AABB SUMMARY: DONATION OF CCP AND BLOOD COMPONENTS FOLLOWING COVID-19 VACCINES OR CCP TRANSFUSION - Updated 12 15 2020

DONOR DEFERRALS:

1-Blood donor deferral following COVID-19 vaccines is not required. Consider the following:
   • FDA does not have a policy requiring deferral of routine blood donors following COVID-19 vaccination.
   • In response to questions from AABB, FDA:
     o Confirmed that it would be reasonable to have no donor deferral following mRNA COVID-19 vaccines.
     o Offered that a 14-day deferral is reasonable following a live-attenuated vaccine (we are expecting very few of those).
   • Any decision to update policies for deferral following COVID vaccines is left to the discretion of the Medical Director.
   • For more information from AABB Standards and FDA – refer to the Resources Section below.

2-Donation following CCP transfusion requires deferral.
   • CCP donors must meet all allogeneic blood donor criteria and deferral requirements, including the 3-month deferral from the date of CCP transfusion.

3-Individuals receiving COVID-19 vaccines are not eligible to donate CCP – FDA’s Nov 2020 CCP EUA guidance (bottom of page 6) FDA states:
   Note: You should not collect COVID-19 convalescent plasma from individuals who have received an investigational COVID-19 vaccine because of the uncertainty regarding the quality of the immune response produced by such investigational vaccines.
   • FDA also shared information during the AABB Annual Meeting Session, Live with FDA on the CCP Regulatory Landscape - refer to slide 29 for CCP donation after vaccination and slides 27-28 for blood donation.

4-Recovered COVID-19 patients who are eligible to donate CCP and also receive a COVID-19 vaccine after recovery are currently deferred from CCP donation per FDA Guidance, refer to #3 above. However, FDA is actively looking at this donor eligibility issue and had the following response to an inquiry from AABB:
   • There will not be an immediate decision – it will take some weeks.
   • The agency:
     o Is working internally with vaccine and vaccine review.
     o Appreciates those that have asked the question and understand it to be an important issue.

5-FDA confirmed that deferral following receipt of monoclonal antibodies is at the discretion of the physician oversight.

RESOURCES:
• Aug 7th REGULATORY UPDATE: Investigational Vaccines and Deferral for Donors of Blood and Convalescent Plasma
• Nov 20th REGULATORY UPDATE: Evaluating Donor Risk and Deferrals Following Vaccination
• Oct 5th Live with FDA on the CCP Regulatory Landscape AABB Annual Meeting
• AABB Standards – Sept 2020 Guidance for the Standards for Blood Banks and Transfusion Services, 32nd edition - Deferral following COVID-19 vaccines