COPY

COVID-19 CONVALESCENT PLASMA PROCEDURE

PURPOSE: This SOP outlines the procedures to qualify, collect, data entry into BECS, process, store, label and ship COVID-19 Convalescent Plasma (CCP) products. CCP donors are healthy, must be qualified as a regular allogeneic donor and have produced antibodies to that virus. COVID-19 CCP, while not yet proven as an effective treatment for COVID-19, is promising and the safety and efficacy is currently being studied.

SPECIMENS REQUIRED (in addition to 3 EDTA, 1 red top and 1 Babesia tube):
2 13 x 100 Red top tubes

MATERIALS/FORMS:
Form: COVID-19 Convalescent Plasma (CCP) Pre-qualification
Form: COVID-19 Convalescent Plasma Worksheet: Laboratory
Form: CCP Daily Inventory
Form: Informed Consent for an Automated Procedure
Form: Apheresis HLA Worksheet: Collections
Form: HLA Worksheet: Laboratory
Form: Whole Blood- Anti-A/B Titer Testing
Form: Job Aid Registration of CCP Donors
Form: CCP Job Aid-Donor Collections
Form: COVID-19 Antibody Testing Consent
Hospital donor screening form (Supplied by the referring hospital)
COVID-19 Convalescent Plasma label
Low Titer tie tag (Anti-A/B)
"Do not Crossover into General Inventory" tie tag
"COVID-19 Convalescent Plasma" tie tag
"Anti-A/B titer >1:200, transfuse as appropriate" tie tags
"High Titer COVID-19 Convalescent Plasma" tie tag
CCP Donations Crystal Report
AB Female Crystal Report

PROCEDURE:

I. **PRE-SCREENING** (Performed by a clinician/and or CBB donor collections staff member)

a. The clinician and or CBB is responsible to recruit/pre-screen prospective CCP donors.
b. CBB may also recruit donors after dual positive SARS-CoV-2 antibody tests. (See COVID-19 Convalescent Plasma Procedure Addendum SOP)
c. For each prospective CCP donor, the clinician or CBB donor collections staff member must complete and submit either Form: COVID-19 Convalescent Plasma (CCP) Pre-qualification and/or the clinician's hospital donor screening form.
d. If clinician is completing CBB's Form: COVID-19 Convalescent Plasma (CCP) Pre-qualification form and the donor indicates any travel outside of the United States:
    i. The clinician must contact CBB Collections staff in order to determine donor eligibility.
        1. Utilizing the travel information provided by the clinician, CBB Collections staff determines and communicates donor eligibility to the clinician (donor is eligible or not eligible to donate).
        2. Collections staff must provide the clinician with their name.
e. Donors who successfully pass the pre-screening process:

i. Clinician is responsible to provide a copy of the completed Form: COVID-19 Convalescent Plasma (CCP) Pre-qualification (including consent to release medical information) and/or the clinician's hospital donor screening form to CBB. An appointment is scheduled by the clinician or by CBB staff at the clinician's request.

1. Clinician may communicate information to CBB verbally by phone, CBB staff may then complete Form: COVID-19 Convalescent Plasma (CCP) Pre-qualification.
    a. See step 2b below for required information.
    b. The name of the clinician relaying the donor information must be documented.
2. Donor may bring a completed Form: COVID-19 Convalescent Plasma (CCP) Pre-qualification and/or the clinician's hospital donor screening form to CBB.
    a. If the donor brings a completed Form: COVID-19 Convalescent Plasma (CCP) Pre-qualification form, ensure that all fields are complete. If not, contact the clinician immediately.
        i. Ensure that donor DOES MEET Pre-Qualification criteria.
    b. If the donor only brings a completed hospital donor screening form or the donor is a recruited donor per COVID-19 CPP Addendum SOP, complete Form: COVID-19 Convalescent Plasma (CCP) Pre-Qualification form using information provided on the hospital donor screening form.
    Document the following:
        - Name of donor
        - Date
        - Name of the hospital staff member on hospital screening form who pre-qualified donor or CBB staff member completing the form
        - Location of referring hospital and or facility (eg. CBB, SV, Hamot, etc.)
        - **Donor to complete upon registration under *Consent* section:**
            - **Printed donor name**
            - **Donor signature**
            - **Date of signature**
        - **Date of SARS-CoV-2 positive antibody tests from CBB only (if applicable from Safetrace: noted as SCOV-P)**
        - Date of positive COVID-19 PCR test (if applicable)
        - Date of last symptoms – Required for donors who have a documented positive PCR test. Document "NA" if the CCP donor does not have a documented positive PCR and they had no symptoms.
3. Under *Additional Pre-Qualification Blood Donor Criteria:*
    a. Date of most recent COVID-19 vaccine (if applicable)
        i. Document N/A if non-applicable *and* in the sub questions below relating to receiving the vaccine.
    b. If donor DID have a COVID-19 vaccine, answer the following questions by circling the correct response. (yes or no)
    c. Follow the instructions given with each response.
        i. Was a copy of the Covid-19 positive test (PCR) result received by CBB? If yes, continue with following sub questions. If no, defer donor.

ii. Does the copy of the Covid-19 positive test (PCR) result contain the donor's name/and or date of birth? If yes, continue with the following sub questions below. If no, defer donor. If previously received, (repeat donor who had vaccine), continue below.
iii. Is the positive Covid-19 test (PCR) result an FDA approved test? If yes, continue below with following sub questions. If no, defer donor.
iv. Is the date of the Covid-19 vaccination AFTER the date of the positive COVID-19 test? If yes, continue below with following sub questions. If no, donor is NOT eligible to donate CCP. Defer the donor.
v. Did the donor have symptoms of COVID-19? If yes, continue with the following sub questions. If no, defer donor.
vi. Is the date of symptom resolution within 6 months of donation date? If yes, continue below. If no, donor is NOT eligible to donate CCP. Defer the donor.

