Community Blood Bank of Erie County
2646 Peach St. Erie, PA 16508

COPY

COVID-19 CONVALESCENT PLASMA PROCEDURE- ADDENDUM

PURPOSE: This addendum outlines the process for testing allogeneic donors and COVID-19 Convalescent Plasma (CCP) donors for SARS-CoV-2 IgG qualitative antibodies. SARS-CoV-2 IgG qualitative antibody assay is a chemiluminescent microparticle immunoassay intended for the detection of IgG antibodies to SARS-CoV-2 in human serum and plasma. The assay is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. Allogeneic donors who test positive for SARS-CoV-2 antibodies must have a confirmatory test (SARS-CoV-2 IgG qualitative antibody assay using a 2nd manufacturer) performed and resulted as positive in order to be considered for future CCP donation eligibility. These donors are then recruited for future CCP donations. **CCP donors must be confirmed positive as above for SARS-CoV-2 IgG qualitative antibody upon each donation.** CCP donors who are confirmed positive for SARS-CoV-2 antibodies (qualitative) must also be tested for SARS-CoV-2 antibody titer (quantitative) and resulted as, at minimum, reactive and containing a low titer antibody level in order for donated plasma components to be labeled and shipped as CCP. This addendum also describes how to list a need for CCP units with the national clearinghouse.

SPECIMENS REQUIRED (as per COVID-19 Convalescent Plasma Procedure SOP):
2 13 x 100 Red top tubes of donor whole blood

MATERIALS/FORMS:
Form: COVID-19 Convalescent Plasma Worksheet: Laboratory
Form: Qualtex Sample Packing List
Qualtex shipper
Qualtex shipper instructions
Centrifuge
One Greiner 16 x 100 red top tube (empty)
One 13 x 100 plastic pour off tube with cap
Transfer pipets
Arctic Box
Dry ice
Sample tube bag
Packing tape
Gulf Coast form GC254
Form: GC4050 (Client Daily Shipment Schedule)
Form: COVID Antibody Testing Samples – GCRBC

PROCEDURE:

SECTION 1: SARS-COV-2 IgG QUALITATIVE ANTIBODY TESTING

I. **OBTAINING A SAMPLE** (Applicable to allogeneic donors chosen for SARS-CoV-2 IgG qualitative antibody testing **AND ALL CCP donors)**
   a. Collections staff collect 2 extra red top tubes of donor whole blood.
   b. Centrifuge both 13 x 100 red top tubes containing donor whole blood.
   c. Affix a Donor Identification Number (DIN) to an empty 13 x 100 Greiner red top tube and one 13 x 100 plastic pour off tube and transfer the serum approximately equally between both tubes.
      i. DINs must be placed vertically and close to the bottom of the tube cap.
   d. Store the Greiner tube serum sample in a refrigerated storage unit that maintains a temperature between 2 and 8° C until shipment. Note the sample requirements below, freeze serum if testing will not occur within 7 days of collection.

e. Store the second serum sample (13 x 100 plastic pour off tube capped tightly) in a freezer storage unit that maintains a temperature at or below -18° C. Note: this sample is intended to be tested for SARS-CoV-2 IgG qualitative antibodies, 2nd manufacturer, as applicable.
f. Sample requirements are as follows:
    i. Grossly hemolyzed samples are unable to be tested
    ii. Minimum volume of 2 ml
    iii. Stable for 2 days at room temperature
    iv. Stable for 7 days at 2 to 8° C
    v. If testing will not occur within 7 days of collection, sample must be frozen

II. SAMPLE SHIPMENT (first screening test for SARS-CoV-2 IgG qualitative antibodies- allogeneic donors and all CCP donors)

a. Complete Form: Qualtex Sample Packing List
    i. Center prefix is W0456
    ii. Center name is CBBNWPA
    iii. Document the collection date (MMDDYY, Month DDYY or DDMMYY format)
        1. NOTE: Only one collection date per page, all samples on any given Qualtex Sample Packing List must have the same collection date.
    iv. Document all applicable sample IDs (DIN).
    v. Indicate Abbott COVID Antibody test for each sample with a √ or X.
    vi. Attach to Form: COVID-19 Convalescent Plasma Worksheet: Laboratory.
    vii. Give a copy of Form: Qualtex Sample Packing List to Finance Manager.
    NOTE: If testing is ordered using AcQuire website, Form: Qualtex Sample Packing List does not need to be sent with the samples to Qualtex but one must be completed and kept on file at CBB.

b. Order testing via https://portal.qualtexlabs.org/WebApp/login
    i. Enter Username/User Email and Password. Check “I’m not a robot” checkbox.
        1. Note: Password will expire automatically when it is 3 months old.
        2. Username is TCollier, password is Password2 (case sensitive)
    ii. Click “SIGN IN” button, (enabled after entering credentials and successful Captcha verification).
    iii. Dashboard page loads on successful login.
    iv. The menu is displayed on the left side of the screen.
    v. Click “e-Manifest” on the Menu.
    vi. Click “Create.”
    vii. Select desired Center from the drop-down. (Note that default product type is selected automatically but can be changed using the drop-down options.)
        1. Note: Create button is enabled after all fields are completed.
    viii. Select “Create”.
    ix. Enter collection date (default is today’s date, but this can be changed by clicking on the calendar icon).
    x. Select “CVDAS “as the test.
    xi. Scan the DIN; if the sample does not automatically appear in the list below select “Add”.
        1. If an incorrect DIN was entered, select the checkbox next to the DIN and select the trash icon. A pop-up box will ask for confirmation, select “OK”.

