Toolkit for COVID-19 Convalescent Plasma (CCP) under Emergency Use Authorization (EUA)

The Toolkit is under revision based on the February 4th Letter of Authorization. Here is what we know:

1. FDA is in the process of revising its approach to the use of CCP. The agency released this overview announcing this significant change in policy, which links to the:
   - Letter of Authorization
   - Updated Fact Sheet for Health Care Providers
   - Updated Fact Sheet for Patients and Parents/Caregiver

This quote, from the revised Letter of Authorization, provides a high level overview of the changes:

"Having concluded that revising this EUA is appropriate to protect the public health or safety under Section 564(g)(2)(C) of the Act (21 U.S.C. § 360bbb-3(g)(2)(C)), FDA is again reissuing the Letter of Authorization in its entirety with revisions to:

1. include updates based on data from additional clinical trials;
2. clarify that the authorization is limited to use of only high titer COVID-19 convalescent plasma in hospitalized patients early in the course of disease and those hospitalized with impaired humoral immunity;
3. add the Abbott SARS-CoV-2 IgG test (ARCHITECT and Alinity i platforms), Beckman Coulter Access SARS-CoV-2 IgG test, EUROIMMUN Anti-SARS-CoV-2 ELISA (IgG) test, GenScript cPass SARS-CoV-2 Neutralization Antibody Detection Kit test, Kantaro COVID-SeroKlir test, Roche Elecsys AntiSARS-CoV-2 S test, and Siemens ADVIA Centaur SARS-CoV-2 IgG (COV2G) test as acceptable tests to be used for the purpose of qualifying high titer COVID-19 convalescent plasma in the manufacture of COVID-19 convalescent plasma; and
4. change the cutoff of the Ortho VITROS Anti-SARS-CoV-2 IgG test from S/C≥12.0 to S/C≥9.5 for qualification of COVID-19 convalescent plasma as high titer."

2. We also anticipate that FDA will issue a Guidance with revised recommendations for collection and use of CCP.

3. AABB is planning a member-wide communication later today and we will continue to evaluate the situation along with our partners and the rest of this community and to provide updates as new information is available.

If you have questions or concerns, please let us know by emailing regulatory@aabb.org