Iranian Blood Transfusion Organization

IBTO HEAD QUARTER TECHNICAL DEPUTY

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IBTO COVID-19 Convalescent Plasma Collection guideline

Before collecting CCP, consider the following:

Initial preparation for CCP collection:

- Preparation of CCP collection guidelines
- Staff training on new guidelines, as well as on additional requirements which are unique to CCP, such as documentation of SARS-CoV-2 infection and recovery, separation in storage, transportation, and labeling and distribution requirements
- Staff training on being aware that CCP donors are allogeneic donors who are no longer ill
- Preparation of the Blood Establishment Computer System

Donor Recruitment

- Establish a donor recruitment plan for recovered COVID-19 donors to ensure the donor eligibility criteria are met and collections are adequate for use at national level
- Use the list of recovered patients taken from the Ministry of Health
- Call publicly for convalescent plasma donors or make telephone calls or ask physicians for referral with full legal confidentiality
- Encourage local medical partners to provide recovered patients with “hard copy” documentations for both the patient’s initial positive diagnostic test result and a negative test result for SARS-CoV-2 at the time of recovery

Donor eligibility criteria and documentation

- The CCP donor must also meet all allogeneic blood donor eligibility criteria on the day of donation.
- Documentation of SARS-CoV-2 infection (diagnosis) as follows:
    - *Positive PCR diagnostic test at the time of illness,*
      Or
    - *Positive serological test*
      AND
    - *Positive chest CT scan*
      Or
    - *Other hospitalized or outpatient documents with SARS-COV-2 diagnosis signed by the treating physician*
- Donor improvement documents and non-contagiousness:
    - Complete resolution of symptoms at least 28 days prior to donation
      Note: The donor's recovery from COVID-19 prior to donation is based on testing and symptoms disappearance for the safety of other donors and employees and as the evidence that the donor is healthy on the day of donation.
- Donors must be male or females who are nulliparous and without abortion.
- Women's plasma with a history of pregnancy can only be used for research or drug production purposes.
- The CCP donor may donate plasma once every 28 days as permitted by allogeneic donor eligibility criteria.

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Tests

- After donor screening, if convalescent plasma donor is found eligible to donate, COVID-19 rapid antibody test should be performed
- A sample should be taken from all donors for antibody titration
- Other tests as routinely done in case of allogenic blood donors should be equally performed for convalescent plasma donors. A tube sample should be taken for NAT testing so that if the product is in excess, it can be used for research and drug production purposes

CCP preparation process

- CCP collected is FFP type
- CCP can be obtained through both apheresis and whole blood (recovered plasma).
- CCP can be collected for both therapeutic use (injection to patients) and manufacturing use (preparation of plasma-derived products or research purposes)
- Obtain the donor's consent before donating for therapeutic and/or investigational use
- CCP is an allogeneic sample and must comply with all standards of Iranian Blood Transfusion Organization. (Including testing, processing, storage and product tracking)
- Convalescent plasma products should include a purple tie tag making it possible to identify the unit for segregated storage of CCP inventory

LABELING

- Use the “Convalescent Recovered FFP” (CR-FFP) label if plasma collected from whole blood for therapeutic use
- Use the “COVID-19 Convalescent Fresh Frozen plasma” (CC-FFP) label if plasma collected by apheresis method for therapeutic use
- Use the” Convalescent Source FFP” (CS-FFP) label if plasma collected by apheresis method for investigational use