2. To change the collection date of the sample Id, click the calendar icon beside the collection date.

xii. Once all DINs have been entered, select “Submit”.
1. An acknowledgement page appears.
2. Click the “Click here” link to print the e-Manifest.

xiii. The e-Manifest can also be printed by selecting “Status Report” from the menu.
1. Select “Print Report”.

xiv. Attach e-Manifest to Form: COVID-19 Convalescent Plasma Worksheet: Laboratory.
1. The e-Manifest does not need to be placed in the shipper with the samples.

xv. Log out of AcQuire by clicking on the person icon at the top right and select “Log Out”.

c. Prepare and pack 13 x 100 Greiner red top tube serum samples into Qualtex sample shipper for shipment as per Qualtex shipper instructions.

d. Go to www.fedex.com, create a shipment and select “Qualtex San Antonio, Accessioning Lab…” from “My Shipment Profiles” drop down list.
i. Ensure that section 4 (Billing Details) states to bill the recipient and that the account number is 825366849.
ii. Select Priority Overnight as the service type.
iii. Ship the shipment, print the shipping label and secure the shipping label to the Qualtex shipping container.
iv. It is best to only ship samples on Monday, Tuesday, Wednesday and Thursday. Qualtex does accept samples on Saturdays but ensure that Saturday delivery is selected on the FedEx website.

III. RESULT REPORTING AND CONFIRMATORY/REFLEX TESTING

a. **SARS-CoV-2 IgG qualitative antibody test (Abbott COVID Antibody test)** – (the initial screening test that is performed at Qualtex- allogeneic donors and all CCP donors):
i. Results are reported from Qualtex to CBB via email as an attachment.
1. Print attachment and review results.
ii. Once test results are received, build a SafeTrace group for all DINs within the test result report for samples with **NEGATIVE RESULTS ONLY**. (QA enters all positive results so exclude all DINS with positive test results from the group). See Unit/Specimen Processing SOP.
1. Enter the LA subsystem and use the PL function. Press F2.
2. Enter the date as the lab group and press F12. (ex. 10.03.2016)
a. Select the group by entering an “s” next to the correct group and press enter.
3. Tab to the beginning unit number field and barcode the first DIN.
4. Scan the last DIN of the unbroken number sequence into the ending unit number field.
5. Continue building the group in this manner for the remainder of the DINs.
6. Press F12 to update.
7. Press Shift+F1 to print the group. If the group is more than one page, page forward using F8 to print each of the remaining pages of the group.

8. A second staff member must confirm the group is accurate by comparing the SafeTrace print out to the donor sample tubes or any accessioning/results form/printout.
    a. The second staff member must document accuracy by dating and initialing the SafeTrace print out(s) of the group.
9. Once accuracy of the group has been confirmed, the group must be assigned in SafeTrace.
    a. In the LA subsystem, enter the PL function.
    b. Assign the group by entering "a" next to the appropriate group, press enter and then F12.

iii. To enter results in SafeTrace, enter the LA subsystem and use the EL function.
1. F5 to select the appropriate group number.
2. Enter SCOV as the appropriate Test ID.
3. Enter the date, time, tech initials
4. Tab to the result field and enter the appropriate result for the test (N, NR, etc.).
5. F12, F11, F12.

iv. Commit the group results from the LA subsystem in SafeTrace using the PT function.
i. Select the appropriate group from the list by entering "s" next to the group.
ii. Select the run ID by entering "s" and print using F10. Ensure that all unit numbers in the group are present and the results are correct.
1. Enter tech initials in SafeTrace and commit the results using F12, F11 and F12.
2. File the group results (Qualtex and SafeTrace printout) with the card review sheet. Record the SafeTrace group number on the card review sheet.
    a. Make a copy of the Qualtex test result report and deliver to QA.
    b. If the Qualtex test result report contains results for a CCP donation attach a copy of SARS-CoV-2 IgG qualitative antibody test result(s) to Form: COVID-19 Convalescent Plasma Worksheet: Laboratory.

v. **If the initial screening test OR the confirmatory SCOV OR the quantitative antibody titer test is resulted as NEGATIVE/NONREACTIVE or unable to be performed** (allogeneic and all CCP donations):
1. No further testing is necessary.
2. Allogeneic components may be placed in general inventory (plasma components may not be labeled as CCP but may be recovered plasma, FFP, PF24, PRECR as applicable).
3. Plasma components (CCP donations only) will automatically be placed into QPEN in SafeTrace.
4. For CCP donations, donor sample does NOT contain adequate antibodies and the donated plasma may NOT be labeled/shipped as CCP.
5. For CCP donations, ensure that the COVID-19 Convalescent Plasma label is removed from the flap of the FFP storage box.
6. For CCP donations, remove the CCP special process from the donor in SafeTrace by using one of the following methods:
    a. Method 1
        i. Using the DN subsystem and the DS2 function, enter the DIN.

ii. On the following screen, press F4 and select Donor Special Process.
iii. Enter a “d” next to the CCP special process and press F12 to update.
iv. Ensure that the CCP special process was removed.

b. Method 2
i. Using the DN subsystem, DS and the DC functions:
1. Enter a “d” next to the CCP special process and press F12 to update.

