DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

February 9, 2022

Dawn O'Connell
Acting Assistant Secretary for Preparedness and Response
Office of the Assistant Secretary for Preparedness and Response
Office of the Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: EUA 26382 – Emergency Use Authorization of COVID-19 Convalescent Plasma, Reissued on March 9, 2021, under Section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360bbb-3);
Amendment to Allow Use of a New Test as an Acceptable Test for Use in the Manufacture of High Titer COVID-19 Convalescent Plasma

Dear Ms. O'Connell:

This letter is to notify you that we have reviewed data to include the EUROIMMUN Anti-SARS-CoV-2 S1 Curve ELISA (IgG) test as an acceptable Test for Use in the Manufacture of High Titer COVID-19 Convalescent Plasma. This test has been added to *Appendix A: Table of Tests Acceptable for Use in the Manufacture of High Titer COVID-19 Convalescent Plasma* in the December 28, 2021, letter authorizing the emergency use of COVID-19 Convalescent Plasma.

Sincerely,

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Nicole Verdun, MD
Director
Office of Blood Research and Review
Center for Biologics Evaluation and Research