

CPDA-1 BLOOD COLLECTION SYSTEM- blood collection system solution
Haemonetics Corporation

CPDA-1 Blood Collection Set with Sampling System

DESCRIPTION

CPDA-1 Blood Collection Set with Sampling System

Instruction for Use for Systems Containing a Y Sampling Site (YSS) or Sample Diversion Pouch (with or without a pre-attached Samp Lok® 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. Platelets are not intended to be produced when using 'doubles' .

WARNINGS

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

GENERALPRECAUTIONS

Use Aseptic Technique.

Use only if solution is 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.

Store CPDA-1 preserved red blood cells at 1—6 °C for up to 35 days and use as indicated.

* 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.

ADVERSE REACTIONS

There are no known potential adverse reactions associated specifically with the CPDA-1 Blood Collection Set with Sampling System.

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 the Donor *Care*® 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 between Y Sampling Site and the collection bag.*
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, as close as possible to the DCNG.
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 SAMP LOK® VACUUM TUBE HOLDER

When using systems with a pre-attached Samp Lok 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 the Donor Care® 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 Samp Lok 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 the 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 SAMP LOK® VACUUM TUBE HOLDER

1. To collect blood samples, open lid from Samp Lok vacuum tube holder.
2. Open snap-open closure between sample diversion pouch and Samp Lok 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 Samp Lok 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 Samp Lok 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 Samp Lok 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 Samp Lok 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. If desired, seal at or adjacent to "X" marks on the tubing to provide numbered segments of anticoagulated blood for typing or crossmatching.*
2. Load whole blood and remaining bags into centrifuge cup, ensuring that the tubing stays in the top half of the cup.
3. Centrifuge at conditions designed to produce desired components.
4. Carefully remove the unit from the centrifuge and place the collection bag in the plasma expressor.
5. Clamp tubing to extra satellite bag(s), if present.
6. Gently apply expressor pressure.
7. Open snap-open closure on collection bag and express plasma.
8. After plasma is expressed, clamp tubing between satellite bag(s) whole blood bag and release expressor pressure.
9. Seal tubing and detach the bag containing packed red cells, and set aside plasma for further processing.*
10. Gently mix packed red cells.
11. Store CPDA-1 preserved red blood cells at 1—6 °C for up to 35 days and use as indicated.

HOW SUPPLIED

Each shipping case contains 8 foil envelopes. Within each foil envelope resides 3 units of the collection system. Each unit consists of a collection bag with 70 ml of CPDA-1 solution and one empty

bag.

REFERENCES

HAEMONETICS and THE Blood Management Company are trademarks of Haemonetics Corporation.

DonorCare and SampLok are registered trademarks of ITL Corporation, Canberra, Australia.

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

800-537-2802

IFU P/N 147130924

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

HAEMONETICS®

500 ml

Double

CPDA-1

BLOOD COLLECTION SYSTEM

**CPDA-1 Double with Sample Diversion
Pouch**

**For collection of 500 ml of blood and preparation
of red blood cells and plasma**

Each unit consists of a collection bag with 70 ml of CPDA-1 solution and one empty bag. Each 70 ml of CPDA-1 solution contains 2.23 g dextrose (monohydrate), USP; 1.84 g sodium citrate (dihydrate), USP; 0.229 g citric acid (monohydrate), USP; 0.155 g monobasic sodium phosphate (monohydrate), USP; and 0.019 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.

3 Units

Code 130-92

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 #####

YYMM #




151130924





[**Insert Barcode Here**]

(01)20887691307502(30)03(17)YYMM00(10)#####

Envelope Label

Collection Date	Unit Number	EXPIRES
<p>CPDA-1 RED BLOOD CELLS</p> <p>From 500 ml CPDA-1 Whole Blood Store at 1–6 °C.</p> <p>04060</p> 		 62 ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE ADENINE SOLUTION <small>70 ml Anticoagulant Citrate Phosphate Dextrose Adenine Solution for collection of 500 ml of blood. Each 70 ml of CPDA-1 solution contains 2.23 g dextrose (monohydrate), USP; 1.84 g sodium citrate (dihydrate), USP; 0.229 g citric acid (monohydrate), USP; 0.155 g monobasic sodium phosphate (monohydrate), USP; and 0.019 g adenine, USP. Use only if solution is clear.</small>
<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>		670130923 <p>CPDA-1 Affix Collection/Processing I.D. Label Here</p>
<p>130-92 LOT</p> 		<p>Manufactured for: Haemonetics Corporation 400 Wood Road Braintree, MA 02184, USA</p>
<p>1HE0013092</p>		

Collection Bag Label

Collection Date	Unit Number	EXPIRES
<p>Place Product Label here after bag is filled.</p> <p>3</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>		 02 Affix grouping label here after all required testing has been completed. 675130922 <p>CPDA-1 Affix Collection/Processing I.D. Label Here</p>
<p>130-92 LOT</p> 		<p>Manufactured for: Haemonetics Corporation 400 Wood Road Braintree, MA 02184, USA</p>
<p>3HE0013092</p>		

Plasma Bag Label

CPDA-1 BLOOD COLLECTION SYSTEM

blood collection system solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:53157-130
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	DEXTROSE MONOHYDRATE	2.23 g in 70 mL
SODIUM CITRATE (UNII: 1Q73Q2JULR) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL, SODIUM CATION - UNII:LYR4M0NH37)	SODIUM CITRATE	1.84 g in 70 mL
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	0.229 g in 70 mL
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN) (PHOSPHATE ION - UNII:NK08V8K8HR, SODIUM CATION - UNII:LYR4M0NH37)	SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE	0.155 g in 70 mL
ADENINE (UNII: JAC85A2161) (ADENINE - UNII:JAC85A2161)	ADENINE	0.019 g in 70 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53157-130-92	24 in 1 CARTON		
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	BN800077	11/06/1980	

Labeler - Haemonetics Corporation (057827420)

Establishment

Name	Address	ID/FEI	Business Operations
Haemonetics Manufacturing Inc		078598396	manufacture(53157-130)