7. On Form: COVID-19 Convalescent Plasma Worksheet: Laboratory, indicate NA in the column labeled “CCP / CCP Titer Tie Tag Attached”.
8. Discard the frozen aliquot of serum from the donation (the sample intended for confirmatory SARS-CoV-2 IgG qualitative antibody titer testing).
9. For CCP donations:
   a. Notify QA of the DIN and that the SARS-CoV-2 IgG qualitative antibody test result is negative. QA must then notify the donor and/or the referring facility as applicable.
   b. Notify Hospital Services Coordinator to remove all of the donor’s qualification documents from the binder and to send them to QA for archiving.
      i. Provide Hospital Services Coordinator with the donor’s name.
   c. If donor is male and at least 28 days post symptom resolution, the plasma may be placed into the general fresh frozen plasma inventory.
      i. If collected less than 28 days post symptom resolution, discard the plasma using QC20 (MISC) and enter a comment referring to a negative SCOV and <28 days.
      ii. The plasma component must be released from QPEN in SafeTrace.
      iii. Release the plasma component using the LA subsystem and the CA function using the Y function to override the prohibiting factor.
         1. Using the CN function, enter unit number, product code, status of QUAR. Press F11 to update.
         2. Reenter the unit number, product code and a status of ****. Press F11 to update.
   d. If donor is female and at least 28 days post symptom resolution:
      i. Whole blood donation (types A, B or O) and the donation was collected less than 6 days ago, release the plasma as above and modify into recovered plasma.
      ii. Whole blood donation (types A, B or O) and the donation was collected greater than 5 days ago, discard the plasma as above, indicating donor is female, negative SCOV and unable to test for Parvo.
      iii. Alyx donation (types A, B or O) discard the plasma.
      iv. Whole blood or Alyx donation (type AB and HLAN/never pregnant), at least 28 days post symptom resolution, release the plasma as above and place into general fresh frozen plasma inventory.
      v. If any donation was collected less than 28 days post symptom resolution, discard the plasma as above, indicating donor is female, negative SCOV and <28 days.

vi. **IF the initial screening SCOV test is resulted as POSITIVE** (allogeneic and all CCP donations):
1. Do not enter the result into SafeTrace,
   a. A copy of the results may be kept in the laboratory as a record of pending test results.
2. A confirmatory test (SARS-CoV-2 IgG qualitative antibody, 2nd manufacturer) must be performed at Gulf Coast Regional Blood Center. Refer to the following section for instructions.

IV. SARS-CoV-2 IgG QUALITATIVE ANTIBODY CONFIRMATORY TESTING, 2ND MANUFACTURER

a. Testing is performed at Gulf Coast Regional Blood Center.
b. To accession:
   i. Complete Gulf Coast form GC254-
      1. Complete requisition date
      2. Client name (CBB of Erie County)
      3. Sample ID# (See attached)
      4. Contact name (Tracy Collier)
      5. Sample collection date (See attached)
      6. Contact phone (814-456-4206)
      7. Samples submitted is/are (check Serum)
      8. Source (check Blood Donor)
      9. Place checkmark next to COVID Antibody Testing
      10. Print 3 copies, place one copy in the sample shipper, give one copy to the Finance Manager and retain a copy in the laboratory.
   ii. Complete Form: COVID Antibody Testing Samples – GCRBC
      1. Enter date of shipment, number of samples in shipment, number of boxes in shipment and packed by (initials may be used).
      2. Enter date of collection, DIN, place a √ or X in the Roche COVID Antibody Testing (qualitative) column for all samples.
      3. For CCP donations only- Also place a √ or X in the Reflex + to Ortho COVID IgG Antibody Testing (quantitative) column.
      4. Print 3 copies, place one copy in the sample shipper, give one copy to the Finance Manager and retain a copy in the laboratory (attach to corresponding Gulf Coast form GC254).
c. Place frozen serum aliquot samples in a sample bag, place sample bag in an Arctic box with dry ice (approximately 2.5 kg as per Dry Ice Shipment SOP), place Form GC254 and Form: COVID Antibody Testing Samples – GCRBC under the box flap and seal box with packing tape.
   i. Ensure dry ice label is placed on the side of the Arctic Box and completed.
d. Go to www.fedex.com, create a shipment and select “Gulf Coast, National Donor Testing Services…” from “My Shipment Profiles” drop down list.
   i. Use CBB’s account number for billing.
   ii. Select Priority Overnight as the service type.
   iii. Select dry ice under the special services section.

