



Our STN: BL 103898/5105

**SUPPLEMENT APPROVAL
May 26, 2023**

Medion Grifols Diagnostics AG
Attention: Alisha McReynolds
Grifols Shared Services North America, Inc.
4560 Horton Street
Emeryville, CA 94608

Dear Alisha McReynolds:

We have approved your request received December 2, 2022, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Reagent Red Blood Cells (RRBCs), for a change in the RRBCs typing for antigens I, f, Jsa, Mg, Yta to be performed according to the availability of typing reagents.

We will include the 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