- Under the *Results* section:
  - Check DOES NOT MEET or DOES MEET
  - CBB appointment date and time.
- Signature and date of CBB staff member completing the form

If any of the above information is missing from the hospital donor screening form, contact the clinician immediately.

f. Walk-in CCP donors: Donors may present at CBB or call not knowing that they must first be pre-screened by a clinician or CBB staff. Please follow the steps below if you encounter a walk-in CCP donor or phone call from a donor who is interested in donating CCP.
   i. Ask donor if they were ever tested for COVID-19 (PCR test) or COVID-19 antibodies:
      1. **No- Let donor know that they must have been tested positive for COVID-19 and had symptoms or have had two confirmed positive antibody tests to be a convalescent plasma donor. Do not call the hospital point person. Continue with step ii. below.**
      2. **Yes- Document and continue with step ii. below.**
   ii. Ask donor for their name, phone number and email address and document.
   iii. Inform donor that, in order to become a CCP donor, they must first be pre-screened by a clinician or have had two positive antibody tests, which CBB will test for with a ***successful*** blood donation. If the donor is interested in attempting to qualify as a CCP donor, have them schedule an appointment. All donation types are acceptable. Give all information collected to recruitment, marketing and collections.

g. POTENTIAL CCP DONORS ONLY: When potential CCP donors recruited by CBB present for their appointment (if applicable)
   i. Proceed with registering the donor per Donor Registration SOP.
   ii. Provide the donor with the following: Form: COVID-19 Antibody Testing Consent, CBB Donor Portal instructions, and disclaimer.
   iii. Instruct donor to read and complete the consent.
   iv. Explain to donor that antibody testing will only be performed if their donation is successful.
   v. Explain to donor that COVID-19 antibody test results will be available in the donor portal. If results are positive, they will be contacted.
   vi. Proceed to screen donor per Donor/Selection Screening SOP

1. Ensure Form: COVID-19 Antibody Testing Consent is complete and attach to the DHC.
2. Proceed to draw donor following the applicable donation type.
    a. Draw 490 mL for Whole blood and by pass EBV or 610 grams on Gram scale.
    b. Completely fill pouches on selected procedure.
    c. Draw two extra red tops.
    d. Deliver the 2 extra properly labeled red tops to the lab.

h. The original (or original fax) Form: COVID-19 Convalescent Plasma (CCP) Pre-qualification and/or hospital donor screening form must be kept on file with the Hospital Services Coordinator.

II. REGISTRATION

a. On a daily basis, registration staff review HemaCollect donor schedule for the following collection day to determine if any CCP donors are scheduled. If so, registration staff retrieve and copy the donors completed Form: COVID-19 Convalescent Plasma (CCP) Pre-qualification and/or the hospital donor screening form from the CCP binder located in the Hospital Service Coordinator's office.
b. CCP donors are to be scheduled for donations Monday, Tuesday, Thursday and Friday 9:00 a.m. – 3:00 p.m.; Wednesday 11:00 a.m. – 5:00 p.m. and Saturday 9:00 a.m. – 11:00 a.m. or at a mobile drive by appointment.
c. Recruitment, Marketing and Collections schedule and reschedule appointments. All appointments need to have CCP documented in the appointment notes.
d. CCP donors who present at CBB for CCP donations must have had a completed Form: COVID-19 Convalescent Plasma (CCP) Prequalification and/or a hospital donor screening form on file at CBB.
    i. If CCP donor is a directed donor, refer to Directed/Dedicated Donation SOP.
e. To complete donor registration, refer to Donor Registration SOP.
    i. Register all CCP donors as whole blood until Collections Staff determines if donor qualifies for a plasma donation. Collections staff will then notify Registration staff to update the donor visit.
f. Provide 2 (two) copies of Form: Informed Consent for Automated Procedure to donor. Collections staff will determine if the donor is eligible for an apheresis procedure or a whole blood donation.
g. Document and highlight "CCP" on the top front of the Donor History Card (DHC).
h. Attach donor's completed Form: COVID-19 Convalescent Plasma (CCP) Pre-qualification to the DHC (and any additional forms submitted by the referring facility).

III. DONOR SCREENING

a. Assure required Form: COVID-19 Convalescent Plasma (CCP) Pre-Qualification and/or hospital donor screening form is complete and correct. See section I.e.i.2 and 3 for required information.
b. If donor is female or transgender (birth gender female), complete Form: Apheresis HLA Worksheet Collections as per Plasma from Female Donor SOP.
    i. Female donors who have never been pregnant or have tested HLA negative since their last pregnancy are eligible for CCP donation (this includes female donors of ALL blood types).
    ii. Female donors of any blood type that have previously tested positive for HLA are NOT eligible to donate CCP (will have a special process of HLAP in SafeTrace).