iv. Schedule a pick up as appropriate.
v. Ensure that email notifications to cbb.testing@fourhearts.org are set up for pick up and delivery activities.
vi. Ship the shipment, print the shipping label (two copies) and secure the shipping label to the shipping container.
1. Place a copy of the shipping label with corresponding Gulf Coast form GC254/ Form: COVID Antibody Testing Samples – GCRBC.
vii. It is best to only ship samples Monday through Thursday.

e. Complete and email, fax or phone Form: GC4050 (Client Daily Shipment Schedule) to ClientDailyShipmentSchedule@giveblood.org , 713-795-0553 or 713-791-6663 respectively.
i. Complete First Shipment Box packed on and time
ii. Complete Total number of samples and Total number of shipping boxes.
iii. Enter the UPS/FedEx tracking number

V. RESULTING SARS-CoV-2 IgG QUALITATIVE ANTIBODY CONFIRMATORY TESTING, 2ND MANUFACTURER

Note: This test is reported to CBB via email from Gulf Coast. The email contains a link to click to access/print the test result report from a secure server. Gulf Coast reports this test as the abbreviation “COVD” and is resulted in SafeTrace as SCOV.

a. If the result is **NEGATIVE/NONREACTIVE** (allogeneic and CCP donations):
i. This is the test of record, the presence of SARS-CoV-2 antibodies has not been confirmed.
ii. Commit test result as negative for SCOV using =LA, ET. A second tech must fully commit the test result using OT. Date and initial the test result report.
iii. See steps described above in section labeled “If the initial screening test OR the confirmatory SCOV OR the quantitative antibody titer test is resulted as NEGATIVE or unable to be performed (allogeneic and CCP donations)”.
iv. Give a copy of the test result report(s) to QA and retain a copy in the laboratory (attach to corresponding shipping label/Gulf Coast form GC254/ Form: COVID Antibody Testing Samples – GCRBC).
v. If the test result report contains results for a CCP donation attach a copy to Form: COVID-19 Convalescent Plasma Worksheet: Laboratory.

b. If the result is **POSITIVE/REACTIVE** (allogeneic donations only):
i. This confirms the presence of SARS-CoV-2 antibodies in the donor.
ii. The result may be temporarily committed as positive in SafeTrace using ET for SCOV. Date and initial the test result report.
iii. Do NOT OT the test result in SafeTrace.
iv. Give a copy of the test result report to QA for final commitment of the result. Retain a copy in the laboratory (attach to corresponding shipping label/Gulf Coast form GC254/ Form: COVID Antibody Testing Samples – GCRBC).
v. If the test result report contains results for a CCP donation attach a copy to Form: COVID-19 Convalescent Plasma Worksheet: Laboratory.
vi. Donor will then be recruited for future CCP donations.

c. If the result is **POSITIVE/REACTIVE** (CCP donations only):

i. This confirms the presence of SARS-CoV-2 antibodies in the donor.
ii. ET the SCOV result in SafeTrace as positive, date and initial the test result report.
iii. A second tech must OT the result in SafeTrace, date and initial the test result report.
iv. Retain a copy of the test result report in the laboratory (attach to corresponding shipping label/Gulf Coast form GC254/ Form: COVID Antibody Testing Samples – GCRBC/Form: COVID-19 Convalescent Plasma Worksheet: Laboratory).
v. Please note that this donation must also be tested for SARS-CoV-2 antibody titer (quantitative) and resulted as, at minimum, reactive/positive and containing a low titer antibody level in order for donated plasma components to be labeled and shipped as CCP.
1. The sample should have been accessioned to reflex to Ortho COVID IgG Antibody Testing and the antibody titer test result is reported in tandem with the Roche confirmatory test.

VI. RESULTING SARS-CoV-2 IgG ANTIBODY TITER (QUANTITATIVE)

Note: This test is reported to CBB via email from Gulf Coast. The email contains a link to click to access/print the result report from a secure server. This test is reported by Gulf Coast as “COV2” and is resulted in SafeTrace as SCOT. This test is only performed on CCP donations that test positive for the screening test and also the confirmatory test.

a. If the result is “NR” or nonreactive (negative) and the signal-to-cutoff (S/C) Value is reported as <1.0:
i. The plasma components do not contain an adequate amount of COVID-19 antibodies and cannot be labeled/shipped as CCP.
ii. See steps above in section labeled “If the initial screening test OR the confirmatory SCOV OR the quantitative antibody titer test is resulted as NEGATIVE or unable to be performed”.

b. If the result is “R” or reactive (positive) and the signal-to-cutoff (S/C) Value is reported as ≥1.0 but less than 12.0:
i. The plasma components contain an adequate amount of COVID-19 antibodies and can be labeled/shipped as low titer CCP.
ii. Commit the test result using =LA, ET as LPOS for the test SCOT. Date and initial the test result report.
iii. A second tech must fully commit the result using OT, date and initial the test result report.
iv. Place a tie tag stating “Low Titer COVID-19 Convalescent Plasma” on each plasma component.
1. On Form: COVID-19 Convalescent Plasma Worksheet: Laboratory, place a √ or X in the CCP Titer Tie Tag column.
2. This label is placed on the opposite side of the tie tag stating “COVID-19 Convalescent Plasma”.

