



Our STN: BL 125396/21

**SUPPLEMENT APPROVAL**  
**October 10, 2025**

Stanford Blood Center  
Attention: Manmeet K. Singh  
3373 Hillview Avenue  
Palo Alto, CA 94304

Dear Manmeet Singh:

We have approved your request received April 3, 2025, to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for Whole Blood and blood components to manufacture Apheresis Convalescent Plasma, High Titer, Anti-SARS-CoV-2 for the treatment of COVID-19 in patients with immunosuppressive disease or receiving immunosuppressive treatment.

We hereby approve the five container labels submitted April 3, 2025, and the addendum to your Circular of Information submitted under amendment # 6, dated September 11, 2025, which must be available for distribution with the product.

This approval applies to your establishment located at 3373 Hillview Avenue, Palo Alto, California (Registration Number 2970004) operating under U.S. License Number 1858.

We will include information contained in the above-referenced supplement in your BLA file.

Sincerely,

Wendy Paul, MD  
Acting Director  
Division of Blood Components and Devices  
Office of Blood Research and Review  
Center for Biologics Evaluation and Research