Association for the Advancement of Blood & Biotherapies

01 14 22

Toolkit Updated 01/14/22
COVID-19 Convalescent Plasma (CCP) Under Emergency Use Authorization

The Toolkit was updated 01 14 22 to reflect the new information in FDA's January 7, 2022 Investigational CCP Guidance for Industry which was revised based on the:

- FDA's December 28, 2021 Revised EUA for Use of COVID-19 Convalescent Plasma
- FDA's December 27, 2021 Decision Memorandum (Clinical Memorandum)

AND recent clarifications from FDA shared on AABB's Thursday Forum in response to your questions.

This Toolkit is intended to:

- **supplement but not replace your review of the three documents listed above. AABB encourages members to review these documents to support a comprehensive understanding of your regulatory responsibilities.**
- provide an update of the revised "Scope of Authorization" and titer requirements in the Dec 2021 EUA
- provide an update of the blood donor eligibility pathways to qualify vaccinated and unvaccinated CCP donors, in the Jan 2022 CCP Guidance, and
- help you identify what has, and has not changed in the Dec EUA and Jan CCP guidance**.**

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1 - Tracking Changes in the January 2022 CCP Guidance (pdf)

AABB has created a table to track changes at-a-glance for the January 7, 2022 Investigational COVID-19 Convalescent Plasma Guidance.

Key changes include:

- The guidance reflects that the "EUA authorizes COVID-19 convalescent plasma with high titers of anti-SARS-CoV-2 antibodies for the treatment of COVID-19
  - in patients with immunosuppressive disease or receiving immunosuppressive treatment
  - in either the outpatient or inpatient setting."
- FDA revised the recommendations for vaccinated donors to permit CCP donation by individuals who are vaccinated first, then infected. Section III.B.1.d.i.1 was revised to remove the prior requirement that vaccinated donors "received the COVID-19 vaccine after diagnosis of COVID-19". **This change permits CCP donation by vaccinated donors who have a breakthrough infection, resulting in CCP with boosted antibody titers.**
- Section III.B.1.b was revised to permit individuals to donate CCP 10 days following complete resolution of symptoms.
- FDA has also updated Fact Sheet for Health Care Providers and Fact Sheet For Patients and Parents/Caregivers [see the EUA}

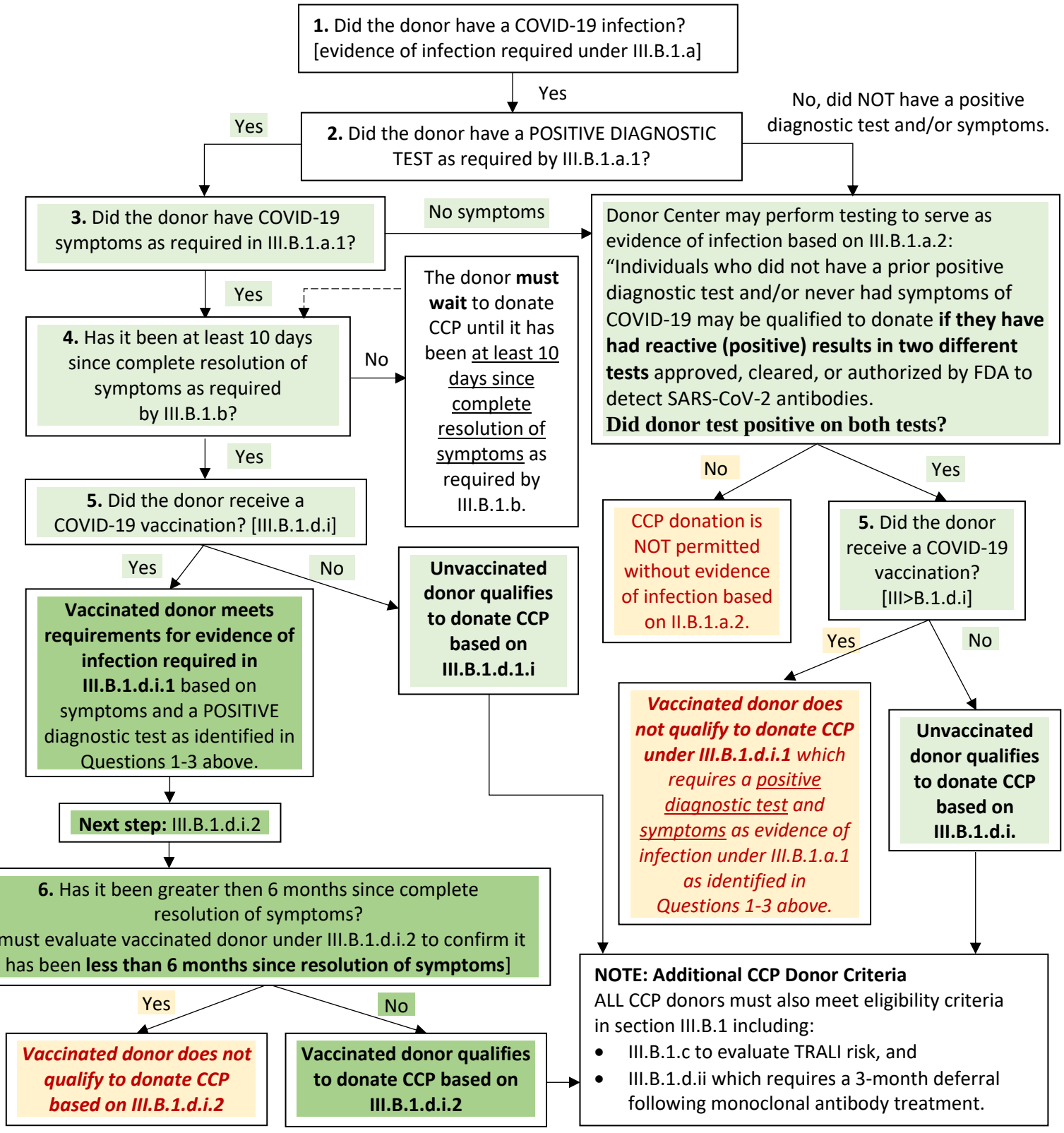
AABB encourages members to review the following revised documents along with the guidance to support your comprehensive understanding of the revised recommendations:

- ✓ FDA's December 28, 2021 Revised EUA for Use of COVID-19 Convalescent Plasma
- ✓ FDA's December 27, 2021 Decision Memorandum (Clinical Memorandum)

Refer to the flowchart and Q&A on pages 3-4.

2 - PATHWAY TO QUALIFY VACCINATED AND UNVACCINATED CCP DONORS

Based on Jan 2022 Guidance: Investigational COVID-19 Convalescent Plasma



3 – Responses to your CCP Questions

- FDA's Responses to your CCP Questions
- SLIDES: AABB's Jan 13th Thursday Forum clarifying regulatory pathways, including FDA responses to your questions.

4 – Tracking Changes in the December 28, 2021 EUA for Use of CCP (pdf)

AABB has created a table to track changes at-a-glance for the December 28, 2021 EUA for the Use of CCP.

Key changes include:

- Authorizes the use of CCP "with high titers of anti-SARS-CoV-2 antibodies for the treatment of COVID-19 in patients with immunosuppressive disease or receiving immunosuppressive treatment in either the outpatient or inpatient setting"
- Revises the list of "acceptable tests and increased qualifying result cutoffs (listed in Appendix A of the EUA) to be used in the manufacture of CCP with high titers of anti-SARS-CoV-2 antibodies."
- Updates the Fact Sheet for Health Care Providers and Fact Sheet For Patients and Parents/Caregivers