



**GOVERNMENT OF KARNATAKA**

No: HFW 313 ACS 2020

Karnataka Government Secretariat  
Vikasa Soudha  
Bengaluru, Date: 21.08.2020

**CIRCULAR**

**Subject:** Guidelines for COVID-19 convalescent plasma therapy

**Reference:** 1. Updated clinical management protocol for COVID-19 from Ministry of Health Family Welfare, Government of India dated 03.07.2020  
2. Guidance document on COVID-19 convalescent plasma (CCP) therapy from Indian Society of Transfusion Medicine (ISTM) dated 25.07.2020

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Ministry of Health and Family Welfare, Government of India has allowed 'Off Label' use of convalescent plasma in patients with moderate COVID-19 disease who are not improving (oxygen requirement is progressively increasing) despite use of steroids. Special prerequisites while considering convalescent plasma therapy include:

- ABO compatibility and cross matching of the donor plasma
- Neutralizing titer of donor plasma should be above the specific threshold (if the latter is not available, plasma IgG titer (against S-protein RBD) above 1:640 should be used)
- Recipient should be closely monitored for several hours post transfusion for any transfusion related adverse events
- Use should be avoided in patients with IgA deficiency or immunoglobulin allergy
- Dose: Dose is variable ranging from 4 to 13 ml/kg (usually 200 ml single dose given slowly over not less than 2 hours)

At present, use of convalescent plasma therapy is based on limited available evidence. As the situation evolves, and when more data become available, the evidence will be accordingly incorporated, and recommendation upgraded. Further, use of convalescent plasma therapy is subject to its limited availability in the state as of now. Currently, convalescent plasma therapy should only be used in a defined subgroup of patients as recommended.

This document provides guidelines for use of convalescent plasma therapy in COVID-19 patients. These guidelines will be updated as more evidence becomes available and based on GOI guidelines from time to time. However, an informed and shared decision making is essential before prescribing convalescent plasma therapy.

## COVID Convalescent Plasma (CCP) Donors

### Searching for Donors:

- Blood bank should identify potential CCP donors from the list of COVID-19 recovered patients and recruit them as plasma donors.
- Blood bank should seek help and coordination of NGO (non-government organization) working for this "cause". Patient's family may be advised to search voluntary COVID-19 recovered patient willing for CCP donation through social media platforms and mass media amongst their 'near and dear ones' or/and through various NGOs which are maintaining a data-base of the persons who have recovered from COVID-19 disease.
- Family members may be advised to search for blood group compatible donors fulfilling donor eligibility criteria as vide below. Due care and caution has to be exercised by the blood bank to prevent paid/professional donations.
- Patients admitted in COVID institutions/ hospitals for treatment shall be counselled during their stay and also during discharge regarding uses of CCP and motivate them
- Since the donation is purely voluntary in nature, Government of Karnataka provides sum of Rs: 5000/- towards nutrition and care of donor (Annexure-1)
- **ABO and Rh (D) blood group compatibility:** Only ABO blood group compatibility is required in plasma donation. Rh (D) blood group can be ignored, provided anti-D antibodies are not present in Rh (D) Negative donor.

### Compatibility of convalescent COVID plasma (CCP)

Patient Blood Group	Compatible CCP donor
A	A, AB
B	B, AB
AB	AB
O	O, A, B, AB

### Additional requirements:

- Written informed consent for donation of convalescent plasma shall be taken. Refer donor Informed Consent Form (ICF), ICMR template (Annexure 2) from the donor in addition to regular donor health questionnaire cum consent form.
- Blood bank should possess license for plasmapheresis.
- Blood bank/hospital should have facility to measure serum protein.
- Blood bank should have facility to measure anti-SARS-CoV-2 IgG antibodies.

### Eligibility criteria for the CCP donor

- To mitigate the risk of Transfusion Related Acute Lung injury (TRALI), donors shall be males or nulliparous females of over 50 kg of body weight.
- The donor shall be in the age group of 18 to 60 years.

- Recovered patient (CCP donor) should preferably have had symptoms (fever, cold, cough, etc.) since there is a greater probability of presence of anti-SARS-CoV-2 IgG antibodies as compared to an asymptomatic patient. However, even asymptomatic donors may be accepted, if anti-SARS-CoV-2 IgG antibodies are present.
- Complete resolution of symptoms at least 14 days prior to donation, preferably, with one negative RT-PCR test report for SARS-CoV-2 virus infection from nasopharyngeal/throat swab,

OR

Complete resolution of symptoms 28 days prior/ post discharge. RT-PCR negative report is not mandated in this situation.

- Prior diagnosis of COVID-19 disease is not mandatory since anti-SARS-CoV-2 IgG antibodies, being performed now, are direct evidence of prior COVID-19 disease.
- Donor should be advised to donate not more than twice a month. The maximum number of times that a donor can donate is twice a month/fortnightly (24 times a year).

**Note:** In addition, donor eligibility criteria for whole blood/Apheresis donation will be followed in accordance to the Drugs & Cosmetics Act 1940 and rules therein (as amended till March 2020).