Note: Regardless of HLA status including "never tested" (with the exception of HLAP), proceed with CCP procedure. HLA testing will be completed by lab if applicable.

iii. Never tested
1. For Alyx plasma, write in "AFFP Donation" next to "Never Tested" on Form: Apheresis HLA Worksheet: Collections.
2. For whole blood, check box "WB donation" under the heading "Never Tested".

c. Screen CCP donor as per Donor Selection/Screening SOP.
d. Qualify donor for apheresis plasma donation per Screening Plasma Apheresis Donors SOP (Alyx) or whole blood donation as applicable.
i. If the donor qualifies for an apheresis plasma donation and the donor's veins are suitable for an apheresis donation, even first time donors should be encouraged to donate on Alyx.
ii. If donor does not qualify for automation, screen for whole blood donation and adapt Form: Apheresis HLA Worksheet: Collections for completion as specified above.
iii. Notify registration of changes to donation type if necessary.
e. In order to donate, all CCP donors must meet regular allogeneic donor requirements.
f. Defer donors per Donor Deferrals SOP if applicable. Medical Director may be contacted for questions or concerns if needed. The Quality Assurance Director or designee will notify the appropriate point person(s) at the referring hospital of CCP donor deferrals if applicable.
g. DHC, Form: COVID-19 Convalescent Plasma (CCP) Pre-qualification (and any additional forms submitted by the referring facility), Informed Consent for an Automated Procedure x 2 (if applicable) and Form: Apheresis HLA Worksheet: Collections, is reviewed by Donor Collections Management or senior staff ***prior*** to phlebotomy.

IV. COLLECTIONS (Only for CCP donors/*not potential* CCP donors)

a. Place DINs on 2 extra red top tubes in addition to standard tubes per Bag Selection, Preparation & Tube Identification SOP. A second phlebotomist must inspect tubes for correct DIN.
b. Document "CCP" on all four whole blood donation bags or apheresis plasma containers.
i. Follow Operation of the Alyx SOP to collect an apheresis plasma donation.
ii. Follow Phlebotomy SOP to collect a whole blood donation.
1. If using Macomix HM20 Mixer, bypass EBV to collect 490ml per Operation of the Macomix HM20 Mixer SOP.
2. If using gram scale, follow Use of a Gram Scale SOP.
c. Perform phlebotomy per Phlebotomy Procedure SOP.
d. Bactivam pouch must be filled **completely.**
e. Collect 2 extra red top tubes in addition to standard tubes per Phlebotomy SOP.

Note: Macomix is programmed to scan 5 tubes so two tubes will not be scanned with barcode scanner.

i. In the event of tubes not being full, confirm with lab regarding sufficient amount of blood in tubes.
f. Collections Management or senior staff will review the following ***prior*** to donor leaving phlebotomy area:
i. Match DINS on DHC, tubes, and blood/plasma products
ii. Ensure completion of DHC, Form: COVID-19 Convalescent Plasma (CCP) Pre-qualification and/or hospital donor screening form, Informed Consent for an Automated Procedure x 2 (if applicable) and Form: Apheresis HLA Worksheet: Collections (if applicable)
g. The following items must be delivered to the lab with the CCP product:

i. DHC
   1. Form: COVID-19 Convalescent Plasma (CCP) Pre-qualification (attached to DHC) along with any additional forms submitted by the referring facility)
   2. Informed Consent for an Automated Procedure (attached to DHC if applicable)
   3. Form: Apheresis HLA Worksheet: Collections (attached to DHC if applicable)

h. Rescheduling
   i. Encourage donor to return for second CCP donation and schedule:
      1. Apheresis plasma - 28 days from donation date
      2. Whole blood donation – 56 days from donation date
   ii. Original Form: COVID-19 Convalescent Plasma (CCP) Pre-qualification and/or hospital donor screening form is kept in the Hospital Services Coordinator's office for future reference.

V. DATA ENTRY

a. All CCP donors are identified by "CCP" which is documented on the top front portion of the DHC.
   i. Form: COVID-19 Convalescent Plasma (CCP) Pre-qualification and/or hospital donor screening form is attached to all CCP donor's DHCs.
b. Enter CCP donor and donation information in SafeTrace as per Donor Card Entry/Duplicate Donor Check SOP.
c. Enter a special process of CCP in SafeTrace for all CCP donors.
d. Provide a Xerox Copy of all CCP DHCs, Form: Apheresis HLA Worksheet: Collections, Form: COVID-19 Convalescent Plasma (CCP) Pre-qualification and any additional forms submitted by the referring facility to the laboratory and Quality Assurance Director or designee.

VI. LABORATORY

a. **PROCESSING BLOOD COMPONENTS**
   i. Upon receipt of blood containers labeled with "CCP":

NOTE: Collections staff deliver the DHC and corresponding completed Form: COVID-19 Convalescent Plasma (CCP) Pre-qualification (and any additional forms submitted by the referring facility) along with CCP donation.

NOTE: Copies of all CCP donor DHCs and the corresponding completed Form: COVID-19 Convalescent Plasma (CCP) Pre-qualification and/or hospital donor screening form are provided by data entry personnel to the laboratory, after data entry is complete.

NOTE: CCP donations must have 3 EDTA tubes, 3 red top tubes and 1 Babesia tube collected (used for regular donor screening tests and SARS-CoV-2 antibody testing).

