



## SUPPLEMENT APPROVAL

June 24, 2022

Alba Bioscience Limited  
Attention: Christine Ginocchio  
141 South Windsor Avenue  
New York, NY 11718

Dear Christine Ginocchio:

We have approved your requests received April 1, 2022, to supplement your Biologics License Applications (BLAs) submitted under section 351(a) of the Public Health Service Act to revise the Instructions for Use to implement the ORTHO Optix™ Reader for the semi-automated testing of the following ORTHO™ Sera Blood Grouping Reagent products:

### STN Name of Biological Products

BL 125304/77	Blood Grouping Reagent, Anti-D (Monoclonal) (IgM)
BL 125309/71	Blood Grouping Reagent, Anti-N (Murine Monoclonal) (IgG)
BL 125310/68	Blood Grouping Reagent, Anti-Le <sup>a</sup> (Murine Monoclonal)
BL 125311/64	Blood Grouping Reagent, Anti- Le <sup>b</sup> (Murine Monoclonal)
BL 125314/85	Blood Grouping Reagent, Anti-D (Monoclonal Blend)
BL 125342/41	Blood Grouping Reagent, Anti-Fy <sup>b</sup>
BL 125567/20	Blood Grouping Reagent, Anti-Fy <sup>a</sup> (Monoclonal) (IgG)
BL 125568/20	Blood Grouping Reagent, Anti-Jk <sup>a</sup> (Monoclonal)
BL 125569/21	Blood Grouping Reagent, Anti-Jk <sup>b</sup> (Monoclonal)
BL 125570/18	Blood Grouping Reagent, Anti-S (Monoclonal) (IgG)
BL 125571/18	Blood Grouping Reagent, Anti-s (Monoclonal) (IgG)
BL 125572/20	Blood Grouping Reagent, Anti-K (Monoclonal)
BL 125573/19	Blood Grouping Reagent, Anti-P1 (Murine Monoclonal)

### LABELING

We hereby approve the draft package insert labeling submitted under amendment 2, dated June 10, 2022. This is a reminder that as of September 24, 2014, medical devices that are licensed under the PHS Act are subject to certain provisions of the final Unique Device Identifier (UDI) rule. These provisions include the requirement to provide a UDI on the device label and packages (21 CFR 801.20), format dates on the device label in accordance with 21 CFR 801.18, and submit data to the Global Unique Device Identification Database (GUDID) (21 CFR 830 Subpart E). Additionally, please identify each device identifier implemented for the subject device, and the device identifiers that

have been discontinued for the subject device as a labeling change in an annual report consistent with 21 CFR 601.12(f)(3). For more information on these requirements, please see the UDI website at <http://www.fda.gov/udi>.

Please submit all final printed labeling as PDF electronic copy (eCopy) at the time of use and include implementation information on Form FDA 356h as appropriate.

Two draft copies of the proposed introductory advertising or promotional labeling may be voluntarily submitted for advisory comment with a completed Form FDA 2253 to the Advertising and Promotional Labeling Branch at the following address:

Food and Drug Administration  
Center for Biologics Evaluation and Research  
Document Control Center  
10903 New Hampshire Ave.  
WO71–G112  
Silver Spring, MD 20993-0002

We will include information contained in the above-referenced supplements in your BLA files.

Sincerely,

Orieji Illoh, MD  
Director  
Division of Blood Components and Devices  
Office of Blood Research and Review  
Center for Biologics Evaluation and Research