## Blood Bank

### Pre-donation health screening and testing:

- Once the donor has completed questionnaire on medical history, physical examination shall be done. If the donor is found eligible, the pre-donation samples collected (2 EDTA samples & 1 plain sample).
- Blood samples are tested for:
  - complete blood counts (CBC)
  - ABO and Rh D blood group
  - Antibody screen
  - Routine TTD (Transfusion Transmissible Diseases – anti HIV 1 & 2, anti-HCV, HBsAg, test for Malaria and Syphilis)
  - Serum proteins and anti-SARS-CoV-2 IgG antibodies- these two tests are specifically for CCP plasmapheresis donation
- Total serum protein of > 6gm/dl is not (should not be) a criteria for CCP plasmapheresis, however presence of anti-SARS-CoV-2 IgG antibodies are pre-requisite for CCP plasmapheresis donation.
- Though the DCGI document dated 1<sup>st</sup> July 2020 mentions a titer of 1:640, it is recommended that in absence of quantitative test kits, at least the qualitative test (Yes/No) should be used for deciding upon donor eligibility. The donors with negative anti-SARS-CoV-2 IgG antibodies should be deferred.
- It is recommended to keep a donor serum sample frozen at < -30° Celsius



### **Plasmapheresis procedure:**

- Once the donor has been screened and found eligible, the plasmapheresis procedure shall be initiated.
- Any automated cell separator (apheresis machine) may be used.
- Maximum CCP Volume collection that is allowed is 500 ml.
- If the apheresis machine does not have dedicated plasmapheresis program, the plateletpheresis procedure may be modified in a manner that at least 400 ml (two therapeutic doses of 200 ml each) plasma is obtained and minimum possible number (and volume) of platelets are collected. This by-product (where platelets are collected separately and later on suspended in the plasma) may be discarded or returned to the donor (depending on the cell separator). The maximum volume that can be collected in one session is 500 ml.

### **Storage of the CCP product:**

- CCP has to be stored at temperature  $< -30^{\circ}$  Celsius.
- Convalescent plasma collected through apheresis is aliquoted as 200ml bags and is frozen within 8 hours and stored as "Convalescent Frozen Plasma – For COVID patients only" at  $< -30$  degree Celsius.
- The unit may be quarantined in "un-tested" if any test result is pending. It should be moved to "tested" compartment once the testing results are satisfactory.
- Separate shelf of deep freezer (or if possible, separate deep freezer) shall be dedicated for CCP.
- The plasma units should be transported in temperature-controlled conditions.

### **CCP Recipient**

- As per ICMR definition: Patients admitted with RT-PCR confirmed COVID-19 illness and has either PaO<sub>2</sub>/ FiO<sub>2</sub>: 200-300 OR Respiratory Rate  $> 24$ /min and SaO<sub>2</sub>  $< 93\%$  on room air
- As per MOHFW definition: Adolescent or adult with presence of clinical features of dyspnea and or hypoxia, fever, cough, including SpO<sub>2</sub>  $< 94\%$  (range 90-94%) on room air, Respiratory Rate  $\geq 24$  per minute OR Child with presence of clinical features of dyspnea and or hypoxia, fever, cough, including SpO<sub>2</sub>  $< 94\%$  (range 90-94%) on room air, Respiratory Rate  $\geq 24$  per minute

### **Receiving of cross-match request and patient's sample:**

- Once patient's request form for CCP is received, the blood group is performed, if not done previously. It is a good practice to perform group and screen for all patients at the time of admission.
- A separate consent form (besides regular consent that is part of hospital/blood bank protocol) is required. Refer patient Informed Consent Form (ICF) ICMR template; (Annexure 2).
- The request form should mention "off-label" use of CCP.

- A blood component requisition by a qualified physician, from another designated COVID-19 treatment hospital or a hospital treating COVID-19 patient may also be accepted.
- The CCP of a particular blood group stored in a blood bank may be transferred or exchanged with another licensed blood center, depending on actual need as advised by physician. Appropriate documentation including blood component transfer records should be maintained by both the licensed blood centers.
  - Name and unique ID of patient
  - Unique ID of the unit
  - ABO blood group of the patient and CCP Unit
  - Date of issue (dd/mm/yyyy)
  - Name and ID of the technical person who performed the crossmatch

#### **Thawing and cross-matching the CCP unit :**

- The plasma unit is thawed and the plasma bag segment is used for minor crossmatch with patient's RBC (red blood cells).
- ABO and Rh group specificity should be followed during allotment of convalescent plasma to the recipient.
- The crossmatch may be performed with the plasma bag segment. The bag should be thawed at 37<sup>0</sup> Celsius only if the crossmatch comes as compatible to prevent repeated thawing and refreezing of the unit.
- The minor crossmatch using donor plasma and patient red blood cells is performed
- If red cells alloantibody screening is performed on the donor's samples, no minor cross-matching is required. If the blood center does not have the red cells alloantibody screening facility, a minor crossmatch is indicated.
- If the unit is crossmatch compatible, the unit is issued with minimum labelling requirements as follows
- The minimal labelling requirement on the plasma bag:
  - Unique identification number
  - ABO blood group
  - TTI screening negative results
  - Name of the product: COVID-19 CONVALESCENT PLASMA
  - Date of Collection (dd/mm/yyyy)
  - Date of Expiry (dd/mm/yyyy)
  - Volume of the product (in ml)

