holder during sample collection.
16. Maintain forward pressure on the vacuum tubes during sample collection. Note: After the last tube is collected, it is recommended that the vacuum tube holder be left in place.
17. Collect appropriate volume of blood into collection bag as indicated on packaging. Note: Mix blood and anticoagulant frequently during collection, for example, once every 45 seconds, and immediately after collection. If blood agitation device is used, follow manufacturer's operating instructions.
18. After required amount of blood has been collected, seal donor tubing close to snap-open closure.*
19. Clamp donor tubing between the Y connector and DCNG, as close as possible to the DCNG.
20. Release any remaining pressure from donor's arm.
21. DCNG must be held stationary while the needle is withdrawn into it. While holding sides of DCNG near the front, grasp the tubing below the clamp and pull the needle into the DCNG until it locks into place, and the needle hub engages the bottom of the DCNG.
22. Insert the DCNG into the vacuum tube holder, if desired. Note: It is recommended that the DCNG be inserted securely into the vacuum tube holder, prior to discarding.
23. Seal donor tubing adjacent to DCNG.* Detach and discard needle, DCNG, sample diversion pouch and tubing.*
24. Strip tubing between seal and collection bag.
25. Continue to "Processing Instructions", Section IV, Step 1.

III. WHEN USING SYSTEMS WITH A PRE-ATTACHED SAMPLOK® VACUUM TUBE HOLDER

1. To collect blood samples, open lid from SampLok vacuum tube holder.
2. Open snap-open closure between sample diversion pouch and SampLok vacuum tube holder.
3. Position the sample diversion pouch downwards so that the air rises to the top of the pouch and away from the SampLok vacuum tube holder. Note: Drawing air into the vacuum tube may cause hemolysis.
4. Collect blood samples from the sample diversion pouch into vacuum tubes within approximately four minutes to avoid possible clot formation.
5. Ensure the vacuum tubes are centered within the SampLok vacuum tube holder during sample collection.
6. Maintain forward pressure on the vacuum tubes during sample collection.
7. The lid may be closed on the SampLok vacuum tube holder after sample collection.
8. Return to Section II, Step 17. Note: When collection of unit is complete, and the donor needle is engaged in the DCNG, open the lid of the SampLok vacuum tube holder and insert the DCNG into the holder. Twist until it locks into place. An audible click will confirm that it is locked

IV. PROCESSING INSTRUCTIONS

1. Process whole blood within 72 hours of collection.
2. Mix whole blood/anticoagulant thoroughly.
3. Load whole blood and satellite bags into centrifuge cup, ensuring that the tubing stays in the top half of the cup.
4. Centrifuge at appropriate conditions to produce desired components.
5. Carefully remove the unit from the centrifuge and place the red cell storage bag in the plasma expressor.
6. Clamp tubing to extra satellite bags, if present.
7. Gently apply expressor pressure.
8. Open snap-open closure to satellite bag and express plasma.
9. After plasma is expressed, clamp tubing between red cell storage bag and Y connector, and release expressor pressure.
10. Clamp tubing between the Y connector and plasma bag.
11. Hang AS-3 bag above red cell storage bag and remove clamp from tubing to the red cell storage bag.
12. Open snap-open closure on the bag containing the AS-3 additive solution and transfer to the bag containing the red cells. Note: AS-3 solution should be added to the packed red blood cells immediately after removal of plasma.
Transfer AS-3 solution under one of the following processing conditions:
 - a. within 8 hours of collection if whole blood is held at room temperature.
 - b. within 72 hours of collection if whole blood is refrigerated.
13. Seal tubing and detach the bag containing packed red cells, and set aside plasma for further processing.*
14. Gently mix packed red cells and AS-3 solution.

15. 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 is not used, whole blood or red blood cells in CP2D alone may be stored at 1–6 °C for up to 21 days.

