



**Our STN: BL 103778/5091**

**SUPPLEMENT APPROVAL  
March 10, 2021**

Ortho-Clinical Diagnostics, Inc.  
Attention: Ms. Leah Van De Water  
100 Indigo Creek Drive  
Rochester, NY 14626

Dear Ms. Van De Water:

We have approved your request submitted December 18, 2020, received December 22, 2020 to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for Reagent Red Blood Cells to update the Instructions for Use (IFU) of 0.8% ORTHO Reagent Red Blood Cell to reference ORTHO Optix Reader instrument.

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

Sincerely,

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