#### **Clinical use of CCP therapy**

It is important to select the patient appropriately. Only moderately affected patients as defined below have shown to benefit from the CCP therapy. For infusion of plasma, standard operating procedure for transfusion of FFP should be followed with special care to monitor these patients during and post-24 hours of transfusion. Patient should be provided CCP therapy if:



- Moderate disease with increasing oxygen requirements should receive CCP therapy. It should be done before the patient goes into multiple organ failure. Failure of steroid therapy is not required before giving plasma.
- Patient should not have history of Ig A (immunoglobulin A) deficiency syndrome or allergy to immunoglobulins.
- One or two therapeutic units of 200-250 ml each should be administered to the patients on two consecutive days, 24 hours apart, if first unit is tolerated well, depending on the condition of the patient. It is advised that donor CCP units provided to patient should preferably be from two different donors.
- Patient should be closely monitored for adverse effects of plasma and appropriate intervention should be instituted, if needed.
- CCP therapy may be given along with other therapies like Remdesivir, Tocilizumab, etc.
- Patient should be monitored for improvement/deterioration after CCP therapy.
- Based on any new guidelines issued either by Government of India or Government of Karnataka

#### SOP for plasma transfusion (Annexure-3):

- Check the following details on the compatibility label attached to the bag; exactly match the details on the patient's chart
  - a. Patient's name
  - b. Patient's hospital reference number
  - c. Patient's ward
  - d. Patient's ABO & Rh group
- Check for any leakage from the plasma bag
- The thawed plasma collected should be taken directly to the ward without any delay
- FEP to be used immediately
- Once FEP is thawed, it cannot be cancelled
- Plasma once released from the Blood Bank **shall not be taken back**
- The final patient identity check:
  - a. The staff nurse should undertake final identity check at the Patient's bedside just before commencing the administration of the blood products
  - b. Check the bag for clot/hemolysis/contamination/precipitates
  - c. Check the patient's IP matches with the details on the compatibility label attached to the plasma bag
  - d. Check that the patient's blood group matches with that on plasma bag
  - e. Check the expiry date on the bag
- Always use a new sterile blood set
- Collect a pre-transfusion & post-transfusion blood and urine sample of the patient
- **Rate of Infusion**
  - Healthy individual – 2 to 3 ml/Kg/hour (1 unit in 1.5hrs)
  - Volume overload/heart patients – 1 ml/Kg/hr ( 1 unit in 4hrs)

## Monitoring the transfused patient

- Monitor the patient:
  - a. Before starting the transfusion
  - b. As soon as the transfusion is started
  - c. 15 minutes after starting the transfusion
  - d. At least every hour during transfusion
  - e. On completion of the transfusion
  - f. 4 hours after completing the transfusion
- At each of these stages, record the following information on the patient's chart.
  - a. Patient's general appearance
  - b. Temperature
  - c. Pulse
  - d. Blood pressure
  - e. Respiratory rate and oxygen saturation
- Record:
  - a. Time of starting of transfusion
  - b. Time of completion of transfusion
  - c. Volume and type of all products transfused
  - d. Blood unit number of all products transfused
  - e. Any adverse effects: Severe reactions most commonly present during the first 15 minutes of a transfusion. All patients, in particular unconscious patients should be monitored during this period and for the first 15 minutes of each subsequent unit.

## Donor Care

- The donor should be provided with good care before, during and after the plasmapheresis procedure
- Any adverse donor reactions should be adequately and promptly managed and recorded. (Annexure-4)
- The donor should be observed for 30 minutes and refreshment will be provided soon after the completion of procedure.
- Proper hydration will be ensured during the observation period. Juice and water will be provided
- He /she will be appreciated, thanked and a participation certificate will be provided before leaving the blood bank premises
- The donor is advised to take adequate fluid intake in next 24 hours.
- Since the donation is purely voluntary in nature, Government of Karnataka provides a sum of Rs: 5000/- towards nutrition and care of donor (Annexure-1)
- Potential donors with abnormal TTI test results should be referred to appropriate healthcare institutions for further investigation, confirmation, counseling, treatment and care.

### **Patient's sample storage**

- The patient's sample has to be stored for seven days at  $-40^{\circ}$  Celsius. Donor's sample may be archived at  $< -30^{\circ}$  Celsius for future testing
- The existing infrastructure & facilities at district level shall be utilized for collection & infusion of CCP.
- The Blood safety officer at district level is identified nodal person. Deputy Director – Blood Safety is the State Nodal Officer for overall monitoring of the activity.

*(Jawaid Akhtar)* 21/08/2020  
(Jawaid Akhtar)

Additional Chief Secretary to Govt.  
Health and Family Welfare Department

### **To:**

- 1) Commissioner, BBMP
- 2) All Deputy Commissioners
- 3) All Chief Executive Officer of Zilla Panchayat
- 4) Commissioner, HFWS
- 5) Mission Director, NHM
- 6) Executive Director, SAST
- 7) Director, HFWS
- 8) Director, Medical Education.
- 9) All DHOs
- 10) All District Surgeons / District Surveillance Officer

### **Copy to:**

- 1) Chief Secretary to Govt., of Karnataka
- 2) PS to Hon. Minister for HFW
- 3) PS to Hon. Minister for Medical Education.



