June 2, 2021

Nikki Bratcher-Bowman  
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. Bratcher-Bowman:

This letter is to notify you that we have reviewed data to include the DiaSorin LIASON  
SARS-CoV-2 Trimeric$ 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 March 9, 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