Collection of COVID-19 Convalescent Plasma

https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/recommendations-investigational-covid-19-convalescent-plasma

FDA.gov

Health care providers or acute care facilities seeking to use COVID-19 convalescent plasma should include information in the IND submission that the COVID-19 convalescent plasma will be obtained from an FDA-registered blood establishment that follows the donor eligibility criteria and donor qualifications described below in collecting plasma from donors.

Donor Eligibility

COVID-19 convalescent plasma must only be collected from individuals who meet all donor eligibility requirements (21 CFR 630.10, 21 CFR 630.15). Note the additional donor eligibility requirements for the collection of plasma by plasmapheresis in 21 CFR 630.15 (b). Donation testing for relevant transfusion-transmitted infections must be performed (21 CFR 610.40) and the donation must be found suitable (21 CFR 630.30).

COVID-19 convalescent plasma is collected from individuals who meet the following qualifications:

- Evidence of COVID-19 documented by a laboratory test either by:
  - A diagnostic test (e.g., nasopharyngeal swab) at the time of illness

    OR

  - **a positive serological test for SARS-CoV-2 antibodies after recovery,** if prior diagnostic testing was not performed at the time COVID-19 was suspected.

AND

- Either one of the following
  - Complete resolution of symptoms at least 28 days prior to donation.

    OR

  - Complete resolution of symptoms at least 14 days prior to donation, AND Negative results for COVID-19 either from one or more nasopharyngeal swab specimens or by a molecular diagnostic test from blood.

See next page

Male donors, or female donors who have not been pregnant, or female donors who have been tested since their most recent pregnancy and results interpreted as negative for HLA antibodies.

- SARS-CoV-2 neutralizing antibody titers, if available
    - When measurement of neutralizing antibody titers is available, we recommend neutralizing antibody titers of at least 1:160. A titer of 1:80 may be considered acceptable if an alternative matched unit is not available.
    - When measurement of neutralizing antibody titers is not available, consider storing a retention sample from the convalescent plasma donation for determining antibody titers at a later date.

Registered and licensed blood establishments that collect plasma intended for transfusion do not need to request a supplement to their license or obtain their own IND to collect and manufacture COVID-19 convalescent plasma for investigational use provided they:

1) follow their standard operating procedures for plasma collection and all applicable regulations, and

2) collect plasma from individuals that meet the donor qualifications specified above, which would be included in the applicable IND(s) held by a health care provider or other sponsor.

Once manufactured, the COVID-19 convalescent plasma may be distributed for investigational use. Blood establishments do not need to request an alternative procedure or exception under 21 CFR 640.120(a) to collect COVID-19 convalescent plasma.

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