



Advancing Transfusion and
Cellular Therapies Worldwide

October 2, 2020

CMS Clarifies How Final Rule Applies to Testing for COVID-19

AABB received a formal response from the Centers for Medicare and Medicaid Services (CMS) today about the Association's inquiry as to whether the Final Rule applies to the testing of donor samples for SARS-CoV-2.

According to new information from CMS, when testing is “performed on donor samples to confirm the donor has the antibodies necessary to qualify the product as convalescent plasma [and] is intended to detect SARS-CoV-2,” it is subject to guidelines set forth in “[Interim Final Rule \(IFC\), CMS-3401-IFC, Updating Requirements for Reporting of SARS-CoV-2 Test Results by Clinical Laboratory Improvement Amendments of 1988 \(CLIA\) Laboratories, and Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency.](#)”

AABB notes that because of this, reporting requirements referenced in CMS's [QSO-20-37 document](#), released on Aug. 26, 2020, must be followed. “All CLIA-certified laboratories that perform or analyze any test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 [e.g., molecular, antigen, antibody] are required to report, regardless of the type of laboratory [type of CLIA certificate] performing the testing,” officials from CMS told AABB today.

Other important details from today's communication with CMS include:

- All SARS-CoV-2 results—both positive and negative—must be reported regardless of the testing method.
- This regulation is effective as of Sept. 23, 2020. Centers are required to retroactively report testing results back to Sept. 23. CMS also directs facilities to report testing results according to local and state requirements.
- The Final Rule only applies to post-donation testing performed during the manufacturing process—for example, to determine whether a unit should be labeled as COVID-19 convalescent plasma, or as FFP or PF24—if antibody test results are shared with the donor.

Per AABB's role as a CLIA provider, our Accreditation Department is available to help facilities implement changes to adhere to these regulations. AABB's assessors will begin working with facilities to ensure they are compliant with this interpretation of the Final Rule.

AABB will continue to work with CMS on this issue on behalf of our membership and will seek additional clarification as needed. In addition, AABB has developed a CLIA verification form, which will be available in the APEX accreditation portal as soon as it is approved by CMS. Individuals with questions may contact accreditation@aabb.org.