HOW SUPPLIED

Each shipping case contains 8 foil envelopes. Within each foil envelope resides 3 clear pouches containing an individual collection system. Each unit consists of a collection bag with 70ml of CP2D solution, an additive bag with 110ml of AS-3 solution, and two empty CLX bags.

PRINCIPAL DISPLAY PANEL

AS-3 RED BLOOD CELLS ADENINE-SALINE ADDED 16.5 mEq sodium added

From 500ml CP2D Whole Blood Store at 1–6 °C

Anticoagulant Citrate Phosphate Double Dextrose Solution

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

See circular of information for indications, contraindications, cautions and methods of infusion. VOLUNTEER DONOR. This product may transmit infectious agents. Rx only. PROPERLY IDENTIFY INTENDED RECIPIENT.

CP2D 500

121-94

Collection Date	Unit Number	EXPIRES
<p>AS-3 RED BLOOD CELLS ADENINE - SALINE ADDED 16.5 mEq sodium added.</p> <p>04230</p> <p>From 500 ml CP2D Whole Blood. Store at 1–6 °C.</p> <p>See circular of information for indications, contraindications, cautions and methods of infusion.</p> <p>VOLUNTEER DONOR</p> <p>This product may transmit infectious agents. Rx only. PROPERLY IDENTIFY INTENDED RECIPIENT.</p>		<p>84</p> <p>ANTICOAGULANT CITRATE PHOSPHATE DOUBLE DEXTROSE SOLUTION</p> <p>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. Use only if solution is clear.</p> <p>670121942</p> <p>CP2D Affix Collection/Processing I.D. Label Here</p>
121-94	LOT #####	Manufactured for: Haemonetics Corporation 400 Wood Road Braintree, MA 02184, USA
<p>1HE0012194</p>		<p>Insert Barcode Here</p> <p>000#####</p>

Red cell storage in CLX bag limited to 21 days. Store platelets 5 days at 20–24°C

CLX Container CP2D 500

See circular of information for indications, contraindications, cautions and methods of infusion. VOLUNTEER DONOR. This product may transmit infectious agents. Rx only. PROPERLY IDENTIFY INTENDED RECIPIENT.

121-94

Collection Date	Unit Number	EXPIRES
<p>Place Product Label here after bag is filled.</p> <p>See circular of information for indications, contraindications, cautions and methods of infusion.</p> <p>VOLUNTEER DONOR</p> <p>This product may transmit infectious agents. Rx only.</p> <p>PROPERLY IDENTIFY INTENDED RECIPIENT.</p>		 <p>04</p> <p>Affix grouping label here after all required testing has been completed.</p> <p>CLX[®] Container</p> <p>675121942</p> <p>CP2D</p> <p>500</p>
		<p>Red cell storage in CLX[®] bag limited to 21 days. Store platelets 5 days at 20—24 °C.</p>
121-94	LOT	#####
	Insert Barcode Here	
6HE0012194	000#####	

110ml of preservative AS-3 solution contains 1.21g dextrose (monohydrate), USP; 0.647 g sodium chloride (dihydrate), USP; 0.451 g sodium chloride USP; 0.304 g monobasic sodium phosphate (monohydrate), USP; and 0.033g adenine, USP. Contains 16.5 mEq of sodium.

Use only if solution is clear.

See circular of information for indications, contraindications, cautions and methods of infusion. VOLUNTEER DONOR. This product may transmit infectious agents. Rx only. PROPERLY IDENTIFY INTENDED RECIPIENT.

