 <p>PHILIPPINE HEART CENTER INCIDENT COMMAND POST</p>	Document Type	Document Code: SOP-ICP-019
	STANDARD OPERATING PROCEDURE	
	Document Title	Effective Date: April 27, 2020
	PLASMA APHERESIS (FOR COVID-19 COVALESCENT PLASMA COLLECTION)	
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I. PURPOSE

To collect 250 cc to 400 cc of plasma from a single donor to cater to special cases for patients with COVID-19 SARS COV-2 illness.

II. SCOPE

From donor selection to storage of plasma pheresis.

III. POLICY

The Philippine Heart Center Blood Bank staff shall follow the proper donor selection of recovered patient from COVID-19 and procedure in plasma pheresis.


IV. RESPONSIBILITY

Blood Bank staff on duty shall ensure the following:

1. Proper donor selection of recovered patient from COVID-19 for apheresis procedures.
2. Preventive measures (use of Personal Protective Equipment) in donor screening and testing.
3. Proper instructions and information to donors selected for apheresis.
4. Proper installation of a pheresis machine.
5. Proper handling and storage of plasma pheresis collected.

V. DEFINITION OF TERMS

1. **Plasma Apheresis donation-** is the process of removal of blood plasma from and to the blood circulation. Blood is removed from the body, blood cells and plasma are separated, and the blood cells are returned while the plasma is collected and frozen to preserve it for eventual use as fresh frozen plasma or as an ingredient in the manufacture of a variety of medication.
2. **ACD-A** (Acid Citrate Dextrose – Adenine) – an anticoagulant solution

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3. **FFP** – Fresh Frozen Plasma
4. **CCP** – Covid-19 Convalescent Plasma
5. **0.9% Sodium chloride solution (NSS)** – Normal saline solution, for donor fluid replacement.

VI. CLINICAL SIGNIFICANCE

Plasma pheresis procedures are by design intended to collect large volume of plasma (250 to 400 cc) from an individual, thereby providing a more consistent product with fewer donor exposures for the patient. The convalescent plasma will be for rescue treatment for severely ill COVID-19 patients or suspect patients (awaiting diagnostic test results) with clinical signs and symptoms of SARS-COV-2, as emergency investigational new drug.


VII. MATERIALS

1. Haemonetics MCS+ machine
2. Haemonetics MCS+ Extended Storage Platelet (ESP)/ Plasma Apheresis Set
3. Haemonetics platelet protocol card (with modified parameters)
4. Anticoagulant solution (500 mL) {ACD-A}
5. Venipuncture materials and extra clamps
6. 0.9% Sodium chloride solution (Normal Saline Solution:NSS)

VIII. PROCEDURE

1. PRINCIPLE

The procedure for plasma pheresis donation is much the same as normal blood donation. The blood will be extracted from the arm through a sterile, disposable kit that is housed in a special machine called a cell-separator which removes the required components from the blood by using another machine called a centrifuge. The remaining blood is returned to the donor using the same needle.


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2. DONOR SELECTION


- 2.1 Recovered from COVID-19 should have or present documentation of PCR diagnostic test at time of illness or positive serological test for SARS-COV-2 antibodies after recovery if prior diagnostic testing was not performed. There should be complete resolution of symptoms at least 28 days or permitted by allogeneic donor eligibility criteria.
- 2.2 For Female donors: Perform HLA antibody screening if with history of pregnancy, either full-term or terminated. (for Transfusion-related Acute Lung Injury (TRALI) mitigation.
- 2.3 The CCP donor may donate plasma once every 28 days as permitted by a physician and allogeneic donor eligibility criteria, not exceeding 1000mL of plasma collection.
- 2.4 Accept the donor if he / she has passed the general criteria used to select donors for whole blood donation including the health history, vital signs and weight.
- 2.5 Check if venipuncture site is optimal for apheresis. Defer if otherwise.
- 2.6 Accept if the donor's Mean Corpuscular Volume (MCV) is 80fL or higher.
- 2.7 Accept if the donor's Hematocrit is not less than 40% and not more 44%.
- 2.8 Accept if Hemoglobin is atleast 12.5 g/dL for females and 13.0 g/dL in males.
- 2.9 Accept if with WBC count and platelet count is within normal range.
- 2.10 Complete screening tests are performed on a donor sample(s) before performing the procedure.
- 2.11 Check if the donor is negative/nonreactive to transfusion-transmissible infections before starting the apheresis procedure.
- 2.12 Refer to Blood Testing Technical Procedures for donor testing.