NOTE: If an AB female donor donates CCP, place a DIN on Form: HLA Worksheet: Laboratory and document CCP next to the DIN. Write "See Form: COVID-19 Convalescent Plasma Worksheet: Laboratory". Denote CCP on AB Female Crystal report.
   1. Document the following on Form: COVID-19 Convalescent Plasma Worksheet: Laboratory:

a. Date of Collection
b. Referring Facility (found on Form: COVID-19 Convalescent Plasma (CCP) Pre-qualification)
c. Donor Identification Number (DIN)
d. Donation Type- WB or Alyx
   NOTE: Alyx donations PF24 Room Temp are not eligible for CCP, only FFP (8 hour) and PF24 donations are eligible.
e. If Alyx, # of units or NA if WB
f. Indicate card review using a √ or X
g. Indicate blood type (NA if unknown)
h. Indicate Anti-A/B Titer testing ordered (NA if type AB)
   i. Upon receipt of results, indicate receipt using √ or X
i. Indicate SARS-CoV-2 AB testing ordered (see SOP addendum)
   i. Upon receipt of results, indicate receipt using √ or X
j. Document the date of symptom resolution (found on Form: COVID-19 Convalescent Plasma (CCP) Pre-qualification).
   i. If donor did not have symptoms, denote NA and also indicate "Do Not Crossover into General Inventory".
k. Using the date of collection:
   i. Document the # of days that the donor is post symptom resolution
      1. Indicate NA if donor did not have symptoms.
   ii. Indicate if the donor is between 14 and 27 days post symptom resolution.
      1. Indicate NA if donor did not have symptoms.
   iii. Indicate if the donor is ≥ 28 days post symptom resolution.
      1. Indicate NA if donor did not have symptoms.
   iv. If between 14 and 27 days post symptom resolution, indicate that "Do Not Crossover into General Inventory" tie tag(s) were attached to the unit(s).
      1. Attach "Do Not Crossover into General Inventory" tie tag on main collection container of a whole blood donation.
      2. Attach "Do Not Crossover into General Inventory" tie tag on each applicable Alyx plasma container (ie. if three aliquots will result from the donation, place a tie tag on 3 of the plasma containers).
      3. If ≥28 days post symptom resolution, it is not necessary to attach this tie tag to the unit(s).
l. Donor gender
m. For female donors only (indicate NA in all applicable fields for male donors):

   NOTE: Refer to Plasma from Female Donor SOP to determine product suitability. For CCP donations only, females of ALL blood types are considered eligible to donate CCP.
   i. Date of last pregnancy
   ii. Never pregnant
   iii. HLAP or NOFP
   iv. Previous HLA negative
   v. Date of last HLA result
   vi. HLA ordered
   vii. HLA result

NOTE: If the donation is whole blood and the donor is HLAP, the plasma unit may be modified into a recovered plasma unit ***ONLY IF*** the donor is ≥28 days post symptom resolution. Remove the CCP special process using =DN, DS2, enter DIN, F4, select Donor Special Process and delete the CCP special process, F12 to update. Document modification using the comment section.

n. Product(s) released from QUAR
NOTE: All products are in QPEN due to a CCP special process
o. CCP / CCP High Titer tie tag attached
    i. This tie tag must be placed on all CCP units. The tag states "COVID-19 Convalescent Plasma" and, on the other side of the tie tag, place "High Titer COVID-19 Convalescent Plasma" as appropriate (See SOP Addendum).
p. For handling, storage, shipment, testing and resulting of the 2 extra red top sample tubes, see SOP addendum.
q. Crystal report generated
    i. CCP Donations Crystal Report is located on the Lab Reports map drive.
    ii. Run report for dates encompassing the work order for the day.

2. All CCP donations (except type AB) must have Anti-A and Anti-B titer testing performed. Refer to Processing Whole Blood Low Titer SOP and Form: Whole Blood- Anti-A/B Titer Testing.
    a. On Form: Whole Blood- Anti-A/B Titer Testing: (attach to Form: COVID-19 Convalescent Plasma Worksheet: Laboratory and order the testing via email to IBC.)
        i. Indicate the unit is CCP in the same field as the collection date.
        ii. Write NA in the fields for segments added and initials.
        iii. Document date sent for testing and tech initials.
        iv. Upon receipt of Anti-A/B titer results:
            1. Indicate that results were received
            2. Circle the appropriate result (see Titer result algorithms below)
                a. If N:
                    i. Indicate tie tag, date and initials
                    ii. Place low titer tie tag on unit(s) with DIN and initials of committing tech.
                b. If P:
                    i. √ or X WB released but write CCP in the field also.
                    ii. Indicate NA for NOFP and CF field
                    iii. Indicate Removed WBLT (if applicable, ie. donor has donated prior and had a WBLT special process), otherwise NA
                    iv. Place appropriate "Anti-A/B titer >1:200, use as type-specific only" tie tag on unit(s).

b. Anti-A/B Titer result algorithms

Blood Type	Anti-A titer result	Anti-B titer result	WBLT result	Appropriate tie tag
O	Neg	Neg	N	Low Titer (blue tie tag)
O	Neg	Pos	P	Anti-B titer >1:200, transfuse as appropriate
O	Pos	Neg	P	Anti-A titer >1:200, transfuse as appropriate
O	Pos	Pos	P	Anti-A/Anti-B titers >1:200, transfuse unit as appropriate
A	Neg	Neg	N	Low Titer (blue tie tag)
A	Neg	Pos	P	Anti-B titer >1:200, transfuse as appropriate
B	Neg	Neg	N	Low Titer (blue tie tag)
B	Pos	Neg	P	Anti-A titer >1:200, transfuse as appropriate.