c. If the result is “R” or reactive (positive) and the signal-to-cutoff (S/C) Value is reported as ≥12.0:

i. The plasma components contain an adequate amount of COVID-19 antibodies and can be labeled/shipped as high titer CCP.
ii. Commit the test result using =LA, ET as HPOS for the test SCOT. Date and initial the test result report.
iii. A second tech must fully commit the result using OT, date and initial the test result report.
iv. Place a tie tag stating "High Titer COVID-19 Convalescent Plasma" on each plasma component.
v. On Form: COVID-19 Convalescent Plasma Worksheet: Laboratory, place a √ or X in the CCP Titer Tie Tag column.
vi. This label is placed on the opposite side of the tie tag stating "COVID-19 Convalescent Plasma".

VII. LISTING A NEED FOR CCP UNITS FROM THE NATIONAL CLEARINGHOUSE

a. The National Clearinghouse is organized through the Blood Centers of America (BCA).
b. Go to https://www.bcadata.com/Dashboard/rdLogon.aspx
c. The username is jgriebel, password is Jgriebel2
d. Select Resource Sharing
e. Dropdown box- List Excess and Needs
f. Fill in empty fields that apply
g. Add a contact name and 24/7 phone # in the comment field
h. Finally hit Submit data at the bottom and OK.
i. If there is a concern, call or email the following BCA staff:
    i. Jennifer Kapral at 972.345.7419 jkapral@bca.coop , Ann Darcy at 401-381-0600 adarcy@bca.coop or Karen O'Hara at 401.644.6466 kohara@bca.coop
j. Once listing is posted, a BCA member will contact CBB/phone number provided in listing within 2 hours. It is critical to respond promptly.

CONTROLS:

1. A negative SCOV test result automatically places components into QPEN.
2. Donations testing negative for SCOV must not be shipped as CCP units.
3. Samples intended for SCOV testing are stored in a refrigerated storage unit that maintains a temperature between 2 and 8° C or ≤ - 18° C until shipment.

REPORTING AND INTERPRETING:

1. SCOV results are reviewed/entered by two techs and are attached to Form: COVID-19 Convalescent Plasma Worksheet: Laboratory.
2. Form: COVID-19 Convalescent Plasma Worksheet: Laboratory is reviewed by the Technical Director/Laboratory Supervisor and QA.

REFERENCES:

1. COVID-19 Convalescent Plasma Procedure SOP
2. Operation Of Trucise Total System SOP
3. Red Blood Cells SOP
4. Donor Blood Testing Review SOP
5. Unit/Specimen Processing SOP
6. AcQuire Client Admin User Manual
7. Dry Ice Shipment SOP
8. FDA Guidance for Industry: Investigational COVID-19 Convalescent Plasma, 2.SEP.2020

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COVID-19 CONVALESCENT PLASMA PROCEDURE- ADDENDUM

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Original Effective Date	Revised by	Revision	Supersedes Revision #
06.01.2020	T. Collier	NEW ADDENDUM TO COVID-19 CONVALESCENT PLASMA PROCEDURE	NA
		Deleted: **tested** For clarification, this test is in addition to and does not replace/is not the equivalent of SARS-CoV-2 neutralizing antibody titer testing (to be performed when available, continue to save serum and plasma samples from each donation as per COVID-19 Convalescent Plasma Procedure SOP). 1 16 x 100 Red top tube filled with plasma from the plasma component Sterile Connecting Device Sterile sample pouch a. If donation is whole blood: (Refer to Red Blood Cells SOP) i. Centrifuge and separate plasma from packed red blood cells. ii. Leave a long tail of tubing on the plasma component and save 3 extra Donor Identification Numbers (DIN). b. Using a sterile connecting device (SCD) attach a sterile sample pouch to the tubing on the unit of plasma or mother bag (if apheresis plasma donation). Refer to Operation Of Trucise Total System SOP. i. Affix DIN to sample pouch. c. Remove approximately 6 mls of plasma from the donation into the sample pouch and transfer sample into a 16 x 100 red top tube. d. Affix a DIN placed vertically and near the tube cap. Must use Greiner 13 x 100 red top tube Password1 Enter SARS-CoV-2 IgG qualitative antibody test results: (The SafeTrace test code is **SCOV**) / Inv Use Warning and plasma future neutralizing If SARS-CoV-2 IgG qualitative antibody test result is **Positive**: i. Donor sample contains adequate antibodies and the donated plasma may be labeled/shipped as CCP. a. If SARS-CoV-2 IgG qualitative antibody test result is **Negative** (or unable to be performed): ii. Ensure that the “Caution: New Drug—Limited by Federal (or United States) law to investigational use. COVID-19 Convalescent Plasma” tie tag is removed. Added: allogeneic donors and ies Allogeneic donors who test positive for SARS-CoV-2 antibodies must have a confirmatory test (SARS-CoV-2 IgG qualitative antibody assay using a 2nd manufacturer) performed and resulted as positive in order to be considered for future CCP donation eligibility. These donors are then recruited for future CCP donations **confirmed positive as above** CCP donors who are confirmed positive for SARS-CoV-2 antibodies (qualitative) must also be tested for SARS-CoV-2 antibody titer (quantitative) and resulted as, at minimum, reactive and containing a low titer antibody level in order for donated plasma components to be labeled and shipped as CCP. This addendum also describes how to list a need for CCP units with the national clearinghouse. (as per COVID-19 Convalescent Plasma Procedure SOP): 2 13 x 100 Red top tubes of donor whole blood Qualtex shipper Centrifuge One Greiner 16 x 100 red top tube (empty) One 13 x 100 plastic pour off tube with cap Transfer pipets Arctic Box Dry ice Sample tube bag Packing tape	1.000