**Annexure - 1**

**Government of Karnataka order for provision of Rs: 5000/- towards nutrition and care of CCP donor**



**ಕರ್ನಾಟಕ ಸರ್ಕಾರದ ನಡವಳಿಗಳು**

**ವಿಷಯ:** ಕೋವಿಡ್-19 ಸೋಂಕಿನಿಂದ ಗುಣಮುಖರಾದವರು ಕೋವಿಡ್-19 ಸಕ್ರಿಯ ರೋಗಿಗಳ ಚಿಕಿತ್ಸೆಗಾಗಿ ಪಾ...ಸಾ. ದಾನ ಮಾಡಿದಲ್ಲಿ, ಅವರಿಗೆ ಆರೈಕೆ ಭತ್ಯೆಯಾಗಿ ರೂ.5,000/- ಗಳನ್ನು ನೀಡುವ ಬಗ್ಗೆ.

**ಓದಲಾಗಿದೆ:** ಉಪ ಕುಲಪತಿ ಮತ್ತು ಅಧ್ಯಕ್ಷರು, ಕೋವಿಡ್-19ನ ಮಾನವ ಶಕ್ತಿ ಮತ್ತು ತರಬೇತಿ ಕಾರ್ಯವಹಿ ಇವರ ಪತ್ರ ದಿನಾಂಕ:30.06.2020

**ಪ್ರಸ್ತಾವನೆ:**

ಮೇಲೆ ಓದಲಾದ ಪತ್ರದಲ್ಲಿ, ದಿನಾಂಕ: 30.6.2020ರಂದು ಕೋವಿಡ್-19 ಗೆ ಸಂಬಂಧಿಸಿದ ಮಾನವ ಶಕ್ತಿ ಮತ್ತು ತರಬೇತಿ ಕಾರ್ಯವಹಿಯ ಕ್ಷೇತ್ರ ಸಮಿತಿಯ ಸಭೆ ನಡವಿದಲ್ಲಿ, ಸದರಿ ಸಭೆಯಲ್ಲಿ, ಕೋವಿಡ್-19 ಸೋಂಕಿನಿಂದ ಚೇತರಿಸಿಕೊಂಡವರು ಆಸ್ಪತ್ರೆಯಿಂದ ಬಿಡುಗಡೆ ಪಡೆದ 140ಂದ 28 ದಿನಗಳೊಳಗಾಗಿ ಸಕ್ರಿಯ ಕೋವಿಡ್ ರೋಗಿಗಳ ಚಿಕಿತ್ಸೆಗಾಗಿ ಪಾ...ಸಾ. ದಾನ ಮಾಡಿದಲ್ಲಿ, ಅಂತಹವರಿಗೆ ಗುಣಮಟ್ಟದ ಆಹಾರ ಪಟ್ಟಿಯಾಗಿ ರೂ.5000.00 (ಐದು ಸಾವಿರ) ಗಳವರೆಗೂ ನೀಡಬಹುದೆಂದು ಶಿಫಾರಸ್ಸು ಮಾಡಿರುತ್ತಾರೆ.

ಪ್ರಸ್ತಾವನೆಯನ್ನು ಸರ್ಕಾರವು ಕೂಲಂಕಷವಾಗಿ ಪರಿಶೀಲಿಸಿ ಈ ಕೆಳಕಂಡಂತೆ ಅದರಿಸಿದೆ  
ಸರ್ಕಾರದ ಆದೇಶ ಸಂಖ್ಯೆ:ಆಕುಕ 240 ಸಿಬಿಎಂ 2020  
ಬಿಂಗಲೂರು,ದಿನಾಂಕ: 15.07.2020

ಪ್ರಸ್ತಾವನೆಯಲ್ಲಿ ವಿವರಿಸಿರುವ ಅಂಶಗಳ ಹಿನ್ನೆಲೆಯಲ್ಲಿ, ಕೋವಿಡ್-19 ಸೋಂಕಿನಿಂದ ಗುಣಮುಖರಾದವರು ಆಸ್ಪತ್ರೆಯಿಂದ ಬಿಡುಗಡೆ ಪಡೆದ 140ಂದ 28 ದಿನಗಳೊಳಗಾಗಿ, ಸಕ್ರಿಯ ಕೋವಿಡ್ ರೋಗಿಗಳ ಚಿಕಿತ್ಸೆಗಾಗಿ ಪಾ...ಸಾ. ದಾನ ಮಾಡಿದಲ್ಲಿ, ಅವರಿಗೆ ಆರೈಕೆ ಭತ್ಯೆಯಾಗಿ ರೂ.5000/- (ಐದು ಸಾವಿರ ರೂಪಾಯಿಗಳು ಮಾತ್ರ) ಗಳನ್ನು ನೀಡಲು ಕೆಳಕಂಡ ಷರತ್ತುಗಳನ್ನೊಳಪಡಿಸಿ ಅನುಮೋದನೆ ನೀಡಿದೆ.