3. Process whole blood donations as per Red Blood Cells and Plasma for Transfusion SOPs.
    a. The red blood cell portion of a CCP donation that was collected at least 28 days post symptom resolution is eligible to be placed into general inventory (the plasma portion will remain as a CCP until the national need has ended and then may be crossed into general inventory at that time).
        i. These donations do not require a “Do Not Crossover into General Inventory” tie tag attached.
        ii. Place interim product code labels on components as usual.
    b. The red blood cell portion of a CCP donation that was collected <28 days post symptom resolution is NOT eligible for use in general inventory and must be discarded. (A whole blood unit should already have had a “Do Not Crossover into General Inventory” tie tag attached prior to centrifugation)
        i. May use discard code of QC20 (miscellaneous) and then add a comment in the CA, E functions that the donation was a CCP of <28 days post symptom resolution.
        ii. Attach the “Do Not Crossover into General Inventory” tie tag on the plasma unit and process/store plasma unit as below.
4. Process Alyx plasma donations as per Plasma for Transfusion SOP.
    a. Donations collected between 14 and 27 days post symptom resolution must have a “Do Not Crossover into General Inventory” tie tag attached to each aliquot prior to storage.
    b. Place interim product code labels on components as usual and store as below.

b. **STORAGE**
    i. Serum samples: see SOP Addendum
    ii. Store red blood cells as per Red Blood Cells, Leukocytes Reduced SOP.
    iii. Store plasma units as per Plasma for Transfusion and Operation of MP1100 Microcascade SOPs.

1. Place plasma units within a plasma storage box, label box with expiration date and place a "COVID-19 Convalescent Plasma" label on the left side of the bottom flap of the box (ensure that the expiration date is not covered).
2. Place frozen units in a bin labeled "In Process CCP", once test result commitment is performed label as below and store CCP units in a bin for the referring facility or store at CBB for stock.
   NOTE: All CCP units (including blood type AB from males or females) should be stored in the "In Process CCP" bin. Do not place AB female CCP in the purple bin in SU7.
   NOTE: Female CCP units may only be removed from the "In Process CCP" bin after HLA test results are received.

c. **LABELING**
   i. In SafeTrace:
      1. Enter the LA subsystem and use the FL function.
      2. Scan the DIN and product code, press F11.
      3. Press F11 to print the final label.
      4. Using the FV function, validate the label.
      5. Obliterate the FDA license number on all CCP final labels using indelible ink.
      6. On Form: COVID-19 Convalescent Plasma Worksheet: Laboratory, √ or X column "FDA license # blacked out on label".
      7. Store labeled units in bin for referring facility/for stock at CBB and maintain temperature of ≤ -18° C until consignment.

d. **DISTRIBUTION**

NOTE: The FDA has issued an Emergency Use Authorization (EUA) for the administration of CCP (fully effective May 31, 2021). Upon the effective date, all CCP units must be labeled as high COVID-19 antibody titer as determined by any of the tests listed in the most current EUA. If investigational units (units that are unable to be titer tested) remain in inventory after the effective date, the investigational units may be administered but must be transfused under an IND.

NOTE: Consign and ship all units to the referring hospital/upon hospital request when available in inventory. (See the Technical Director for current price.) Denote CCP in the memo section of the consignment ticket. Refer to Form: COVID-19 Convalescent Plasma Worksheet: Laboratory to determine the referring facility. Other scenarios may occur, see examples below.

   i. Units in inventory to ship to referring facility/upon hospital request
      1. Consign and pack CCP units as per Blood Transport SOP.
         a. While using the SA function, change the default product price to the appropriate amount. (See note above.)
         b. Add a memo stating "CCP".
         c. Print the consignment ticket twice (or Xerox the original twice). Place the original in the shipper, provide a copy to the Finance Manager, Hospital Services Coordinator and Technical Director.
         d. Ensure the FDA license number has been obliterated on the final label of the CCP plasma component and that all necessary tie tags are present.
   ii. Units that have been transferred from one hospital to another:
      1. Upon receipt of the Blood Exchange Form, transfer the unit in SafeTrace as per Inventory-External Recording (TX) SOP.

iii. The Technical Director or designee reports collection/distribution of all CCP units to Blood Centers of America as directed, as applicable.

e. **ORDERING CCP UNITS FROM THE NATIONAL CLEARINGHOUSE**
   i. If a hospital is in need of a unit of CCP that is unavailable locally, the need must be posted in the national clearinghouse. See SOP addendum.

CONTROLS:

a. Form: COVID-19 Convalescent Plasma (CCP) Pre-qualification must be complete and on file for each CCP donation.
b. If applicable, forms received from the referring facility must be complete and on file for each CCP donation.
c. Form: COVID-19 Antibody Testing Consent must be complete and attached to the DHC of potential CCP donors recruited by CBB.
d. Form: COVID-19 Convalescent Plasma Worksheet: Laboratory and CCP Donations Crystal Report are completed on each day of collection.
e. CCP donors must have a documented positive COVID-19 test and had symptoms OR have had reactive (positive) results in two different tests approved by FDA to detect SARS-CoV-2 antibodies, and must be free of COVID-19 symptoms for 14 days or more at time of donation.
f. If CCP is not transfused and/or the need for CCP declines, donations collected at least 28 days post symptom resolution are eligible to be placed into general inventory.
   a. Remove all tie tags.

      NOTE: Units collected prior to 28 days post symptom resolution are NOT eligible to be placed into general inventory and must be discarded.

