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.

TABLE OF CONTENTS

| 1 - Tracking Changes in the January 2022 CCP Guidance | 2 |
| 2 - Pathway to Qualify Vaccinated and Unvaccinated CCP Donors | 3 |
| 3 – Responses to your CCP Questions | 4 |
| 4 - Tracking Changes in the December 28, 2021 EUA for Use of CCP | 4 |
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

1. Did the donor have a COVID-19 infection? [evidence of infection required under III.B.1.a]
   - Yes
   - No

2. Did the donor have a POSITIVE DIAGNOSTIC TEST as required by III.B.1.a.1?
   - Yes
   - No, did NOT have a positive diagnostic test and/or symptoms.

3. Did the donor have COVID-19 symptoms as required in III.B.1.a.1?
   - Yes
   - No symptoms

4. Has it been at least 10 days since complete resolution of symptoms as required by III.B.1.b?
   - Yes
   - No

5. Did the donor receive a COVID-19 vaccination? [III.B.1.d.i]
   - Yes
   - No

   **Unvaccinated donor qualifies to donate CCP based on III.B.1.d.i**

   **Vaccinated donor meets requirements for evidence of infection required in III.B.1.d.i.1 based on symptoms and a POSITIVE diagnostic test as identified in Questions 1-3 above.**

   **Next step: III.B.1.d.i.2**

6. Has it been greater then 6 months since complete resolution of symptoms? [must evaluate vaccinated donor under III.B.1.d.i.2 to confirm it has been less than 6 months since resolution of symptoms]
   - Yes
   - No

**Vaccinated donor does not qualify to donate CCP based on III.B.1.d.i.2**

**Vaccinated donor qualifies to donate CCP based on III.B.1.d.i.2**

**Unvaccinated donor qualifies to donate CCP based on III.B.1.d.i.**

**Vaccinated donor does not qualify to donate CCP under III.B.1.d.i.1 which requires a positive diagnostic test and symptoms as evidence of infection under III.B.1.a.1 as identified in Questions 1-3 above.**

**CCP donation is NOT permitted without evidence of infection based on II.B.1.a.2.**

**Did donor test positive on both tests?**

- No
- Yes

**Vaccinated donor meet requirements for evidence of infection required in III.B.1.d.i.1 based on symptoms and a POSITIVE diagnostic test as identified in Questions 1-3 above.**

**Vaccinated donor qualifies to donate CCP based on III.B.1.d.i.**

**NOTE: Additional CCP Donor Criteria**

ALL CCP donors must also meet eligibility criteria in section III.B.1 including:
- III.B.1.c to evaluate TRALI risk, and
- III.B.1.d.ii which requires a 3-month deferral following monoclonal antibody treatment.
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