**ಷರತ್ತುಗಳು:**

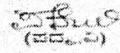
1. ಇದಕ್ಕೆ ತಗಲುವ ವೆಚ್ಚವನ್ನು 2020-21ನೇ ಸಾಲಿನಲ್ಲಿ, ಸುವರ್ಣ ಆರೋಗ್ಯ ಸುರಕ್ಷಣಾ ಟ್ರಸ್ಟಿನ ಲೆಕ್ಕ, ಬಿ.ಬಿ.ಫೆ:2210-80-101-0-01ರಡಿ ಒದಗಿಸಿರುವ ಅನುದಾನದಿಂದ ಭರಿಸತಕ್ಕದ್ದು.
2. ಒಂದು ವ್ಯಕ್ತಿಯಿಂದ ಒಂದು ಬಾರಿಗೆ ಮಾತ್ರ ಪಾ...ಸಾ. ದಾನ ಪಡೆಯತಕ್ಕದ್ದು.
3. ಅಂತಹ ವ್ಯಕ್ತಿಗಳ ಆಧಾರ್ ಸಂಖ್ಯೆ, ವಿಳಾಸ ಮತ್ತು ಮೂಲವಾಸಿ ಸಂಖ್ಯೆಯನ್ನು ಕಡ್ಡಾಯವಾಗಿ ಪಡೆದು ದಾಖಲೆಗಳನ್ನು ನಿರ್ವಹಿಸತಕ್ಕದ್ದು.
4. ದಾನ ಪಡೆದ ಪಾ...ಸಾ.ವನ್ನು ಯಾವ ವ್ಯಕ್ತಿಯ ಚಿಕಿತ್ಸೆಗೆ ಒಳಪಡಿಸುತ್ತದೆಯೋ ಆ ವ್ಯಕ್ತಿಯ ಸಂಪೂರ್ಣ ಮಾಹಿತಿಯ ದಾಖಲೆಯನ್ನು ನಿರ್ವಹಿಸತಕ್ಕದ್ದು.

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ಈ ಆದೇಶವನ್ನು ಆರ್ಥಿಕ ಇಲಾಖೆಯ ಬಿಪಿಆರ್ ಸಂಖ್ಯೆ:ಆ 249 ವೆಚ್ಚ-5/2020,ದಿನಾಂಕ:14.07.2020ರಲ್ಲಿ ನೀಡಿರುವ ಸಹಮತದನ್ವಯ ಜಾರಿಪಡಿಸಲಾಗಿದೆ.

ಕರ್ನಾಟಕ ರಾಜ್ಯವಾರು ಆದೇಶಾನುಸಾರ  
ಮತ್ತು ಅವರ ಹೆಸರಿನಲ್ಲಿ

  
(ಪದ್ಮ) 15/7/2020

ಸರ್ಕಾರದ ಅಧೀನ ಕಾರ್ಯದರ್ಶಿ

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ಆರೋಗ್ಯ 1&2



## Annexure – 2

### Informed consent for COVID-19 convalescent plasma donation

#### **1. General information about COVID-19 and convalescent whole blood or Plasma for COVID-19 treatment**

- Coronaviruses are a large family of viruses which may cause illness in animals or humans. In humans, several coronaviruses are known to cause respiratory infections ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS). The most recently discovered coronavirus causes coronavirus disease COVID-19. COVID-19 is the infectious disease caused by the most recently discovered coronavirus. This new virus and disease were unknown before the outbreak began in Wuhan, China, in December 2019. COVID-19 is now a pandemic affecting many countries globally.
- The most common symptoms of COVID-19 are fever, dry cough, and tiredness. Other symptoms that are less common and may affect some patients include aches and pains, nasal congestion, headache, conjunctivitis, sore throat, diarrhea, loss of taste or smell or a rash on skin or discoloration of fingers or toes. These symptoms are usually mild and begin gradually. Some people become infected but only have very mild symptoms. Most people (about 80%) recover from the disease without needing hospital treatment. Around 1 out of every 5 people who gets COVID-19 becomes seriously ill and develops difficulty breathing. Older people, and those with underlying medical problems like high blood pressure, heart and lung problems, diabetes, or cancer, are at higher risk of developing serious illness. However, anyone can catch COVID-19 and become seriously ill. People of all ages who experience fever and/or cough associated with difficulty breathing/shortness of breath, chest pain/pressure, or loss of speech or movement should seek medical attention immediately. If possible, it is recommended to call the health care provider or facility first, so the patient can be directed to the right clinic.
- The disease is believed to be spread primarily from person to person through small droplets from the nose or mouth, which are expelled when a person with COVID-19 coughs, sneezes, or speaks. These droplets are relatively heavy, do not travel far and quickly sink to the ground. People can catch COVID-19 if they breathe in these droplets from a person infected with the virus. This is why it is important to stay at least 1 meter) away from others. These droplets can land on objects and surfaces around the person such as tables, doorknobs and handrails. People can become infected by touching these objects or surfaces, then touching their eyes, nose or mouth. This is why it is important to wash your hands regularly with soap and water or clean with alcohol-based hand rub.

## 2. What will happen if you agree to donate blood?

- Testing your blood

If you agree to donate plasma for the treatment of COVID-19, we will ask you to come to the blood donation centre and we will first take a small amount of your blood (about 10 mL), about a tablespoonful, from a vein in your arm using a single use sterile syringe and needle and do some tests that will tell us the type of blood that you have and also whether your blood can be used for treatment of COVID-19. If the amount of hemoglobin is too low or if your blood has the possibility of causing disease in another person, or you are not able to donate due to some other reason, we will not be able to accept your blood donation. If that happens, we will explain to you in detail the reasons why your blood cannot be taken, and if you need to have any medical treatment. If, however, you are suitable to donate, we will arrange a suitable time for the donation.