Gulf Coast form GC254
Form: GC4050 (Client Daily Shipment Schedule)
Form: COVID Antibody Testing Samples – GCRBC

I. **(Applicable to allogeneic donors chosen for** SARS-CoV-2 IgG qualitative antibody **testing AND ALL CCP donors)**

a. Collections staff collect 2 extra red top tubes of donor whole blood.
b. Centrifuge both 13 x 100 red top tubes containing donor whole blood.
c. Affix a Donor Identification Number (DIN) to an empty 13 x 100 Greiner red top tube and one 13 x 100 plastic pour off tube and transfer the serum approximately equally between both tubes.
i. DINs must be placed vertically and close to the bottom of the tube cap.

the Greiner tube serum
Note the sample requirements below, freeze serum if testing will not occur within 7 days of collection.

e. Store the second serum sample (13 x 100 plastic pour off tube capped tightly) in a freezer storage unit that maintains a temperature at or below -18° C. Note: this sample is intended to be tested for SARS-CoV-2 IgG qualitative antibodies, 2nd manufacturer, as applicable.

(first screening test for SARS-CoV-2 IgG qualitative antibodies- allogeneic donors and all CCP donors)
Password2
13 x 100 Greiner red top tube serum
AND CONFIRMATORY/REFLEX TESTING
– (the initial screening test that is performed at Qualtex- allogeneic donors and all CCP donors):
from Qualtex to CBB
Print attachment and review results.

ii. Once test results are received, build a SafeTrace group for all DINs within the test result report for samples with NEGATIVE RESULTS ONLY. (QA enters all positive results so exclude all DINS with positive test results from the group). See Unit/Specimen Processing SOP.

1. Enter the LA subsystem and use the PL function. Press F2.
2. Enter the date as the lab group and press F12. (ex. 10.03.2016)
a. Select the group by entering an “s” next to the correct group and press enter.
3. Tab to the beginning unit number field and barcode the first DIN.
4. Scan the last DIN of the unbroken number sequence into the ending unit number field.
5. Continue building the group in this manner for the remainder of the DINs.
6. Press F12 to update.
7. Press Shift+F1 to print the group. If the group is more than one page, page forward using F8 to print each of the remaining pages of the group.
8. A second staff member must confirm the group is accurate by comparing the SafeTrace print out to the donor sample tubes or any accessioning/results form/printout.
a. The second staff member must document accuracy by dating and initialing the SafeTrace print out(s) of the group.
9. Once accuracy of the group has been confirmed, the group must be assigned in SafeTrace.
a. In the LA subsystem, enter the PL function.
b. Assign the group by entering “a” next to the appropriate group, press enter and then F12.

iii. To enter results in SafeTrace, enter the LA subsystem and use the EL function.

1. F5 to select the appropriate group number.
2. Enter SCOV as the appropriate Test ID.
3. Enter the date, time, tech initials
4. Tab to the result field and enter the appropriate result for the test (N, NR, etc.).
5. F12, F11, F12.

iv. Commit the group results from the LA subsystem in SafeTrace using the PT function. i. Select the appropriate group from the list by entering “s” next to the group.
ii. Select the run ID by entering “s” and print using F10. Ensure that all unit numbers in the group are present and the results are correct.

1. Enter tech initials in SafeTrace and commit the results using F12, F11 and F12.
2. File the group results (Qualtex and SafeTrace printout) with the card review sheet. Record the SafeTrace group number on the card review sheet.
a. Make a copy of the Qualtex test result report and deliver to QA.
b. If the Qualtex test result report contains results for a CCP donation

If the initial screening test OR the confirmatory SCOV OR the quantitative antibody titer test is resulted as NEGATIVE/NONREACTIVE or unable to be performed (allogeneic and all CCP donations):

1. No further testing is necessary.

1. 2. Allogeneic components may be placed in general inventory (plasma components may not be labeled as CCP but may be recovered plasma, FFP, PF24, PRECR as applicable)

(CCP donations only)
For CCP donations
by using one of the following methods:
Method 1
Method 2
Using the DN subsystem, DS and the DC functions:
Enter a "d" next to the CCP special process and press F12 to update.
/ CCP Titer
confirmatory
IgG qualitative
For CCP donations:
Provide Hospital Services Coordinator with the donor's name.
indicating donor is female, negative SCOV and unable to test for Parvo.
indicating donor is female, negative SCOV and <28 days.

ii. **IF the initial screening SCOV test is resulted as POSITIVE** (allogeneic and all CCP donations):
1. Do not enter the result into SafeTrace,
a. A copy of the results may be kept in the laboratory as a record of pending test results.
2. A confirmatory test (SARS-CoV-2 IgG qualitative antibody, 2nd manufacturer) must be performed at Gulf Coast Regional Blood Center. Refer to the following section for instructions.