3. HAEMONETICS PROCEDURAL STEPS

- 3.1 Open the Haemonetics MCS+ machine cover.

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- 3.2 Fully extend the weigher arm.
- 3.3 Insert the platelet protocol card if not yet inserted.
- 3.4 Power-on the Haemonetics MCS+ machine.
- 3.5 Self test: Turn the centrifuge knob when asked by the machine.
- 3.6 Select for Plasma Collection/NSS compensation. Press Draw.
- 3.7 Install the disposable kit (Haemonetics MCS+ Extended Storage Platelet (ESP)/ Plasma Apheresis Set) on a step by step procedure as instructed by the machine.
- 3.8 Read the corresponding messages to verify the installation.
- 3.9 Press Draw button to load the pumps.
- 3.10 Read the screen and follow the instructions.
- 3.11 Spike the anticoagulant (ACD-A 500 mL).
- 3.12 Press Prime to prime the disposable kit.
- 3.13 Enter donor information and procedure program in the Haemo Calculator.
- 3.14 Set the target amount of Plasma volume in the Haemo Calculator and the minimum amount of yield of platelet count.
- 3.15 Press Help to go to Main display.
- 3.16 Press Modify to adjust Draw/Return to safe setting (40 mL/min recommended).
- 3.17 Prepare the donor for the procedure. Place cuff on the donor's arm. Press cuff to inflate.
- 3.18 Perform the proper aseptic technique for venipuncture procedure.
- 3.19 Adjust the pump rate as necessary.
- 3.20 Once procedure is complete, remove the needle from the donor.
- 3.21 Divide the collected plasma pheresis into two, each contain 200 mL if minimum of 400 mL is reached.


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- 3.22 Remove the disposable kit from the machine.
- 3.23 Close the cover, then turn-off the machine.
- 3.24 Test the collected plasma pheresis for Total Protein: Albumin-Globulin ratio (TPAG) if within normal.
4. LABELING: Apheresis Plasma bags are labeled with the following information:
 - 4.1 Indicated as "Apheresis Convalescent Plasma" with the volume of plasma collected and approximate mL of ACD-A used.
 - 4.2 ABO and Rh typing (from previously obtained sample of the donor)
 - 4.3 Donor serial number
 - 4.4 Extraction date
 - 4.5 Expiration date
 - 4.6 Indicated: Collected from a donor with pre-existing antibodies to SARS COV-2. (Indicate the result of IgG/IgM titer if available).
5. REVERSE TYPING

An adequate sample from the segment of collected blood components is tested for reverse typing for verification of donor's ABO typing.
6. STORAGE
 - 6.1 Plasma is frozen solid within 8 hours of collection for FFP and stored for at least -18°C or colder, with a storage lesion of 1 year.
 - 6.2 Plasma is arranged according to blood type for proper blood inventory. A separate compartment shall be used for storing CCP.
7. INVENTORY

Enter date of inventory. Serial number and blood type to daily blood census and enter the actual count on the 24 Hours Blood Facility Report.
8. POST DONATION CARE

(see SOP-ICP-019)

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IX. REFERENCES

American Association for Blood Bank. (2020). COVID-19 Convalescent Plasma Collection:
Donor Eligibility, Processing, Labeling and Distribution.