- Collection and storage of blood or plasma units

For the donation, we will ask you to come to the blood bank, where you will be given something to drink (water or juice) before the donation of blood or the liquid part of your blood (plasma). Donating blood is very simple. The nurse/doctor will then ask you to lie on a couch. The inner area of one of your elbows will be cleaned with an antiseptic solution before a trained health worker inserts a sterile needle, connected to a special apheresis machine, into your vein. A small tube will be connected to a machine that will collect the liquid part of the blood into a separate bag, and return the red part of your blood back to your body. To stop the blood from clotting, a liquid, known as an anticoagulant, will be automatically mixed with the blood as it is pumped from the body into the machine. The trained health worker will collect about half a litre (e.g. small mineral water bottle) of plasma. This procedure will take about 45-60 minutes. You will be given light refreshments after the procedure. After resting for about 15-30 minutes, you will be able to return to your normal activities, although you should avoid strenuous activities for the rest of the day. You should drink plenty of fluids over the next 24 hours. Your body will replace the lost fluid within about 36 hours.

- What happens next?

The plasma has been collected will be stored in a freezer with an identification number. It will not have your name on it. When there is a patient who is likely to benefit from the use of plasma donated by you, it will be taken out from the stock, and brought to room temperature, and then given to the patient through a vein. We will keep a close watch on the patient and record everything, so that we learn from the experience and know more about its use in the treatment of COVID-19.

## 3. Possible risks and discomforts

Taking blood from your arm may sometimes cause bruising, mild pain or discomfort and in very rare circumstances, infection. We will take all preventive measures to minimize these risks. Some people may feel light-headed or little giddy, especially while donating plasma. This lasts for only a few minutes and quickly subsides.

**4. Confidentiality**

Any information that you provide and all test results will be treated confidentially. The blood bank personals that test your blood have the responsibility to inform you of all the blood test results, and to advise you on any treatment they think you will require.

**5. Will I know who receives my blood?**

A patient with early COVID-19 disease would receive your plasma. It is difficult to predict who exactly will receive the plasma that you donate. The person must have a compatible blood type to yours. Your name will not be on the plasma you have donated, it will just be identified with a unique donation number. So, no one will know whose plasma is being given to the patient. And you will not know who receives it either. But be assured that it will be used for a patient who requires it and all information about you and your donation will remain confidential.

**6. Will the person who receives the plasma know who has provided it?**

No, no-one, including the person who receives your plasma, will know who has provided the blood. This is so that your privacy can be protected. Be assured that the plasma that we collect will be treated with respect.

**7. Expenses and payments**

There will be no charges to you for any cost related to this donation. There will be no payment for you to participate in this donation either.

**8. Participation and withdrawal from donation**

You are free to decide whether or not to donate plasma. If you do not meet the donor suitability criteria, you will be immediately informed by the Blood Bank Medical Officer. Once your plasma has been collected, you can request that it is withdrawn at any time prior to it being transfused to a patient by informing the attending doctor. You cannot request that your plasma donation should not be used for transfusion, once it has been given to a patient. Your decision to request the discard of your plasma, if it has not been transfused, will not affect your future care.

**9. 9. Who to contact if you have any questions?**

If you have any questions, feel free to contact us at our Blood Bank Landline No.08026700001 your signature documents your permission for the donations.

Signature of Donor	Full Name	Date of Signature
		----- / ----- / -----





### Annexure – 3

#### **STANDARD OPERATING PROCEDURE**

#### **S5L CONCURRENT PLASMA COLLECTION ON S5L – COM – TEC**

**Purpose of this document:** The purpose of these documents is to serve as a guide for experienced Apheresis personal with directions to utilize single needle Apheresis protocol on COM.TEC for Concurrent Plasma Collection using Single Needle functionally closed S5L kit.

**Scope/ Application:** To collect the Concurrent Plasma using the platelet Apheresis protocol in the blood center with the help of the COM.TEC cell Separator for use in patients with actively bleeding and multiple coagulation deficiencies.

**Responsibility:** The procedure is performed by trained technical / medical personnel under the supervision of the Medical officer who is responsible for the smooth conduction of the process.

**Principle:** Concurrent Plasma collection during Platelet Apheresis is the procedure in which donor blood is passed through Centrifugal Apheresis machine which collects and desired Plasma and platelets from the blood and returns remaining blood components back to the donor body.

#### **Prerequisites:**

1. Properly screened healthy donor is selected for donation. Donor selection follows the standard blood donation criteria.
2. The donor is tested for the Transfusion Transmitted Diseases prior to the procedure.
3. He should not be fasting prior to the procedure, however, should refrain from oily /fatty food.
4. A prominent and easily accessible antecubital vein on one of the arms is selected for Apheresis.
5. Informed written consent is taken from the donor.

#### **Materials Required:-**

- COM.TEC Blood cell separator.
- S5L Single needle Disposable kit
- ACD-A anticoagulation -500 ml
- Normal Saline (0.9% NACL) -1000ml
- Material for Phlebotomy: Betadine, Spirit, Cotton Swabs, Sticking plaster, local anaesthetic
- Tube Sealer
- EDTA tubes for product sampling
- Oral Calcium Tablets
- Emergency Medicines Tray
- COM.TEC Operator's Manual



### Procedure Description of the Concurrent Plasma with S5L Kit –

The procedure comprises five main steps. The Steps are as follows.

