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 COVID-19 Convalescent Plasma (CCP) donors for SARS-CoV-2 IgG qualitative antibody. 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. **CCP donors must be tested for SARS-CoV-2 IgG qualitative antibody upon each donation.** 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).

SPECIMENS REQUIRED:
1 16 x 100 Red top tube filled with plasma from the plasma component

MATERIALS/FORMS:
Form: COVID-19 Convalescent Plasma Worksheet: Laboratory
Form: Qualtex Sample Packing List
Qualtex shipper instructions
Sterile Connecting Device
Sterile sample pouch

PROCEDURE:

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

I. OBTAINING A SAMPLE

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.
e. Store sample in a refrigerated storage unit that maintains a temperature between 2 and 8° C until shipment.
f. Sample requirements are as follows:
    i. Grossly hemolyzed samples are unable to be tested
    ii. Minimum volume of 2 ml
    iii. Must use Greiner 16 x 100 red top tube
    iv. Stable for 2 days at room temperature
    v. Stable for 7 days at 2 to 8° C
    vi. If testing will not occur within 7 days of collection, sample must be frozen

II. SAMPLE SHIPMENT

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 Password1 (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 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

a. SARS-CoV-2 IgG qualitative antibody test (Abbott COVID Antibody test) results are reported via email as an attachment.
b. Enter SARS-CoV-2 IgG qualitative antibody test result into SafeTrace using the LA subsystem and the ET function as per Donor Blood Testing Review SOP. The SafeTrace test code is **SCOV**.
    i. Indicate "ET", initials and date on result form.
c. A second tech must commit the SCOV result using the LA subsystem and the OT function.
    i. Indicate "OT", initials and date on result form.
d. Attach SARS-CoV-2 IgG qualitative antibody test result(s) to Form: COVID-19 Convalescent Plasma Worksheet: Laboratory.
e. 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.
f. If SARS-CoV-2 IgG qualitative antibody test result is **Negative** (or unable to be performed):
    i. Donor sample does NOT contain adequate antibodies and the donated plasma may NOT be labeled/shipped as CCP.
    ii. Plasma components will automatically be placed into QPEN in SafeTrace.
    iii. Ensure that the "Caution: New Drug—Limited by Federal (or United States) law to investigational use. COVID-19 Convalescent Plasma" tie tag is removed.
    iv. Ensure that the COVID-19 Convalescent Plasma label is removed from the flap of the FFP storage box.
    v. Remove the CCP special process from the donor in SafeTrace.
        1. Using the DN subsystem and the DS2 function, enter the DIN.
        2. On the following screen, press F4 and select Donor Special Process.
        3. Enter a "d" next to the CCP special process and press F12 to update.
        4. Ensure that the CCP special process was removed.
    vi. On Form: COVID-19 Convalescent Plasma Worksheet: Laboratory, indicate NA in the column labeled "CCP / Inv Use Warning Tie Tag Attached".
    vii. Discard the frozen aliquots of serum and plasma from the donation (the samples intended for future SARS-CoV-2 neutralizing antibody titer testing).
    viii. 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.
    ix. Notify Hospital Services Coordinator to remove all of the donor's qualification documents from the binder and to send them to QA for archiving.

x. **If donor is male** and at least 28 days post symptom resolution, the plasma may be placed into the general fresh frozen plasma inventory.
    1. 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.
    2. The plasma component must be released from QPEN in SafeTrace.
        a. Release the plasma component using the LA subsystem and the CA function using the Y function to override the prohibiting factor.
        b. Using the CN function, enter unit number, product code, status of QUAR. Press F11 to update.
            i. Reenter the unit number, product code and a status of ****. Press F11 to update.

xi. **If donor is female** and at least 28 days post symptom resolution:
    1. 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.
    2. Whole blood donation (types A, B or O) and the donation was collected greater than 5 days ago, discard the plasma as above.
    3. Alyx donation (types A, B or O) discard the plasma.
    4. 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.
    5. If any donation was collected less than 28 days post symptom resolution, discard the plasma as above.

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 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. AcQuire Client Admin User Manual

COPY

COVID-19 CONVALESCENT PLASMA PROCEDURE-ADDENDUM

.

Original Effective Date	Revised by	Revision	Supersedes Revision #
06.01.2020	T. Collier	NEW ADDENDUM TO COVID-19 CONVALESCENT PLASMA PROCEDURE	NA

REVIEW/APPROVAL/IMPLEMENTATION

REVIEWED BY:			
Department Head	**Name**	**Signature**	**Date**
Technical Director	Tracy Collier	Tracy M Collier	5/20/2020
Finance Manager	Sarah Uglow	Sarah L Uglow	5/20/2020
Executive Director	Deann Renaud	Deanna Renaud	5/21/2020
APPROVED BY:			
Position	**Name**	**Signature**	**Date**
QA Director	Kristin Kramer	Kristin Kramer	5-20-2020
Medical Director	Jeffrey A. Richmond, MD	JRichmond	5-27-2020
IMPLEMENTATION DATE:	JUN 01 2020		

ANNUAL REVIEW			
MEDICAL DIRECTOR	DATE	MEDICAL DIRECTOR	DATE

COPIES: GENERAL PROCEDURES, WEBSITE

RETIRED SOP

SOP RETIRED BY	TITLE	SIGNATURE	DATE RETIRED
COPIES RECEIVED			
HR/Finance	LAB	ED	CBB