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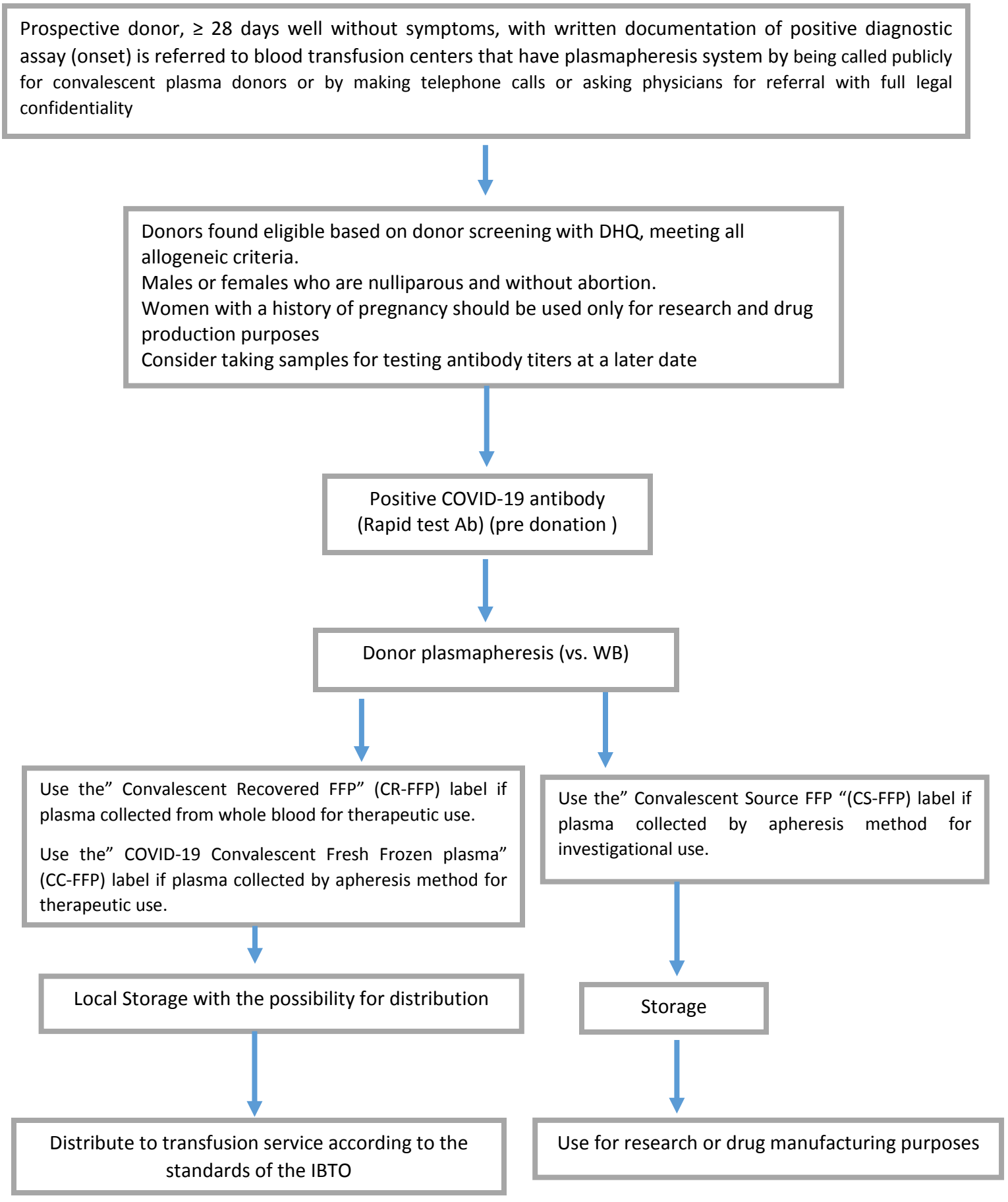

COVID-19 Convalescent Plasma Implementation Checklist:

Initial preparation (headquarters):

- Preparation of SOPs and guideline on how to prepare
- Staff Training
- Feasibility study
- Preparation of URS for necessary changes in the software
- Implementation of ISBT code
- Preparation of plasma sets and devices and consumable items required by the collecting center

Initial preparation (in the collecting center)

- Feasibility study
- Staff training on relevant instructions, including donor selection, instructions for the use of sets, maintenance requirements, transportation and distribution.
- Label preparation

Donor Eligibility and Collections

- Process defined for donor recruitment
- Process defined for donor screening (allogeneic with additional requirements and documentation)
- The process of using rapid test Ab kits or ELISA screening tests if available

Convalescent Plasma Processing

- Calibration / validation of plasmapheresis devices and the presence of relevant sets
- Process defined for segregating convalescent plasma from other frozen inventory

Labeling, Release and Distribution

- Process defined to ensure products are labeled appropriately
- Process defined for distribution of plasma only at the request of the treating physician
- Process defined for the calculation of hospital demand levels for convalescent plasma met