121-94

Collection Date	Unit Number	EXPIRES
<p>Place Product Label here after bag is filled.</p> <p>See circular of information for indications, contraindications, cautions and methods of infusion.</p> <p>VOLUNTEER DONOR</p> <p>This product may transmit infectious agents. Rx only.</p> <p>PROPERLY IDENTIFY INTENDED RECIPIENT.</p>		 02 110 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. Contains 18.5 mEq of sodium. Use only if solution is clear.
		679121942
121-94 LOT #####		CP2D 500
 5HE0012194		Manufactured for: Haemonetics Corporation 400 Wood Road Braintree, MA 02184, USA  Insert Barcode Here 000#####

CP2D/AS-3 500ml QUAD

BLOOD COLLECTION SYSTEM with Nutricel Additive Solution

CP2D/AS-3 Quadruple with Sample Diversion Pouch

For collection of 500ml of blood and preparation of red blood cells, plasma and platelets

Each unit consists of a collection bag with 70ml of CP2D solution, an additive bag with 110ml of AS-3 solution, and two empty CLX satellite bags. Each 70ml of CP2D solution contains 3.57 g dextrose (monohydrate), USP; 1.84g sodium citrate (dihydrate), USP; 0.229 g citric acid (monohydrate), USP; and 0.155g monobasic sodium phosphate (monohydrate), USP. Each 110ml 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, non pyrogenic fluid path. Sterilized by steam. See accompanying directions for use. Rx only. 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.

3 Units Code 121-94

HAEMONETICS®

500 ml

Quad

CP2D/AS-3

**BLOOD COLLECTION SYSTEM
with Nutricel® Additive Solution**
CP2D/AS-3 Quadruple with Sample
Diversion Pouch

For collection of 500 ml of blood and preparation
of red blood cells, plasma and platelets

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. **Rx only**. 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.

US Pats. 5,968,619; 5,721,024; 6,060,138

3 Units

Code 121-94

Manufactured for: Haemonetics Corporation
400 Wood Road
Braintree, MA 02184, USA

By: Haemonetics Manufacturing Inc.
1630 Industrial Park Street
Covina, CA 91722, USA

www.haemonetics.com
888-489-5938

LOT #####

YYYY-MM #

151121943



[**Insert Barcode Here**]

(01)20887691311264(30)03(17)YYMM00(10)#####

REFERENCES

HAEMONETICS, *THE* Blood Management Company and Nutricel are registered trademarks of Haemonetics Corporation. DonorCare and SampLok are registered trademarks of ITL Corporation, Canberra, Australia.

MANUFACTURER

Manufactured for: Haemonetics Corporation

400 Wood Road

Braintree, MA 02184, USA

By: Haemonetics Manufacturing Inc

1630 Industrial Park Street

Covina, CA 91722, USA

Visit us at www.haemonetics.com

Phone: 888.489.593

NUTRICEL ADDITIVE SOLUTION - CP2D

cp2d/as-3 anticoagulant and additive system solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:53157-100
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROSE (UNII: IY9XDZ35W2) (DEXTROSE - UNII:IY9XDZ35W2)	DEXTROSE	3.57 g in 70 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN)	

Product Characteristics

Color	yellow (yellowish solution)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53157-100-96	8 in 1 BOX		
1	NDC:53157-100-95	3 in 1 POUCH		
1	NDC:53157-100-94	70 mL in 1 BAG		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	BN8 20915	09/13/2013	

NUTRICEL ADDITIVE SOLUTION - AS-3

cp2d/as-3 anticoagulant and additive system solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:53157-101
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROSE (UNII: IY9XDZ35W2) (DEXTROSE - UNII:IY9XDZ35W2)	DEXTROSE	1.21 g in 110 mL
ADENINE (UNII: JAC85A2161) (ADENINE - UNII:JAC85A2161)	ADENINE	0.033 g in 110 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	yellow (yellowish solution)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53157-101-99	8 in 1 BOX		
1	NDC:53157-101-98	3 in 1 POUCH		
1	NDC:53157-101-97	110 mL in 1 BAG		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	BN8 20915	09/13/2013	

Labeler - Haemonetics Manufacturing Inc. (078598396)

Registrant - Haemonetics Manufacturing Inc. (078598396)

Establishment

Name	Address	ID/FEI	Business Operations
Haemonetics Manufacturing Inc.		078598396	manufacture(53157-100)

Revised: 9/2013

Haemonetics Manufacturing Inc.