VIII. SARS-CoV-2 IgG QUALITATIVE ANTIBODY CONFIRMATORY TESTING, 2ND MANUFACTURER

a. Testing is performed at Gulf Coast Regional Blood Center.
b. To accession:
i. Complete Gulf Coast form GC254-
1. Complete requisition date
2. Client name (CBB of Erie County)
3. Sample ID# (See attached)
4. Contact name (Tracy Collier)
5. Sample collection date (See attached)
6. Contact phone (814-456-4206)
7. Samples submitted is/are (check Serum)
8. Source (check Blood Donor)
9. Place checkmark next to COVID Antibody Testing
10. Print 3 copies, place one copy in the sample shipper, give one copy to the Finance Manager and retain a copy in the laboratory.
ii. Complete Form: COVID Antibody Testing Samples – GCRBC
1. Enter date of shipment, number of samples in shipment, number of boxes in shipment and packed by (initials may be used).
2. Enter date of collection, DIN, place a √ or X in the Roche COVID Antibody Testing (qualitative) column for all samples.
3. For CCP donations only- Also place a √ or X in the Reflex + to Ortho COVID IgG Antibody Testing (quantitative) column.
4. Print 3 copies, place one copy in the sample shipper, give one copy to the Finance Manager and retain a copy in the laboratory

(attach to corresponding Gulf Coast form GC254).

c. Place frozen serum aliquot samples in a sample bag, place sample bag in an Arctic box with dry ice (approximately 2.5 kg as per Dry Ice Shipment SOP), place Form GC254 and Form: COVID Antibody Testing Samples – GCRBC under the box flap and seal box with packing tape.
   i. Ensure dry ice label is placed on the side of the Arctic Box and completed.

d. Go to www.fedex.com, create a shipment and select "Gulf Coast, National Donor Testing Services…" from "My Shipment Profiles" drop down list.
   i. Use CBB's account number for billing.
   ii. Select Priority Overnight as the service type.
   iii. Select dry ice under the special services section.
   iv. Schedule a pick up as appropriate.
   v. Ensure that email notifications to cbb.testing@fourhearts.org are set up for pick up and delivery activities.
   vi. Ship the shipment, print the shipping label (two copies) and secure the shipping label to the shipping container.
      1. Place a copy of the shipping label with corresponding Gulf Coast form GC254/ Form: COVID Antibody Testing Samples – GCRBC.
   vii. It is best to only ship samples Monday through Thursday.

e. Complete and email, fax or phone Form: GC4050 (Client Daily Shipment Schedule) to ClientDailyShipmentSchedule@giveblood.org , 713-795-0553 or 713-791-6663 respectively.
   i. Complete First Shipment Box packed on and time
   ii. Complete Total number of samples and Total number of shipping boxes.
   iii. Enter the UPS/FedEx tracking number

IX. **RESULTING SARS-CoV-2 IgG QUALITATIVE ANTIBODY CONFIRMATORY TESTING, 2ND MANUFACTURER**

Note: This test is reported to CBB via email from Gulf Coast. The email contains a link to click to access/print the test result report from a secure server. Gulf Coast reports this test as the abbreviation "COVD" and is resulted in SafeTrace as SCOV.

a. If the result is **NEGATIVE/NONREACTIVE** (allogeneic and CCP donations):
   i. This is the test of record, the presence of SARS-CoV-2 antibodies has not been confirmed.
   ii. Commit test result as negative for SCOV using =LA, ET. A second tech must fully commit the test result using OT. Date and initial the test result report.
   iii. See steps described above in section labeled "If the initial screening test OR the confirmatory SCOV OR the quantitative antibody titer test is resulted as NEGATIVE or unable to be performed (allogeneic and CCP donations)".
   iv. Give a copy of the test result report(s) to QA and retain a copy in the laboratory (attach to corresponding shipping label/Gulf Coast form GC254/ Form: COVID Antibody Testing Samples – GCRBC).
   v. If the test result report contains results for a CCP donation attach a copy to Form: COVID-19 Convalescent Plasma Worksheet: Laboratory.

b. If the result is **POSITIVE/REACTIVE** (allogeneic donations only):
   i. This confirms the presence of SARS-CoV-2 antibodies in the donor.
   ii. The result may be temporarily committed as positive in SafeTrace using ET for SCOV. Date and initial the test result report.
   iii. Do NOT OT the test result in SafeTrace.
   iv. Give a copy of the test result report to QA for final commitment of the result. Retain a copy in the laboratory (attach to corresponding shipping label/Gulf Coast form GC254/ Form: COVID Antibody Testing Samples – GCRBC).
   v. If the test result report contains results for a CCP donation attach a copy to Form: COVID-19 Convalescent Plasma Worksheet: Laboratory.
   vi. Donor will then be recruited for future CCP donations.