REPORTING AND INTERPRETING:

a. Form: COVID-19 Convalescent Plasma Worksheet: Laboratory is reviewed by the Technical Director/Laboratory Supervisor and QA.
b. The red blood cell and plasma portions of a CCP donation that was collected at least 28 days post symptom resolution are eligible to be placed into general inventory.
c. The red blood cell portion of a CCP donation that was collected <28 days post symptom resolution are NOT eligible for use in general inventory and must be discarded.
d. DHC, Form: COVID-19 Convalescent Plasma (CCP) Pre-qualification, any applicable forms received from the referring facility, Informed Consent for an Automated Procedure x 2 (if applicable) and Apheresis HLA Worksheet: Collections is reviewed by Donor Collections Management or senior staff prior to phlebotomy.
e. Form: COVID-19 Antibody Testing Consent is reviewed by Donor Collections staff prior to phlebotomy.

REFERENCES:

1. Donor Registration SOP
2. Directed/Dedicated Donation SOP
3. Donor Selection/Screening SOP
4. Screening Plasma Apheresis Donors SOP
5. Plasma from Female Donor SOP
6. Donor Deferrals SOP
7. Bag Selection, Preparation & Tube Identification SOP
8. Phlebotomy Procedure SOP
9. Operation of the Alyx SOP
10. Operation of the Macomix HM20 Mixer SOP
11. Use of a Gram Scale SOP
12. Donor Card Entry/Duplicate Donor Check SOP
13. Red Blood Cells SOP

14. Plasma for Transfusion SOP
15. Red Blood Cells, Leukocytes Reduced SOP
16. Operation of MP1100 Microcascade SOP
17. Blood Transport SOP
18. Processing Whole Blood Low Titer SOP
19. Inventory-External Recording (TX) SOP
20. SOP addendum
21. FDA Guidance for Industry: Investigational COVID-19 Convalescent Plasma, February 112021
21. EUA Fact Sheet for Patients, COVID-19 Convalescent Plasma February 4, 2021
22. EUA Fact Sheet for Health Care Providers, COVID-19 Convalescent Plasma February 4, 2021

Original Effective Date	Revised by	Revision	Supersedes Revision #
4.27.2020	T. Collier T. Wurst J. Stephany D. Rosenthal	NEW SOP	NA
	K. Kramer	Deleted: **PLEASE NOTE: DO NOT RESCHEDULE THE DONOR IF IT HAS BEEN OVER 4 MONTHS FROM THE INITIAL POSITIVE COVID-19 TEST RESULT** **$722.00** $722.00 Added: Current price (See the Technical Director for current.price. The current price	1.000
	T. Collier T. Wurst K. Kramer	Deleted: have also recovered from SARS-CoV-2 therefore most likely 1 13 x 100 EDTA tube 1 “Caution: New Drug—Limited by Federal (or United States) law to investigational use. oDate of NEGATIVE COVID-19 test Do not take any more information and i. Ask donor and document where they were treated for COVID-19 (ie. Hamot, SV) and who their physician was. ii. If donor was not treated at a facility, ask their preference for which hospital (Hamot or SV) and document. 1. If the donor does not have a preference, attempt to spread the donors evenly between the 2 hospitals. i. you are going to contact the clinician and that the clinician will contact them to set up a CCP donation pre-screening appointment at the preferred facility. ii. After the donor leaves: 1. If the donor’s facility preference is Hamot, call the appropriate Hamot point person. Names/numbers of the appropriate point person(s) are located at the front desk. Communicate to the point person(s): a. A walk-in CCP donor visited CBB today. b. Convey the information obtained from the prospective donor. 2. If the donor’s facility preference is Saint Vincent, call the appropriate Saint Vincent point person(s). Names/numbers of the appropriate point person(s) are located at the front desk. Communicate to the point person(s): a. A walk-in CCP donor visited CBB today. b. Convey the information obtained from the prospective donor. NOTE: IT IS ACCEPTABLE TO MAKE A DAILY PHONE CALL TO THE POINT PERSON AT EACH HOSPITAL WITH A LIST OF POTENTIAL DONORS INSTEAD OF CALLING FOR EACH INDIVIDUAL DONOR Note: Procedure will be performed by Collections Tech II or Collections Tech III. extra EDTA (tall purple) and 1 extra EDTA (tall purple) and 1 5 2 future A small portion of the donation (approximately 6 mls of plasma) will also be removed for qualitative antibody testing of each donation. 21 21	1.001