- Installation of the kit
- Priming
- Separation
- Reinfusion
- Removal of the Apheresis Kit

### Operational Aspect:-

#### 1. Selection of the Platelet Program

Press the 1 Key, instrument will display the software version installed along with the continue key option, press the continue key. Use up ' ' and Down ' ' arrow keys for selecting the program Platelet Donation . Press ok key. Use the arrow keys to select Plt-5d and press Ok key.

NOTE: Printer should be always kept on during the procedure

#### 2. Installation of the Kit:-

The Message install S5L prompts the operator to install the apheresis set.

- Open all pump leads
- Press the TURN PUMP key
- Deposit the packaging on the centrifuge door. Ensure that each pump line segment is located under the matching colour coded pump
- Take the rolled-up tubing out of the packaging, close the red inlet clamp just below the branch to the pre-sampling bag.
- Close the white needle clamp and suspend the connecting line literally at the upper right of the device
- Suspend the concentrate bag from the rear hook on the left of the device.
- Close the clamps between the concentrate bags and the PC sampling bag.
- Suspend the empty Bag above the return drip chamber
- Suspend the Plasma bag above clamp 4.
- Suspend the single needle bag at the left side of the plasma bag.
- Install all pump line segments so that colour of pump coding match.
- Press TURN PUMP keys.
- Close all Pump doors
- Install the return air drip chamber in the air detector.
- Install the plasma line in clamp 4 between the Y piece and drip chamber.
- Install the plasma line section marked by yellow tas into the Hb /Hct detector.
- Insert the line leading to empty bag in clamp 5
- Insert the return line clamp 1.
- Insert the inlet line of the cell pump into cell detector.
- Insert the green coloured drip chamber of the ADC line into the drip chamber and pull the drip chamber completely down.
- Install the ACD pump tubing into ACD pump and hit the TURN PUMPS key
- Install the saline line in clamp 2

- Install the single needle collecting /return line in clamp 3 between the blue marks.
- Install the inlet line leading to the single needle control with the red mark below the Y connector in clamp 6
- Install the pressure filters into appropriate ports inlet-red, Outlet –Blue
- Install the separation chamber in the correct S5L Dual chamber holder.
- Push the centrifuge holder onto the guide rail until it is felt to be locked.
- Pass the centrifuge tubing through the line guide.
- Rotate the chamber counter clockwise to verify the correct installation.
- Close the centrifugation followed by placing the air protect in the holder.

### 3. Priming:-

Connect saline line to normal saline container. Connect the ACD tubing to ACD-A bag. After connecting the lines, press PRIME key. The alarm test screen will be displayed following pressing the PRIME key. This test is performed automatically start and end of the test is indicated by audible alarms. Alarm test is followed by priming of the whole kit using saline to remove any air in the kit and processed saline is diverted to the diversion bag. Once priming is over machine gives an option for selecting second priming to remove all air still present in the kit second priming is optional.

**NOTE:- Primed kit should be used within 8 hours and Installed kit should be used within 24 hours**

### 4. Concurrent Plasma Collection (Optional)

To collect the concurrent plasma along with platelets-

- Access the Procedure Menu screen by pressing Menu and OK key.
- Decreases the default platelet yield and PC volume to minimum value (1.0x10<sup>11</sup> & 100mL).
- Select the PLS Harvest option by using down '↓' and OK key.
- Enter the plasma volume by using plus (+) and minus (-) soft keys up to maximum 500 mL and press OK to confirm the changes.

### 5. Separation :-

- Insert the needle after vein puncture. Open the white needle clamp and collect at least 20 ml of blood, close the white needle clamp and seal off the pre-sampling bag
- Open the red clamp on the inlet line
- Apply the single needle cuff to the fully extended and relaxed upper arm of the donor
- Connect the cuff to the cuff port to on the rear connector panel and ensure the connected line is not squeezed or kinked
- By pressing the START key the cuff is inflated up to 50mmhg facilitate the puncturing of the donor. Inflate cuff can be skipped by pressing the CONTINUE key
- Enter the donor values like Sex, Height, weight and pre platelet and pre HCT count in the donor value entry screen and press OK key.