c. If the result is **POSITIVE/REACTIVE** (CCP donations only):
   i. This confirms the presence of SARS-CoV-2 antibodies in the donor.
   ii. ET the SCOV result in SafeTrace as positive, date and initial the test result report.
   iii. A second tech must OT the result in SafeTrace, date and initial the test result report.
   iv. Retain a copy of the test result report in the laboratory (attach to corresponding shipping label/Gulf Coast form GC254/ Form: COVID Antibody Testing Samples – GCRBC/Form: COVID-19 Convalescent Plasma Worksheet: Laboratory).
   v. Please note that this donation must also be tested for SARS-CoV-2 antibody titer (quantitative) and resulted as, at minimum, reactive/positive and containing a low titer antibody level in order for donated plasma components to be labeled and shipped as CCP.
      1. The sample should have been accessioned to reflex to Ortho COVID IgG Antibody Testing and the antibody titer test result is reported in tandem with the Roche confirmatory test.

X. **RESULTING SARS-CoV-2 IgG ANTIBODY TITER (QUANTITATIVE)**

Note: This test is reported to CBB via email from Gulf Coast. The email contains a link to click to access/print the result report from a secure server. This test is reported by Gulf Coast as "COV2" and is resulted in SafeTrace as SCOT. This test is only performed on CCP donations that test positive for the screening test and also the confirmatory test.

a. If the result is "NR" or nonreactive (negative) and the signal-to-cutoff (S/C) Value is reported as <1.0:
   i. The plasma components do not contain an adequate amount of COVID-19 antibodies and cannot be labeled/shipped as CCP.
   ii. See steps above in section labeled "If the initial screening test OR the confirmatory SCOV OR the quantitative antibody titer test is resulted as NEGATIVE or unable to be performed".

b. If the result is "R" or reactive (positive) and the signal-to-cutoff (S/C) Value is reported as ≥1.0 but less than 12.0:
   i. The plasma components contain an adequate amount of COVID-19 antibodies and can be labeled/shipped as low titer CCP.
   ii. Commit the test result using =LA, ET as LPOS for the test SCOT. Date and initial the test result report.

iii. A second tech must fully commit the result using OT, date and initial the test result report.
iv. Place a tie tag stating "Low Titer COVID-19 Convalescent Plasma" on each plasma component.
1. On Form: COVID-19 Convalescent Plasma Worksheet: Laboratory, place a √ or X in the CCP Titer Tie Tag column.
2. This label is placed on the opposite side of the tie tag stating "COVID-19 Convalescent Plasma".

c. If the result is "R" or reactive (positive) and the signal-to-cutoff (S/C) Value is reported as ≥12.0:
i. The plasma components contain an adequate amount of COVID-19 antibodies and can be labeled/shipped as high titer CCP.
ii. Commit the test result using =LA, ET as HPOS for the test SCOT. Date and initial the test result report.
iii. A second tech must fully commit the result using OT, date and initial the test result report.
iv. Place a tie tag stating "High Titer COVID-19 Convalescent Plasma" on each plasma component.
v. On Form: COVID-19 Convalescent Plasma Worksheet: Laboratory, place a √ or X in the CCP Titer Tie Tag column.
vi. This label is placed on the opposite side of the tie tag stating "COVID-19 Convalescent Plasma".

XI. LISTING A NEED FOR CCP UNITS FROM THE NATIONAL CLEARINGHOUSE

a. The National Clearinghouse is organized through the Blood Centers of America (BCA).
b. Go to https://www.bcadata.com/Dashboard/rdLogon.aspx
c. The username is jgriebel, password is Jgriebel2
d. Select Resource Sharing
e. Dropdown box- List Excess and Needs
f. Fill in empty fields that apply
g. Add a contact name and 24/7 phone # in the comment field
h. Finally hit Submit data at the bottom and OK.
i. If there is a concern, call or email the following BCA staff:
i. Jennifer Kapral at 972.345.7419 jkapral@bca.coop , Ann Darcy at 401-381-0600 adarcy@bca.coop or Karen O'Hara at 401.644.6466 kohara@bca.coop
j. Once listing is posted, a BCA member will contact CBB/phone number provided in listing within 2 hours. It is critical to respond promptly.

or ≤ - 18°
Unit/Specimen Processing SOP
Dry Ice Shipment SOP
FDA Guidance for Industry: Investigational COVID-19 Convalescent Plasma, 2.SEP.2020

COPY

COVID-19 CONVALESCENT PLASMA PROCEDURE- ADDENDUM

REVIEW/APPROVAL/IMPLEMENTATION

REVIEWED BY:			
Department Head	**Name**	**Signature**	**Date**
Technical Director	Tracy Collier		9-25-2020
Finance Manager	Sarah Uglow		9/24/2020
Executive Director	Deanna Renaud		9/24/2020
APPROVED BY:			
Position	**Name**	**Signature**	**Date**
QA Director	Kristin Kramer		9-23-2020
Medical Director	Jeffrey A. Richmond, MD		9-28-2020
IMPLEMENTATION DATE:	OCT 05 2020		

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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