/ Investigational Use Warning
"Caution: New Drug—Limited by Federal (or United States) law to investigational use",
i. and contains a space for the Investigational New Drug (IND) # (for the clinician to complete).
a. Extra EDTA and red top spun, poured off and frozen.
i. Centrifuge the samples using the pre-programmed spin program in use.
ii. On the pour off tubes:
1. Adhere a DIN
2. Document the collection date
3. Document "Plasma" or "Serum"
iii. Transfer serum and plasma into the respective pour off tubes.
iv. Store samples in a storage unit that maintains ≤ -18° C.
v. Samples will be tested at a later date for COVID-19 antibody titers. a.
Unit(s) shipped to referring facility
21
Store poured off
and plasma
i. in a storage unit that maintains a temperature ≤ -18° C.
until
may
There are currently 3 FDA recognized pathways for health care provider usage of investigational CCP. A hospital may ONLY request and receive CCP units if they are under an investigational new drug application (IND) consisting of either a single-patient emergency IND (eIND) and/or an expanded access IND (EAP) hosted by the Mayo Clinic or are using the units for clinical trials. In the near future, and this would be a fourth acceptable pathway for hospitals to receive CCP. If a requesting hospital does not participate in any one of these pathways, they CANNOT receive any units of CCP.
BARDA reimbursement will occur if the hospital uses the unit under an eIND, under the Mayo EAP or under an EUA (Emergency Use Authorization). When units are eligible for BARDA reimbursements, change the dollar amount to $0.00 on the SA screen during consignment. When the units are NOT eligible for BARDA reimbursements (hospital is using CCP for clinical trials or under a traditional IND), change the dollar amount to the current price per unit.
i. for stock purposes (or request by the referring hospital is necessary):
a. Document which type of pathway (see above) the hospital is utilizing.
i. eIND
ii. Expanded access (EAP) IND (Mayo)
iii. Emergency Use Authorization (EUA)
iv. Clinical trial
which type of pathway and that the unit is
for stock
i. Units requested by a hospital for immediate transfusion:
1. These requests must occur at least verbally. The requesting hospital may also fax or email the request after requesting CCP verbally.
a. Obtain the name of the requestor (the person requesting).
b. Document which type of pathway (see above) the hospital is utilizing. Ask this question EVERY time a request is made (some hospitals are using multiple pathways).
i. eIND
ii. Expanded access (EAP) IND (Mayo)
iii. Emergency Use Authorization (EUA)
iv. Clinical trial
2. Consign and pack requested CCP units as per Blood Transport SOP.
a. While using the SA function, change the default product price to the appropriate amount. (See note above.)
b. Add a memo stating the requestor's name, which type of pathway and that the unit is "CCP for immediate transfusion".
c. Print the consignment ticket twice (or Xerox the original twice). Place the original in the shipper, provide a copy to the Finance Manager, Hospital Services Coordinator and Technical Director.
ii. Units requested by a hospital for clinical trials:
1. These requests must occur at least verbally. The requesting hospital may also fax or email the request after requesting CCP verbally.
a. Obtain the name of the requestor (the person requesting).
b. Document Clinical Trial
2. Consign and pack requested CCP units as per Blood Transport SOP.
a. While using the SA function, change the default product price to the current price.
b. Add a memo stating the requestor's name and that the unit is "CCP for clinical trial".
c. Print the consignment ticket twice (or Xerox the original twice). Place the original in the shipper, provide a copy to the Finance Manager, Hospital Services Coordinator and Technical Director.
call the receiving facility and document the following on the Blood Exchange Form:

a. The name of the requestor (the person requesting)
b. Which type of pathway (see above) the hospital is utilizing.
    i. eIND
    ii. Expanded access (EAP) IND (Mayo)
    iii. Clinical trial
c. Your initials, date and time

2. Provide a copy of the Blood Exchange Form to the Technical Director.
    a. After investigation, a determination must be made regarding billing and the Finance Manager must be contacted.

(except those intended for traditional IND or clinical trials
21
and must have a negative COVID-19 test.
At the inception of this SOP, COVID-19 neutralizing antibody titer testing is unavailable. Testing will be performed at a future date and result reporting will be performed at that time per each donation to applicable hospital facilities (ie. the receiving facility).

Added:
2
Form: COVID-19 Antibody Testing Consent
(Anti-A/B)
"Low Titer COVID-19 Convalescent Plasma" tie tag
"High Titer COVID-19 Convalescent Plasma" tie tag
/and or CBB donor collections staff member)
and or CBB
CBB may also recruit donors after dual positive SARS-CoV-2 antibody tests. (See COVID-19 Convalescent Plasma Procedure Addendum SOP)
or CBB donor collections staff member
below
or the donor is a recruited donor per COVID-19 CPP Addendum SOP
the hospital staff member on hospital screening form who pre-qualified donor or
and or facility
CBB
– Required for donors who have a documented positive PCR test (most likely hospital recruited CCP donors). Document "NA" if the CCP donor does not have a documented positive PCR and they had no symptoms.
or call
or CBB staff.
or phone call from a donor who is interested in donating CCP.
(PCR test) or COVID-19 antibodies:
Positive
and had symptoms or have had two confirmed positive antibody tests
Continue with step ii. below.
or have had two positive antibody tests which CBB will test for with a ***successful*** blood donation. If the donor is interested in attempting to qualify as a CCP donor, have them schedule an appointment. All donation types are acceptable. Give all information collected to recruitment, marketing and collections.

f. POTENTIAL CCP DONORS ONLY: When potential CCP donors recruited by CBB present for their appointment:
    i. Proceed with registering the donor per Donor Registration SOP.
    ii. Provide the donor with the following: Form: COVID-19 Antibody Testing Consent, CBB Donor Portal instructions, and disclaimer.
    iii. Instruct donor to read and complete the consent.
    iv. Explain to donor that antibody testing will only be performed if their donation is successful.
    v. Explain to donor that COVID-19 antibody test results will be available in the donor portal. If results are positive, they will be contacted.
    vi. Proceed to screen donor per Donor/Selection Screening SOP
        1. Ensure Form: COVID-19 Antibody Testing Consent is complete and attach to the DHC.
        2. Proceed to draw donor following the applicable donation type.
            a. Draw 490 mL for Whole blood and

