



To: Directors of Clinical Laboratories
Directors of Transfusion Services

Date: January 26, 2022

Subject: CCP Unavailable

On December 28, 2021 the FDA updated the [emergency use authorization \(EUA\) for convalescent plasma \(CCP\)](#). They modified the indications for use as well as the testing assays required to qualify a product as CCP.

CCP No Longer Available

The updated EUA no longer includes the testing assay LifeSouth uses. As a result, our existing inventory of CCP no longer qualified as CCP and was relabeled as regular plasma (FFP).

At this time, LifeSouth has no plasma components that meet the new EUA criteria. Due to the limited use cases and extremely low demand, LifeSouth has no immediate plans to implement the new testing assay required for production of CCP or to resume production of CCP. We will monitor future requests for this product and make changes if needed.

Nationwide, little to no CCP is available due to the modifications in testing requirements. Old inventory is also unable to be tested on the new assays due to sample-type restrictions. Due to lack of production on a national level, we are unable to import CCP at this time. If you are in critical need of CCP, please contact us (tabroaderick@lifesouth.org) and we will attempt to source it for you. Availability is not guaranteed due to a lack of production on a national level.

An Explanation of the EUA Changes

There is no recognized safety issue with any units of CCP produced and transfused prior to December 28th. An EUA does not represent FDA approval, and therefore is subject to changes based on additional data as it is generated. While the testing used for high titer CCP production prior to the December 28th EUA gave a numeric result, most tests were classified as qualitative when submitted for FDA authorization (i.e. results are either positive or negative). The new EUA requires one of a limited number of newer, quantitative tests which are authorized by the FDA to report a numeric value. These quantitative tests look for the same IgG antibody to the spike protein of SARS-CoV-2 as previously utilized qualitative tests.

If you have any questions regarding CCP or the EUA, please contact our Vice President of Medical Services, Dr. Chris Lough, at cmlough@lifesouth.org.