**Annexure – 4**

**Protocol for management of adverse reaction for Apheresis donations**

Category	Grade 1	Grade 2	Grade 3
<p>A.1. Blood outside vessel</p> <p>--- Hematoma</p> <p>---- Arterial puncture</p> <p>--- Delayed bleeding</p>	<ul style="list-style-type: none"> <li>No Outside Medical Care (OMC)</li> <li>Localized to venipuncture site</li> </ul>	<ul style="list-style-type: none"> <li>OMC (EMR, ER, PCP, Urgent care), no hospitalization, or</li> <li>Activity of Daily Life (ADL) <math>\leq</math> 2 weeks, or</li> <li>Generalized beyond venipuncture site</li> </ul>	<ul style="list-style-type: none"> <li>Hospitalization, or</li> <li>ADL <math>\leq</math> 2 weeks, or</li> <li>Severe sequelae, or</li> <li>Surgical intervention</li> </ul>
<p>A.2. Arm pain</p> <p>-- Nerve injury /irritation</p> <p>---Other arm pain</p>	<ul style="list-style-type: none"> <li>No OMC</li> <li>Duration <math>\leq</math> 2 weeks</li> </ul>	<ul style="list-style-type: none"> <li>OMC (EMR, ER, PCP, Urgent care), no hospitalization, or</li> <li>Duration &gt; 2 weeks to <math>\leq</math> 6 months or (ADL) <math>\leq</math> 2 weeks.</li> </ul>	<ul style="list-style-type: none"> <li>Duration &gt; 6 Months,</li> <li>ADL <math>\leq</math> 2 weeks,</li> </ul>
<p>A.3. Localized infection/inflammation of vein or soft tissue</p> <p>--- Superficial thrombophlebitis</p> <p>--- Cellulitis</p>	<ul style="list-style-type: none"> <li>No OMC</li> </ul>	<ul style="list-style-type: none"> <li>OMC (EMR, ER, PCP, Urgent care), no hospitalization, or</li> <li>(ADL) <math>\leq</math> 2 weeks, or</li> <li>Resolved with oral antibiotics</li> </ul>	<ul style="list-style-type: none"> <li>Hospitalization, or</li> <li>(ADL) <math>\leq</math> 2 weeks, or</li> <li>Resolved with IV treatment</li> </ul>
<p>A.4. Other major blood vessel injury</p> <p>-- Deep venous thrombosis</p> <p>-- Arteriovenous fistula</p> <p>-- Compartment syndrome</p> <p>-- Brachial artery pseudoaneurysm</p>			<ul style="list-style-type: none"> <li>Diagnoses medically confirmed, or</li> <li>Treated with anticoagulant therapy</li> <li>Required surgical intervention</li> </ul>
<p>B. Vasovagal reactions</p> <p>-- Vasovagal reaction, no loss of consciousness (LOC)</p> <p>-- Vasovagal reaction with LOC</p>	<ul style="list-style-type: none"> <li>NO OMC</li> </ul>	<ul style="list-style-type: none"> <li>OMC (EMR, ER, PCP, Urgent care), no hospitalization, or</li> <li>(ADL) <math>\leq</math> 2 weeks, or</li> <li>Suture of lacerations (s), or</li> <li>IV rehydration</li> </ul>	<ul style="list-style-type: none"> <li>Hospitalization, or</li> <li>(ADL) <math>\leq</math> 2 weeks, or</li> <li>Fracture (s), medically confirmed concussion, dental injury requiring dental procedure, e.g. cap/crown dental implant, bridge, tooth extractive dentures</li> </ul>

*(Handwritten signature)*



<p>C. Related to apheresis</p> <ul style="list-style-type: none"> <li>-- Citrate reaction</li> <li>-- Hemolysis</li> <li>-- Air embolism</li> <li>-- Infiltration</li> </ul>	<ul style="list-style-type: none"> <li>● No OMC</li> <li>● Citrate toxicity (including carpopedal spasm)</li> <li>● Resolved with or without oral calcium</li> </ul>	<ul style="list-style-type: none"> <li>● OMC (EMR, ER, PCP, Urgent care), no hospitalization, or</li> <li>● (ADL) <math>\leq 2</math> weeks, or</li> <li>● Citrate toxicity requiring intravenous calcium</li> </ul>	<ul style="list-style-type: none"> <li>● Hospitalization, or</li> <li>● (ADL) <math>\leq 2</math> weeks, or</li> <li>● Abnormal cardiac rhythm medically diagnosed</li> </ul>
<p>D. Allergic Reaction</p> <ul style="list-style-type: none"> <li>-- Local allergic reaction</li> <li>-- Generalized (anaphylactic) reaction</li> </ul>	<ul style="list-style-type: none"> <li>● No OMC</li> <li>● Managed with over the counter medications :- topical steroids, antihistamine</li> </ul>	<ul style="list-style-type: none"> <li>● OMC (EMR, ER, PCP, Urgent care), no hospitalization, or</li> <li>● Generalized reaction including bronchospasm, laryngospasm managed with inhalation or oral bronchodilator and / or autoinjector (Epipen)</li> </ul>	<ul style="list-style-type: none"> <li>● Hospitalization, or</li> <li>● Generalized reaction including bronchospasm, laryngospasm, requiring management with intravenous steroids and / or epinephrine but NOT intubation or tracheostomy</li> </ul>
<p>E. Other serious complication</p> <ul style="list-style-type: none"> <li>-- Acute cardiac symptoms</li> <li>-- Myocardial infarction</li> <li>-- Cardiac arrest</li> <li>-- Transient ischemic attack</li> <li>-- Cerebrovascular accident (Stroke)</li> </ul>			<p>Diagnoses medically confirmed</p>
<p>F. Other</p>	<ul style="list-style-type: none"> <li>● No OMC</li> <li>● No injury</li> </ul>	<ul style="list-style-type: none"> <li>● OMC (EMR, ER, PCP, Urgent care), no hospitalization, or</li> <li>● Duration <math>&gt;2</math> weeks to <math>\leq 6</math> months or</li> <li>● (ADL) <math>\leq 2</math> weeks</li> </ul>	<ul style="list-style-type: none"> <li>● Hospitalization, or</li> <li>● Duration <math>&gt;6</math> months,</li> <li>● ADL <math>&gt;2</math> weeks, or</li> <li>● Surgical intervention</li> </ul>

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