		by pass EBV or 610 grams on Gram scale. b. Completely fill pouches on selected procedure. c. Draw two extra red tops. d. Deliver the 2 extra properly labeled red tops to the lab. .e.i. if applicable. **(Only for CCP donors/*not potential* CCP donors)** 2 2 Provide a Xerox copy of all potential CCP donors' DHC and Form: COVID-19 Antibody Testing Consent to the Quality Assurance Director or designee. 3 SARS-CoV-2 14 **/ CCP Titer** and, on the other side of the tie tag, place either "Low Titer COVID-19 Convalescent Plasma" or "High Titer COVID-19 Convalescent Plasma" as appropriate (See SOP Addendum). e. For handling, storage, shipment, testing and resulting of the 2 extra red top sample tubes, see SOP addendum. Anti-A/B 14 see SOP Addendum or store at CBB for stock after Obliterate the FDA license number on all CCP final labels using indelible ink. 3. On Form: COVID-19 Convalescent Plasma Worksheet: Laboratory, √ or X column "FDA license # blacked out on label". **/for stock at CBB** **has** **(fully effective December 01, 2020).** **/upon hospital request** /upon hospital request Ensure the FDA license number has been obliterated on the final label of the CCP plasma component and that all necessary tie tags are present. as applicable Form: COVID-19 Antibody Testing Consent must be complete and attached to the DHC of potential CCP donors recruited by CBB. **and had symptoms OR have had reactive (positive) results in two different tests approved by FDA to detect SARS-CoV-2 antibodies, and** Form: COVID-19 Antibody Testing Consent is reviewed by Donor Collections staff prior to phlebotomy. Operation of the Alyx SOP 2.SEP.2020 EUA Fact Sheet for Patients, COVID-19 Convalescent Plasma August 23, 2020 EUA Fact Sheet for Health Care Providers, COVID-19 Convalescent Plasma August 23, 2020	
4.27.20	T. Collier	Deleted: Denote the referring facility name or abbreviation on the plasma container(s). Provide a Xerox copy of all potential CCP donors' DHC and Form: COVID-19 Antibody Testing Consent to the Quality Assurance Director or designee. Added: Upon receipt of results, indicate receipt using √ or X	1.002
4.27.20	T. Collier	Deleted: **December** **2020** **2.SEP.2020** **Added:** March 2021 Upon the effective date, all CCP units must be labeled as high or low COVID-19 antibody titer as determined by the Ortho Vitros IgG test. If investigational units (units that are unable to be titer tested) remain in inventory after the effective date, the investigational units may	1.003

		be administered but must be transfused under an IND. 16.NOV.2020	
4.27.20	T. Collier T. Wurst K. Kramer	Deleted: “Low Titer COVID-19 Convalescent Plasma” tie tag IND# is not required **U** (most likely hospital recruited CCP donors) either “Low Titer COVID-19 Convalescent Plasma” or and plasma s are or may not are **or low** **Ortho Vitros IgG test.** August 23, 2020 August 23, 2020 Added: **Donor to complete upon registration u** **Date of SARS-CoV-2 positive antibody tests from CBB only (if applicable from Safetrace: noted as SCOV-P)** Under Additional Pre-Qualification Blood Donor Criteria: a. Date of most recent COVID-19 vaccine (if applicable). i. Document N/A if non-applicable and in the sub questions below relating to receiving the vaccine. b. If donor DID have a COVID-19 vaccine, answer the following questions by circling the correct response. (yes or no) c. Follow the instructions given with each response. i. Was a copy of the Covid-19 positive test (PCR) result received by CBB? If yes, continue with following sub questions. If no, defer donor. ii.Does the copy of the Covid-19 positive test (PCR) result contain the donor’s name/and or date of birth? If yes, continue with the following sub questions below. If no, defer donor. If previously received, (repeat donor who had vaccine), continue below. Iii.Is the positive Covid-19 test (PCR) result an FDA approved test? If yes, continue below with following sub questions. If no, defer donor. iv.Is the date of the Covid-19 vaccination AFTER the date of the positive COVID-19 test? If yes,continue below with following the sub questions. If no, donor is NOT eligible to donate CCP. Defer the donor.v.Did the donor have symptoms of COVID-19? If yes, continue with following sub questions. If no, defer donor. vi.Is the date of symptom resolution within 6 months of donation date? If yes, continue below. If no, donor is NOT eligible to donate CCP. Defer the donor. (if applicable) (two) And 3 Donor’s If donor did not have symptoms, denote NA and also indicate “Do Not Crossover into General Inventory”. Indicate NA if donor did not have symptoms. High Is May 31 **any of the tests listed in the most current EUA** **February 11, 2021** **February 4, 2021**	1.004

COPY

COVID-19 CONVALESCENT PLASMA PROCEDURE

REVIEW/APPROVAL/IMPLEMENTATION

REVIEWED BY:			
Department Head	**Name**	**Signature**	**Date**
Technical Director	Tracy Collier		2-22-21
Collections Management	Jennifer Stephany		2-23-2021
IT Specialist	Jason Radel		2-23-2021
Finance Manager	Sarah Uglow		2/23/2021
Recruitment Manager	Deanna Rosenthal		2/24/2021
Executive Director	Deanna Renaud		2/23/21
APPROVED BY:			
Position	**Name**	**Signature**	**Date**
QA Director	Kristin Kramer		2-22-2021
Medical Director	Jeffrey A. Richmond, MD		2-24-21
IMPLEMENTATION DATE:	MAR 01 2021		

ANNUAL REVIEW			
MEDICAL DIRECTOR	DATE	MEDICAL DIRECTOR	DATE

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RETIRED SOP

SOP RETIRED BY	TITLE	SIGNATURE	DATE RETIRED
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HR/Finance	LAB	ED	CBB
BRDM	WNYM	WNYV	